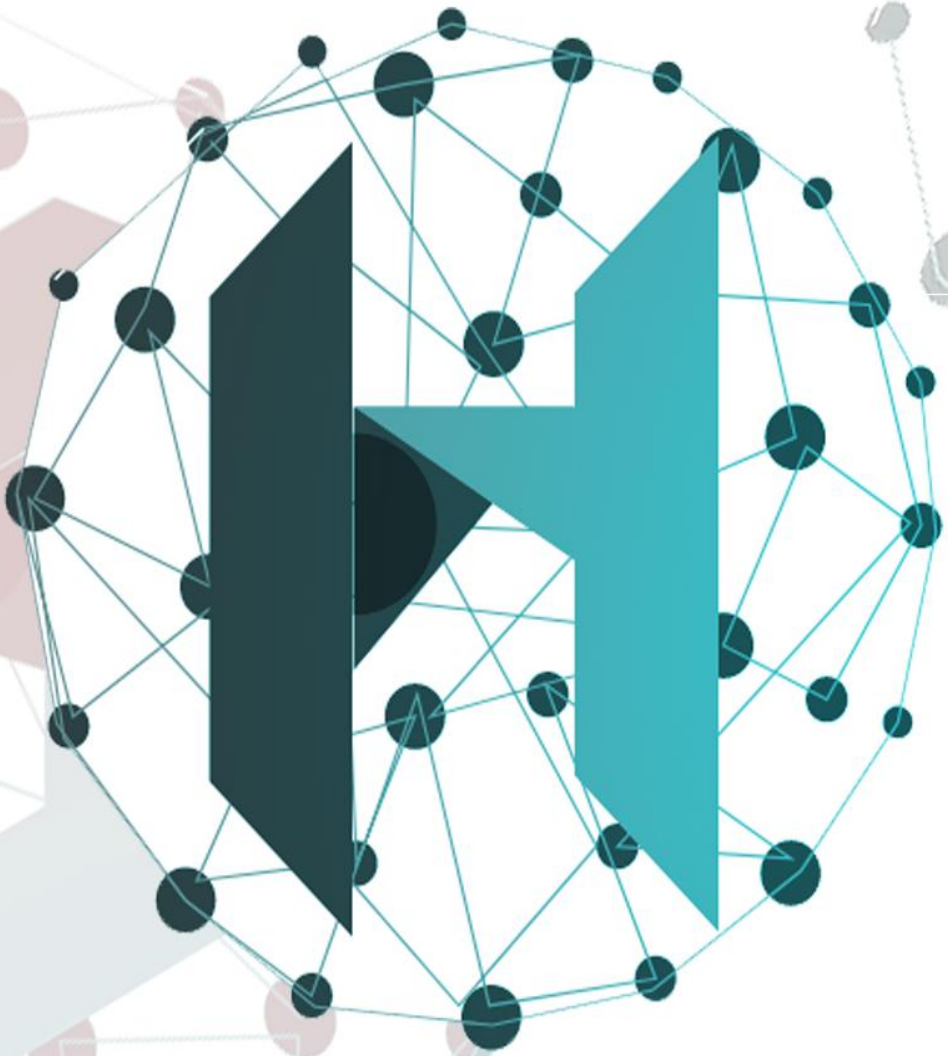
Volume 6 July 2026 Number 2



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E-ISSN: 2773-6040

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Published by

IIUM Press

IIUM Press
International Islamic University Malaysia
Jalan Gombak, 53100 Kuala Lumpur, Malaysia
Phone: (+603) 6421 5014, Fax: (+603) 6421 6298

E ISSN 2773 6040

HALALSPHERE
E-ISSN: 2773 6040

HALALSPHERE
Volume 6, Issue 2, July 2026
https://doi.org/10.31436/hs.v6i2

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Editorial Note

From source to assurance: Charting the next frontier of halal research

Yumi Zuhanis Has-Yun Hashim
Editor-in-Chief

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Malaysia has earned international recognition as a global leader in halal certification and governance. Yet sustaining this leadership requires addressing one of the most pressing research challenges of the halal ecosystem namely our continued dependence on imported raw materials across multiple halal sectors, including food, pharmaceuticals, biopharmaceuticals, cosmetics, and personal care products (Hashim & Ahmad, 2026).

While certification assures compliance at the point of production, the principle of *halalan toyyiban* demands integrity throughout the entire value chain, beginning with the origin of raw materials such as depicted in MS 1500:2019 (DSM, 2019a) and MS2424:2019 (DSM, 2019b). Incidents such as the 2020 halal meat cartel scandal further underscored the vulnerabilities associated with fragmented and opaque supply chains.

The next frontier of halal research should therefore move beyond product certification towards strengthening upstream halal ecosystems. Priority should be given to developing localized and sustainable sources of halal raw materials, resilient "farm-to-fork" (and, where relevant, "source-to-patient") supply chains, and integrated halal industrial ecosystems.

Equally important is research on practical implementation of digital traceability technologies including blockchain, the Internet of Things (IoT), artificial intelligence, and interoperable data platforms; to enhance transparency, authenticity, and consumer trust (OECD, 2022; GS1, 2023). Interdisciplinary studies that bridge agriculture, biotechnology, pharmaceutical sciences, supply chain management, digital innovation, and *Shari'ah* governance will be instrumental in building a resilient halal ecosystem.

In doing so, research that seeks to advance halal consumption must be guided by *Maqasid al-Shari'ah* and a genuine commitment to strengthen the halal ecosystem beyond the legacy of profit-driven capitalism. As the halal industry enters an era shaped by frontier technologies including advanced biotechnology, synthetic biology, artificial intelligence, precision fermentation, and novel food production; innovation should not be embraced uncritically. Rather, it should be approached through the principle of *ihtiyat* (prudence or precaution), ensuring that emerging technologies undergo rigorous scientific evaluation and *Shari'ah* scrutiny before widespread adoption. Such a precautionary approach does not impede innovation; instead, it safeguards halal integrity, protects public interest (*maslahah)*, and ensures that technological advancement remains aligned with the higher objectives of the *Shari'ah*. In this regard, *ihtiyat* serves not as a barrier to scientific progress but as a governance principle that promotes responsible innovation while preserving the objectives of religion, life, intellect, lineage, wealth, and, by extension, environmental sustainability (Auda, 2008).

As Halalsphere continues to foster scholarly dialogue, we encourage researchers to generate evidence-based solutions that strengthen halal integrity from the source, ensuring that Malaysia's global halal leadership is founded not only on certification excellence but also on scientific innovation, sustainable resource development, resilient supply chains, and the careful stewardship of emerging technologies. By balancing innovation with prudence, the halal ecosystem can remain globally competitive while remaining firmly anchored in the ethical and legal principles that define *halalan ṭayyiban*.

References

Auda, J. (2008). *Maqasid al-Shari'ah* as philosophy of Islamic law: A systems approach. The International Institute of Islamic Thought (IIIT).

Department of Standards Malaysia. (2019a). MS 1500:2019 (Halal food – general requirements. (Third Revision)).

Department of Standards Malaysia, DSM. (2019b). MS 2424:2019 (Halal pharmaceutical – general guidelines)

GS1. (2023). Global traceability standard. https://www.gs1.org/standards/gs1-global-traceability-standard/current-standard

Hashim, Yumi Zuhanis Has-Yun, & Ahmad, Anis Najiha. (2026). Halal gap begins at source. @halal, 8 (42). pp. 22-23.

OECD. (2022). Blockchain at the frontier: Impacts and issues in cross-border co-operation and global governance. OECD Business and Finance Policy Papers, No. 4, OECD Publishing, Paris, https://doi.org/10.1787/80e1f9bb-en

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Islamic public value of halal certification acceleration program: A case study of policy practice by the East Java Provincial Government, Indonesia

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Received: 28/1/2026
Accepted: 5/3/2026
Published: 31/7/2026

Abstract

This study aims to explore Islamic Public Value as the driving force behind the East Java Provincial Government's policy to accelerate halal certification, based on the Neo-Weberian State public administration paradigm. This research approach is qualitative, with an exploratory case study design, to understand in depth the dynamics of values and themes arising in the policy context. Data collection techniques included in-depth interviews, document analysis, and participatory observation. The data were analysed thematically to identify patterns of values that emerged during policy implementation. The results show that there are patterns of Islamic public values articulated in three main themes: (1) the application of Islamic *Shari'ah* principles in public services which is reflected in the government's commitment to ensure halal products in accordance with *Shari'ah* principles, (2) strengthening social cohesion through collaboration between stakeholders where this policy serves as an instrument to strengthen the solidarity of Muslim communities through guaranteeing halal consumption, and (3) social respect and encouragement of non-material motivations that emphasize moral-spiritual aspects such as justice, transparency, and social responsibility in policy implementation. These findings show that the policy of accelerating halal certification is not only oriented towards administrative interests, but also enriches the dimensions of public value derived from Islamic values. This research is expected to make a conceptual contribution to the development of public value studies in policy and to offer practical implications for the formulation and implementation of value-based policies at the local government level.

Keywords: Islamic Public Value; Islamic Public Administration; Halal Certification Policy (East Java)

1. Introduction

Indonesia, as the third-largest Islamic economy in the world, has made significant progress in halal food indicators across various areas, including income, national and international trade, operations, ecosystem, social impact, innovation, and opportunities (SGIE, 2023). The State of the Global Islamic Economy Report (SGIE/SGIER) is an annual report that examines the development of the Islamic economy in various countries, focusing on six key indicators: Islamic finance, halal food, Muslim-friendly tourism, modest fashion, media and recreation, and halal pharmaceuticals and cosmetics. In 2022, Indonesian Muslim consumer spending on halal food and beverages increased by 9.6%, reaching US$1.4 trillion, up from US$1.28 trillion in 2021. Although Indonesia is the largest market in terms of expenditure and ranks first among Organization of Islamic Cooperation (OIC) countries as an importer, with a value of US$25.82 billion, its export position remains in fifth place, with a value of US$13.13 billion (Maryuliano, 2024). This highlights both the potential and the challenges in optimizing Indonesia's role in the global halal economy.

Despite ranking third in the Islamic economy, Indonesia is only 10th among halal producers, with 12.6% of the halal food industry still relying on imports. Data from the Halal Product Guarantee Agency (BPJPH) in 2022 shows that only 749,971 out of 30 million business products have halal certification. Ironically, the world's largest halal producers are dominated by non-Muslim countries such as Brazil and Australia. The global halal market has enormous potential, projected to reach 3.2 trillion US dollars by 2024, driven by the growth of the global Muslim population. However, Indonesia's limited domestic production capacity, despite support from halal regulations and infrastructure, remains the main obstacle to meeting domestic demand and competing in the global market (Romadhoan, 2024). Indonesia has implemented mandatory halal certification for all products circulating in Indonesia through Law No. 33 of 2014 on Halal Product Guarantee (Hambali, 2020; Najiyah, 2016). This regulation applies to both domestic and imported products, aiming to protect Muslim consumers (Syafrida & Hartati, 2019). The Halal Product Guarantee Agency (BPJPH) oversees the certification process, collaborating with other government agencies such as the Food and Drug Supervisory Agency (BPOM) to ensure compliance (Saviera, 2024). For imported products that already have halal certification from countries with mutual recognition agreements, registration with BPJPH is required to obtain a halal registration number (Syafrida & Hartati, 2019). Although this mandatory certification is in line with the Agreement on Technical Barriers to Trade, it is important to ensure it does not create unnecessary trade barriers. As of 2023, the number of halal-certified products stands at 1.42 million products (Hambali, 2020).

The East Java Provincial Government has demonstrated a strong commitment to promoting the development of the halal industry through accelerated halal certification for businesses. A total of 252,490 halal certificates have been issued, with 98.52 percent of them granted to Small and Medium Industries (SMIs) in 2024. This step shows significant growth, with an increase of 38.14 percent or an addition of 96,302 halal certificates since October 21, 2023, when the number of new certificates reached 156,188 (Suara Surabaya, 2024). This achievement not only reflects the success of the halal certification acceleration policy at the regional level but also opens the door to examining the Islamic public values embedded in the policy, based on the Neo-Weberian State paradigm. The East Java Provincial Government serves as a concrete example of the accelerated implementation of the halal certification program. By 2024, the East Java Provincial Government had issued a total of 252,490 halal certificates, with 98.52 percent allocated to Small and Medium Industries (SMIs). This figure represents an increase of 38.14 percent from the previous total on October 21, 2023, which stood at 156,188 certificates. This achievement not only reflects the government's seriousness in facilitating compliance with halal standards but also demonstrates the state's active role in supporting economic growth rooted in Islamic values.

Islamic Public Value (IPV) in this study is conceptualized not as a fully mature grand theory, but rather as a developing normative-analytical framework in the study of Islamic public administration. While the classical Public Value theory, developed by Mark Moore, focuses on value creation through democratic legitimacy, operational capacity, and public authorization, Islamic Public Value expands this perspective by grounding value creation in Islamic epistemology, particularly the integration of governance and belief.

Following Drechsler *et al.* (2024), IPV is understood as a conceptual framework that identifies how Islamic principles—such as *maslahah* (public welfare), *amanah* (honesty), and *maqasid al-shari'ah*—influence public administration practices. Therefore, IPV in this study functions as: (1) A normative framework, as it provides value-based criteria derived from Islamic teachings; (2) an analytical lens, as it is used to interpret empirical findings related to the implementation of halal certification policies; (3) A contextual governance model, when integrated with the Neo-Weberian State paradigm. IPV is not considered a stand-alone predictive theory, but rather a value-oriented analytical approach that helps explain how religious norms are institutionalized in modern bureaucratic governance.

In this context, it is important to view halal certification policy not only from a legal and administrative perspective, but as a manifestation of Islamic Public Values. This approach emphasizes integrating *Shari'ah* principles and public interests into state policy. Three aspects of Islamic Public Values must be considered, with this study focusing on: (1) *Shari'ah* Implementation, which is reflected in the strengthening of the halal product assurance system; (2) Social Cohesion, which is built through collective community participation in halal practices; and (3) Social Respect and Non-Material Motivation, which is seen in the increasing ethical awareness of business actors in prioritizing religious and moral values, rather than merely economic profit orientation (Drechsler *et al.*, 2024). These three aspects represent the three axes of Islamic public values: in theory and practice, in space and time, and in governance and belief (Drechsler *et al.*, 2025). Furthermore, this policy can be analysed through the Neo-Weberian State (NWS) paradigm, which combines the characteristics of classical Weberian bureaucracy, such as professionalism, legality, and formal rationality, with the need for public participation and responsiveness to local values. Within the NWS framework, the state is not only the holder of formal legal authority but also an active agent of values that facilitate public will, shaped by society's socio-cultural characteristics (Bouckaert, 2022). Therefore, the halal certification policy in East Java can be understood as a state practice of institutionalizing Islamic values into modern bureaucratic governance.

This study describes, understands, and analyses in detail the implementation of Islamic values in public administration policies and practices, reviewed from the concept of the evolution of the Neo-Weberian State paradigm. The findings of this research are expected to enrich academic understanding of Islamic Public Administration and Islamic Public Value as a contextualization of governance within the principles of the Neo-Weberian State, provide new perspectives on the integration of Islamic values into public administration, and serve as a reference for the development of more contextual theories and practices of public administration.

1.1 Neo-Weberian State

The Neo-Weberian State (NWS) bureaucratic reform framework model developed by Pollitt & Bouckaert is a recommended guide for developing countries, because classical Weberian bureaucracies are organized according to generally defined standards, while NWS ensures the three core functions of the "whole-of-government" strategy in the context of "whole society" context, namely: the provision of inclusive and fair services, resilient crisis management, and effective innovation for government and society (Bouckaert, 2022)—the ability and decision to comply with the law. Moreover, bureaucratic issues in developing countries need to be addressed (Hanafie, 2017). In an increasingly globalized world, the government's response to social change will rely on established methods until society decides it is time for fundamental change. Moreover, only then will the functions of the state, not its tools, be evaluated against the laws or values under which those institutional functions are carried out (Lynn Jr., 2008).

The Neo-Weberian State (NWS) framework is essential in this study because halal certification is not merely a religious practice but a formally institutionalized public policy embedded within a rational-legal administrative order. While Islamic Public Value (IPV) provides the normative foundation for governance grounded in Islamic epistemology, it does not, by itself, fully explain how religious values are operationalized within bureaucratic systems (Drechsler *et al.*, 2023). As part of the emerging research agenda in Islamic Public Administration, IPV is conceptualized as a normative-analytical framework rather than a predictive grand theory (Drechsler *et al.*, 2023).

The Neo-Weberian State paradigm provides the necessary institutional lens to analyse this transformation. The NWS model emphasizes the continued centrality of the state, the reaffirmation of legal-rational authority, professionalized bureaucracy, and a renewed public service orientation (Bouckaert, 2007; Pollitt & Bouckaert, 2011). Unlike New Public Management, which prioritizes market logics and

managerial efficiency, NWS restores the state's strategic and coordinating role while incorporating citizen-oriented responsiveness.

In the context of halal certification in Indonesia, Islamic legal norms are translated into standardized procedures, audit mechanisms, regulatory oversight, and inter-agency coordination involving institutions such as the Halal Product Guarantee Agency (BPJPH) and the Indonesian Ulama Council (MUI). This institutional arrangement illustrates how religious principles are bureaucratically formalized within a modern administrative state. The Neo-Weberian State framework is particularly relevant because it explains how Islamic Public Value is not only normatively articulated but structurally embedded in governance practice. This study thus argues that in Muslim-majority contexts, the Neo-Weberian State does not necessarily secularize governance; rather, it may function as an institutional vehicle through which religiously grounded public values are rationalized, standardized, and implemented within the state apparatus.

1.2 Islamic public value

Islam has a significant and crucial impact on how public spaces are organized and managed, challenging the dominant Western view that religion and public administration should be separated. Islamic principles and values are inherently linked to public administration and the common good, and Islamic public administration is fundamentally based on fulfilling divine expectations and achieving sacred goals, rather than being separate from religion. This can be seen in three dimensions: in theory and practice, in space and time, and in governance and faith (Drechsler *et al.*, 2024).

Islamic Public Value (IPV) emerges within the broader research agenda of Islamic Public Administration as an effort to systematically integrate Islamic epistemology into contemporary public administration theory (Drechsler *et al.*, 2023). Rather than constituting a fully consolidated grand theory, IPV is more appropriately conceptualized as a normative-analytical framework that examines how Islamic moral principles shape the creation, institutionalization, and evaluation of public value within governance systems. The conceptual roots of IPV may be traced to classical Public Value theory developed by Mark Moore (1995), which emphasizes value creation through democratic legitimacy, operational capacity, and public authorization. However, Islamic Public Value departs from Moore's predominantly secular-democratic foundation by grounding the notion of public value in Islamic ontology and epistemology. In this perspective, public value is not derived solely from aggregated citizen preferences or procedural legitimacy, but from alignment with divine guidance (*wahy*), the objectives of Islamic law (*maqasid al-shari'ah*), and the pursuit of collective welfare (*maslahah*) (Drechsler *et al.*, 2023).

Drechsler *et al.* (2023) position Islamic Public Administration and Islamic Public Value within a non-Western governance paradigm that integrates spiritual accountability with bureaucratic legitimacy. Expanding this argument, Hariani and Soegiono (2025) demonstrate that Islamic Public Administration represents a morally grounded yet administratively legitimate governance model, particularly visible in faith-based community services that operate alongside or in support of state institutions. They argue that Islamic governance traditions emphasize justice, compassion, and social responsibility as foundational principles for public administration, and that faith-based actors function not only as social agents accountable to society but also as moral agents accountable before God. This dual accountability reinforces ethical discipline, transparency, and service orientation within public administration practice. Their analysis further shows that Islamic governance frameworks do not inherently promote exclusivism; rather, they often produce inclusive social services that transcend religious boundaries, thereby strengthening social cohesion and public trust in multicultural settings.

In this light, Islamic Public Value encompasses both material and non-material dimensions of governance outcomes. It reflects the institutional translation of *Shari'ah* principles into formal administrative mechanisms, the promotion of collective welfare and social justice, and the generation of moral recognition and dignity among policy beneficiaries. Hariani and Soegiono (2025) emphasize that Islamic Public Administration is capable of balancing sacred values with modern administrative demands such as accountability, performance, and professional ethics, thereby offering an alternative paradigm to purely secular governance models. This perspective aligns with Drechsler *et al.* (2023), who argue that Islamic Public Administration should not be understood as a theological replacement for modern bureaucracy, but as a research agenda that integrates Islamic ethical commitments into contemporary governance structures.

Importantly, Islamic Public Value must be distinguished from broader discussions of Islamic political theory or macro-level Islamic governance models. While Islamic political thought often focuses on state legitimacy, sovereignty, or historical caliphate structures, Islamic Public Value concentrates specifically on how values are created, justified, and operationalized within concrete public policy processes. It functions as a bridge between normative Islamic ethics and empirical public administration analysis, allowing scholars to examine how religiously grounded principles are rationalized, standardized, and embedded within modern institutional arrangements. In this sense, Islamic Public Value provides a structured analytical lens for understanding how Islamic moral commitments coexist with and shape contemporary administrative practice.

1.3 Halal certification acceleration program

The Free Halal Certification Program constitutes one of the operational instruments within Indonesia's broader Halal Certification Acceleration Policy framework. This program is administered by the Halal Product Guarantee Agency (BPJPH) under the Ministry of Religious Affairs. It is specifically designed to facilitate halal certification for micro and small enterprises (MSEs). Under this scheme, business actors may obtain halal certification in the self-declaration (Self Declare) category, in which compliance with halal standards is affirmed by the business operator and verified through a regulated administrative process. The program is legally grounded in BPJPH Head Decision No. 33 of 2022, which provides technical guidelines for assisting the halal product process and determining certification obligations for micro and small enterprises based on self-declaration mechanisms (Kominfo Jatim, 2023).

As part of the acceleration policy, the Free Halal Certification Program seeks to reduce financial and administrative barriers

that often prevent small enterprises from entering the formal halal certification system. Certification is expected to strengthen consumer trust and expand marketing networks, particularly among Muslim consumers who prioritize halal compliance (Epriliyana, 2019). Beyond market expansion, formal certification also enhances a business's legal standing, thereby improving access to financial capital and institutional support (Yuwita *et al.*, 2021). From a regulatory perspective, business legality further provides legal protection and clearer accountability structures (Anugrah *et al.*, 2021). In the specific context of halal certification, however, the policy is not solely economic in orientation; it is also intended to provide moral and religious assurance to halal consumers, reinforcing confidence that products comply with Islamic principles. This normative dimension of value creation will be explored further in the subsequent discussion.

2. Research methodology

This study employs an exploratory qualitative case study design to examine how Islamic Public Value (IPV) is articulated and institutionalized within the halal certification acceleration policy framework in East Java. An exploratory qualitative approach is appropriate when research seeks to understand complex institutional processes, normative dimensions, and value-based motivations embedded in public policy implementation. Such an approach allows the researcher to capture the interaction between regulatory structures, religious authority, and socio-economic actors within a specific governance context (Creswell & Creswell, 2018). A single-case design was selected to enable in-depth contextual analysis of East Java Province, which has demonstrated significant progress in halal certificate issuance and institutional coordination within Indonesia's halal governance system.

The field research was conducted between February and June 2025 in East Java Province. The province was selected purposively due to its leading position in halal certification implementation and its active provincial facilitation programs targeting micro and small enterprises. Focusing on a single region allowed for analytical depth in examining how Islamic Public Value components are operationalized through bureaucratic procedures and multi-actor collaboration within a Neo-Weberian institutional setting. A purposive sampling strategy was used to ensure participants had direct knowledge and involvement in halal certification governance. A total of 10 informants participated in this study. These consisted of one official from the Provincial Cooperative and SME Agency responsible for facilitation programs, one representative from the Provincial Halal Task Force (regional office of BPJPH) as regulatory authority, one representative from the East Java branch of the Indonesian Ulama Council (MUI) as the substantive issuer of halal *fatwas*, one representative from a Halal Inspection Body (LPH) responsible for technical audits, and six SME actors who had participated in the self-declare certification scheme. Participants were selected based on three criteria: direct involvement in the implementation of halal certification, a minimum of 1 year of program engagement, and willingness to participate in recorded interviews. This selection ensured that institutional, regulatory, and beneficiary perspectives were adequately represented.

Data collection was conducted using three primary techniques: semi-structured in-depth interviews, document analysis, and participatory observation. Interviews lasted between 60 and 90 minutes and were guided by a protocol covering five thematic areas: the perceived purpose of halal certification policy, motivations behind SME participation, institutional coordination mechanisms, perceived public value outcomes, and implementation challenges. All interviews were recorded with participant consent and transcribed verbatim for analysis.

Document analysis involved reviewing regulatory and institutional materials relevant to halal certification governance. These included BPJPH Head Decision No. 33 of 2022, provincial facilitation reports, halal certification statistical data, institutional coordination documents, SIHALAL platform documentation, and official public communications. Documents were selected based on their relevance to policy design, implementation mechanisms, administrative procedures, and distribution of institutional authority. This analysis enabled the researcher to trace how *Shari'ah* principles were translated into bureaucratic rules and administrative instruments.

Participatory observation was conducted during halal certification facilitation sessions, socialization programs, halal festivals, verification processes, and coordination meetings among institutional actors. The researcher observed administrative workflows, interactions between government officials and SME actors, and the framing of halal certification in economic, regulatory, and religious terms. Field notes were systematically recorded after each session to capture contextual dynamics and non-verbal interactions that complemented interview data.

Data analysis was conducted through a thematic analytical strategy following Braun and Clarke's six-step framework: familiarization with the data, initial coding, theme identification, theme review, theme definition, and analytical interpretation (Ahmed *et al.*, 2025). The analysis began with a comprehensive review of the entire dataset, including interview transcripts, field notes, and institutional documents. Data were segmented into meaningful analytical units and coded to identify recurrent patterns related to values, motivations, institutional roles, and governance mechanisms. These codes were then clustered into broader thematic categories.

The analytical strategy combined deductive and inductive logic (Tengku Kasim & Mansor, 2021). Deductively, the Islamic Public Value framework and the Neo-Weberian State perspective were used as theoretical lenses to guide initial coding and interpretive orientation. Inductively, empirical data were allowed to generate emerging value components and contextual insights, which were subsequently compared with theoretical constructs to ensure coherence and analytical consistency. Through this iterative process, three major value components were identified and analytically linked to institutional mechanisms within halal certification governance.

To enhance credibility and trustworthiness, several validation strategies were applied. First, data triangulation was conducted by comparing findings from interviews, documents, and observations across institutional sources. Second, member checking was undertaken with selected participants to confirm interpretative accuracy. Third, peer debriefing was conducted with two public administration scholars to evaluate analytical logic and thematic coherence. Finally, an audit trail documenting coding decisions and analytical steps was maintained to ensure transparency and methodological rigor. Through this systematic and transparent procedure, the study

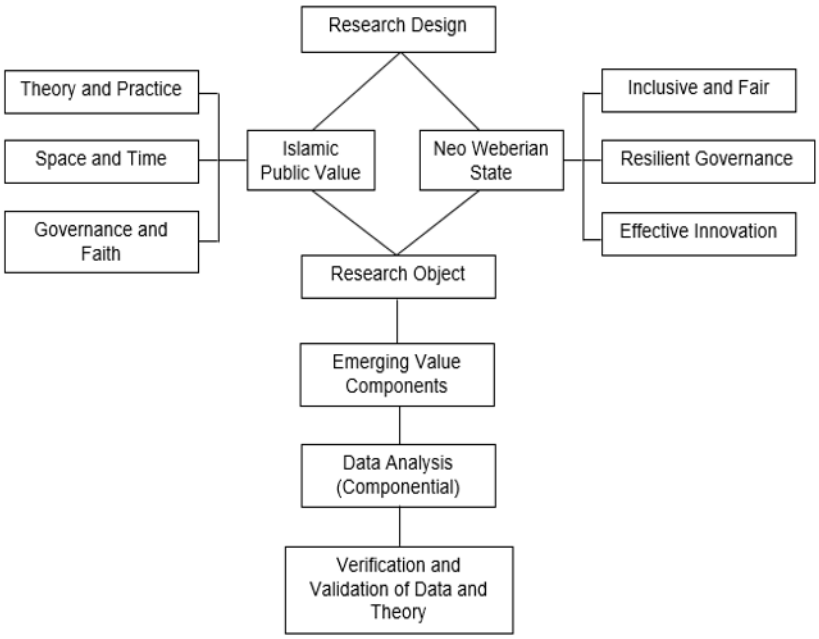

Figure 1: Research method process framework.

ensures analytical depth in examining how halal certification policy functions not merely as a regulatory instrument but as a governance arena where Islamic Public Value is institutionalized within a Neo-Weberian bureaucratic structure.

3. Results and discussion

3.1 Finding

The three thematic components presented in this study were not predetermined categories but emerged through a structured deductive–inductive analytical process. During the first stage of analysis, field notes and policy documents were repeatedly read to identify recurring patterns in motivations, institutional roles, and value expressions. Open coding generated initial labels such as "spiritual responsibility," "*fatwa* compliance," "consumer assurance," "institutional synergy," "religious legitimacy," and "government facilitation." In the second stage, these codes were grouped into broader analytical clusters based on conceptual similarity. The clustering process revealed three dominant value orientations consistently appearing across data sources: (1) institutionalization of *Shari'ah* principles, (2) collective trust and social solidarity, and (3) moral recognition and non-material motivation. These clusters were then interpreted through the analytical lens of Islamic Public Value (IPV) and examined in light of the structural characteristics of the Neo-Weberian State (NWS).

From the data collection process using document analysis and direct observation, it became evident that religious considerations and the influence of local religious figures significantly shaped the implementation of halal certification policy in East Java. Observations conducted in the halal culinary zones initiated by the provincial government showed that many small- and medium-sized industry players expressed a willingness to participate in certification, not merely for market expansion but also to ensure religious compliance. Several business actors explicitly framed certification as a form of accountability to Islamic *fatwas* and as a manifestation of obedience to halal prescriptions. These empirical patterns were systematically categorized into the three main components of Islamic Public Value discussed below.

3.1.1 Application of Islamic law

The first theme emerged from recurring references to religious obligation and institutional enforcement of halal norms. Interview transcripts and policy documents consistently indicated that the acceleration of halal certification represents a state effort to formalize *Shari'ah* principles within a modern regulatory framework. The involvement of the Indonesian Ulama (MUI) of East Java as the substantive authority issuing halal *fatwas*, alongside Halal Inspection Bodies (LPH) conducting technical audits under the Halal Assurance System standards, demonstrates how religious doctrine is translated into administrative procedure. This religious orientation was strongly reflected in the statements of SME actors. One SME participant stated:

"...For us, halal certification is not only about market access. It is about ensuring that what we sell is religiously accountable before Allah. Profit is important, but barakah is more important..." (Interview, SME-3, March 2025).

This statement illustrates that certification is perceived not merely as regulatory compliance but as a spiritual act of accountability. The emphasis on barakah (divine blessing) indicates that economic rationality is intertwined with theological considerations.

At the institutional level, government actors explicitly acknowledged the translation of religious norms into bureaucratic mechanisms. An official from the East Java Halal Task Force emphasized:

"...Our role is to translate religious fatwas into administrative systems. Certification is where Shari'ah principles meet bureaucratic procedures..." (Interview, Gov-2, February 2025).

This statement provides direct empirical evidence of how *Shari'ah* norms are operationalized through standardized administrative procedures. Field observations during verification sessions further showed structured documentation review, inspection of production processes, and formal issuance mechanisms. These practices reflect Neo-Weberian State characteristics, particularly the reliance on rule-based authority and legal-rational bureaucracy. However, unlike secular regulatory systems, the substantive content of these procedures is derived from Islamic legal principles.

The application of Islamic law within the halal certification policy is not inferred normatively but grounded in empirical expressions from both SME actors and state officials. The data demonstrate that *Shari'ah* institutionalization operates simultaneously as moral guidance and administrative governance, aligning with the Islamic Public Value dimension of protecting religion and ensuring public welfare (*maslahah*).

3.1.2 Social cohesion

The second theme was derived from codes related to trust, collaboration, and collective participation. Observations during facilitation programs and coordination meetings revealed structured cooperation between the Provincial Cooperative and SME Agency, the Halal Product Guarantee Agency (BPJPH), MUI, LPH institutions affiliated with universities, and SME communities.

During observation at a halal culinary zone, several business actors expressed that displaying the halal logo increased customer trust. One participant noted:

"Customers ask less when they see the halal logo. It builds immediate trust." (Field note, April 2025)

This field note demonstrates that the halal label functions as a visible trust mechanism in socio-economic interactions. Certification reduces transactional uncertainty and strengthens relational confidence between producers and consumers. The halal logo thereby transcends administrative labelling and becomes a symbol of collective assurance grounded in shared religious values.

Policy documents further emphasize cross-sectoral facilitation and collaborative governance as implementation strategies. This inter-institutional synergy reflects Neo-Weberian State characteristics, where central authority is maintained while participatory engagement is encouraged. The data show that halal certification creates a governance ecosystem in which public institutions and society interact through shared normative commitments. Social cohesion is not assumed theoretically but observed empirically through patterns of trust-building, collaborative facilitation, and symbolic value attached to halal certification in everyday economic practice.

Findings in the field indicate that economic activities in this halal ecosystem are not isolated but are embedded in the community's religious norms and traditions. This concept of embeddedness shows that economic and political power is subject to a set of social norms, where decisions to produce or consume halal products become part of daily religious practices. As a result, the halal certification policy is not only a government instrument but also an arena for the community to assert its religious identity. This process creates an environment in which Islamic values become an inherent part of public administration itself, in line with the idea that Islamic public administration is fundamentally linked to the achievement of the common good (*maslahah*).

3.1.3 Social respect and non-material motivation

The third theme emerged from repeated references to dignity, moral recognition, and spiritual intention. Although policy documents highlight economic benefits such as market expansion, interview data reveal that non-material motivations play a central role in participation.

A senior SME owner explained:

"...Obtaining halal certification gives us dignity. People see us as entrepreneurs in the midst of a Muslim majority who are responsible for what we sell..." (Interview, SME-5, March 2025)

This statement indicates that halal certification enhances not only product legitimacy but also social standing. Certification is interpreted as moral validation within the community. The concept of dignity (*martabat*) suggests that religious compliance is associated with reputational capital and ethical credibility.

Additional interview data showed expressions such as "seeking Allah's pleasure" and "fulfilling responsibility as Muslims," reinforcing that spiritual motivations are primary drivers of participation. These empirical findings demonstrate that public policy effectiveness in religiously embedded societies depends on alignment with deeply internalized value systems.

From a Neo-Weberian perspective, this reflects governance that derives legitimacy not solely from formal authority but from normative resonance with societal ethics. Within the Islamic Public Value framework, this dimension represents governance rooted in faith-based accountability, where compliance emerges from moral consciousness rather than purely instrumental cost–benefit calculations.

Halal certification policies can be interpreted as a form of official recognition and respect by the state for the religious identity of its citizens, particularly in protecting the rights of Muslim consumers. For SME actors, having a halal certificate not only enhances product image but also significantly provides "social respect" and moral legitimacy within society. The status of being a verified halal producer elevates their social standing. This process is accelerated by the active role of community leaders and local officials who promote halal certification. When leaders advocate for this policy, they serve as enablers, reinforcing the value of social respect and transforming halal certification into a widely valued and followed social norm.

3.1.4 Component analysis

This section does not merely restate the empirical findings presented earlier but provides a second-level analytical interpretation of the results discussed in the Component Analysis section. While the previous section identified three core components of Islamic Public Value emerging from the data—namely the institutionalization of *Shari'ah* principles, social cohesion, and social respect with non-material motivation—this part advances the discussion by situating those components within a broader theoretical and governance framework. In other words, the findings section identified the values that emerged from the data. In contrast, this section explains how and why those values operate within the Neo-Weberian State structure and contribute to the construction of Islamic Public Value in policy practice. This discussion functions as an analytical extension rather than a repetition, deepening the interpretation by linking empirical patterns to conceptual arguments and governance theory.

Table 1: Overview of the implementation of halal certification services policy on Islamic public value components

Main Axis of IPV	Form of Service or Implementation	Value Components
Theory and Practice	- Coordination and guidance based on *fatwas* for all Halal Inspection Institutions (LPH) in East Java by the East Java MUI. - Mapping of products and socialization of the Halal Product Assurance System (SJPH) by the East Java Regional Office of the Ministry of Religious Affairs' Halal Task Force. - Provision of the PUSAKA and SIHALAL platforms to facilitate halal certification registration with a self-declaration system.	Implementation of Islamic Law
Space and Time	- Establishment of halal culinary areas in regencies/cities in East Java. - Assistance for tourism awareness groups to accelerate the certification of MSMEs in tourist areas in East Java, by the East Java Culture and Tourism Office. - Cooperation between the East Java Halal Task Force and Islamic community organizations and universities to assist in the halal product certification process.	Social Cohesion
Governance and Faith	- Halal Certification Program for micro and small businesses with an evaluation mechanism for honesty, religious intent, and social empowerment through a developed system (SIHALAL). - East Java Halal Industry Festival and halal festivals in districts/cities as a form of halal promotion and providing access for sellers and buyers of halal products. - Indonesia Halal Industry Awards (IHYA) is a form of government appreciation to individuals and industry players who play an active role in the development of the Halal Industry.	Social Respect & Non-Material Motivation

The implementation of Islamic Public Value in the halal certification acceleration program in East Java is manifested in three main interrelated axes. First, in the theory and practice axis, the value of *Shari'ah* Implementation is realized through services that institutionalize religious principles into modern governance. This is evident in the coordination and guidance of all Halal Certification Bodies (LPH) across East Java by the Indonesian Ulama Council (MUI) based on *fatwas*, the mapping of products and promotion of the Halal Product Assurance System (SJPH) by the Halal Task Force, as well as the provision of digital platforms such as PUSAKA and SIHALAL, which simplify registration through a self-declaration system. Second, along the axes of space and time, the value of Social Cohesion is built through the creation of a collaborative halal ecosystem.

Its implementation includes establishing halal culinary zones in various districts/cities, providing assistance from the tourism office to MSMEs in tourist areas, and cooperation between the Halal Task Force and Islamic community organizations and universities to support the halal product process. Third, on the governance and faith axis, the values of Social Respect and Non-Material Motivation are cultivated through programs that appreciate spiritual and ethical aspects. This is reflected in the evaluation mechanisms for honesty and

the intent of worship within the SIHALAL system, the organization of halal festivals to promote and expand market access, and the awarding of honours such as the Indonesia Halal Industry Awards (IHYA) as a form of government recognition for halal industry practitioners.

The implementation of Islamic Public Value (IPV) in the halal certification program contains various interrelated and layered value components. The *Shari'ah* Implementation component is not merely compliance with religious commands to produce and consume halal and *toyyib* products but also serves as a practical educational tool on Islamic business ethics (*fiqh muamalah*) and the internalization of accountability and trustworthiness values for business actors. Furthermore, this program strengthens Social Cohesion by encouraging solidarity and collaboration among various actors in the halal ecosystem, thereby building broader social legitimacy and public trust. This policy also guarantees the rights of Muslim communities in a pluralistic society while revitalizing local Islamic cultural values. At a deeper level, this program fosters social respect and non-material motivation, where halal certification reflects the moral integrity and religious intent of business actors, not merely a legal symbol. This value also includes strengthening environmentally friendly production ethics and preserving ethical consumption culture, thereby providing spiritual and social incentives in the form of a good reputation and higher standing in society.

Table 2: Summary of the substantial value of halal certification services from Islamic public value components

Value Components	Description
Implementation of Islamic Law	Compliance with religious commands: Halal certification embodies the principles of halal and *toyyib*, serving as a form of obedience to Islamic law in consumption and production. Strengthening the values of *Shari'ah* education: The certification process becomes a practical learning tool for *fiqh muamalah* and Islamic business ethics. Internalization of accountability and trustworthiness values: Business actors learn to be honest about raw materials and production processes, as well as to maintain trustworthiness towards Muslim consumers.
Social Cohesion	Community solidarity in the halal economy: Halal certification encourages collaboration among businesses, communities, religious institutions, and the government to build a halal ecosystem. Social legitimacy and public trust: Halal-certified products enjoy greater trust from people from all backgrounds. Protection of Muslim minorities in a pluralistic society: This policy guarantees Muslims the right to purchase products consistent with their beliefs while also promoting social inclusion. Revitalization of local Islamic cultural values: Halal practices are revived as part of the local traditions of Indonesia's Muslim communities.
Social Respect & Non-Material Motivation	The moral integrity of business actors: Halal certification is not only a legal symbol but also a reflection of religious devotion and moral integrity. Strengthening ethical consumption and environmentally friendly production (ecological values): The certification process considers cleanliness, safety, and environmental sustainability. Preservation of ethical consumption culture: Reviving the culture of clean, pure, and healthy living inherited from Islamic law and ancestral traditions. Spiritual and social incentives: Halal-certified businesses gain higher social status, such as recognition, a good reputation, and business blessings.

The implementation of Islamic Public Value (IPV) in the halal certification program contains various interrelated and layered value components. The *Shari'ah* Implementation component is not merely compliance with religious commands to produce and consume halal and *toyyib* products, but also serves as a practical educational tool on Islamic business ethics (*fiqh muamalah*) and the internalization of accountability and trustworthiness values for business actors. Furthermore, this program strengthens Social Cohesion by encouraging solidarity and collaboration among various actors in the halal ecosystem, thereby building broader social legitimacy and public trust. This policy also guarantees the rights of Muslim communities in a pluralistic society while revitalizing local Islamic cultural values. At a deeper level, this program fosters social respect and non-material motivation, where halal certification reflects the moral integrity and religious intent of business actors, not merely a legal symbol. This value also includes strengthening environmentally friendly production ethics and preserving ethical consumption culture, thereby providing spiritual and social incentives in the form of a good reputation and higher standing in society.

4. Research limitations

This study has several limitations. First, it employs a single-case study design focusing solely on East Java, which may limit generalizability to other regions. Second, the cultural and religious characteristics of East Java may influence the prominence of spiritual motivations. Third, the study relies primarily on qualitative self-reported data, which may reflect subjective interpretations. Future research may conduct comparative studies across provinces or countries to examine variations in the implementation of Islamic Public Value across different governance contexts.

5. Conclusions

The policy of accelerating halal certification in East Java is a concrete manifestation of the Neo-Weberian State (NWS) paradigm, which has successfully integrated Islamic public values into a rational, participatory, and modern bureaucratic framework. This study shows that the program's success is not only driven by legal-administrative mechanisms but also by three interrelated components of Islamic Public Value. First, the implementation of *Shari'ah* serves as the primary foundation, where the state, through institutions such as the Indonesian Ulama Council (MUI) and the Halal Product Guarantee Agency (BPJPH), institutionalizes the principle of *maslahah* (public welfare) by protecting the rights of Muslim consumers. At the same time, for businesses, compliance is understood as a spiritual responsibility. Second, the program has proven to strengthen social cohesion by building collective trust among producers, consumers, and the government, creating a collaborative ecosystem rooted in shared religious values. Third, and most notably, is the strong social respect and non-material motivation, where the main motivation of business actors is spiritual (seeking Allah's pleasure) and ethical, which is then reinforced by state recognition and social legitimacy from the community. Thus, the halal certification policy in East Java is not merely the implementation of regulations but a responsive governance practice that effectively aligns national objectives with the spiritual and social values prevalent in society, demonstrating that public policy can achieve optimal effectiveness when it addresses dimensions of faith and local wisdom.

Based on these findings, several academic and practical recommendations can be formulated. Academically, further research is needed to explore how the IPV concept can be applied to other public policy sectors in countries with Muslim majorities, such as education, health, and social services. Comparative studies across regions in Indonesia or between countries can also enrich the understanding of variations in the implementation of NWS based on local values. Additionally, developing a more detailed theoretical framework for measuring the impact of non-material motivation on public policy compliance is a promising area of research. Practically speaking, both central and local governments are advised to integrate spiritual and ethical narratives into public policy socialization, rather than focusing solely on economic incentives. Regulators such as BPJPH can refine systems like SIHALAL to not only verify technical aspects but also capture and appreciate the non-material motivations of business actors in the evaluation. For industry players, especially SMEs, these findings underscore the importance of building a brand not only on product quality but also on a foundation of moral integrity and spiritual values that have proven capable of fostering consumer loyalty and strong social legitimacy.

References

Ahmed, S. K., Mohammed, R. A., Nashwan, A. J., Ibrahim, R. H., Abdalla, A. Q., Ameen, B. M. M., & Khdhir, R. M. (2025). Using thematic analysis in qualitative research. Journal of Medicine, Surgery, and Public Health, *6*, 100198. https://doi.org/10.1016/j.glmedi.2025.100198

Anugrah, D., Dialog, B. L., Tendiyanto, T., Budiman, H., & Rahmat, D. (2021). Legal counselling on the importance of business entity legality as a form of legal protection for business actors. Journal of Community Service. 4(1), 91–96. https://doi.org/10.25134/empowerment.v4i01.4058

Bouckaert, G. (2022). The neo-Weberian state: From ideal type model to reality?. UCL Institute for Innovation and Public Purpose. https://www.ucl.ac.uk/bartlett/sites/bartlett/files/bouckaert_g._2022_the_neo-weberian_state_from_ideal_type_model_to_reality_0.pdf

Creswell, J. W., Creswell, J. D. (2018). Qualitative, Quantitative, and Mixed Methods Approaches. Fifth Edition. London: SAGE Publications.

Drechsler W., Kattel R., Chafik S. (2024). Islamic public administration and Islamic public value: Towards a research agenda. Sage Journals Public Policy and Administration, Vol. 39(4) 608–624. https://doi.org/10.1177/09520767231201799

Epriliyana, N. N. (2019). The urgency of food safety permits (P-IRT) in building consumer trust and improving marketing networks. Indonesian Journal of Management and Business, 5(1), 21–31. https://jurnal.unmuhjember.ac.id/index.php/JMBI/article/view/2580/2049

Hambali, H. (2020). Mandatory halal certification for foreign products according to the Agreement on Technical Barriers to Trade (Technical Barriers to Trade Agreement). Nurani Hukum: Jurnal Ilmu Hukum. 2(2) 48–61. DOI:10.51825/NHK.V2I2.8840

Hariani, N. J., & Soegiono, A. N. (2023). Islamic public administration and Islamic public value: Towards a research agenda. Halduskultuur: The Estonian Journal of Administrative Culture and Digital Governance, 24(1), 41–58. https://doi.org/10.32994/hk.v24i1.369

Lynn, Jr, LE. (2008). What is a neo-Weberian state? reflections on a concept and its implications. The University of Chicago. Corpus ID: 178254106

Moore, M. H. (1995). Creating public value: Strategic management in government. Harvard University Press. ISBN 0-674-17558-1

Romadhoan, S. (2024). Indonesia, the country with the largest Muslim population, is ranked 10th in the world for the halal industry. Muhammadiyah University of Sidoarjo. https://umsida.ac.id/3-dosen-umsida-dampingi-sertifikasi-halal/

State of the Global Islamic Economy Report. (2023). The state of the global Islamic economy 2023/24 report. https://digilib.itb.ac.id/assets/files/2024/MjAyNCBUUyBQUCBSQU1BREhJQU4gLSBCQUIgMS5wZGY.pdf

Syafrida, H. R. (2019). Halal certificate obligations for imported products in Indonesia. Journal of Social & Cultural Syar-i. Vol. 6 No. 4

Tengku Kasim, T.S.A. & Mansor, F. (2021). Pedagogy based on inductive and deductive approaches: Practice in Islamic finance education. Journal of Islamic Management and Finance, Vol. 1 No. 1 (2021) 63–77. https://doi.org/10.22452/ojimf.vol1no1.5

Yuwita, N., Sri Astutik, S. B., & Sri Rahayu. (2021). Legal assistance for micro, small, and medium enterprises through the online single submission system in Lemahbang Village, Sukorejo District. Khidmatuna: Journal of Community Service, 2(1), 41–48. https://doi.org/10.51339/khidmatuna.v2i1.322

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Halal integrity risks and compliance strategies in non-halal-certified food SMEs in Negeri Sembilan: A descriptive study

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Received: 29/1/2026
Accepted: 26/7/2026
Published: 31/7/2026

Keywords:
Halal integrity; Halal compliance; Small and Medium Enterprises (SMEs); Local food premises; Halal risk management.

Abstract

The halal food sector plays an important role in maintaining consumer confidence in Malaysia, where most of the population is Muslim. Although Malaysia has an established halal certification system, more than 90% of food and beverage businesses are small and medium-sized enterprises (SMEs), many of which operate without halal certification. This raises concerns about how halal integrity is maintained in daily operations, as non-certified businesses may rely on personal religious understanding and informal practices. This study aims to identify halal integrity risks among non-certified SME food establishments and examine the practices and challenges they face in maintaining halal compliance. Data were collected via a 22-item online questionnaire administered to 41 SME operators and employees in Nilai and Tampin, Negeri Sembilan. The data were analysed using SPSS, including reliability testing and descriptive statistics. The findings showed strong awareness of *halalan toyyiban* (87.8%) and farm-to-table traceability (82.9%). However, gaps were found in supplier verification: 45% were unaware of their suppliers' official halal status, and only 12.2% conducted on-site verification. While utensil segregation was widely practised (87.8%), documentation remained weak (34.1%). The main challenges were infrastructure costs (mean = 4.48) and administrative complexity (mean = 4.21). The study recommends repositioning the SME Halal Integrity Shield (SHIS) as a practical tool to facilitate the adoption of the Internal Halal Control System (IHCS) under MPPHM 2020, as amended by *Pekeliling* Bil. 1/2026.

1. Introduction

The global halal industry has evolved from a purely religious requirement to a robust business standard emphasising hygiene, safety, and quality, known as *halalan toyyiban*. In the Malaysian context, the small and medium-sized enterprises (SMEs) sector forms the backbone of the food and beverage industry, meeting the daily nutritional needs of a predominantly Muslim population (Department of Statistics of Malaysia [DOSM], 2022). Official halal certification is jointly administered by the Department of Islamic Development Malaysia (JAKIM) and the respective State Islamic Religious Councils/Departments, such as the Jabatan Hal Ehwal Agama Islam Negeri Sembilan (JHEAINS) for Negeri Sembilan, operating as competent authorities under the Trade Descriptions (Certification and Marking of Halal) Order 2011. However, many local SMEs continue to operate without formal accreditation and instead rely on "Muslim ownership" as an informal substitute for halal insurance (Samsudin & Yusof, 2017). This dependency creates a context in which religious trust often precedes formal verification, neglecting technical compliance requirements.

The rapid growth of the food industry, accelerated by digital advertising and social media trends, has increased the complexity of halal supply chains. The main problem lies in the "integrity gap" observed in non-certified SMEs, where the lack of formal audits increases the risk of cross-contamination and accidental use of dubious raw materials (Zailani *et al.*, 2015). While smaller operators face hurdles that prevent them from formalizing compliance, the governing procedural baseline, the Manual Prosedur Pensijilan Halal Malaysia (Domestik) 2020 (MPPHM 2020, including amendments via *Pekeliling* Bil. 1/2026), explicitly dictates that the product standard MS 1500:2019 must be read together with procedural and management system manuals. Without standardised internal controls as outlined in the Malaysian Halal Management System (MHMS 2020), the risk of a 'halal drift', where standards deteriorate due to operational negligence, becomes a crucial issue for consumer protection and *Shari'ah* compliance (Ismail & Omar, 2020).

To address these vulnerabilities, this study focuses on the micro-level operational realities of food establishments in Nilai and Tampin, Negeri Sembilan. Selecting these semi-urban localities provides a targeted regional proxy to evaluate how local market dependency affects supply chain integrity. Two main objectives guide this study:

1. Identify specific halal integrity risks in non-certified agri-food SMEs, with a focus on supplier verification and raw material sourcing.
2. Analyse the operational challenges and obstacles that prevent these local entities from obtaining official Halal certification under the current regulatory framework.

2. Literature review

2.1 The multidimensional concept of *halalan toyyiban*

The contemporary understanding of halal integrity has evolved beyond the binary classification of what is permitted (halal) and what is forbidden (*haram*). Modern research indicates that halalan toyyiban is a holistic framework that combines adherence to *Shari'ah* law with safety, hygiene, and quality standards. As Saffinee & Jamaludin (2024) note, the *toyyib* aspect serves as a quality assurance mechanism, ensuring that the animal is not only ritually slaughtered but also free of contamination and harmful pathogens.

However, an operational gap exists between high-level theological concepts and field-level execution in micro-enterprises. While large corporations integrate toyyiban into their formal Quality Management Systems (QMS), small operators often limit halalan toyyiban to the absence of pork or alcohol, neglecting technical requirements such as cross-contamination protocols and cold-chain traceability. Crucially, certification compliance in Malaysia is governed procedurally by MPPHM 2020 (issued under Section 7(2) of the Trade Descriptions Act 2011 [Act 730]) and structurally by MHMS 2020. MS 1500: 2019 serves as a technical product standard rather than the governing administrative procedure. Evaluating SME practices against MS 1500: 2019 alone, without engaging MPPHM 2020 and MHMS 2020, provides an incomplete compliance benchmark.

2.2 Institutional pressures and supply chain non-conformance

Supply chain management remains the most vulnerable point to halal integrity failures due to the complexity of ingredient sourcing. Mohd Noor & Ahmad (2020) point out that SMEs often suffer from information unevenness, trusting upstream suppliers based on verbal assurances or personal relationships, rather than verifying valid JAKIM certificates. This trust-based sourcing creates severe vulnerabilities in markets where unverified imported inputs or fraudulent halal claims occur (Sholahuddin *et al.*, 2025).

Under MPPHM 2020, Section (General Requirements for Raw Materials), and MHMS 2020, raw material control is mandatory. Animal-based inputs require valid halal certification from recognized bodies, imported materials must originate from approved establishments, and non-certified inputs require complete supporting documentation (e.g., specifications and flow charts). MHMS 2020 mandates a Raw Material Masterlist containing producer details, certification body accreditation, and certificate expiry dates. Failure to maintain supplier verification is not merely a soft vulnerability; under MPPHM 2020, procuring raw materials of doubtful status constitutes a formal Major Non-Conformance, whereas using confirmed non-halal inputs constitutes a Serious Non-Conformance leading to immediate certification refusal or revocation.

2.3 Financial barriers: Fee schedules vs. capital expenditure

The literature consistently identifies structural barriers that prevent SMEs from entering the formal halal ecosystem. Mudau (2024) found that the burden of administrative documentation is often too high for micro-enterprises without dedicated quality-control staff. However, a common misconception is that the primary hurdle is the official certification fee levied by competent authorities.

Under MPPHM 2020 (as amended by Pekeliling Bil. 1/2026), the official fee schedule is structured to accommodate smaller businesses:

- Processing Fee: RM20
- Micro-Enterprises (Turnover < RM300,000): RM100 certification fee
- Small Enterprises (Turnover RM300,000 – RM15 million): RM400 certification fee

Mulyana, Maulidizen, and Julian (2024) offer a different perspective, suggesting that the obstacle is not entirely financial, but rather a knowledge gap regarding the application process itself. The true economic barrier facing non-certified SMEs is not the nominal application fee, but the capital expenditure (CapEx) required for facility modernization. Meeting JAKIM/JHEAINS infrastructure standards, such as specialized non-porous flooring, dedicated drainage, physical layout zoning, and industrial stainless-steel fittings, demands a substantial financial investment.

2.4 Human capital and regulatory alignments

Shift in halal studies emphasises the "human element" within food systems. Ismail and Omar (2020) argue that even in state-of-the-art facilities, halal integrity can be compromised by a single untrained employee. They suggest that "halal human capital," the combination of religious knowledge and technical skills in food management, is the strongest protection against cross-contamination. In many SMEs, reliance on a rotating workforce or part-time staff often means regular training is overlooked.

This aligns directly with statutory mandates. MPPHM 2020 General Requirements Part IV –clause 12 (a)(b) specifies that food handlers must undergo halal awareness training within three months of employment and refresher training at least once every three years. Furthermore, MHMS 2020 clause 5 (8)(c)(d) requires competency training for Internal Halal Committee (Jawatankuasa Halal Dalaman - JKHD) members. Relying solely on "Muslim ownership" does not guarantee technical proficiency in managing chemical cross-contact or critical control points. Standardised training modules are necessary to bridge this operational gap (Masudin *et al.*, 2025).

3. Methodology

This study uses a quantitative descriptive study to empirically investigate halal integrity risks and operational compliance among non-certified food SMEs in Nilai and Tampin, Negeri Sembilan.

3.1 Sampling and respondent profile

A non-probability purposive (deliberate) sampling strategy was utilized to select 41 respondents (n = 41), consisting of food business owners, managers, and food handlers. Purposive sampling was required because non-certified SMEs lack a centralized, official sampling frame or public registry (Creswell, 2014; Sekaran & Bougie, 2016).

Table 1: The knowledge practice gap in halal raw material sourcing (n=41)

Construct / variables	Frequency ($\bar{x}$)	Percentage (%)	Mean score ($\bar{x}$)
Knowledge area			
Awareness of the *halalan toyyiban* Concept	36	87.8%	4.61
Importance of farm-to-table traceability	34	82.9%	4.45
Area of operational activity			
Exclusive use of JAKIM-certified suppliers	24	58.5%	3.12
Regular review of the halal certifications of suppliers	19	46.3%	2.85
Critical integrity gap	--	**-41.5%**	--

(Source: Developed for this study)

To be included in the study, participants had to meet three inclusion criteria:

1. Operate or work within a food and beverage SME located in Nilai or Tampin, Negeri Sembilan.
2. Prepare, process, or sell unpackaged food directly to consumers.
3. Currently operates without a formal JAKIM/JHEAINS Halal Certification.

Given the exploratory focus on a specific geographical niche, a sample size of n = 41 provides a suitable baseline for descriptive statistical analysis. However, because non-probability sampling was employed, findings are interpreted specifically within the context of the surveyed cohort rather than generalized across all non-certified SMEs nationwide.

3.2 Data collection instrument and validation

Data were collected using a structured online questionnaire containing 22 items across four functional sections:

- **Section A:** Demographic and Business Profile (4 items).
- **Section B:** Halal Knowledge and Supply Chain Sourcing (6 items; measured via nominal yes/no choices and 5-point Likert scales from 1 = Strongly Disagree to 5 = Strongly Agree).
- **Section C:** Operational Compliance Practices (6 items; measured via reported operational frequency).
- **Section D:** Perceived Barriers to Formal Halal Certification (6 items; 5-point Likert scale).

The questionnaire items were adapted from established literature on SME halal compliance (Zailani *et al.*, 2015; Samsudin & Yusof, 2017). Content validity was established prior to distribution through review by a panel of three academic experts in Halal Management from Universiti Sains Islam Malaysia (USIM). Internal consistency was evaluated using Cronbach's alpha, yielding coefficients above 0.78 across all Likert-scale constructs, indicating acceptable scale reliability.

3.3 Methodological limitations

A key limitation of this study is its reliance on self-reported survey data. Self-administered questionnaires are subject to social desirability bias, in which respondents may overstate their operational compliance relative to actual practices. In contrast, official regulatory evaluations under MPPHM 2020 (Part VI & VII) are conducted via rigorous on-site field audits involving at least two qualified inspectors empowered to

examine physical premises, review documentation, review ingredient lots, and conduct unannounced monitoring checks. Consequently, the reported compliance figures in this study reflect self-perceived operational discipline; actual field compliance during a formal audit may be lower, further underscoring the underlying compliance risks.

4. Findings and discussion

Data were analysed using SPSS using descriptive statistics, including frequencies, percentages, and mean scores ($\bar{x}$), and standard deviations (SD).

4.1 Knowledge profile and sourcing verification gaps

The empirical results reveal a clear divergence between high conceptual awareness of halal principles and low technical verification in supply chain management. As detailed in Table 1, 87.8% of respondents ($\bar{x}$ = 4.61) reported understanding the concept of *halalan toyyiban*, and 82.9% ($\bar{x}$ = 4.45) acknowledged the importance of farm-to-table traceability. However, this religious awareness does not translate into verification practices. Only 58.5% ($\bar{x}$ = 3.12) explicitly restrict raw material purchasing to JAKIM-certified suppliers, and only 46.3% ($\bar{x}$ = 2.85They regularly review the validity of their vendors' certifications.

When asked directly about vendor verification, 45.0% of operators admitted they did not know the official halal certification status of their main suppliers, while only 12.2% conducted on-site verification visits or requested physical certificate copies. Sourcing in this cohort relies primarily on informal interpersonal trust rather than auditable verification. However, as Mohd Noor and Ahmad (2020) noted, the risk of halal drift remains high without physical verification of certificates.

4.2 Operational compliance dichotomy

Operational compliance, evaluated against core technical elements, reveals a dichotomy: strong adherence to physical hygiene practices coupled with neglect of documentation controls.

As illustrated in Table 2, 87.8% of surveyed venues enforce strict physical segregation of kitchen utensils, and 78.0% maintain systematic separation of raw and cooked items. Personal protective equipment (PPE) compliance stands at 73.2%.

Table 2: SME operational compliance levels across functional domains (n = 41)

Compliance category	Operating criteria	Compliance level (%)	Classification
Food preparation	Use of halal utensils	87.8%	**High**
Memory check	Separation of raw materials from processed items	78.0%	**Moderate**
Hygiene (*Toyyib*)	Use of personal protective equipment (PPE)	73.2%	**Moderate**
Documentation	Storage of Invoices/Halal Document	34.1%	**Critical**
Supplier Verification	On-site verification of the vendor's visit to the supplier's premises	12.2%	**Critical**

(Source: Developed for this study)

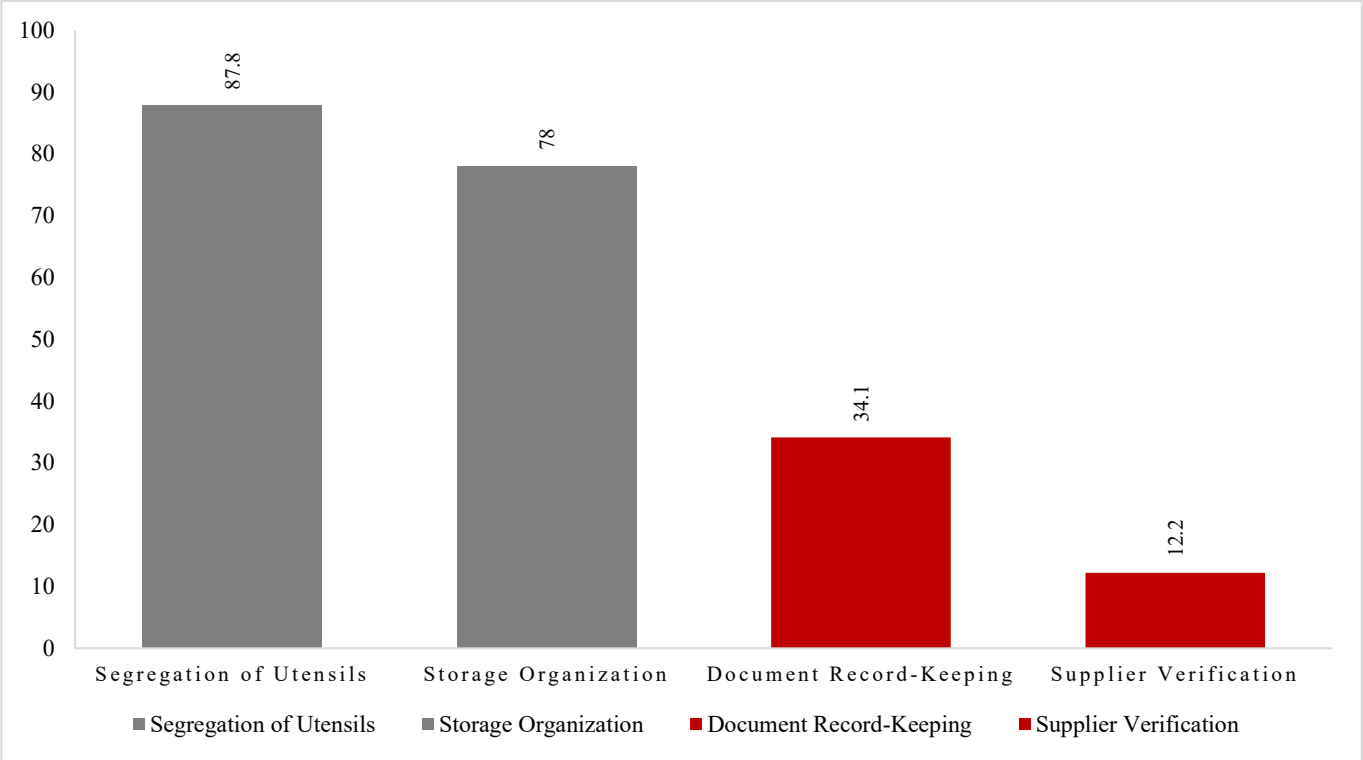

Figure 1: Operational Compliance Levels Among Non-Certified Food SMEs (n=41).

In contrast, compliance with administrative requirements drops sharply: only 34.1% of SMEs maintain standardized records or store purchase receipts for raw materials, and only 12.2% verify supplier credentials.

Figure 1 demonstrates that while non-certified SMEs maintain visible, physical food handling controls, they lack the "invisible" administrative records needed to verify compliance. In a food safety or halal audit, the absence of purchase records and vendor documentation prevents verification of the origin of raw materials.

4.3 Structural and financial certification barriers

An evaluation of perceived barriers indicates that physical infrastructure costs constitute the primary obstacle to formal certification.

As shown in Table 3, the cost of facility modernization emerged as the single highest barrier ($\bar{x} = 4.48, SD = 0.52$). This confirms that the real economic hurdle is the capital expenditure required to modify building layouts, install non-absorbent surfaces, upgrade drainage systems, and prepare partitioned zones to meet regulatory codes. Administrative complexity and the MYeHALAL documentation process ranked second ($\bar{x} = 4.21, SD = 0.61$). Attitudinal factors such as relying solely on Muslim ownership status ($\bar{x} = 3.68$) ranked lower, showing that operators are hindered more by financial and technical requirements than by a lack of intent.

5.0 Discussion

5.1 Re-evaluating supply chain risks under MPPHM 2020 non-conformance grades

The empirical findings demonstrate that non-certified SMEs operate predominantly on a "trust model" rather than a "verification model". Operators frequently assume ingredients obtained from local wet markets or Muslim vendors are inherently halal. However, under MPPHM 2020 and MHMS 2020, this trust-based approach creates systemic non-conformances.

Table 3: Ranking of Perceived Barriers to Formal Halal certification (n = 41)

Level	Barriers to certification	Average ($\bar{x}$)	Std. Deviation	Severity
1	Financial burden (costs for the modernisation of the facilities)	4.48	0.52	Very High
2	Administrative complexity (bureaucracy)	4.21	0.61	High
3	Lack of technical knowledge about MYeHALAL by JAKIM	3.95	0.74	High
4	Perception of the frugality of the status of "Muslim property"	3.68	0.88	Moderate
5	Difficulty in finding 100% certified suppliers	3.42	0.92	Moderate

(Source: Developed for this study)

When evaluated against official audit criteria, the supply chain vulnerabilities identified in Section D constitute formal non-conformances:

- **Major Non-Conformance:** Procuring critical inputs (such as poultry or meat products) without verifying valid halal certificates or failing to maintain an updated Raw Material Masterlist under MHMS 2020 raw material control protocols.

- **Minor Non-Conformance:** Inability to produce purchase invoices, delivery receipts, or batch logs during inspection, as observed among the 65.9% of SMEs lacking standard record-keeping.

- **Serious Non-Conformance:** Any accidental mixing, storage, or use of non-certified or non-halal inputs resulting from unverified suppliers, which leads to immediate audit failure or withholding of certification.

Framing these findings within official non-conformance grades highlights that non-certified SMEs face direct audit failure unless supply chain verification is addressed.

5.2 Deconstructing the cost barrier

The empirical data in Table 3 clarify the nature of the financial barrier facing SMEs. Abstract claims citing "high certification fees" conflate administrative fees with facility renovation costs. Under the fee schedule outlined in MPPHM 2020 (*Pekeliling* Bil. 1/2026), the statutory certification fee for micro-enterprises is RM100, while small enterprises pay RM400 for a two-year certification period. The administrative fee itself is manageable for most businesses. The primary financial barrier stems from the capital expenditure (CapEx) required to upgrade physical premises, including structural layout changes, specialized flooring, drainage overhauls, and dedicated pest control systems to meet technical standards. Regulatory authorities can better assist micro-enterprises by offering practical, graduated guidance on facility compliance rather than simply reducing administrative fees.

5.3 The compliance dichotomy and MPPHM 2020 clause 26 – scope (1)

This study highlights a clear compliance dichotomy: high physical discipline in kitchen operations (87.8% utensil segregation) alongside severe administrative deficiencies (34.1% record-keeping and 12.2% supplier verification). While strong physical segregation reflects genuine religious intent (*niyat*) and basic kitchen hygiene, physical discipline alone does not equal full compliance during a formal audit. Clause 26 of MPPHM 2020 specifies that an official halal audit evaluates 15 distinct operational areas, including documentation, raw material management, supply chain traceability, and internal controls, as per MHMS 2020. Physical hygiene represents only one evaluated component. Without auditable documentation, an establishment cannot prove traceability. In halal certification, what cannot be traced, verified, and documented cannot be legally validated by audit authorities.

5.4 Repositioned framework: SHIS as an IHCS implementation tool

To address these vulnerabilities without imposing immediate industrial-scale costs, this study evaluates the SME Halal Integrity Shield (SHIS). Rather than presenting SHIS as a new parallel regulatory framework, the study reframes SHIS as an operational facilitation tool designed to help micro and small enterprises implement the existing Internal Halal Control System (IHCS) required under MHMS 2020.

MHMS 2020 mandates three core IHCS elements for micro and small enterprises:

1. Halal Policy (*Polisi Halal*)
2. Raw Material Control / Halal Risk Control Procedure (*Kawalan Bahan Mentah / Kawalan Risiko Halal*)
3. Traceability Procedure (*Kebolehkesanan*)

As shown in Figure 2, the four progressive levels of SHIS align directly with these statutory IHCS elements, providing a step-by-step implementation guide:

Pillar 1: Verification pillar (Raw material control foundation)

Level 1 addresses the critical finding where 45.0% of SMEs do not know their suppliers' official halal status. This pillar operationalizes the MHMS 2020 Raw Material Control requirement by establishing a simple, physical Supplier Registry. Operators maintain a dedicated binder containing active copies of supplier JAKIM halal certificates and purchase receipts, establishing an auditable paper trail without requiring complex software.

Pillar 2: Process pillar (*Toyyib* & traceability protocol)

Level 2 builds upon existing physical practices (87.8% utensil segregation) by formalizing the 3S Protocol: Segregation, Sanitation, and Storage. Using visual controls, such as color-coded cutting boards, labelled preparation knives, and clear storage zoning, micro-enterprises prevent cross-contamination

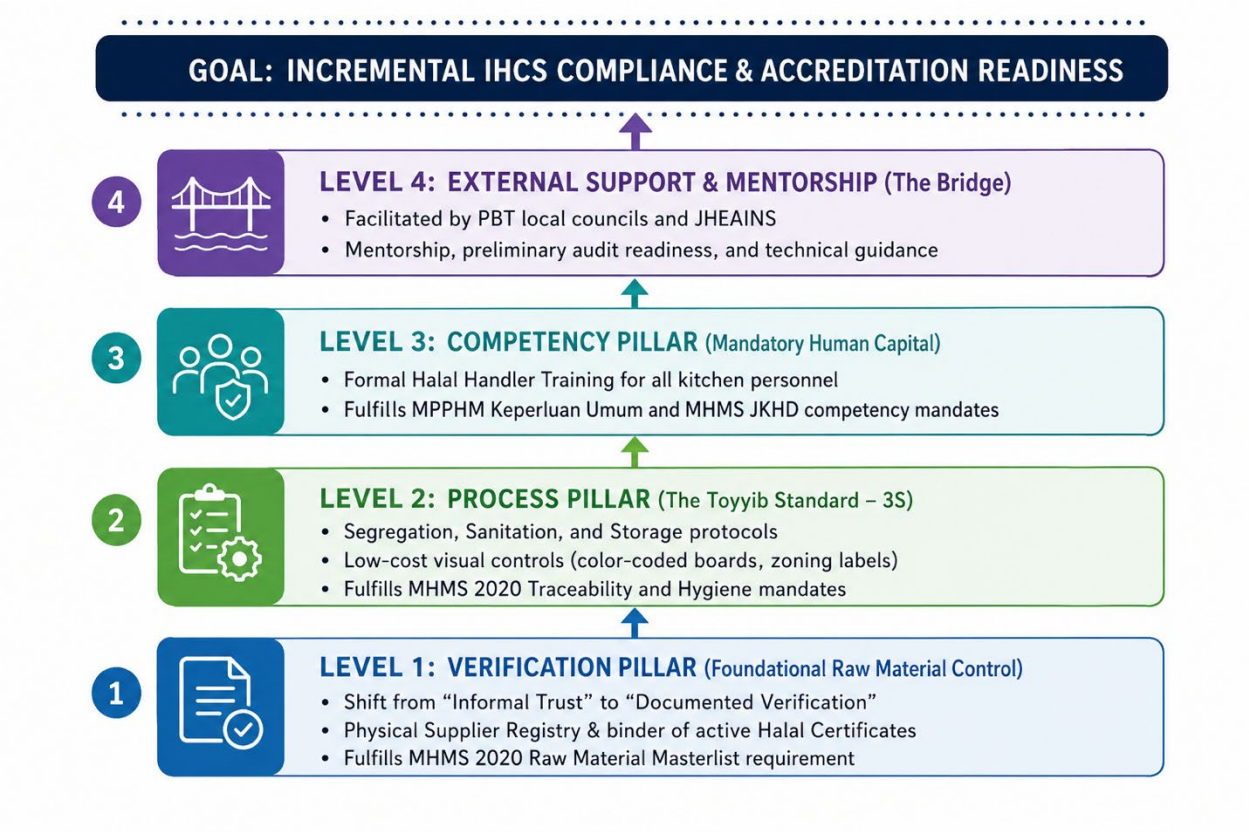

Figure 2: The SME Halal Integrity Shield (SHIS) framework for incremental IHCS compliance.

and establish basic batch traceability, as required by IHCS Element 3.

Pillar 3: Competency pillar (Halal human capital)

Level 3 focuses on workforce capability and on fulfilling MPPHM 2020 training mandates. This pillar requires all food handlers to complete basic Halal Handler Training courses recognized by JAKIM/JHEAINS. Standardized training ensures that staff understand cross-contact risks, chemical sanitation protocols, and document retention requirements, moving beyond reliance on Muslim ownership status alone.

Pillar 4: External support pillar (Mentorship and compliance bridge)

Level 4 engages local municipal councils (PBTs) and state religious departments (JHEAINS) to provide developmental support alongside regulatory enforcement. Local authority health inspectors can incorporate basic IHCS checklists during routine municipal licensing visits, offering technical guidance to help informal operators gradually upgrade facilities toward formal certification readiness.

6. Conclusion

This study evaluated halal integrity risks, operational compliance practices, and certification barriers among non-certified food SMEs in Nilai and Tampin, Negeri Sembilan. The empirical findings reveal a clear operational contrast within this cohort. While operators demonstrate strong personal religious awareness and high physical discipline in kitchen operations (87.8% utensil segregation), their compliance is undermined by severe administrative gaps. The lack of supplier verification (with 45.0% unaware of vendor certification status) and poor document retention (34.1%) leave these establishments exposed to supply chain non-conformance and halal drift. Furthermore, this study clarifies that the primary barrier to formal certification is not the statutory application fee, but the capital expenditure required for modernising facility infrastructure, along with administrative complexities.

To bridge this compliance gap, regulatory authorities should consider three targeted approach adjustments:

1. **Promote IHCS as an Incremental Step:** Reposition the Internal Halal Control System (IHCS) under MHMS 2020 using practical implementation toolkits like SHIS, encouraging micro-enterprises to build baseline supply chain documentation before applying for full certification.
2. **Clarify Fee vs. CapEx Guidance:** Publicise the fee schedule under MPPHM 2020 (*Pekeliling* Bil. 1/2026) to correct the misconception that application fees are prohibitive, while offering practical guidance on cost-effective facility layout modifications.
3. **Expand Local Regulatory Support:** Partner with local municipal councils (PBTs) and JHEAINS to offer developmental mentorship during routine municipal licensing inspections, assisting informal food operators in establishing auditable supplier registers.

For future research, because this study relied on a descriptive sample of 41 respondents across two districts in Negeri Sembilan, the findings cannot be generalized across all SMEs nationwide. Future research should expand sample sizes across diverse urban and rural localities, utilize inferential statistical modelling to test compliance predictors, and incorporate direct

multi-inspector field audits to compare self-reported compliance against formal audit outcomes. Ultimately, advancing *halalan toyyiban* assurance across the food sector requires strengthening supply chain verification and record-keeping among the majority of uncertified small businesses that serve consumers daily.

Acknowledgments

The authors also sincerely thank the anonymous reviewers and the handling editor for their constructive feedback and insightful suggestions, which significantly improved the quality and rigor of this manuscript.

Conflict of interest

The authors do not declare competing interests.

Declaration of AI

The authors also want to highlight the use of Gemini's generative AI tool and ChatGPT to paraphrase, refine style, and improve manuscript readability. This tool was used to improve the clarity and consistency of the text. However, all content, theological analyses, and conclusions presented in this manuscript remain the sole responsibility of the author.

Author's contribution

Siti Syahirah Saffinee designed the study, supervised the writing process, and was responsible for the critical review and final revision of the manuscript. Nor Farah Aiesha Nor Isamudin led the data collection, designed the research methodology, and wrote the first version of the paper. Both authors have read and accepted the published version of the manuscript.

References

Creswell, J. W. (2014). Research design: Qualitative, quantitative, and blended approaches (4th ed.). Thousand Oaks, CA: Sage.

Department of Islamic Development Malaysia (JAKIM). (2020). Malaysian halal management system 2020 [MHMS 2020]. Putrajaya: JAKIM.

Department of Islamic Development Malaysia (JAKIM). (2026). *Pekeliling* Bil. 1/2026: Pindaan manual prosedur pengeluaran sijil pengesahan halal Malaysia. Putrajaya: JAKIM.

Department of Statistics Malaysia. (2022). Micro, small, and medium enterprises (MSMEs) performance 2022.

Department of Statistics Malaysia. Department of Statistics Malaysia. (2022). Small and medium-sized enterprise (SME) performance 2022.

Hair, J. F., Black, W. C., Babin, B. J., & Anderson, R. E. (2019). Multivariate data analysis (8th ed.). Andover, UK: Cengage Learning.

Ismail, N., & Omar, S. R. (2020). Human capital and halal compliance in small and medium-sized enterprises. Journal of Islamic Marketing, 11(6), 1395–1412. https://doi.org/10.1108/JIMA-04-2019-0085

Mohd Noor, M. N., & Ahmad, S. (2020). Supplier verification and halal integrity in Malaysian food SMEs. Journal of Food Service Business Research, 23(4), 348–364 https://doi.org/10.1080/15378020.2020.1712345

Mudau, A. D. (2024). A case study on stakeholder perceptions in supporting local governments for the development and promotion of small, medium, and micro enterprises (SMEs) (PhD thesis, Tshwane University of Technology).

Rahman, F., & Said, J. (2020). Operational challenges and halal compliance in small food businesses. Asian Business and Accounting Review, 13(1), 101–122. https://doi.org/10.22452/ajba.vol13no1.5

Saffinee, S. S. & Jamaludin, M. A. (2024). Halal gastronomy: Quality of food management in the local tourist market. Asian People's Review (APJ), 7(2), 199–208.

Samsudin, S., & Yusof, R. (2017). Barriers to halal certification for small and medium-sized enterprises in Malaysia. International Journal of Economics, Commerce and Management, 5(12), 23–36.

Sholahuddin, M., Ridho, M. R., & Abdullah, M. A. (2025). Halal food fraud in Indonesia: A *sharia*-based review and strategic solutions. Indonesian Journal of Islamic Economic Law, 2(2), 179–201.

Standards Malaysia. (2019). MS 1500:2019 Halal Food - General Requirements (Fourth Revision). Department of Standards Malaysia.

Zailani, S., Arrifin, Z., Wahid, N.A., Othman, R., & Fernando, Y. (2015). Halal traceability and halal tracking systems to strengthen the halal supply chain of the food industry in Malaysia. Journal of Food Technology, 13(1), 1–11.

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Operationalising *Maqasid al-Shari'ah* through *toyyib* principles in labour ethics: Challenges and recommendations for the garment industry in Bangladesh

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Received: 15/4/2026
Accepted: 18/7/2026
Published: 31/7/2026

Keywords:
*Toyyib; Maqasid al-Shari'ah; G*arment industry; Labour ethics; Bangladesh

Abstract
The ready-made garment (RMG) industry of Bangladesh contributes significantly to the national economy but remains ethically fragile due to poor working conditions, wage injustice, and unsafe environments. This study operationalises *toyyib* as an applied ethical lens grounded in *Maqasid al-Shari'ah* to examine labour practices, identify ethical violations, and propose reform pathways. Data were collected through 22 semi-structured interviews where workers, managers, policymakers, and Islamic scholars participated. The findings reveal misalignment between existing labour practices and Islamic ethical requirements, particularly in relation to wages, working hours, workplace safety, hygiene, rest facilities, and the protection of workers' dignity. These issues are compounded by weak law enforcement and a lack of awareness of Islamic ethical obligations. The study advances Islamic labour ethics by empirically translating *Maqasid* objectives into assessable workplace conditions through the concept of *toyyib*.

1. Introduction

The ready-made garment (RMG) industry is a cornerstone of Bangladesh's economy, contributing significantly to export earnings and employment generation, particularly for women from low-income and rural backgrounds (Ahmed & Nathan, 2014; Islam & Rakib, 2019). Over the past three decades, the rapid expansion of the sector has positioned Bangladesh as one of the world's leading apparel exporters. Despite its economic significance, extensive research has documented persistent ethical challenges within the industry, including low wages, unsafe working conditions, excessive working hours, job insecurity, and gender-based vulnerabilities (Begum *et al.*, 2008; Kabir *et al.*, 2022; Saha, 2023).

Global attention to labour ethics in Bangladesh's garment industry intensified following the Rana Plaza collapse in 2013, which exposed the severe human cost of neglecting worker safety and ethical responsibility in pursuit of economic competitiveness (Islam & Deegan, 2010; Ahmed & Nathan, 2014). In response, a range of regulatory reforms, international safety accords, and Corporate Social Responsibility (CSR) initiatives were introduced to improve labour standards and workplace safety. While these interventions have improved factory inspections and structural safety, studies indicate that ethical deficiencies persist at the operational level, particularly in relation to wages, working hours, dignity, and worker participation (Haque & Azmat, 2015; Islam & Rakib, 2019).

Existing labour governance frameworks, including CSR mechanisms and International Labour Organization (ILO) standards, largely emphasise compliance, audit performance, and risk management (Islam & Deegan, 2010; Reinecke *et al.*, 2019). While these frameworks improve formal compliance, they often fail to address workers lived experiences of moral harm, dignity violations, and ethical responsibility beyond regulatory minimums. Furthermore, although such frameworks provide important baseline protections, scholars argue that compliance-oriented approaches frequently prioritise documentation over substantive ethical transformation, resulting in symbolic or cosmetic compliance (Haque & Azmat, 2015; Rahman, K., 2021). Consequently, labour ethics are frequently reduced to procedural obligations, whilst workers lived experiences of injustice, vulnerability, and moral harm remain insufficiently addressed.

This limitation is particularly significant in Muslim-majority contexts such as Bangladesh, where ethical values, religious beliefs, and moral accountability play an important role in shaping social and economic life (Dusuki & Abdullah, 2007; Chapra, 2008). Islamic ethical thought does not treat labour as a purely contractual or economic activity; rather, work is understood as a moral responsibility governed by justice (*'adl*), trust (*amanah*), and excellence (*ihsan*) (Ali, 1988; Ali & Al-Owaihan, 2008). From this perspective, labour practices that compromise dignity, safety, or fairness constitute not only regulatory but also moral failure.

Two Islamic ethical constructs are particularly relevant for evaluating labour practices: *Maqasid al-Shari'ah* as the higher-order ethical framework, and *toyyib* as its operational manifestation in everyday workplace practices. The concept of

toyyib, when grounded in the objectives of *Maqasid al-Shari'ah*, extends beyond legal permissibility (halal) to emphasise wholesomeness, balance, and the avoidance of harm in all aspects of production and employment (Dusuki & Abdullah, 2007). In labour contexts, *toyyib* requires that wages, working conditions, and managerial practices protect workers' physical well-being, psychological health, and dignity. Similarly, *Maqasid al-Shari'ah* provides a higher-order ethical framework aimed at safeguarding essential human interests, including life, wealth, intellect, dignity, and faith (Chapra, 2008). Contemporary scholars argue that *Maqasid* offers a normative foundation for evaluating modern socio-economic institutions, including labour governance and industrial relations.

Despite their relevance, empirical studies that operationalise *toyyib* alongside *Maqasid al-Shari'ah* to assess concrete labour practices in labour-intensive industries remain scarce. Studies on Bangladesh's garment industry have predominantly relied on economic, legal, and human rights perspectives, with minimal engagement with workers' ethical experiences interpreted through Islamic moral objectives (Begum *et al.*, 2008; Islam & Rakib, 2019; Kabir *et al.*, 2022). Moreover, research on Islamic Work Ethics has largely focused on organisational behaviour and conceptual discussions, leaving a gap in understanding how Islamic ethics can inform labour practices in large-scale manufacturing sectors (Ali & Al-Owaihan, 2008).

In response to these gaps, this study examines labour ethics in Bangladesh's garment industry through an integrated *toyyib* and *Maqasid al-Shari'ah* framework. Drawing on qualitative data from garment workers, factory managers, policymakers, and Islamic scholars, the study aims to examine how existing labour practices reflect or contradict *toyyib* principles when viewed through the lens of *Maqasid al-Shari'ah*. Three research objectives guide the study: (1) to identify labour practices that violate *toyyib* principles and *Maqasid al-Shari'ah* objectives, particularly in relation to wages, working hours, workplace safety, job security, and workers' dignity; (2) to explain the structural and policy failures that sustain these unethical practices; and (3) to propose *toyyib*-oriented ethical and policy recommendations for labour reform. By bridging Islamic ethical theory with empirical labour realities, the study contributes to the growing literature on Islamic labour ethics. It offers context-sensitive insights for policymakers and industry actors seeking ethically sustainable labour governance.

2. Literature review

2.1 Ethical challenges in the garment industry

The global garment industry has been widely examined for its role in generating employment and export revenue, particularly in developing economies; however, it is also frequently associated with labour exploitation and ethical violations (Reinecke *et al.*, 2019). Studies consistently report that cost-driven competition, buyer pressure, and fragmented supply chains contribute to low wages, excessive working hours, unsafe working environments, and limited job security for workers (Islam & Deegan, 2010; Haque & Azmat, 2015).

In Bangladesh, the ready-made garment (RMG) sector has attracted extensive scholarly attention due to its economic importance and recurring labour rights concerns. Empirical research documents persistent ethical challenges, including wage insufficiency, occupational health risks, verbal abuse, and restricted worker participation in decision-making (Begum *et al.*, 2008; Ahmed & Nathan, 2014; Islam & Rakib, 2019). These challenges are not isolated incidents but are embedded within structural and institutional arrangements governing the industry.

Gender-based ethical concerns are particularly prominent within the RMG sector. Female workers, who constitute the majority of the workforce, experience disproportionate vulnerabilities related to harassment, lack of privacy, inadequate sanitation facilities, and limited maternity protection (Begum *et al.*, 2008; Saha, 2023). Such conditions raise serious ethical questions regarding dignity, justice, and equality in labour practices.

The Rana Plaza collapse in 2013 marked a critical moment in global awareness of labour ethics in Bangladesh's garment industry. In response, national labour reforms, international safety accords, and CSR initiatives were introduced to improve workplace safety and compliance (Ahmed & Nathan, 2014; Islam & Deegan, 2010). While these interventions have contributed to improvements in factory inspections and infrastructure, studies indicate that ethical deficiencies persist in everyday labour practices, particularly regarding wages, working hours, and worker voice (Haque & Azmat, 2015; Islam & Rakib, 2019). In addition, although existing studies document widespread ethical violations in the garment industry, they rely primarily on regulatory, economic, or human-rights frameworks. As a result, moral values, dignity, and Islamic ethical accountability receive limited attention. This is an important omission in Muslim-majority contexts such as Bangladesh. This gap calls for ethical approaches that move beyond compliance toward moral responsibility.

2.2 Islamic work ethics and labour responsibility

Islamic Work Ethics (IWE) conceptualizes labour as a moral responsibility grounded in justice (*'adl*), trust (*amanah*), and social accountability, rather than as a purely contractual relationship (Ali, 1988; Ali & Al-Owaihan, 2008). Work is viewed as an act of ethical significance, linking individual effort to collective social welfare and moral accountability before God and society. Empirical studies on IWE suggest that Islamic ethical values can positively influence organisational behaviour, employee commitment, and fairness in management practices (Ali, 1988; Ali & Al-Owaihan, 2008). However, the majority of this literature focuses on organizational settings, leadership behaviour, and individual attitudes, with limited attention to labour-intensive manufacturing sectors. As a result, the relevance of Islamic Work Ethics for addressing labour exploitation and structural injustice in industrial environments remains underexplored.

In addition, scholars further argue that while IWE provides a normative ethical foundation, its practical application requires integration with broader governance frameworks to address systemic labour issues (Dusuki & Abdullah, 2007). Without such integration, Islamic ethical principles risk remaining abstract ideals rather than operational tools for labour reform. To engage more directly with the conditions under which work is carried out in labour-intensive industries, the concept of toyyib provides a complementary framework for evaluating the quality, safety, and dignity of everyday workplace practices.

2.3 *Toyyib* as an ethical standard in labour practices

The concept of *toyyib* extends beyond legal permissibility (halal) to encompass wholesomeness, fairness, balance, and the avoidance of harm in all aspects of life, including economic and labour activities (Dusuki & Abdullah, 2007). In labour contexts, *toyyib* requires that working conditions preserve workers' physical safety, psychological well-being, and dignity, and that employment relationships are free from exploitation and injustice. In practical terms, *toyyib*-compliant labour practice includes wages that are sufficient for a decent standard of living and paid promptly, reflecting the Prophetic injunction to pay the worker "before his sweat dries" (*Sunan Ibn Majah*); working hours that preserve time for rest, family, and worship; clean, ventilated, and safe production floors with adequate sanitation and rest facilities; supervision that is respectful and free from verbal abuse or harassment; and employment terms that offer security rather than fear of arbitrary dismissal.

Although *toyyib* is frequently discussed in relation to halal consumption and production, its application to labour ethics remains limited in existing literature. Studies on labour governance rarely employ *toyyib* as an evaluative ethical standard for wages, working hours, workplace safety, or managerial conduct. This omission represents a significant gap, particularly in Muslim-majority contexts where ethical expectations are shaped by Islamic moral values (Chapra, 2008). Three considerations justify extending *toyyib* to labour ethics. First, the *Qur'anic* pairing of *halalan toyyiban* (*Qur'an* 2:168) indicates that permissibility alone is insufficient: goodness attaches to how a product is made, not only to the product itself, and a garment produced through exploited labour cannot meaningfully be described as *toyyib*. Second, *toyyib* supplies evaluative criteria at the level of everyday practice, such as wages, hours, safety, hygiene, and dignity, where both compliance frameworks and the *Maqasid* remain too abstract to be directly assessed. Third, in Muslim-majority contexts like Bangladesh, attaching labour reforms in theconcept of *toyyib* aligns with the Islamic ethical business concept of *toyyib* aligns with the Islamic ethical business models outlined by Dusuki and Abdullah (2007). This connection provides a culturally relevant and actionable framework for both workers and employers.

2.4 *Maqasid al-Shari'ah* and ethical labour governance

While *Maqasid al-Shari'ah* defines the overarching moral objectives of labour relations, *toyyib* functions as the ethical qualifier through which these objectives are realised and evaluated in concrete workplace practices. *Maqasid al-Shari'ah* refers to the higher objectives of Islamic law aimed at safeguarding essential human interests, including life, wealth, intellect, dignity, and faith (Chapra, 2008). Classical scholars conceptualized *Maqasid* as a framework for promoting human welfare and preventing harm, while contemporary scholars argue for its relevance in evaluating modern socio-economic institutions and governance systems (Dusuki & Abdullah, 2007; Chapra, 2008).

Applied to labour ethics, *Maqasid al-Shari'ah* provides normative criteria for assessing whether employment systems protect workers' fundamental rights and well-being. Labour practices that compromise safety, dignity, or economic security directly contradict *Maqasid* objectives, indicating ethical failure at both institutional and moral levels. Despite growing scholarly interest in *Maqasid*-based governance, empirical applications of this framework in labour-intensive industries remain scarce. Much of the existing literature treats the *Maqasid* conceptually, without systematically linking its objectives to the everyday workplace realities faced by industrial workers. To meaningfully evaluate such realities, *Maqasid* objectives must be operationalised through ethical lenses capable of assessing the tangible conditions under which work is performed. Accordingly, this study conceptualises *Maqasid al-Shari'ah* as defining the normative ends of labour ethics, whilst *toyyib* serves as an interpretive and operational workplace conditions.

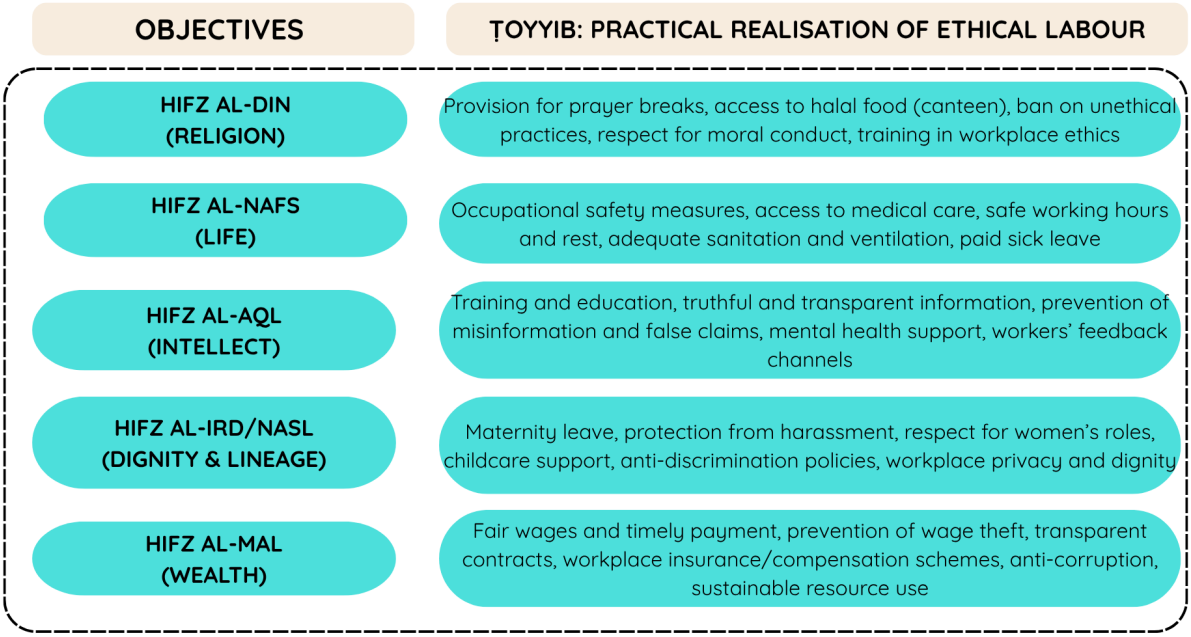

Figure 1: Applying *Maqasid al-Shari'ah* and *toyyib* for ethical workplace practices in the garment industry. (Author's adaptation, 2025).

Figure 1 visualises this integration by mapping key *Maqasid* dimensions onto specific *toyyib*-compliant workplace practices relevant to the garment industry. The protection of life (*Hifz al-Nafs*) is operationalised through *toyyib* indicators such as structurally safe and well-ventilated premises, hygienic sanitation, rest facilities, and working hours that safeguard physical and psychological health; the protection of wealth (*Hifz al-Mal*) through wages that are sufficient for basic needs, transparently calculated, and paid on time; the protection of dignity (*Hifz al-'Ird*) through harassment-free supervision and gender-sensitive facilities; the protection of intellect (*Hifz al-'Aql*) through freedom from chronic exhaustion; and the protection of faith (*Hifz al-Din*) through respect for workers' religious obligations. Therefore, in reverse, wage injustice, excessive working hours, unsafe workplaces, gender-based neglect, and job insecurity are not generic management failures but identifiable violations of specific *Maqasid* objectives and of the *toyyib* standard of wholesome employment.

Conceptually, this study does not treat *toyyib* and *Maqasid al-Shari'ah* as parallel constructs. Rather, *Maqasid al-Shari'ah* provides the normative foundation by defining the moral objectives of labour relations. At the same time, *toyyib* functions as the applied ethical qualifier that reflects how these objectives are realised or violated in everyday workplace practices. In other words, *Maqasid al-Shari'ah* explains what ethical labour should aim to achieve, while *toyyib* explains what ethical labour should look like in practice. This approach helps connect Islamic ethical ideals with the real experiences of workers on the factory floor.

2.5 Research gaps and positioning of the study

The reviewed literature reveals several critical gaps. First, studies on Bangladesh's garment industry predominantly rely on economic, legal, and human-rights-based frameworks, with limited engagement with Islamic ethical perspectives (Ahmed & Nathan, 2014; Islam & Rakib, 2019). Second, while Islamic Work Ethics has been explored in organisational contexts, its application to labour exploitation in manufacturing sectors remains limited (Ali & Al-Owaihan, 2008). Third, empirical integration of *toyyib* and *Maqasid al-Shari'ah* as a combined ethical framework for labour analysis is largely absent. Moreover, workers' moral perceptions and ethical experiences are often marginalised in labour governance research, which tends to prioritise institutional compliance and policy analysis (Haque & Azmat, 2015; Saha, 2023). This gap constrains the ability of existing frameworks to capture ethical harm as experienced by workers themselves.

Positioned within these gaps, this study empirically evaluates labour ethics in Bangladesh's garment industry using an integrated *toyyib* and *Maqasid al-Shari'ah* framework. To address this gap, the study adopts an integrated *toyyib–Maqasid* heuristic framework that links ethical objectives with concrete workplace practices. *Maqasid al-Shari'ah* defines the moral ends of labour relations. *Toyyib*, on the other hand, serves as the evaluative lens through which everyday working conditions are assessed. This study draws directly on workers' lived experiences, together with insights from factory managers, policymakers, and Islamic scholars, to assess ethical violations, explain their structural causes, and identify *toyyib*-oriented reform pathways. In doing so, the study connects Islamic ethical theory with actual industrial practice and advances a morally grounded, context-sensitive approach to labour ethics in a labour-intensive industry.

3. Materials and methods

3.1 Research design

This study adopts a qualitative exploratory research design to examine labour practices in Bangladesh's ready-made garment (RMG) industry through the ethical framework of *toyyib* and *Maqasid al-Shari'ah*. A qualitative approach is appropriate for this study, as it enables an in-depth understanding of workers' lived experiences, perceptions, and ethical concerns, which quantitative methods cannot adequately capture (Creswell, 2014; Denzin & Lincoln, 2018).

The study is grounded in an interpretivist paradigm, which assumes that social realities are constructed through individual experiences and interactions. This perspective allows for the exploration of how different stakeholders: workers, managers, policymakers, and Islamic scholars interpret labour practices and ethical responsibilities within the garment industry (Saunders *et al.*, 2019). Given the limited empirical research applying Islamic ethical frameworks in labour contexts, an exploratory design was considered suitable for generating new insights.

3.2 Participants and sampling

The study involved twenty-two (22) participants selected from four key stakeholder groups within Bangladesh's garment industry: garment workers (shop-floor employees from sewing, cutting, finishing, and dyeing sections), factory management (supervisors, human resource personnel, managers, owners, and directors), government officials (including trade union representatives and district labour administrators), and Islamic scholars with expertise in Islamic law, *Maqasid al-Shari'ah*, and *toyyib* principles.

Purposive sampling was employed to identify participants with relevant experience and knowledge of labour conditions, regulatory processes, or Islamic ethical principles. This sampling strategy is appropriate for qualitative research where the objective is to gain rich, contextual insights rather than statistical generalisation. Participants were selected against explicit eligibility criteria: each had to be directly involved in the garment industry or in a relevant regulatory or scholarly role; factory-based participants were required to have a minimum of six months' experience in the Ready-Made Garment (RMG) sector; and only individuals willing to share their perspectives were included. To ensure diversity and representation, the sample balanced male and female participants to capture gender-specific experiences, particularly relevant given that women constitute the majority of the RMG workforce, and was drawn from multiple locations (Dhaka, Gazipur, Savar, and Narayanganj for factory-based roles; Gombak, Malaysia for Islamic scholars), with interviews conducted both in person and online to accommodate participants' availability and geographical constraints. The full demographic composition is presented in Table 1. In addition, the inclusion of multiple stakeholder groups enabled source triangulation, whereby the same labour practices were examined from complementary points (Nowell *et al.*, 2017).

3.3 Data collection procedures

A total of 22 semi-structured interviews were conducted between May and July 2025 in convenient locations and

Table 1: Demographic profile

Category	Code Range	Number of Participants	Gender Distribution	Roles/Position	Location
Factory Workers	C.5, C.6, C.7, C.10, C.11, C.12, C. 13, C.17, C.15, C.19, C.20	11	6 Female, 5 Male	Sewing operators, cutting & finishing workers, machine operators, technicians, coordinators	Bangladesh
Factory Management	C.1, C.3, C.4, C.8, C.14, C.9, C.16	7	7 Male	Supervisors (QC), HR personnel, factory managers, owners, directors	Bangladesh
Government Officials	C.2, C.18	2	1 Female, 1 Male	Trade union representatives, district labour administrators, policy officials	Bangladesh
Islamic Scholars	C.21, C.22	2	2 Female	Islamic ethics experts, lecturers	Malaysia
Total		22	—	—	—

comfortable for participants, including factory offices, neutral meeting spaces, and, in some cases, online sessions. Semi-structured interviews were selected because they allow participants to express their experiences while enabling the researcher to probe deeper into key issues related to labour conditions, governance, and ethical practices (Kvale & Brinkmann, 2009).

Each interview lasted between 30 and 50 minutes, depending on the availability and willingness of participants, who were given the option to speak in either Bangla or English. With participants' consent, interviews were audio-recorded and supplemented by the researcher's field notes, ensuring accuracy in capturing participants' voices and facilitating a richer analysis during the transcription and coding process.

Given that the research was conducted whilst the researcher was based in Malaysia and the study site was in Bangladesh, a combination of strategies was employed to access participants. Some interviews were conducted directly by the researcher via online platforms, allowing participants to share their experiences virtually whilst maintaining confidentiality. To complement this, a trained research assistant based in Bangladesh conducted face-to-face interviews following the same interview protocol, ensuring consistency in data collection across both modes. This arrangement enabled the researcher to engage with participants despite geographical constraints, whilst also reaching those who preferred in-person interaction. The research assistant received detailed training on the study's objectives, the semi-structured interview guide, and ethical procedures, including confidentiality, voluntary participation, and informed consent. Data collection continued until thematic saturation was achieved, whereby no new ethical categories or substantive insights emerged from additional interviews (Saunders *et al.*, 2018).

The recordings were transcribed verbatim and subsequently translated into English for analysis. Care was taken to preserve the original meaning and contextual nuance of participants' responses throughout the translation process.

3.4 Data analysis

The collected data were analysed using thematic analysis, following the six-phase framework proposed by Braun and Clarke (2006). This analysis involves systematic coding and pattern identification in qualitative data, making it suitable for exploring complex social and ethical issues. It began with data familiarisation through repeated reading of transcripts, followed by the generation of initial codes related to labour conditions, worker experiences, and governance practices. These codes were then organised into broader themes, including wage injustice, working conditions, governance failures, and ethical reform pathways.

The study employed both inductive and deductive approaches. While themes emerged from the data (inductive), they were interpreted through the ethical lens of *toyyib* and *Maqasid al-Shari'ah* (deductive). This integration enabled the study to connect empirical findings with Islamic ethical principles such as justice, dignity, and welfare (Chapra, 2008; Dusuki & Abdullah, 2007).

In addition, to enhance the credibility of the analysis, data were compared across different participant groups, and representative quotations were used to support key findings. This approach ensured transparency and strengthened the validity of the interpretations (Nowell *et al.*, 2017). The workers provided first-hand accounts of everyday conditions. Managers explained the operational and commercial pressures shaping those conditions; government officials clarified the regulatory framework and its enforcement. On the other hand, Islamic scholars offered an interpretation of these accounts against *toyyib* and *Maqasid al-Shari'ah*. Where accounts converged across groups, for example, workers, managers, and officials independently describing weak enforcement, confidence in the finding was strengthened; where they diverged, such as differing descriptions of compliance practices, the divergence was itself treated analytically as evidence of policy–practice gaps. This cross-group corroboration enhanced the credibility and depth of the findings.

3.5 Ethical considerations

Ethical considerations were carefully addressed throughout the research process. Informed consent was obtained from all participants prior to the interviews, and they were informed of the study's purpose, their voluntary participation, and their right to withdraw at any time (Saunders *et al.*, 2019). To ensure confidentiality, participants were assigned codes (e.g., C.1; C.2) (See Table 1), and all identifying information was removed

Table 2: Summary of key findings

Theme 1: Violation of *toyyib* Principles	Theme 2: Challenges	Theme 3: Scholarly and Actionable Solutions
Workers in Bangladesh's garment industry face and endure the following unethical labour practices: 1. Wage Injustice 2. Exploitative Work Hours 3. Lack of Rest & Facilities 4. Unsafe & Unhygienic Conditions 5. Gender-Specific Neglect & Harassment 6. Job Insecurity	The study identified: 1. Weak enforcement of labour laws 2. Corruption in & non-compliance 3. Profit-Over-Welfare Model 4. Policy–practice gaps 5. Weak Worker Representation	Recommendation include: 1. Fair Wage and Financial Justice 2. Safe & Hygienic and restful Workplace 3. Respect for Women Workers and Gender Equality 4. Participatory Policy and Strong Worker Representation 5. Decent Work Hours and Job Security 6. Transparent Governance and Ethical Compliance

from the transcripts. Data were securely stored and used solely for academic purposes. Given the sensitive nature of labour issues, particular attention was paid to protecting participants from potential risks, including workplace retaliation. Table 1 presents the demographic profile of the 22 participants in this study, categorized by stakeholder group, gender, role, and location.

Factory workers (n = 11) constituted the largest group. This group provides direct insights into labour conditions and lived experiences. Factory management (n=7) participants contributed organisational perspectives, while government officials (n=2) provided regulatory insights. Islamic scholars (n=2) offered ethical interpretations based on *toyyib* and *Maqasid al-Shari'ah*. The diversity of participants enabled triangulation and enhanced the credibility of the findings by capturing multiple dimensions of labour practices.

4. Results and discussion

4.1 Overview of findings

The analysis of interview data revealed three interrelated themes reflecting the ethical condition of labour practices in Bangladesh's ready-made garment (RMG) industry. As shown in Table 2, the first theme addresses Research Objective 1 by identifying violations of *toyyib* values and *Maqasid* objectives related to wages, working hours, workplace safety, job security, and women's dignity. The second theme addresses Research Objective 2 by explaining the structural and policy failures including weak enforcement, symbolic compliance, profit-driven business models, and limited worker participation that sustain unethical labour practices (Islam & Deegan, 2010; Reinecke *et al.*, 2019). The third theme addresses Research Objective 3 by presenting *toyyib*-oriented ethical and policy recommendations proposed by participants to improve labour welfare and governance in the garment industry.

Overall, the identified themes reveal a consistent gap between existing labour practices and the ethical ideals articulated by *toyyib* and *Maqasid al-Shari'ah*. These conditions represent failures to realise *Maqasid al-Shari'ah*, as reflected in non-*toyyib* labour practices, undermining fairness, justice, human dignity, and the protection of life and wealth (*Hifz al-Nafs, Hifz al-Mal*). Similar to prior studies, the findings indicate that ethical violations are systemic rather than isolated and are shaped by structural, economic, and governance-related factors (Ahmed & Nathan, 2014; Haque & Azmat, 2015).

These structural and policy shortcomings hinder ethical labour practices, allowing systemic exploitation and failing to ensure compliance with *toyyib* principles. Regulatory frameworks are insufficient to safeguard worker rights or promote equitable working conditions. These findings are discussed in the following sub-sections.

4.2 Theme 1: Violations of *toyyib* and *Maqasid al-Shari'ah* in labour practices

Theme 1 fulfils Research Objective 1 by identifying and analysing concrete labour practices related to wages, working hours, workplace safety, job security, and workers' dignity. Using the integrated *toyyib–Maqasid* framework, this theme evaluates whether these practices protect or undermine key *Maqasid* objectives, particularly the protection of life (*Hifz al-Nafs*), wealth (*Hifz al-Mal*), and dignity (*Hifz al-'Ird*). The findings demonstrate widespread ethical misalignment between existing practices and Islamic ethical requirements. Consistent with earlier research on the RMG sector, participants described labour conditions that undermine justice, dignity, and human well-being (Begum *et al.*, 2008; Kabir *et al.*, 2022). These conditions represent direct violations of multiple *Maqasid al-Shari'ah* objectives. This theme draws primarily on workers' first-hand testimony, supplemented by factory management's own acknowledgment of practices such as undisclosed wage deductions (Section 4.2.1); the corresponding government-official and scholarly perspectives that corroborate these accounts are presented in Themes 2 and 3, where the same underlying practices are examined from complementary points.

4.2.1 Wage injustice

Wage injustice emerged as one of the most prominent concerns among participants. Workers consistently reported that their earnings were insufficient to meet basic living needs, reflecting a disconnect between wage structures and economic realities.

One worker stated:

"My salary is not enough for rent, food, and my family. Even with overtime, I still struggle every month." (C.6, Factory Worker)

A factory management participant likewise acknowledged problems of wage:

"Even now, some factories deduct wages or make workers work until midnight but pay them only for work until 10 PM." (C.1, Factory management)

These findings align with previous studies that highlight persistent wage insufficiency in the garment sector (Ahmed & Nathan, 2014; Islam & Rakib, 2019). From a *Maqasid al-Shari'ah* perspective, such practices violate the protection of wealth (*Hifz al-Mal*) and undermine workers' dignity. Within the *toyyib* framework, wages that fail to ensure basic well-being are not ethically acceptable (Chapra, 2008). Beyond confirming prior findings, these interviews reveal the mechanism of the ethical harm: unexplained deductions render wages unpredictable as well as insufficient, transferring business risk onto those least able to bear it and breaching the trust (*amanah*) inherent in the employment contract. The violation of *Hifz al-Mal* is therefore twofold (1) workers' wealth is diminished in quantity and (2) destabilised in reliability. Assessed against *toyyib* indicators, a wage is ethically adequate only when it is sufficient for basic needs, transparent in calculation, and paid punctually; the testimonies indicate failure on all three counts. This distinguishes the present analysis from compliance audits, which verify only whether the statutory minimum wage has been paid.

4.2.2 Excessive working hours and physical strain

Participants consistently reported excessive working hours driven by production targets and shipment deadlines. Mandatory overtime and insufficient rest were described as routine, leading to physical exhaustion and psychological stress. These findings align with previous studies documenting exploitative working-hour regimes in the RMG industry (Islam & Rakib, 2019; Saha, 2023).

"Many of our workers are women who start early in the morning and often return home late, especially during high production seasons" (C.4, Factory Management)

Such conditions are consistent with prior research findings on excessive working hours in labour-intensive industries (Saha, 2023). These practices contradict the *Maqasid* objective of protecting life and well-being (*Hifz al-Nafs*) and violate the ethical principle of balance (*mizan*) emphasized in Islamic teachings (Chapra, 2008). The working-hour regime described by participants operates as a structural condition rather than an occasional demand: overtime is driven by shipment deadlines set upstream by buyers, making exhaustion a predictable output of the business model rather than an exception to it. Chronic fatigue endangers life and health (*Hifz al-Nafs*) and simultaneously erodes intellect and judgment (*Hifz al-'Aql*), raising the risk of workplace accidents. Measured against the *toyyib* indicator of balance hours that leave room for rest, family, and worship, mandatory late-night work fails not because it exceeds a statutory ceiling but because it subordinates the worker's whole human welfare to production targets.

4.2.3 Unsafe and unhygienic working conditions

Despite improvements following the Rana Plaza incident, participants reported ongoing concerns related to workplace safety and hygiene. Issues such as overcrowding, poor ventilation, and inadequate sanitation facilities were frequently mentioned:

"The working area is crowded, and sometimes it feels difficult to breathe." (C.5, Factory Worker)

These findings are consistent with studies documenting persistent occupational health risks in the garment industry (Kabir *et al.*, 2022). From an Islamic ethical perspective, such conditions violate the obligation to protect human life and safety, which is central to *Maqasid al-Shari'ah* (Dusuki & Abdullah, 2007). The persistence of these hazards more than a decade after Rana Plaza suggests that audit-driven reform has addressed visible, inspectable risks such as building integrity while leaving everyday environmental harms—overcrowding, heat, poor ventilation, inadequate sanitation—largely intact. From a *Maqasid* perspective, *Hifz al-Nafs* encompasses cumulative harms to health, not only catastrophic ones. At the same time, the *toyyib* emphasis on cleanliness (*taharah*) sets a proactive hygiene standard that goes beyond hazard avoidance. The observation that conditions improve when buyers visit (Section 4.4.2) reinforces the interpretation that safety often functions as a performance for external audiences rather than an internalised ethical obligation.

4.2.4 Gender-based neglect and dignity violations

Female participants highlighted specific challenges related to dignity and well-being, including inadequate sanitation facilities, lack of privacy, and limited support during health-related needs:

"There are not enough proper facilities for women, and sometimes we feel uncomfortable at work." (C.7, Factory Worker)

These findings align with existing literature on gender-based vulnerability in the garment industry (Begum *et al.*, 2008; Saha, 2023). Such conditions violate the protection of dignity (*Hifz al-'Ird*) under *Maqasid al-Shari'ah*, reinforcing the need for gender-sensitive labour practices. Importantly, the gendered harm described here operates through neglect as much as through overt harassment: the absence of adequate sanitation, privacy, and health-related support imposes routine indignity on a majority-female workforce. In *Maqasid* terms, this is a compound violation of dignity (*Hifz al-'Ird*) directly, and of life and health (*Hifz al-Nafs*), where women continue working through illness or pain for fear of penalties. A *toyyib*-compliant workplace would treat gender-sensitive facilities not as an optional amenity but as a baseline condition of wholesome employment, since ethical obligations attach to the actual composition and needs of the workforce.

4.2.5 Job insecurity

Participants described pervasive job insecurity, including fear of dismissal due to illness, family emergencies, or raising workplace concerns:

"Helpers or junior machine operators feel insecure, especially during order gaps or cancellations. One big cancellation from a buyer, and we might have to halt production lines temporarily—which directly affects workers".

He further added that:

"Workers usually ignore early symptoms due to fear of wage deduction or being marked absent. Many don't report until

their health worsens." (C.15, Factory Worker)

Similar patterns of employment precarity have been documented in earlier studies on labour governance in the RMG sector (Islam & Rakib, 2019). From a *toyyib* perspective, employment relationships characterised by fear and disposability contradict principles of justice and trust (*amanah*). Job insecurity, therefore, represents not only economic vulnerability but also ethical harm. The deeper ethical significance of this finding is that insecurity functions as a mechanism of control: fear of dismissal suppresses complaints, deters sick workers from reporting illness, and thereby sustains the other violations documented in this theme. Job insecurity is thus not merely one harm among several but a structural amplifier of them. In *Maqasid* terms, it simultaneously threatens wealth (*Hifz al-Mal*), life and health (*Hifz al-Nafs*), and dignity (*Hifz al-'Ird*); in *toyyib* terms, an employment relationship premised on disposability cannot be considered wholesome, however formally lawful each dismissal may be.

4.3 Theme 2: Structural and policy failures

Theme 2 addresses Research Objective 2 by explaining why unethical labour practices persist despite the existence of labour laws and compliance mechanisms. This theme links ethical violations identified in Theme 1 to systemic factors such as weak law enforcement, corruption, profit-driven production models, policy–practice gaps, and limited worker representation. These findings demonstrate that ethical misalignment is structurally embedded rather than the result of isolated managerial behaviour. The second theme highlights that unethical labour practices persist due to systemic governance failures rather than isolated managerial misconduct. This finding aligns with studies emphasising structural determinants of labour exploitation in global supply chains (Islam & Deegan, 2010; Reinecke *et al.*, 2019).

4.3.1 Weak enforcement of labour laws, corruption & non-compliance

Participants identified weak enforcement of labour laws as a key factor contributing to unethical practices. Although policies exist, their implementation remains inconsistent:

"There are rules, but they are not always followed properly." (C.12, Factory Worker)

This reflects broader concerns about symbolic compliance and governance inefficiencies (Haque & Azmat, 2015; Transparency International Bangladesh, 2017). From an Islamic ethical perspective, weak enforcement undermines trust (*amanah*) and justice (*'adl*), which are essential principles in governance (Chapra, 2008).

4.3.2 Profit-over-welfare models

The findings indicate that profit maximization and cost-cutting pressures significantly influence labour practices. Factory owners often prioritise efficiency over worker welfare:

"Buyers demand low prices, so factories try to reduce costs wherever possible." (C.4, Factory Management)

This aligns with global supply chain research highlighting the role of economic pressures in labour exploitation (Reinecke *et al.*, 2019). While profit is a legitimate goal, *toyyib* principles emphasise that economic activities must not compromise ethical standards and human well-being (Dusuki & Abdullah, 2007).

4.3.3 Weak worker representation

Participants reported limited opportunities for workers to express concerns or participate in decision-making processes:

"We are afraid to complain because we might lose our jobs." (C.2, Government Official)

This lack of participation reflects a power imbalance within the workplace and contradicts the Islamic principle of consultation (*shura*), which promotes inclusive and participatory governance (Chapra, 2008).

4.4 Theme 3: *Toyyib*-oriented ethical reform

Theme 3 focuses on ethically grounded recommendations proposed by workers, managers, policymakers, and Islamic scholars. Drawing on *toyyib* principles and *Maqasid* objectives, this theme outlines practical reform pathways including fair wage structures, safe and hygienic workplaces, gender-sensitive facilities, reasonable working hours, participatory governance, and transparent enforcement. These recommendations translate Islamic ethical principles into actionable labour governance measures. Participants proposed several recommendations aligned with *toyyib* principles and *Maqasid al-Shari'ah*. These include fair wages, improved working conditions, and stronger governance mechanisms. Each sub-theme below deliberately sequences worker, government-official, and Islamic scholar perspectives on the same issue. As described in the following sub-section on fair wages, a worker's testimony of financial hardship is followed by a government official's call for cost-of-living-based reform and a scholar's explanation of fair wages as a *Maqasid* obligation.

4.4.1 Fair wage and financial justice

The findings indicate that fair wage systems are central to achieving *toyyib*-compliant labour practices. Participants consistently emphasized that current wage structures fail to meet basic living needs, necessitating reforms grounded in economic justice and ethical accountability. Workers highlighted the inadequacy of wages to sustain their daily lives, reflecting a disconnect between income and the cost of living. One worker explained:

"After paying for food, school fees, and medicine, there's hardly anything left. When prices go up, we just reduce our meals." (C.11, Factory Worker)

This testimony demonstrates the lived reality of financial insecurity, which contradicts the principle of justice (*'adl*) and undermines workers' dignity (*karamah*). Similarly, a government representative emphasized the need for structural reform:

"Wages should reflect the real cost of living, allowing workers to live with dignity rather than just surviving." (C.2, Government Official)

From an Islamic ethical perspective, fair wages are not optional but constitute an obligation under *Maqasid al-Shari'ah*, particularly in protecting wealth (*Hifz* al-*Mal*) and well-being.

This is further reinforced by scholarly insight:

"Fair wage is not charity; it is an obligation to protect dignity and life." (C.21, Scholar)

These findings align with the existing literature, which demonstrates that fair compensation enhances worker morale, productivity, and social welfare (Ahmed & Nathan, 2014; Dusuki & Abdullah, 2007). Therefore, establishing fair and transparent wage systems is essential for achieving both ethical compliance and sustainable labour practices.

4.4.2 Safe, hygienic, and dignified working environment

The findings further highlight the need for safe and hygienic working conditions as a core component of *toyyib* labour practices. Participants reported that inadequate sanitation, lack of rest, and unsafe environments continue to affect their physical and psychological well-being. A female worker described:

"There is still a lack of hygiene, especially for women… we have to work even when we are in pain because asking for rest leads to warnings." (C.6, Factory Worker)

Another worker revealed discrepancies between compliance and actual practice:

"When buyers visit, everything becomes clean, but otherwise many problems continue." (C.19, Factory Worker)

These findings indicate that workplace safety is often superficial and driven by external audits rather than genuine concern for worker welfare. From a *Maqasid al-Shari'ah* perspective, such conditions violate the protection of life (*Hifz al-Nafs*) and contradict the principle of *taharah* (cleanliness), which is fundamental in Islamic ethics. Scholars' perspectives reinforce this view:

"Cleanliness is not optional; it is part of faith and ethical responsibility." (C.21, Scholar)

Additionally, gender-specific challenges further highlight ethical deficiencies. Female workers reported a lack of privacy and safety:

"The toilets are dirty and unsafe… we feel ashamed and scared." (C.19, Factory Worker)

These conditions reflect systemic neglect of gender-sensitive needs and align with previous research highlighting vulnerability among female garment workers (Begum *et al.*, 2008; Saha, 2023). Therefore, ensuring safe, hygienic, and dignified working environments is essential for aligning labour practices with *toyyib* principles.

4.4.3 Participatory governance and worker representation

The findings reveal a significant gap in worker participation and representation within organisational decision-making processes. Participants consistently reported that workers have limited voices and are often excluded from discussions affecting their welfare:

"We don't know who represents us… committees exist, but they don't talk to us." (C.19, Factory Worker)

Another participant added:

"When workers speak, it is seen as complaining." (C.18, Government Official)

These findings indicate that participation mechanisms are often symbolic rather than functional, reflecting a top-down governance structure. From an Islamic perspective, this contradicts the principle of consultation (*shura*), which promotes inclusivity and shared responsibility in decision-making.

4.4.4 Decent work hours and job security

Another key finding relates to excessive working hours and job insecurity, which significantly affect workers' well-being. Participants reported long working hours, mandatory overtime, and fear of job loss:

"Sometimes we work 10–12 hours… we fear losing our job if we complain." (C.3, Factory Worker)

"When production is slow, workers are fired without notice." (C.12, Factory Worker)

These findings reflect structural instability and exploitation, which contradict the *Maqasid* objective of protecting life and dignity. From an Islamic ethical perspective, labour conditions must ensure balance, fairness, and security. Experts interviewed further support this:

"Exploiting workers through long hours violates justice and dignity." (C.21, Scholar)

"Islam views labour as a noble activity and mandates good standards in employer-employee relations. The Qur'an establishes the foundational principle of human dignity in Surah Al-Isra (17:70)" (C.22, Scholar)

These findings align with the existing literature, which highlights the negative impact of excessive working hours on health and productivity (Dusuki & Abdullah, 2007). Therefore, ensuring reasonable working hours and job security is essential for ethical labour practices.

4.4.5 Transparent governance and ethical compliance

The findings also highlight significant issues related to transparency and ethical governance. Participants reported that policies often exist only on paper and are not effectively implemented in practice. The participants noted:

"They (polices) look good on paper, but they don't speak to our workers' realities" (C.16, Factory Management)

"Companies manipulate the system because workers cannot take legal action." (C.7, Factory Worker)

These findings indicate a gap between formal compliance and actual practice, reflecting systemic governance failure. From a *toyyib* perspective, ethical governance requires sincerity (*ikhlas*), trust (*amanah*), and accountability. A scholar emphasised:

"...toyyib compliance means being accountable not only to laws but also to Allah." (C.21, Scholar)

These findings align with research highlighting symbolic compliance and corruption in labour governance systems (Haque & Azmat, 2015; Transparency International Bangladesh, 2017). Therefore, strengthening transparency and accountability mechanisms is essential for achieving ethical labour practices.

Overall, the findings demonstrate that labour challenges in the garment industry are deeply rooted in structural and ethical deficiencies. While compliance-based frameworks have improved certain aspects of safety and monitoring, they have failed to address fundamental issues related to dignity, fairness, and worker well-being. By applying a *Maqasid*-based ethical framework operationalised through *toyyib* principles, this study provides a holistic framework for evaluating labour practices. Unlike conventional approaches, this framework integrates moral accountability with economic and social considerations, offering a more sustainable and ethical model for labour governance (Chapra, 2008; Dusuki & Abdullah, 2007).

5. Conclusion and recommendation

This study evaluated labour practices in Bangladesh's garment industry through an integrated *toyyib–Maqasid al-Shari'ah* framework, demonstrating that ethical violations related to wages, safety, dignity, and job security are systemic rather than incidental. By foregrounding workers' lived experiences and linking them to Islamic ethical objectives, the study shows that compliance-based governance mechanisms remain insufficient for addressing substantive ethical harm. The findings highlight the relevance of *toyyib* and *Maqasid al-Shari'ah* as a morally grounded framework for labour evaluation and reform in Muslim-majority contexts.

By empirically linking workers' lived experiences with Islamic ethical objectives, this study demonstrates that ethical labour reform requires more than regulatory compliance. It requires moral accountability grounded in *toyyib* and *Maqasid al-Shari'ah*. Drawing on qualitative evidence from garment workers, factory managers, policymakers, and Islamic scholars, the findings demonstrate that ethical challenges in the industry are not merely operational shortcomings but reflect deeper structural and moral failures. Persistent issues such as wage injustice, unsafe working conditions, excessive working hours, job insecurity, and gender-based neglect continue to undermine workers' dignity and well-being, despite the presence of labour laws and international compliance mechanisms (Ahmed & Nathan, 2014; Islam & Rakib, 2019; Kabir *et al.*, 2022).

The study further reveals that these ethical violations are sustained by governance-related weaknesses, including weak enforcement of labour regulations, symbolic compliance practices, profit-driven business models, and limited worker participation. These findings are consistent with earlier research highlighting how compliance-oriented governance frameworks often prioritise audit performance and reputational management over substantive ethical transformation (Islam & Deegan, 2010; Haque & Azmat, 2015; Reinecke *et al.*, 2019). From an Islamic ethical perspective, such governance failures represent breaches of justice (*'adl*) and trust (*amanah*), undermining moral accountability at both

Table 3: Recommendations for implementing *toyyib*-compliant labour practices in Bangladesh's garment industry

Stakeholder	Key Recommendations	Link to Findings
Garment Factory Owners	• Implement fair and transparent wage systems. • Ensure safe, hygienic, and gender-sensitive work environments. • Monitor working hours to prevent forced overtime. • Develop grievance mechanisms and worker feedback channels.	Responds to findings on wage injustice, unsafe conditions, gender neglect, and lack of worker voice, (Theme 1)
Government & Regulatory Bodies	• Strengthen labour law enforcement through regular audits. • Penalize factories violating ethical standards. • Promote transparency and reduce corruption in inspections. • Support worker education and union representation	Addresses weak enforcement, corruption, and limited worker awareness identified in Theme 2.
International Buyers	• Include ethical labour compliance in sourcing decisions. • Support factories implementing *toyyib*-aligned practices. • Encourage supply chain accountability and sustainability.	Reflects the role of global pressure in cost-cutting and labour exploitation (Theme 2).
Policy & Academia	• Develop *toyyib*-compliant labour certification schemes. • Conduct awareness programs on Islamic labour ethics. • Integrate *toyyib* and *Maqasid* principles into labour policies.	Tackles the policy–practice gap and absence of ethical frameworks.

institutional and organisational levels (Chapra, 2008).

Building on these findings, the study proposes a set of targeted *toyyib*-oriented recommendations, summarised in Table 3, to guide ethical reform in the garment industry. Theoretically, this study contributes to the literature on Islamic labour ethics this study contributes to the literature on Islamic labour ethics by empirically operationalising *toyyib* alongside *Maqasid al-Shari'ah* within a labour-intensive industrial context. While prior studies have largely treated Islamic ethics conceptually or within organizational behaviour research (Ali, 1988; Ali & Al-Owaihan, 2008), this study demonstrates how these ethical principles can be applied to evaluate concrete labour practices and governance structures. The integration of workers' lived experiences with Islamic moral objectives offers a holistic ethical framework that extends beyond compliance-based approaches.

From a practical and policy perspective, the findings highlight the need for labour governance reforms that embed moral responsibility alongside regulatory enforcement. *Toyyib*-oriented reforms-such as fair wages aligned with living costs, safe and hygienic workplaces, gender-sensitive practices, participatory governance, and transparent enforcement mechanisms-are essential for achieving ethically sustainable labour practices. These reforms require shared responsibility among factory owners, government authorities, and international buyers, rather than placing ethical accountability solely on producers (Dusuki & Abdullah, 2007; Chapra, 2008). See Table 3.

Despite its contributions, this study has limitations. The qualitative design and focus on selected industrial regions limit the generalisability of the findings. Future research could employ mixed-methods approaches, comparative cross-country analyses, or sector-specific studies to further examine the applicability of *toyyib* and *Maqasid al-Shari'ah* across diverse labour contexts. Nevertheless, this study underscores the relevance of Islamic ethical principles as a complementary framework for advancing justice, dignity, and human well-being in contemporary industrial labour systems.

References

Ahmed, N., & Nathan, D. (2014). Improving wages and working conditions in the Bangladesh garment sector: The role of horizontal and vertical relations. Capturing the Gains Working Paper Series, 21, 1–30.

Ali, A. J. (1988). Scaling an Islamic work ethic. The Journal of Social Psychology, 128(5), 575–583. https://doi.org/10.1080/00224545.1988.9922911

Ali, A. J., & Al-Owaihan, A. (2008). Islamic work ethic: A critical review. Cross Cultural Management: An International Journal, 15(1), 5–19. https://doi.org/10.1108/13527600810848791

Begum, F., Ali, R. N., Hossain, M. A., & Shahid, S. B. (2008). Harassment of women garments workers in Bangladesh. Journal of the Bangladesh Agricultural University, 6(2), 291–296.

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. Qualitative Research in Psychology, 3(2), 77–101.

Chapra, M. U. (2008). The Islamic vision of development in the light of *Maqasid al-Shari'ah*. Islamic Development Bank.

Creswell, J. W. (2014). Research design: Qualitative, quantitative, and mixed methods approaches (4th ed.). Sage.
Denzin, N. K., & Lincoln, Y. S. (2018). The Sage handbook of qualitative research (5th ed.). Sage.

Dusuki, A. W., & Abdullah, N. I. (2007). *Maqasid al-Shari'ah*, maslahah, and corporate social responsibility. American Journal of Islamic Social Sciences, 24(1), 25–45.

Haque, M. Z., & Azmat, F. (2015). Corporate social responsibility, economic globalization and developing countries: A case study of the ready-made garments industry in Bangladesh. Sustainability Accounting, Management and Policy Journal, 6(2), 166–189. https://doi.org/10.1108/SAMPJ-04-2014-0028

Islam, M. A., & Deegan, C. (2010). Media pressures and corporate disclosure of social responsibility performance. Accounting and Business Research, 40(2), 131–148.

Islam, M. S., & Rakib, M. A. (2019). Labour laws in the garment sector of Bangladesh: A workers' view. Yuridika, 34(3), 413–430.

Kabir, H., Maple, M., Islam, M. S., & Usher, K. (2022). A qualitative study of the working conditions in the ready-made garment industry and the impact on workers' health and well-being. Environmental and Occupational Health Practice, 4, eohp.2021-0020-OHW. https://doi.org/10.1539/eohp.2021-0020-OHW

Kvale, S., & Brinkmann, S. (2009). InterViews: Learning the craft of qualitative research interviewing (2nd ed.). Sage.

Nowell, L. S., Norris, J. M., White, D. E., & Moules, N. J. (2017). Thematic analysis. International Journal of Qualitative Methods, 16(1), 1–13

Rahman, K. (2021, August 16). Overview of corruption and anti-corruption in Bangladesh: Focus on ready-made garments (RMG), health, environment, and anti-corruption actors. U4 Anti-Corruption Helpdesk, Chr. Michelsen Institute (CMI).

Reinecke, J., Donaghey, J., Bocken, N., & Lauriano, L. (2019). Business models and labour standards: Making the connection. Academy of Management Perspectives, 33(4), 411–431.

Saha, H. (2023). Rights of the women worker of ready-made garment industry in Bangladesh: Gaps between law and practice. International Journal of Law and Society, 6(1), 102–111. https://doi.org/10.11648/j.ijls.20230601.24

Saunders, M., Lewis, P., & Thornhill, A. (2019). Research methods for business students (8th ed.). Pearson.

Saunders, B., Sim, J., Kingstone, T., Baker, S., Waterfield, J., Bartlam, B., & Jinks, C. (2018). Saturation in qualitative research: Exploring its conceptualization and operationalization. Quality & quantity, 52(4), 1893-1907.

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Galactomyces ferment filtrate in cosmetics: A jurisprudential analysis via *Istihalah*

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Received: 18/5/2026
Accepted: 28/7/2026
Published: 31/7/2026

Keywords:
Galactomyces ferment filtrate; *Istihalah*; Halal cosmetics; Transformative purification; T*aharah*

Abstract

This study examines the permissibility (halal) status of Galactomyces Ferment Filtrate (GFF) in cosmetic products through the Islamic jurisprudential principle of *Istihalah* (transformative purification). Commercially known as Pitera (TM), GFF is a yeast-derived bioactive ingredient widely used in skincare yet associated in popular discourse with sake (Japanese rice wine), raising purity (*I*) concerns among Muslim consumers. Using a qualitative library research methodology, the study analyses GFF across three stages: its biological source and characteristics; its industrial production process; and the application of *Istihalah* to assess the completeness of the transformation. Classical juristic positions from the four *Sunni* schools and contemporary scholarly opinions are surveyed alongside scientific literature. The findings demonstrate that downstream processing eliminates all ethanol from the final ingredient, satisfying the conditions for *Istihalah Sahihah*. GFF is therefore classified as *tahir* (pure) and halal for cosmetic use.

1. Introduction

The global cosmetic industry has experienced extraordinary growth, driven by continuous biotechnological innovation and sustained consumer demand for effective skincare solutions (Elder *et al.*, 2020). For Muslim consumers, ingredient selection carries an additional religious dimension: products must be permissible (halal) and wholesome (*tayyib*) under Islamic law. The *Qur'an* states: "O mankind, eat from whatever is on earth that is lawful and good" (*Al-Baqarah*, 2:168). A related verse prohibits intoxicants: "O you who have believed, indeed, intoxicants, gambling, [sacrificing on] stone altars, and divining arrows are but defilement from the work of Satan, so avoid it that you may be successful" (*Al-Ma'idah*, 5:90). These injunctions situate Islamic jurisprudence at the intersection of consumer ethics and modern cosmetic science.

Among the ingredients attracting contemporary halal discourse is Galactomyces Ferment Filtrate (GFF), a bioactive yeast derivative used by leading brands including SK-II, COSRX, and Manyo Factory (Personal Care Products Council, 2025). Digital media and beauty commentary have popularised the claim that GFF originates as a by-product of sake (Japanese rice wine) production (Santaella-Lam, 2024; Ng, 2021). Since sake is classified as *khamr*—a prohibited and ritually impure substance under unanimous scholarly consensus (an-Nawawi, 2010; Mazri, 2020)—this association raises the question of whether GFF inherits the legal ruling of *khamr*.

Scientific literature extensively validates GFF's cosmetic efficacy: it reduces wrinkles, hyperpigmented spots, and skin roughness over long-term use (Miyamoto *et al.*, 2021, 2023); strengthens the skin's anti-inflammaging defense at the cellular level (Yan *et al.*, 2022); and facilitates wound closure through keratinocyte activation (Chan, 2023; Rovito *et al.*, 2025). Despite this commercial and scientific prominence, no prior academic work has subjected GFF to a systematic examination within Islamic jurisprudence. The only relevant ruling, issued by Dr. Zulkifli Mohamad al-Bakri (2023), conditionally permits GFF not produced through the sake-making process, leaving the question open pending detailed process analysis.

This study aims to bridge that gap by applying the classical principle of *Istihalah*—the doctrine of transformative purification—to a systematic analysis of GFF's production. Three objectives guide the inquiry: (1) to establish the biological profile of GFF and the jurisprudential foundations of *Istihalah*; (2) to investigate the stages of GFF production from cultivation to final cosmetic ingredient; and (3) to apply the principle of *Istihalah* to determine GFF's permissibility ruling.

2. Materials and methods

This study adopts a qualitative, non-empirical library research methodology. Data were gathered from three primary source categories: (1) classical Islamic legal texts (*kutub al-fiqh*) representing the four *Sunni* schools of jurisprudence (*Hanafi, Maliki, Shafi'i,* and *Hanbali*), particularly works about the

doctrine of *Istihalah*, the concept of *najasat* (ritual impurity), and rulings on alcohol and fermentation; (2) contemporary Islamic scholarship including *fatwa*, journal articles in Islamic law, and halal industry standards published by recognised authorities such as Jabatan Mufti Wilayah Persekutuan Malaysia; and (3) peer-reviewed scientific literature on GFF, including studies on its biological taxonomy, fermentation chemistry, cosmetic efficacy, and production processes, as well as relevant patent documents from South Korea and China.

Textual analysis was employed to extract and synthesise relevant juristic positions on *Istihalah* and to map the three constituent elements of the doctrine—raw material (*al-asl*), transformation process (*at-tahawwul*), and final product (*an-natijah*)—onto the documented stages of GFF production. Ingredient analyses of commercial GFF products listed on the INCI (International Nomenclature of Cosmetic Ingredients) database (INCIDecoder) were used to verify the composition of the final formulation, particularly with respect to the presence or absence of ethanol.

3. Results

3.1 Biological profile and cosmetic functions of GFF

Galactomyces is a genus of fungi in the class Saccharomycetes, family Dipodascaceae (Cherian, 2024). The most commercially relevant species is *Galactomyces candidus* (synonym: *Geotrichum candidum*), which is found across fermented food substrates including dairy, kimchi, and kefir (Bae *et al.*, 2024; Kalamaki & Angelidis, 2016; Sipiczki & Hrabovszki, 2023). *Galactomyces geotrichum* holds Generally Recognised as Safe (GRAS) status from the United States Food and Drug Administration (Szudera-Konczal *et al.*, 2023). GFF is formally defined as a filtrate obtained by fermenting a growth medium using *Galactomyces candidus*, G*alactomyces fermentans*, or *Galactomyces reessii* (Cherian, 2024), and is commercially marketed as Pitera (TM) by Procter and Gamble (P&G, 2026). Its bioactive composition—vitamins, minerals, amino acids, small peptides, and oligosaccharides—is readily bioavailable through the skin (Cooper *et al.*, 2019).

GFF has demonstrated multi-functional cosmetic efficacy across four domains. First, anti-aging and texture improvement: long-term application significantly reduces wrinkles, improves skin smoothness, and enhances firmness by stabilising actin cytoskeleton proteins (Crabtree *et al.*, 2025; Miyamoto *et al.*, 2023). Second, pigmentation correction: GFF reduces hyperpigmented spots and suppresses reactive oxygen species in melanocytes via the Nrf2-ARE antioxidant pathway (Cooper *et al.*, 2019; Miyamoto *et al.*, 2021). Third, barrier function and wound repair: GFF activates proliferative genes in keratinocytes and strengthens intercellular adhesion, facilitating wound closure and enhancing the epidermal barrier (Chan, 2023; Nakamizo *et al.*, 2024; Rovito *et al.*, 2025). Fourth, cellular defense and moisturization: GFF upregulates the antioxidative enzyme GPX2 and downregulates the senescence biomarker CDKN2A, thereby delaying cellular aging (Yan *et al.*, 2022). It is used at concentrations up to 90.7% in leave-on moisturising formulations (Cherian, 2024).

The Asia-Pacific region accounts for over 52% of the global Galactomyces skincare market in 2024, and the global fermented face mask market is projected to grow from USD 1.33 billion in 2025 to USD 2.56 billion by 2035 at a compound annual growth rate of 6.8% (Future Market Insights, 2025). This market trajectory underscores both the commercial significance of GFF and the practical importance of establishing its halal status.

3.2 The doctrine of *Istihalah*: Definition, typology, and conditions

The term *Istihalah* derives from the Arabic root *h-w-l*, denoting transformation or change. Technically, al-Husayni (1994) defines it as "the transformation of something from one state to another," while al-Juwayni (2007) specifies that it entails a change in the attributes of the transformed substance without the disappearance of its essence. Wahbah al-Zuhayly (2014) offers the most comprehensive formulation: the inversion of one substance into another differing in its qualities, encompassing the transformation of impure or contaminated substances into pure ones, and of legally prohibited substances into permissible ones.

Two types of *Istihalah* are distinguished in Islamic jurisprudence. First, *Istihalah Sahihah* (accepted transformation) occurs when any substance—licit or illicit in origin—undergoes change through natural or artificial agents such that the resultant substance is categorically halal and legally distinct from the original. Second, *Istihalah Fasidah* (corrupted transformation) involves a change from a permissible to a prohibited substance; the end-product is haram, though it may, under specific conditions, revert to a halal status (Jamaludin & Wan Mohamed Radzi, 2009).

Classical juristic schools hold divergent positions on whether *Istihalah* affects purification. The *Hanafi* school, together with some *Maliki* scholars and Ibn Taymiyyah, affirms that *Istihalah* purifies impure substances when a genuine change in name and qualities has occurred. Ibn Qayyim al-Jawziyyah (1991) articulates this position:

> *It is impossible for the ruling of impurity to remain when its name and qualities have ceased to exist. The ruling is dependent on the name and qualities, revolving around them in both existence and non-existence. Therefore, the texts that address the prohibition of carrion, blood, pig meat, and khamr do not encompass crops, fruits, ash, salt, soil, or vinegar—literally, meaningfully, textually, or analogically.*

On this basis, these scholars accept *Istihalah* through three principal forms: fermentation (as when wine becomes vinegar), combustion (as when filth becomes ash), and dissolution (as when a carcass decomposes in salt) (Abdullah *et al.*, 2011). The *Shafi'i* and *Hanbali* schools adopt a more restrictive position, recognizing transformation only in specific instances—most notably, the natural transformation of wine into vinegar—and rejecting purification by combustion (al-Shirazi, 1995; al-Bahuti, 1968).

Contemporary conditions for *Istihalah Sahihah* in cosmetics have been articulated by Abdul Rab *et al.* (2018) and Redzuan and Mohd Kashim (2025). These scholars require: (1) complete transformation—the process must wholly alter the substance's chemical and physical nature; (2) irreversibility—the change must be permanent with no possibility of reverting to the original state; (3) a new legal identity—the end-product must not carry the legal ruling of the original impure substance; (4) non-interference with acts of worship such as ablution (*wudu'*); (5) harmlessness to the user; and (6) the absence of any

remaining trace of the original *najis* substance in the final product.

3.3 The production process of Galactomyces ferment filtrate

GFF production proceeds through three consecutive stages: preparation and cultivation, fermentation, and downstream processing (filtration, sterilization, and standardisation).

a) Preparation and cultivation - Production begins with the activation of a selected Galactomyces yeast strain in a liquid starter culture (inoculum) (South Korea Patent No. KR101884411B1, 2017). This culture is then introduced into a carbohydrate-rich medium, most commonly rice, though some manufacturers use flour or starch combinations (China Patent No. CN116218694B, 2023). Rice is preferred for its high levels of branched-chain starches, proteins, and polyphenolic compounds, which serve as substrates for yeast metabolism (Sun *et al*., 2025). Optimal conditions maintain a pH of 5.0-5.5 at approximately 30°C (Szudera-Konczal *et al*., 2023). The raw materials at this stage—rice, starch or flour, and Galactomyces yeast—are plant-derived and categorically permissible (*mubah*) under Islamic law.

b) Fermentation - Under controlled parameters of temperature (25-37°C), pH, aeration, and agitation, Galactomyces fungi break down complex starches into simpler sugars, which are then metabolized to yield bioactive compounds: amino acids, peptides, organic acids, vitamins, polyphenols, and polysaccharides (Yang *et al*., 2025). Fermentation is conducted for 35-60 hours (Klimek-Szczykutowicz *et al*., 2024). Critically, like other yeasts catabolising carbohydrate substrates, Galactomyces can produce ethanol as an incidental metabolic by-product (Valinhas *et al*., 2018; Mohd Azhar *et al*., 2017). This is a biochemical consequence of carbohydrate fermentation, not the intended outcome: the explicit purpose of GFF fermentation is the harvest of beneficial metabolites for cosmetic application, a distinction confirmed by manufacturer statements (Mary, 2021). The fermentation process for GFF is thus categorically distinct from sake production, which employs *Aspergillus oryzae* (koji mould) and *Saccharomyces cerevisiae* as primary organisms to achieve ethanol concentrations of 20% or more (Nishida, 2021; Wilkowska & Dzwonnik, 2025).

c) Filtration, sterilisation, and standardisation - Following fermentation, the broth undergoes centrifugation to remove fungal biomass and insoluble particles, followed by multi-stage filtration—including heating to 90°C for 30 minutes and passage through diatomaceous earth—before standardisation for commercial consistency (China Patent No. CN116218694B, 2023; Klimek-Szczykutowicz *et al*., 2024). Analysis of ingredient lists from five leading commercial GFF products—SK-II Facial Treatment Essence, Mixsoon Galactomyces Ferment Essence, COSRX Galactomyces 95 Whitehead Power Essence, Mizon Skin Power Original First Essence, and Some By Mi Galactomyces Glutathione Glow Milky Toner—confirms the complete absence of ethanol in their formulations (INCIDecoder, 2018, 2022, 2024, 2025). Alcohols present in these products (butylene glycol, pentylene glycol, 1,2-hexanediol) are non-intoxicating synthetic solvents and humectants with no relation to *khamr*.

4. Discussion

4.1 Application of *Istihalah*: Analysis of the raw material (*al-Asl*)

The first element in an *Istihalah* analysis is the assessment of raw materials. Where the raw material is an impermissible substance—such as porcine-derived gelatine—the analysis must verify whether the transformation is sufficiently complete to alter the legal ruling. Jamaludin *et al.* (2012) note that the conversion of animal bones and hides to gelatine is physical rather than chemical and therefore does not constitute *Istihalah Sahihah*. However, where both the raw material and the conversion agent are permissible—as in the case of GFF—the question shifts to whether the transformation process and the final product raise new jurisprudential concerns.

In GFF production, the raw materials—rice, starch or flour, and Galactomyces yeast—are plant-derived substances that are categorically *mubah*. The initial production stage is therefore free of jurisprudential concern. The *Istihalah* analysis must accordingly focus on the intermediate fermented broth and the final downstream product.

4.2 Application of *Istihalah*: Analysis of the transformation (*at-Tahawwul*)

The key jurisprudential issue arises at the fermentation stage, where ethanol is produced as an incidental metabolic by-product. This must be distinguished from intentional *khamr* production. *Its purpose defines Khamr*—an intoxicating beverage produced for consumption—and the *Qur'anic* prohibition is grounded in its intoxicating nature and the intent to produce it (*Al-Ma'idah*, 5:90). The principle *al-umur bi-maqasidiha* ("matters are judged by their objectives") supports the view that the incidental generation of ethanol in a process directed toward cosmetic metabolite production does not automatically trigger the rulings applicable to *khamr*.

This interpretation is consistent with the *fatwa* of Malaysia's National Council for Islamic Religious Affairs, as summarised by Mohd Noor (2019), which holds that ethanol produced as a by-product of food or non-khamr manufacturing is not automatically *najis*. Alzeer and Hadeed (2016) add that naturally occurring ethanol at concentrations below 1% may be treated as *mubah* when it is an essential, incidental result of fermentation rather than the product of deliberate anaerobic alcohol production. Dzulkifly Mat Hashim further distinguishes industrial ethanol—defined by its chemical properties—from *khamr*, which is defined by its intoxicating effect and the intent of its production (Ab Ghani & Ismail, 2010).

Nevertheless, the presence of ethanol in the intermediate fermented broth introduces a degree of ambiguity (*shubhah*) that must be resolved by examining the final product. This is precisely the function of the *Istihalah* doctrine: to determine whether the downstream transformation produces a substance that is qualitatively and legally distinct from the impure intermediate.

4.3 Application of *Istihalah*: Analysis of the final product (*an-Natijah*)

Ibn Taymiyyah (1997) provides the decisive jurisprudential principle for this analysis:

> *Once it is known that the impurity has transformed, the water becomes pure, whether in small or large amounts, and the same applies to all liquids. This is because Allah has permitted good things and forbidden impure things, and the impure is distinguished from the good by its qualities. Therefore, when the qualities of water or anything else are those of the good and not the impure, it must be included in the permissible and not the forbidden.*

Al-Tarabulus (1992) specifies that *Istihalah Sahihah* requires a complete transformation of the qualities (*sifat*) of the original substance, accompanied by a change of name and identity. Measuring the commercial GFF formulation against the conditions stipulated by Abdul Rab *et al.* (2018) and Redzuan and Mohd Kashim (2025), the following findings are obtained.

First, a complete and irreversible transformation has been achieved. The fermented broth—containing ethanol and living microorganisms—is converted through centrifugation, heat sterilization at 900C, and multi-stage filtration into a standardized, ethanol-free filtrate. This represents not merely physical removal but a transformation of chemical composition and biological character that cannot be reversed.

Second, the absence of *najis* residue in the final product is confirmed by commercial ingredient analyses of five GFF products, all of which are free of ethanol. The incidental ethanol produced during fermentation has been eliminated in the downstream process, leaving no trace in the final formulation.

Third, GFF is water-soluble and does not form a barrier that would impede ablution (*wudu'*), satisfying the condition that the product must not prevent acts of worship. Fourth, the final product is demonstrably beneficial to skin health rather than harmful. Fifth, GFF possesses a distinct internationally recognized INCI name and a specific set of cosmetic functions entirely unrelated to sake or *khamr*. This constitutes the new legal identity required by classical jurists.

It is also necessary to directly address the widespread claim that GFF is a by-product of sake production. Sake fermentation employs *Aspergillus oryzae* (koji mould) and Saccharomyces cerevisiae as its primary organisms, achieving final ethanol concentrations exceeding 20% (Nishida, 2021; Wilkowska & Dzwonnik, 2025; Walker & Stewart, 2016). These organisms are taxonomically and functionally distinct from the Galactomyces species used in GFF production. While Galactomyces organisms may be found as environmental contaminants in sake breweries, they are not the primary fermentation agents, and commercial GFF is produced in controlled industrial fermenters specifically designed for cosmetic ingredient production. The claim's origin in digital media rather than peer-reviewed scientific literature further undermines its credibility.

The conditional *fatwa* of Dr. Zulkifli Mohamad al-Bakri (2023)—that GFF produced through a distinct process from sake-making is permissible—is thus satisfied by the scientific and manufacturing evidence. All conditions for *Istihalah Sahihah* are met: the transformation is complete, irreversible, and yields a product with a new chemical identity, new name, and new legal status, free from any *najis* residue, non-interfering with worship, and safe for use.

This analysis aligns with the broader jurisprudential framework applied to other fermentation-derived ingredients. Jamaludin and Wan Mohamed Radzi (2009) confirm that vinegar produced from wine represents the paradigmatic case of *Istihalah Sahihah* accepted by the *Hanafi* school and condoned by Ibn Taymiyyah, in which complete chemical transformation yields a new, permissible substance. The transformation of the GFF-fermented broth through heat sterilization and filtration is complete.

5. Conclusion

This study presents the first systematic jurisprudential analysis of Galactomyces Ferment Filtrate (GFF) in cosmetics, applying the classical Islamic doctrine of *Istihalah* across its three analytical dimensions: raw material (*al-asl*), transformation process (*at-tahawwul*), and final product (*an-natijah*). The following conclusions are drawn.

The raw materials of GFF production—rice, starch, and Galactomyces yeast—are categorically permissible (*mubah*), with no impure substance entering the process at the initial stage. The fermentation process produces ethanol as an incidental metabolic by-product, not as its intended output. It is therefore governed by the principle of intentionality in Islamic law (*al-umur bi-maqasidiha*) rather than by the rulings on *khamr* production. Downstream processing—comprising centrifugation, heat sterilization, and multi-stage filtration—removes all ethanol from the final filtrate, as confirmed by ingredient analyses of multiple commercial GFF products. The final ingredient is chemically and physically distinct from the intermediate fermented broth, bears its own internationally recognized name and cosmetic identity, does not interfere with acts of worship, and is safe for use. All conditions for *Istihalah Sahihah* are thereby satisfied.

This study concludes that commercial GFF qualifies as *tahir* (pure) and halal (permissible) for cosmetic use. This finding carries practical significance for multiple stakeholders: Muslim consumers may use GFF-containing skincare products without the doubt (*shubhah*) that has hitherto surrounded the ingredient; halal certification bodies may employ the *Istihalah* framework developed here as a template for evaluating other fermentation-derived cosmetic ingredients; and manufacturers seeking halal certification should document the absence of ethanol in their final formulations and the distinction of their production process from sake manufacturing.

Future research should extend this jurisprudential methodology to other biotechnology-derived cosmetic ingredients—including bacterial ferment filtrates and fermented plant extracts—and should engage the broader question of how Islamic law should systematically accommodate the increasingly complex transformations enabled by modern industrial biotechnology.

References

Ab Ghani, A., & Ismail, M. (2010). Penentuan piawaian alkohol dalam makanan yang dibenarkan dari perspektif Islam. Jurnal Fiqh, 7, 277–299.

Abdul Rab, M. A., Mochammad Sahid, M., Gunardi, S., & Hoque, M. (2018). *Shari'ah* guidelines on the application of *Istihalah* in cosmetic products. Darul Syakir Enterprise.

Abdullah, A. A., Mustafa, H., Ismail, K., Awang, M., Baharum, N., Abd Gani, S., & Arshad, S. (2025). Alcoholic cosmetics products based on the concept of *halalan toyyiban*: An analysis of cleanser products in Malaysia. International Journal of Research and Innovation in Social Science (IJRISS), 5446–5456.

Abdullah, J., Abdul Rahman, S., & Mohd Nor, Z. (2011). Konsep *Istihalah* dan *Istihlak* pada makanan dan barang guna. Jurnal Penyelidikan Islam, 71-92.

al-Bahuti, M. (1968). *Kashshaf al-qina' an matn al-Iqna'* (Vol. 1). Maktabat al-Nasr al-Hadithah.

al-Husayni, A.-M. (1994). *Kifayat al-akhyar fi hall ghayat al-ikhtisar*. Dar al-Khayr.

al-Juwayni, A.-M. (2007). *Nihayat al-matlab fi dirayat al-madhab*. Dar al-Minhaj.

al-Shirazi, A. (1995). *Al-muhadhdhab fi fiqh al-Imam al-Shafi'i*. Dar al-Kutub al-'Ilmiyyah.

al-Tarabulus, A. (1992). *Mawahib al-jalil fi sharh mukhatasar Khalil* (Vol. 1). Dar al-Fikr.

al-Zuhayly, W. (2014). *Al-fiqh al-islami wa adillatuh* (Vol. 7). Dar al-Fikr.

Alzeer, J., & Hadeed, K. A. (2016). Ethanol and its halal status in food industries. Trends in Food Science & Technology, 58, 14–20. https://doi.org/10.1016/j.tifs.2016.09.008

an-Nawawi, Y. (2010). Al-minhaj *sharh sahih Muslim ibn al-Hajjaj* (2nd ed., Vol. 11). Dar Ihya' al-Turath al-'Arabi.

Bae, C.-I., Gwak, Y. S., Eom, S. J., Lee, S., & Kim, M. J. (2024). Effects of storage temperature on the diversity of white colony-forming yeast and correlations between bacterial and yeast communities in salted kimchi cabbage. Food Science and Biotechnology, 34, 1001–1004. https://doi.org/10.1007/s10068-024-01756-2

Baharum, N., Awang, M. D., Arshad, S., & Abd Gani, S. (2020). A study of the literature: The status of alcohol in cosmetic products from a Shariah perspective in Malaysia. Proceedings of the International Conference on Islam, Economy, and Halal Industry (ICIEHI) (pp. 379–393). KnE Social Sciences.

Bamba, T., Hori, Y., Umebayashi, K., Soh, C., Hakozaki, T., Toyama, K., & Hasunuma, T. (2024). Comprehensive metabolic profiling of *Geotrichum candidum* and comparison with Saccharomyces cerevisiae. Journal of Bioscience and Bioengineering, 137(1), 9–15. https://doi.org/10.1016/j.jbiosc.2023.10.004

Chan, L. S. (2023). Keratinocytes. In L. S. Shi (Ed.), Atopic dermatitis: Inside out or inside in (pp. 90–105). Elsevier.

Cherian, P. (2024). Safety assessment of yeast-derived ingredients as used in cosmetics. International Journal of Toxicology. https://doi.org/10.1177/1091581815610508

China Patent No. CN116218694B. (2023). Galactose yeast-like fermentation product filtrate production method.

Cooper, J. K., Kadekaro, A. L., Hakozaki, T., & Boissy, R. E. (2019). Galactomyces ferment filtrate suppresses reactive oxygen species generation and promotes cellular redox balance in human melanocytes. Journal of Clinical and Cosmetic Dermatology, 3(1), 1–10.

Crabtree, S., Jarrold, B. B., Kent, O., Ehrman, M. C., Hawkins, T. J., Korolchuk, V., & Brown, M. (2025). Galactomyces ferment filtrate upregulates anchoring junctions and stabilizes actin, thereby maintaining the Young's modulus of skin cells in vitro. International Journal of Cosmetic Science, 1–14. https://doi.org/10.1111/ics.13015

Elder, A., Ring, C., Heitmiller, K., Gabriel, Z., & Saedi, N. (2020). The role of artificial intelligence in cosmetic dermatology: Current, upcoming, and future trends. Journal of Cosmetic Dermatology, 20(1), 48–52. https://doi.org/10.1111/jocd.13744

Future Market Insights. (2025). Galactomyces ferment filtrate market report. https://www.futuremarketinsights.com/reports/galactomyces-ferment-filtrate-market

Ibn Qayyim al-Jawziyyah, M. (1991). *I'lam al-muwaqqiin 'an rabb al-'alamin*. Dar al-Kutub al-'Ilmiyyah.

Ibn Taymiyyah, T. al-D. (1997). *Al-mustadrak 'ala majmu' fatawa shaykh al-Islam* (Vol. 3). [Publisher details unavailable].

INCIDecoder. (2018). SK-II facial treatment essence ingredient list. https://incidecoder.com/products/sk-ii-facial-treatment-essence

INCIDecoder. (2022). Mizon skin power original first essence ingredient list. https://incidecoder.com/products/mizon-skin-power-original-first-essence-2

INCIDecoder. (2024). Mixsoon Galactomyces ferment essence ingredient list. https://incidecoder.com/

INCIDecoder. (2025). Some by mi Galactomyces glutathione glow milky toner ingredient list. https://incidecoder.com/products/some-by-mi-galactomyces-glutathione-glow-milky-toner

Jamaludin, M. A., Ramli, M. A., Mat Hashim, D., & Ab Rahman, S. (2012). *Fiqh Istihalah*: Integration of science and Islamic law. Revelation and Science, 2(2), 117–123.

Jamaludin, M., & Wan Mohamed Radzi, C. (2009). Teori *Istihalah* dari perspektif Islam dan sains: Aplikasinya pada beberapa produk makanan. Shariah Journal, 17(1), 169–194.

Kalamaki, M., & Angelidis, A. S. (2016). Isolation and molecular identification of yeasts in Greek kefir. International Journal of Dairy Technology, 70(6). https://doi.org/10.1111/1471-0307.12419

Klimek-Szczykutowicz, M., Blonska-Sikora, E. M., Kulik-Siarek, K., Zhussupova, A., & Wrzosek, M. (2024). Bioferments and biosurfactants as new products with potential use in the cosmetic industry. Applied Sciences, 14(9), 1–27. https://doi.org/10.3390/app14094000

Kwasna, H., & Bateman, G. L. (2008). A new species of Galactomyces and first reports of four fungi on wheat roots in the United Kingdom. Sydowia, 60, 69–92.

Mary. (2021). Skincare mengandungi Galactomyces haram sebab mengandungi Sake? Review Mizon [Blog post]. Ampang, Selangor.

Mazri, M. (2020). Hukum penggunaan Sake (sejenis arak) dalam produk kosmetik. Al-Kafi li al-Fatawi, 1737. Jabatan Mufti Wilayah Persekutuan. https://muftiwp.gov.my/ms/artikel/al-kafi-li-al-fatawi/4554

Miyamoto, K., Dissanayake, B., Omotezako, T., Takemura, M., Tsuji, G., & Furue, M. (2021). Daily fluctuation of facial pore area, roughness, and redness among young Japanese women: Beneficial effects of Galactomyces ferment filtrate-containing antioxidative skin care formula. Journal of Clinical Medicine, 10(7), 1–12. https://doi.org/10.3390/jcm10071538

Miyamoto, K., Inoue, Y., Yan, X., Yagi, S., Suda, S., & Furue, M. (2023). Significant reversal of facial wrinkle, pigmented spot, and roughness by daily application of Galactomyces ferment filtrate-containing skin products for 12 months: An 11-year longitudinal skin aging rejuvenation study. Journal of Clinical Medicine, 12(4), 1–13. https://doi.org/10.3390/jcm12041430

Mohamad al-Bakri, Z. (2023, September 18). Produk kosmetik yang mengandungi Galactomyces [Blog post]. https://zulkiflialbakri.com/artikel/produk-kosmetik-yang-mengandungi-galactomyces/

Mohd Azhar, S., Abdulla, R., Jambo, S., Marbawi, H., Gansau, J. A., Mohd Faik, A., & Rodrigues, K. F. (2017). Yeasts in sustainable bioethanol production: A review. Biochemistry and Biophysics Reports, 10, 52–61. https://doi.org/10.1016/j.bbrep.2017.03.003

Mohd Noor, U. (2019). Irsyad al-Fatwa series 290: The ruling of food colouring containing 20% alcohol. Jabatan Mufti Wilayah Persekutuan. https://muftiwp.gov.my/en/artikel/irsyad-fatwa/irsyad-fatwa-umum-cat/3097

Nakamizo, S., Yan, X., & Kabashima, K. (2024). Enhancement of skin barrier function and augmentation of epidermal cell-cell interactions by Galactomyces ferment filtrate. Journal of Dermatological Science, 115(2), 94–97. https://doi.org/10.1016/j.jdermsci.2024.05.003

Ng, R. (2021, May). Active ingredients: Galactomyces [Blog post]. Threebs Malaysia. https://threebs.co/blogs/ingredients/active-ingredients-galactomyces

Nishida, H. (2021). Sake brewing and bacteria inhabiting Sake breweries. Frontiers in Microbiology, 12, Article 637207. https://doi.org/10.3389/fmicb.2021.637207

Noor Fatima, Sherpao, G., Ali, H. S., Ashraf Dogar, M., & Anwar, H. S. (2023). Opinions of the Imams on the ingredients and manufacturing processes of cosmetics are permissible to the Muslim community. Journal of Positive School Psychology, 7(1), 801–806.

P&G (Procter & Gamble). (2026). Our story. SK-II. https://www.sk-ii.com/our-story

Personal Care Products Council. (2025). Galactomyces ferment filtrate. INCIDecoder. https://incidecoder.com/ingredients/galactomyces-ferment-filtrate

Redzuan, A. E., & Mohd Kashim, M. A. (2025). Islamic perspectives on the use of blood plasma in cosmetics: Jurisprudential analysis and contemporary challenges. Journal of Contemporary Islamic Law, 10(1), 43–51.

Rovito, H., Green, L., Black, M., Snowball, J., Jarrold, B. B., & Oblong, J. (2025). Galactomyces ferment filtrate stimulates a wound healing response that can facilitate overcoming a response plateau. Journal of Investigative Dermatology. https://doi.org/10.1016/j.jid.2025.01.010

Santaella-Lam, M. (2024, April). Galactomyces ferment filtrate. Paula's Choice Skincare. https://www.paulaschoice.com/ingredient-dictionary/ingredient-galactomyces-ferment-filtrate.html

Sipiczki, M., & Hrabovszki, V. (2023). *Galactomyces candidus* diversity in the complex mycobiota of cow-milk bryndza cheese comprising antagonistic and sensitive strains. International Journal of Food Microbiology, 388, Article 110101. https://doi.org/10.1016/j.ijfoodmicro.2022.110101

South Korea Patent No. KR101884411B1. (2017). Galactomyces ferment filtrate production process.

Sun, X., Yu, L., Xiao, M., Zhang, C., Zhao, J., Narbad, A., & Tian, F. (2025). Exploring core fermentation microorganisms, flavour compounds, and metabolic pathways in fermented rice and wheat foods. Food Chemistry, 463(1), 1-12. https://doi.org/10.1016/j.foodchem.2024.141060

Szudera-Konczal, K., Myszka, K., Kubiak, P., Drabinska, N., & Majcher, M. A. (2023). The combined effect of lactic acid bacteria and *Galactomyces geotrichum* fermentation on the aroma composition of sour whey. Molecules, 28(11), 1–16. https://doi.org/10.3390/molecules28114417

Valinhas, R. V., Pantoja, L. A., Maia, A. F., Miguel, M. C., Vanzela, A. F., Nelson, D. L., & Santos, A. S. (2018). Xylose fermentation to ethanol by new *Galactomyces geotrichum* and *Candida akabanensis* strains. PeerJ. https://doi.org/10.7717/peerj.4673

Walker, G. M., & Stewart, G. G. (2016). *Saccharomyces cerevisiae* in the production of fermented beverages. Beverages, 2(4), 1–12. https://doi.org/10.3390/beverages2040030

Wilkowska, A., & Dzwonnik, Z. (2025). The use of non-conventional yeast in sake production. Molecules, 30(18), 1–23. https://doi.org/10.3390/molecules30183985

Yan, X., Tsuji, G., Hashimoto-Hachiya, A., & Furue, M. (2022). Galactomyces ferment filtrate potentiates an anti-inflammaging system in keratinocytes. Journal of Clinical Medicine, 11(4), 1–13. https://doi.org/10.3390/jcm11041016

Yang, F., Hu, Y., Wu, M., Guo, M., & Wang, H. (2025). Biologically active components and skincare benefits of rice fermentation products: A review. Cosmetics, 12(1), 1–18. https://doi.org/10.3390/cosmetics12010029

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Veterinary laboratories as a strategic mechanism for public health protection and halal industry development in Brunei Darussalam

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Received: 28/5/2026
Accepted: 19/7/2026
Published: 31/7/2026

Keywords:
Brunei; Food safety; Halal assurance; Public health; Veterinary laboratory

Abstract

The concept of *halalan toyyiban* emphasises that food products must not only comply with halal requirements but also be safe, wholesome, and of good quality. Veterinary laboratories contribute to this principle through scientific testing that supports food safety, public health, and halal assurance. This study aimed to examine the role of Veterinary Laboratory Services (VLS) in safeguarding public health and supporting halal assurance in Brunei Darussalam. A qualitative approach was used, involving semi-structured interviews with six participants, including VLS personnel and an industry representative. Thematic analysis revealed that VLS supports public health through disease surveillance, microbiological testing, molecular analysis, and food safety assessment. Although VLS does not perform halal certification, its laboratory services provide scientific evidence that strengthens halal integrity. Challenges related to human resources, resources, equipment, and accreditation were also identified.

1. Introduction

The concept of *halalan toyyiban* is deeply rooted in food safety standards and Islamic jurisprudence (Musfirah *et al.*, 2015; Maulana, 2020). It emphasises that food must not only be halal according to Islamic guidelines but also *toyyib,* meaning it must be clean, safe, wholesome, and not harmful to human health (Al-Teinaz *et al.*, 2020). Hence, food safety is seen as both a scientific concern and a religious requirement, particularly in Muslim-majority countries such as Brunei Darussalam. To meet these expectations, it is essential to adhere to safe food practices and have credible quality control procedures.

In modern food governance, assurance systems increasingly rely on scientific evidence generated through laboratory testing. Veterinary laboratories play an important role in this framework by supporting disease surveillance, diagnostic testing, and food safety assurance at the interface between animal and human health. Beyond disease detection, veterinary laboratories provide analytical services, including microbiological testing, chemical residue analysis, and contaminant monitoring of animal-derived products, thereby contributing to public health protection and the One Health approach (WHO, 2023). Through these functions, veterinary laboratories serve as important components of national health security systems by enabling early detection, risk assessment, and prevention of foodborne and zoonotic hazards.

The role of veterinary laboratories is also increasingly relevant within halal food systems as global consumers demand products that are not only religiously compliant but also safe, authentic, and of high quality. Laboratory testing complements halal certification by providing scientific evidence for verifying product safety, authenticity, and potential contamination risks. Techniques such as microbiological analysis, chemical residue testing, and PCR-based species identification can detect food safety hazards and species substitution, thereby strengthening traceability, transparency, and consumer confidence in halal products.

In Brunei Darussalam, Veterinary Laboratory Services (VLS) serves as the country's national veterinary laboratory under the Veterinary Laboratory Section, Division of Livestock Industry, Department of Agriculture and Agrifood (DoAA), Ministry of Primary Resources and Tourism (MPRT). VLS supports animal health, livestock development, food safety, and public health through specialised services including animal diagnostics, veterinary public health, feed and biotechnology, and Salmonella reference testing. Its laboratory services include microbiological analysis, molecular testing, serological testing, chemical residue detection, nutritional analysis, and disease surveillance. VLS is accredited under ISO/IEC 17025:2017 for selected chemical and biological testing scopes by SAC-SINGLAS, Singapore, a recognition it has maintained since 2012 (VLS Testing Booklet, 2021).

According to the VLS Testing Booklet (2021), VLS is organised into several specialised sub-units, each focusing on a specific

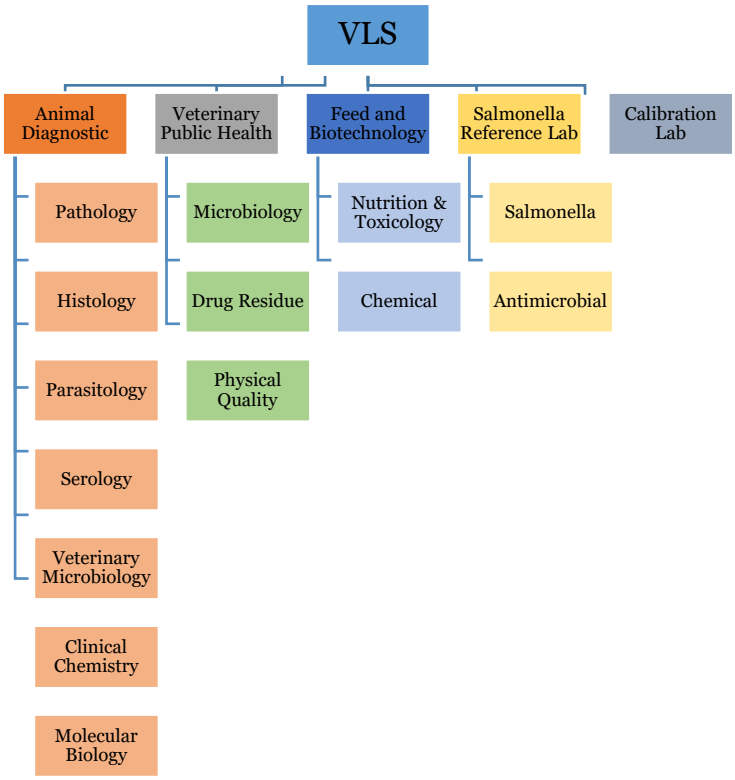

Figure 1: Organisational structure and functional areas of VLS.

aspect of veterinary diagnostics and public health support. The organisational structure and functional areas of these specialised sub-units are illustrated in Figure 1.

Although VLS does not directly conduct halal certification, its laboratory services indirectly support halal assurance by providing scientific evidence related to food safety and product authenticity. Within Brunei's halal governance system, halal certification is administered by the Halal Food Control Division (BKMH), which operates under policies issued by the Ministry of Religious Affairs (Kifli, 2023), while the technical and scientific support is provided by institutions such as VLS, the Department of Scientific Services (DSS), and the Brunei Darussalam Food Authority (BDFA) (VLS Testing Booklet 2021; BDFA, 2022). This demonstrates that halal assurance involves collaboration between religious authorities, regulatory agencies, and scientific institutions.

Despite the recognised importance of veterinary laboratories in food safety and public health, existing studies on halal assurance have largely focused on certification systems, regulatory compliance, consumer behaviour, and food safety management. Meanwhile, veterinary laboratory research has mainly focused on disease surveillance, animal health, and diagnostic services within the One Health framework. Limited attention has been given to veterinary laboratories as scientific institutions that indirectly strengthen halal assurance through laboratory verification, surveillance, and food safety testing. This gap is particularly relevant in Brunei Darussalam, where VLS serves as the country's only national veterinary laboratory supporting animal health, food safety, and public health.

Given the limited empirical evidence on the institutional role of veterinary laboratories in halal assurance, a qualitative approach is particularly appropriate for exploring the experiences, practices, and challenges of VLS personnel and industry stakeholders. This approach enables a deeper understanding of how laboratory services contribute to halal assurance and public health protection within the Brunei context.

Therefore, this study aims to examine the role of Veterinary Laboratory Services (VLS) in safeguarding public health and supporting the development of the halal industry in Brunei Darussalam. Specifically, this study explores (1) how VLS contributes to public health protection, (2) how laboratory testing indirectly supports halal integrity, and (3) the conditions required for VLS further to support Brunei's aspiration as a global halal hub.

2. Materials and methods

2.1 Research design

This study adopted a qualitative research design (Islam & Aldaihani, 2022) to explore the roles, contributions, and challenges of VLS in safeguarding public health and supporting halal assurance in Brunei Darussalam. A qualitative approach was selected because the study aimed to understand participants' professional experiences, institutional practices, and perceptions, which cannot be adequately captured through quantitative measurement. Through semi-structured open-ended interviews, the study obtained detailed insights into VLS operations, inter-agency collaboration, and challenges affecting its contribution to halal assurance.

2.2 Research sample

The study targeted VLS laboratory personnel directly involved in public health and halal assurance-related testing, as well as one industry representative with experience submitting samples to VLS. These participants were selected because their professional experiences and insights provided a first-hand understanding of how VLS contributes to food safety, public health, and halal assurance in Brunei Darussalam.

Purposive sampling was used in this study, with participants selected based on their professional roles, experience, and direct involvement in VLS operations. The inclusion criteria required participants to be currently employed at VLS or directly involved with VLS services, actively involved in laboratory testing, supervision, or decision-making related to animal health, food safety, or halal compliance, and willing to participate voluntarily in the study. A total of six participants were involved in this study, comprising five VLS personnel and one industry representative.

The selected participants represented major functional subunits and decision-making levels within the laboratory, enabling the study to gather informed, relevant perspectives aligned with the research objectives. The sample size was considered appropriate because this study was exploratory in nature and focused on an in-depth investigation of a single national veterinary laboratory in Brunei Darussalam rather than statistical generalisation. As VLS is a specialised government institution with a limited number of personnel directly involved in relevant laboratory functions, the selected participants provided sufficient depth and contextual coverage to address the research objectives meaningfully.

Data saturation was considered achieved when subsequent interviews no longer generated new information, codes, or themes relevant to the research objectives. Following the completion and review of the six interviews, no substantially new themes emerged, indicating that sufficient depth had been achieved to address the study's aims. This approach is consistent with the concept of data saturation, in which data collection may cease when additional interviews no longer yield new insights (Guest *et al.*, 2006, as cited in Islam & Aldaihani, 2022).

2.3 Data collection procedure

Data were collected through open-ended, semi-structured interviews, which allowed predetermined questions to guide the discussion while providing flexibility to explore additional insights from participants. Interviews with VLS were conducted in person and lasted approximately 30-45 minutes per session, while the industry representative participated via a separate interview.

The primary research instrument was an interview guide. It began by gathering background information on the participants' experiences and roles at VLS, followed by questions on laboratory testing activities, contributions towards public health and halal assurance, operational challenges, and future directions for VLS. All interview questions were open-ended, allowing participants to share their experiences, perspectives, and opinions in detail.

To ensure ethical research practices, participants were informed of the study's purpose, confidentiality procedures, and voluntary participation before the interviews were conducted. Written informed consent was obtained prior to the interviews, and participants were informed that they could withdraw from the study at any stage without consequences. With participants' permission, interviews were audio-recorded to ensure transcription accuracy. All recordings and transcripts were stored securely and used strictly for academic purposes.

Secondary data were also used to support the study's findings. These included official VLS publications, government policy documents, halal regulatory frameworks, and related literature relevant to veterinary laboratory services, food safety, and halal assurance. Data triangulation was also applied by comparing interview findings with documentary evidence from these secondary sources, thereby enhancing the credibility and trustworthiness of the study (Donkoh & Mensah, 2023).

2.4 Data analysis

The collected data were analysed using thematic analysis following the six-step framework proposed by Braun and Clarke (2006, as cited in Ahmed *et al.*, 2025). This method enabled the systematic identification, examination, and reporting of recurring themes within the interview data. Interview transcripts and participant responses were manually reviewed and coded to identify recurring ideas and patterns related to VLS roles in public health protection, halal integrity, and halal industry development. The coded data were subsequently grouped into broader themes that represented the study's major findings. This approach allowed participants' experiences and perspectives to be systematically interpreted while preserving the data's overall meaning.

To enhance the trustworthiness of the analysis, coding was performed iteratively, with initial codes reviewed and refined multiple times to ensure consistency and accuracy in theme development. The interview findings were also cross-checked against secondary sources, including official VLS publications, government policy documents, and halal regulatory frameworks, to strengthen their credibility through data triangulation.

The analysis followed a systematic progression from familiarisation with the data, to the generation of initial codes, to searching for themes, to reviewing themes, to defining and naming themes, and to producing the final report in accordance with Braun and Clarke's (2006, as cited in Ahmed *et al.*, 2025) thematic analysis framework.

3. Results and discussion

3.1 Overview of qualitative findings

The findings were derived from semi-structured interviews with six participants, including five VLS officers and one representative from the food industry. The participants were selected based on their direct experience in food safety, veterinary testing, and halal assurance, providing valuable insights into VLS's role and operations in Brunei Darussalam.

To maintain confidentiality, the identities of all participants were anonymised and assigned specific codes (R1-R6) for reporting and analysis purposes, as presented in Table 1. The selected participants represented different roles and functional areas related to VLS operations, including laboratory testing, management, and industry engagement.

Table 1: Respondent profile

Respondent	Code	Organisation/Sub-unit	Years of Experience
Respondent 1	R1	Animal Diagnostic & Veterinary Public Health	26 years
Respondent 2	R2	Animal Diagnostic, Feed & Biotechnology, Salmonella Reference Lab	15 years
Respondent 3	R3	Animal Diagnostic & Veterinary Public Health	12 years
Respondent 4	R4	Animal Diagnostic & Salmonella Reference Lab	15 years
Respondent 5	R5	Overall Laboratory Management	23 years
Respondent 6	R6	Food Industry Representative	28 years

The data were analysed using thematic analysis to identify key themes and recurring patterns across the interviews. The findings are presented based on the main themes that emerged from the analysis and are discussed in relation to the role of VLS in public health protection, halal assurance, operational challenges, and future development.

3.2 VLS as a safeguard for public health

Respondents perceived that VLS plays an important role in safeguarding public health in Brunei Darussalam through comprehensive diagnostic, analytical, and monitoring activities that ensure food safety, animal health, and disease control. Rather than operating in isolation, the work of VLS was reported by respondents to support national animal health programmes, food safety regulation, and public health protection by preventing biological, chemical, and nutritional hazards from reaching consumers.

The findings indicate that VLS contributes to public health through several laboratory functions, including microbiological testing, disease surveillance, residue testing, nutritional analysis, and molecular testing. These activities help ensure that animal-based products are safe, clean, and suitable for consumption. R1 highlighted the importance of microbiological testing in preventing harmful contaminants from reaching consumers:

"For MCL, livestock products are analysed to ensure they are clean, safe for sale and consumption by the public. We ensure that the products are free from bacteria such as Salmonella, Listeria monocytogenes, Campylobacter, E. coli, coliform, and Staphylococcus aureus. This monitoring is important so that harmful bacteria do not reach consumers."

These findings are consistent with broader functions of veterinary laboratories, which extend beyond disease diagnostics to include food safety testing, disease surveillance, and other analytical services that support both animal and public health (Marrana *et al.*, 2022). In the context of Brunei Darussalam, these functions are reflected in the services provided by VLS, where microbiological testing contributes to monitoring potential foodborne hazards and supports preventive measures within the national food safety system (VLS Testing Booklet, 2021).

Similarly, R2 explained that VLS contributes to public health protection through disease monitoring, antimicrobial guidance, and nutritional analysis:

"At VML, we conduct Salmonella testing to monitor livestock farms in Brunei. The aim is to ensure that the farms are free of Salmonella or have controlled levels of it. At SAL/AML, we determine the appropriate antibiotics to use for Salmonella infection, including the appropriate dosage. This helps control the disease and avoid the misuse of antibiotics."

Beyond laboratory diagnostics, respondents indicated that VLS outputs also support regulatory processes within national food safety and animal health systems. R5 highlighted that VLS functions as part of national efforts to maintain food safety and public health:

"This laboratory is under the DoAA, and VLS supports the department's mission to maintain public safety and health through the control of infectious diseases. This effort is in line with Brunei's 2035 Vision, as public health and food safety contribute to the economic stability and well-being of the country."

The presence of systematic disease surveillance and laboratory monitoring supports decision-making by relevant authorities in managing food safety risks and implementing appropriate control measures. Overall, VLS was perceived as a preventive mechanism within Brunei's food system. Its role is not only to conduct laboratory analysis, but also to support early detection, risk reduction, and consumer safety.

3.3 Laboratory testing as support for halal standards

Findings from the interviews showed that veterinary laboratory testing plays a role in supporting halal standards in Brunei, particularly through halal authenticity and safety assurance. Although VLS does not conduct halal certification, respondents perceived that laboratory testing contributed to halal assurance by providing scientific evidence to verify product authenticity, detect contamination, and strengthen confidence in halal products.

One of the key contributions highlighted by the respondents was the use of molecular-based testing, particularly meat speciation analysis, to identify animal species in food products. R1 explained:

"For MBL, one of the tests that really supports halal is meat speciation. Usually, the samples that we received, we need to

ensure the absence of pork DNA or other prohibited species indicators, besides ensuring that it is free from any disease..."

Similarly, R4 emphasised that meat speciation testing supports halal assurance by verifying the authenticity of animal-based products:

"For VLS, most of the halal-related tests are at MBL. They do meat speciation, which can identify species in a product. If the meat is not pure, this test will show it in its result. Therefore, it really helps support the halal industry in Brunei."

Respondents further suggested that halal-related laboratory testing could be expanded beyond meat speciation to strengthen halal assurance in Brunei. R5 emphasised the need to reinforce halal-related testing by stating:

"...We strongly support halal not only from a health perspective, but also from the perspective of Qur'an and Hadith. To improve, we need to strengthen the halal laws further and ensure that more halal-related tests are carried out and strengthened."

However, before adding more tests to improve the halal testing, R3 emphasised the need for more studies and research: "... To improve halal testing further, new tests need to be added. But before adding tests, we need more studies and research."

Overall, the findings indicate that VLS supports halal assurance through scientific verification rather than direct halal certification. By providing reliable laboratory evidence on food safety and product authenticity, VLS strengthens halal integrity and contributes to greater confidence in halal products.

3.4 Challenges faced by VLS personnel

The findings identified several operational and institutional challenges faced by VLS personnel. These include resource and material constraints, workload pressure, limited specialised personnel, technical limitations, equipment dependency, accreditation requirements, and financial constraints.

Respondents reported that shortages of laboratory materials, testing kits, and consumables may affect the ability to consistently perform certain tests. R1 highlighted that the limited availability of testing kits could interrupt laboratory activities, stating that: "Our main challenge is the shortage of kits. When we run out of stock, we must inform clients that the test cannot be performed. Sometimes we borrow from other labs if they have a surplus."

In addition to resource limitations, respondents also highlighted workload pressure due to the responsibility of managing multiple laboratory functions simultaneously. R1 and R2 explained that operating several laboratories with limited human resources creates time constraints, particularly when samples are received concurrently.

"...In addition, because we operate three labs at a time, we must run here and there to complete all the work. The workforce is the same, but the workload is high..." (R1)

"We also face the challenge of managing three laboratories. When samples come in simultaneously for all three laboratories, we must fight for time to complete each test." (R2)

The issue of workforce limitations is particularly significant in specialised laboratory settings, where testing activities often require technical expertise and competency in specific areas. Previous organisational studies suggest that insufficient staffing may increase workload demands and reduce operational efficiency within organisations (Engetou, 2017). In the context of VLS, this shortage may cause delays in processing the sample, reduced laboratory efficiency, and an overload of current staff, which may affect the validity and consistency of test results.

Technical and capacity-related limitations were also identified as important challenges. Respondents highlighted that advanced laboratory equipment requires specialised knowledge, continuous training, and proper maintenance. R3 specifically noted challenges associated with operating LC-MS/MS equipment, including its complexity and the need for additional technical competency.

"The main challenge is how to handle the machine since it is very complex and not 'straightforward'. Not only it is difficult to operate, but the maintenance is also numerous and complicated." (R3)

Furthermore, a shortage of specialised personnel and dependency on limited equipment were identified as factors affecting laboratory sustainability. R5 highlighted the need for more specialised expertise and modern equipment to ensure continuity of testing services.

"From a human resources perspective, we lack chemists and toxicologists. Currently, we only have two specialists..." (R5)

Accreditation and financial sustainability were also identified as important challenges. Maintaining ISO/IEC 17025 accreditation requires continuous investment in equipment maintenance, calibration, consumables, quality assurance activities, and staff competency development. R4 explained that maintaining accredited tests becomes challenging when resources are limited, while R5 highlighted the financial burden of maintaining accreditation.

"Our main challenge is to ensure that all the tests we have remain accredited. To do that, consumables and supplies must always be available, and all equipment must be well maintained." (R4)

"...The fourth challenge is the cost of maintaining ISO accreditation. In a year, the maintenance cost can exceed half a million." (R5)

Overall, the findings indicate that VLS's ability to support public health and halal assurance is closely connected with its operational capacity. Adequate human resources, sufficient resources, reliable equipment, continuous training, and sustainable funding are important conditions for strengthening VLS's role. These findings are comparable with earlier observations by Khalaf (1980), who identified financial limitations, inadequate laboratory infrastructure, shortage of skilled personnel, and insufficient institutional support as major constraints affecting veterinary diagnostic laboratories. Although veterinary laboratory systems have advanced through technological and management improvements, resource availability, technical expertise, and organisational support remain fundamental factors influencing the sustainability and effectiveness of laboratory services.

3.5 Future directions and strategies for VLS

Interview findings indicate that respondents generally viewed the role of VLS as likely to expand in the future, particularly in strengthening food safety, halal assurance, and export facilitation. Several strategies were suggested to improve the effectiveness and sustainability of VLS operations, including strengthening human resources, expanding laboratory testing capacity, improving technical competency, and enhancing industry support.

One of the key strategies identified was strengthening human resources. Respondents highlighted that additional skilled personnel and specialised experts would help improve laboratory efficiency, reduce workload, and allow staff to focus more effectively on specific laboratory functions. R1 noted that the large number of laboratories within VLS requires sufficient staffing to maintain effective operations.

"In terms of improvement, VLS does need more staff. The laboratory is large and has many small laboratories, as the number of existing staff is still not enough." (R1)

Similarly, R4 emphasised that additional qualified experts would enable staff to specialise in specific laboratory areas, thereby improving work quality and supporting the expansion of testing services.

"If a laboratory technician only focuses on one laboratory, the quality of work can be improved. Currently, operating multiple laboratories with one staff is quite challenging..." (R4)

Another important future direction identified was the expansion of laboratory testing capacity, particularly accredited tests. Respondents suggested that expanding testing could strengthen halal assurance and food safety beyond existing services. R1 highlighted the potential to expand halal-related testing beyond meat speciation, while R2 suggested extending testing coverage to processed animal-based products.

"...halal testing can also be improved, not just meat speciation, but by adding other types of halal testing." (R1)

"...In terms of improvement, halal testing and the role of VLS can be expanded not only to raw meat, but also to processed products such as sausages and canned food." (R2)

Participants also emphasised that expansion of testing services requires adequate financial support, specialised expertise, and continuous competency development. R3 noted that although additional tests could strengthen VLS's contribution, further studies and cost considerations are necessary before implementation.

"...However, the addition of tests requires a larger budget. Before making these tests mandatory, further studies should be conducted to ensure that the tests are cost-effective." (R3)

The need for continuous capacity development identified by respondents is consistent with international approaches for strengthening veterinary services. According to VLS (2023), adopting the Performance of Veterinary Services (PVS) Gap Analysis framework developed by the World Organisation for Animal Health (WOAH) represents a strategic approach for strengthening veterinary services. The PVS Gap Analysis provides a systematic evaluation of veterinary service performance against international standards and forms part of the broader PVS Pathway, which guides veterinary services through structured stages of orientation, evaluation, planning, and targeted support for capacity improvement (OIE PVS Pathway Secretary, 2018).

In the context of VLS, this framework may serve as a useful reference for identifying operational gaps and prioritising areas for improvement, particularly in workforce capacity, technical competency, laboratory infrastructure, and service sustainability. Such an assessment-based approach may support the continuous strengthening of VLS and enhance its ability to contribute to animal health, food safety, and halal assurance in Brunei Darussalam.

From the industry perspective, R6 highlighted that VLS testing provides important support in maintaining food safety, hygiene, and halal integrity within food processing operations. However, further improvements could include clearer communication, technical guidance, faster turnaround times, and stronger engagement between VLS and industry stakeholders.

"VLS already provides valuable support, but there are several areas where their assistance could be further strengthened to help companies maintain halal integrity and food safety.... enhanced guidance, clearer communication, and more structured support from VLS would help companies strengthen their halal assurance systems and maintain high food safety standards more effectively." (R6)

Overall, the findings suggest that the future development of VLS depends on continuous investment in human resources, laboratory capacity, accreditation, technological advancement, and stronger collaboration with industry stakeholders. These improvements may further strengthen VLS's contribution to public health and halal assurance in Brunei Darussalam.

3.6 VLS as a technical pillar in Brunei's halal industry development

Respondents highlighted VLS as an enabling institution that supports Brunei's halal assurance ecosystem by providing scientific evidence for product safety, authenticity, and compliance. The findings indicated that laboratory testing, particularly meat speciation and other food-safety-related analyses, helps strengthen consumer trust and maintain the integrity of animal-based products.

Although VLS does not directly issue halal certification, its laboratory services provide technical support that complements the halal certification process. Through scientific verification, VLS helps detect potential risks, such as species adulteration, contamination, and food safety hazards, thereby supporting transparency and trust within the halal supply chain.

The findings further suggest that VLS's contribution to the development of the halal industry depends on its operational capacity and institutional support. Participants identified several factors that influence VLS's ability to expand its role, including sufficient human resources, specialised expertise, laboratory resources, equipment capacity, accreditation scope, inter-agency collaboration, and sustainable financial support. These conditions are important to ensure that VLS can

continue providing reliable scientific evidence to support halal assurance and public health protection.

Strengthening laboratory capacity and expanding testing services may further enhance Brunei's halal ecosystem by providing stronger scientific assurance for both domestic and export markets. The availability of reliable, accredited testing facilities may foster greater confidence among industry stakeholders and consumers in the authenticity and safety of halal products.

Furthermore, respondents noted that strengthening regional collaboration and alignment with international halal standards could further enhance the credibility and competitiveness of Brunei's halal ecosystem.

Overall, VLS can be understood as a technical pillar within Brunei's wider halal governance ecosystem. Its contribution extends beyond laboratory testing alone, as it provides scientific support that strengthens halal assurance, public confidence, and the credibility of Brunei's halal industry. However, the full potential of VLS depends on continuous investment, organisational support, and stronger coordination among relevant stakeholders.

4. Conclusion

This study explored the role of Veterinary Laboratory Services (VLS) in supporting public health protection and halal assurance in Brunei Darussalam. The findings demonstrate that VLS serves as an important technical institution within the broader halal governance ecosystem by providing scientific evidence to support food safety, product authenticity, and regulatory decision-making. While VLS does not perform halal certification, its laboratory activities complement halal assurance systems by strengthening verification processes through scientific testing.

From a theoretical perspective, this study contributes to understanding halal governance by highlighting that halal assurance extends beyond certification mechanisms and requires integration among religious, regulatory, and scientific institutions. The findings reinforce the concept of *halalan toyyiban* by demonstrating that laboratory-based verification contributes not only to halal authenticity but also to the safety, quality, and wholesomeness aspects of food products.

From a policy perspective, the findings suggest that strengthening veterinary laboratory capacity should be considered an important component of national food safety and halal strategies. Policymakers may consider supporting VLS through sustainable funding, workplace development, equipment improvement, and stronger coordination between relevant agencies involved in food safety and halal governance. Enhancing laboratory capacity may improve national preparedness to manage food safety risks, zoonotic diseases, and the growing demand for halal assurance.

For halal regulatory and accreditation agencies, the findings highlight the importance of recognising scientific laboratories as supporting partners within halal assurance frameworks. Greater collaboration among laboratories, halal certification bodies, and industry stakeholders may strengthen the reliability, transparency, and credibility of halal verification systems, particularly for animal-based products.

However, this study has several limitations. The findings were based on a small number of participants from a single veterinary laboratory. They primarily reflected the experiences and perceptions of VLS personnel, with limited representation from industry and other regulatory stakeholders. Therefore, the findings should be interpreted within the institutional context of VLS and are not intended for statistical generalisation. Future studies may involve a broader range of stakeholders, including halal certification authorities, government agencies, industry representatives, and consumers. Comparative studies involving veterinary laboratories across ASEAN or other halal-producing countries may also provide further insights into best practices and the role of scientific institutions in strengthening halal assurance systems.

Overall, this study acknowledges Brunei's aspiration to position itself as a leading halal hub; however, the evidence is qualitative and perception-based, derived primarily from VLS personnel and a single industry representative. Therefore, the findings do not represent a national-level determination of halal hub readiness. Instead, this study identifies the perceived enabling roles of VLS in providing scientific assurance, supporting risk detection, and strengthening compliance within the halal governance ecosystem.

Although VLS alone cannot determine the readiness or competitiveness of Brunei's halal industry, its contribution as a technical pillar remains significant. The effectiveness and scalability of its role depend on several factors, including interagency integration, industry adoption, regulatory support, and sustained investment in laboratory capacity. Addressing constraints related to resource availability, equipment dependency, accreditation requirements, and technical expertise may further strengthen VLS's ability to support halal assurance and public health protection.

Overall, VLS provides essential scientific support that strengthens halal standards, safeguards public health, and contributes to the development of a credible and sustainable halal assurance system in Brunei Darussalam.

5. Acknowledgement

The authors would like to acknowledge everyone involved in completing this study. Special appreciation is extended to the Veterinary Laboratory Services (VLS), Department of Agriculture and Agrifood (DoAA), Ministry of Primary Resources and Tourism (MPRT), Brunei Darussalam, for their support and cooperation throughout the research process. Gratitude is also expressed to all participants who generously shared their time and experiences during the preparation of this study.

6. Conflict of interest

The authors declare no competing interests.

7. AI declaration

Artificial Intelligence (AI) tools, including ChatGPT (OpenAI, San Francisco, CA), were used to assist with language editing, improve sentence structure, and clarify grammar during manuscript preparation. The authors reviewed, verified, and take full responsibility for the accuracy and integrity of the content. No AI tools were used for data analysis, result interpretation, or scientific conclusions.

8. Open access

9. Author contribution

Author 1: project administration, conceptualisation, methodology, formal analysis, investigation, data curation, writing original draft preparation, writing, reviewing, and editing.

Author 2: supervision, critical review, editing, and guidance in refining the manuscript, including providing feedback on structure, clarity, and academic content.

References

Ahmed, S., Mohammed, R.A., Nashwan, A.J., Ibrahim, R.H., Abdalla, A.Q., M. Ameen, B.M., & Khdhir, R.M. (2025). Using thematic analysis in qualitative research. Journal of Medicine, Surgery, and Public Health Volume 6. https://doi.org/10.1016/j.glmedi.2025.100198

Al-Teinaz, Y., Spear, S., & Abd El-Rahim, I. (2020). The halal food handbook. https://doi.org/10.1002/9781118823026

Brunei Darussalam Food Authority. (2022). About. https://bdfa.gov.bn/about/

Department of Agriculture and Agrifood, Brunei Darussalam. (2021). Veterinary Laboratory Services (VLS) testing booklet. Ministry of Primary Resources and Tourism.

Donkoh, S., & Mensah, J. (2023). Application of triangulation in qualitative research. Journal of Applied Biotechnology and Bioengineering, 10(1), 6–9.

Engetou, M.E. (2017). Impact of insufficient personnel on organizational performance (Bachelor's thesis, Centria University of Applied Sciences).

Islam, M. A., & Aldaihani, F. M. F. (2022). Justification for adopting qualitative research method, research approaches, sampling strategy, sample size, interview method, saturation, and data analysis. Journal of International Business and Management.

Khalaf, A. M. (1980). Problems associated with veterinary laboratory diagnosis in developing countries. Proceedings of the 2nd International Symposium of Veterinary Laboratory Diagnosticians. Lucerne, Switzerland.

Kifli, S. N. (2023). Halal certification in Brunei Darussalam: Bureaucratisation in everyday life. In Representing Brunei Darussalam: A sociology of the everyday.

Marrana, M., Appiah, E., Jeannin, M., Gilbert, W., Nilsson, A., Hamilton, K. & Rushton, J. (2022). Reporting on 16 years of laboratory capacity building while exploring the future of WOAH's Laboratory Twinning Programme. Front. Vet. Sci. doi: 10.3389/fvets.2022.1058335

Maulana, A. (2020). The term "*toyyib*" in correlation with foods (Undergraduate thesis, UIN Walisongo Semarang).

Musfirah, S., Man, S., & Ramli, M. A. (2015). Food safety from the perspective of Islamic law. Jurnal Fiqh, 1, 1–28.

Nugraha, A. (2025). The rise of the global halal industry: Trends and key sectors for future direction. Islamic Business Review.

OIE PVS Pathway Secretary. (2018, February). A paper presented during PVS Pathway Orientation Workshop for South Asia and Mongolia. https://rr-asia.woah.org/app/uploads/2020/05/2_overview-of-the-pvs-pathway.pdf

Sekretariat Tetap Wawasan Brunei (2035). Jabatan Perdana Menteri. (2020). Wawasan Brunei 2035.

Veterinary Laboratory Services. (2023). A paper presented during the SEACFMD Laboratory Network Meeting. https://rr-asia.woah.org/app/uploads/2023/11/1-13-brunei.pdf

World Health Organization. (2023). One Health. https://www.who.int/news-room/fact-sheets/detail/one-health

World Organisation for Animal Health. (2008). The role of veterinary services in food safety. https://www.woah.org/app/uploads/2008/09/en-role-des-services-veterinaires-securite-sanitaire-des-aliments

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Halal food control systems: A bibliometric review of the global knowledge structure and research gaps, with critical reflections for the Gulf Region

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Received: 15/5/2026
Accepted: 10/7/2026
Published: 31/7/2026

Keywords:
Bibliometric analysis; Halal food control; Food safety; Emerging economies; Saudi Arabia; Gulf region

Abstract

This study presents a bibliometric and critical review of global research on halal food control systems, with particular attention to countries developing new halal regulatory frameworks, including Saudi Arabia and the wider Arab region. A systematic review of Scopus-indexed publications from 2010 to 2025 was conducted following PRISMA guidelines. The final global corpus comprised 847 peer-reviewed articles analysed using VOSviewer and Biblioshiny through co-authorship, co-citation, bibliographic coupling, keyword co-occurrence, and thematic evolution analyses. An additional subset of 82 Arab-region studies, covering Gulf Cooperation Council and wider Arab League states, was manually coded using the FAO/WHO five-component national food control system framework. The field grew at an annual rate of 18.3%, with Malaysia and Indonesia contributing 43% and 28% of publications, respectively. Five major research clusters were identified: *fatwa*-based legislation; multi-agency governance; inspection, enforcement, and laboratory systems; information, education, communication, and training; and emerging technologies, including blockchain and artificial intelligence. Despite rapid growth, the literature remains geographically concentrated, theoretically underdeveloped, methodologically homogeneous, and largely silent on the cost-benefit implications of halal control systems. Few studies integrate *Maqasid al-Shari'ah* with risk-management approaches or examine halal governance as a complete regulatory system. By applying the FAO/WHO framework, this review moves beyond isolated certification and supply-chain perspectives. It demonstrates that Arab-region halal governance exhibits a distinctive "law-rich but evidence-poor" profile and proposes a research agenda addressing institutional performance, empirical evidence, regulatory effectiveness, and economic trade-offs.

1. Introduction

The global halal food industry has evolved from a niche religious market into a major segment of the global bioeconomy. With an estimated annual value of USD 2.1 trillion and serving nearly 1.9 billion Muslim consumers, the sector is expected to reach USD 2.8 trillion by 2025 (Rejeb *et al.*, 2023). This expansion is primarily driven by demographic shifts and a growing "halal consciousness" among consumers, who increasingly associate halal certification with higher standards of safety, hygiene, and ethics (Osman & Saeed, 2023). However, the industry's rapid growth has outpaced the establishment of robust regulatory frameworks, leading to notable integrity breaches, including porcine DNA contamination in Malaysia and fraudulent certification networks in Europe and the Middle East (Ahmad *et al.*, 2018; Al-Mahmood & Fraser, 2023). These events underscore a fundamental paradox: while the market demands comprehensive "farm-to-fork" integrity, the mechanisms designed to ensure this integrity remain fragmented, reactive, and technologically outdated.

A Halal Food Control System (HFCS) constitutes a complex socio-technical framework. In contrast to conventional food safety regimes, an HFCS must achieve two primary objectives: ensuring technical safety, including hygiene, toxicology, and quality, and upholding religious ontological security, such as *Shari'ah* compliance, halal slaughter, and *najs* evasion (Kohilavani *et al.*, 2013, 2021; López Cifuentes & Sonnino, 2024). Meeting these objectives requires combining food science with Islamic jurisprudence (*fiqh*), a process often marked by interpretive challenges. The benchmark model, developed by Malaysia through JAKIM and the Trade Descriptions Act 2011, provides a template for institutionalizing halal control (Ahmad *et al.*, 2018). Nevertheless, even advanced systems have experienced incidents, such as the "Cadbury incident" and subsequent coordination failures, which highlight the persistent challenges of managing a multi-agency environment wherein religious authority and scientific evidence must be reconciled (Alrobaish *et al.*, 2021; X. Jia & Zhang, 2021).

This review systematically analyses halal food control systems using the FAO/WHO National Food Control System

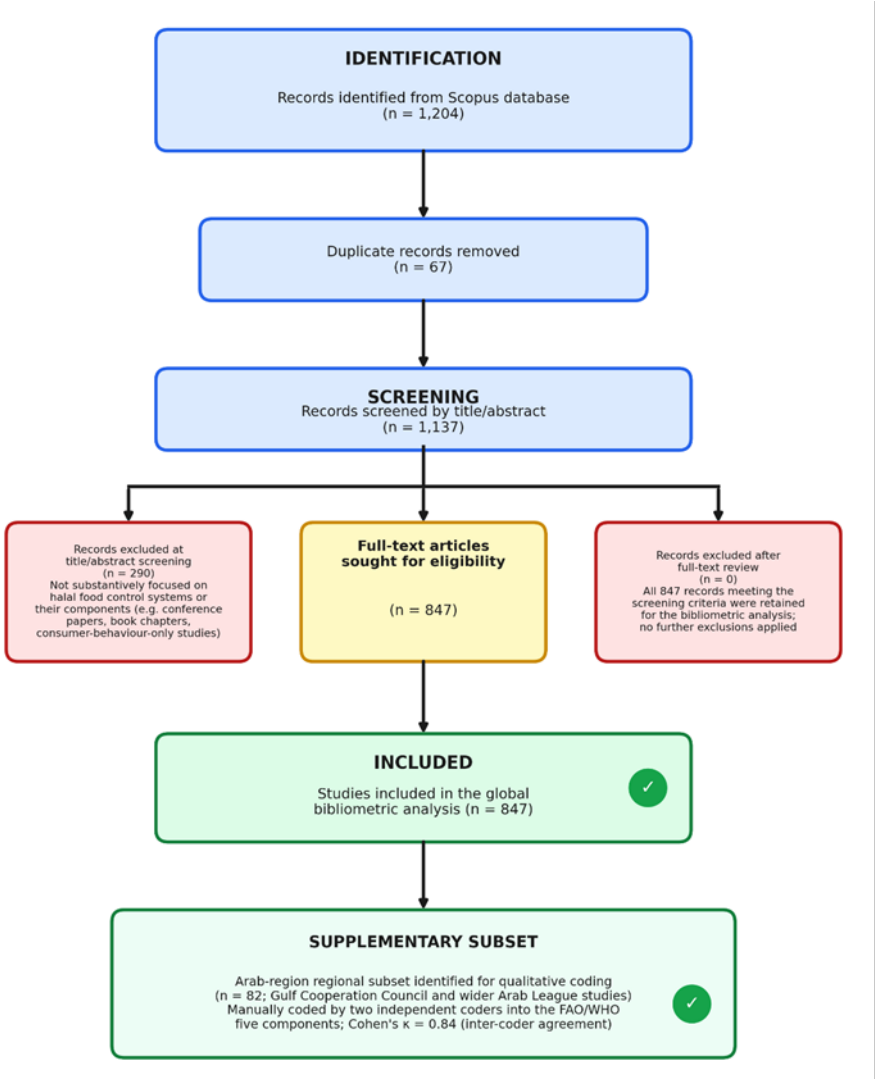

Figure 1: PRISMA Flowchart: Halal Food Control Systems (2010-2025). Note: the n = 847 corpus underwent quantitative bibliometric analysis in full; the n = 82 Arab-region subset is a manually coded sub-sample of this corpus used for the supplementary qualitative analysis reported in Section 3.6. It is not a separate or competing inclusion total.

Framework, which identifies five essential pillars: (a) Legislation and Regulations, (b) Management and Coordination, (c) Inspection Services, (d) Laboratory and Forensic Capabilities, and (e) Information, Education, and Communication (IEC) (Hopper & Boutrif, 2006). Despite significant growth in the literature, with over 800 articles published in the past 15 years, research remains fragmented. Most studies focus on buyer behaviour (Osman & Saeed, 2023), specific certification challenges (Al-Mahmood & Fraser, 2023; Fauzi et al., 2024), or isolated supply chain technologies (Changalima, 2025). There is a notable absence of comprehensive syntheses that evaluate the interactions among these five pillars in building strong national infrastructures, particularly in emerging economies.

The field is also experiencing a "digital turn." The introduction of Industry 4.0 technologies, such as blockchain-enabled traceability, AI-driven authentication, and IoT-based instant monitoring, offers potential to reduce human error and fraud (Helmi Ali et al., 2021; Nawaz et al., 2025). However, adoption in emerging markets is constrained by cost barriers, limited SME readiness, and the absence of harmonised global standards (Bayatzadeh & Talaie, 2025; Jose & Venkatesan, 2023). Accordingly, this bibliometric review serves two purposes: mapping the field's evolutionary trajectory and critically reflecting on the structural imbalances that shape it.

This review addresses four research questions:

1. How has the intellectual structure of halal food control research evolved, and what are the dominant thematic clusters?

2. To what extent does current research address the five FAO/WHO pillars of a national food control system?

3. What are the geographical, theoretical, and methodological "blind spots," particularly regarding the marginalization of Sub-Saharan African and Latin American perspectives?

4. How can emerging economies, such as Saudi Arabia under Vision 2030, leverage this data to develop a globally competitive and religiously robust halal ecosystem?

Table 1: Growth phases of halal food control systems research (2010–2025)

Phase	Years	Avg. Articles/Year	Characteristics
Formative	2010–2014	12	Descriptive, Malaysia-focused
Take-off	2015–2019	38	Triggered by the Cadbury and horsemeat scandals
Acceleration	2020–2025	112	COVID-19, blockchain, AI, supply chain

In contrast to traditional bibliometric studies that primarily present descriptive statistics, this paper adopts a critical-analytical approach. It examines the "Southeast Asian hegemony" in halal discourse, challenges the "regulation-as-panacea" narrative, and explores the contradictions between centralised state control and decentralised market-driven certification (Alrobaish et al., 2021; Suryawan et al., 2022). By synthesizing evidence from over two decades of scholarship, this review provides a theoretical and functional framework for advancing halal food control systems in a globalised, digital era.

In differentiating this review from prior bibliometric treatments of halal research (e.g., Mostafa, 2020; Rejeb *et al.*, 2023; Fauzi *et al.*, 2024), which have generally mapped the field around certification, supply-chain, or consumer-behaviour themes, this review is organised explicitly around the FAO/WHO five-pillar national food control system framework (Hopper & Boutrif, 2006) as its analytical lens, rather than as a post-hoc descriptive label applied to emergent clusters. This framework was selected because it is the most widely endorsed international reference model for evaluating the institutional completeness of national food control systems, providing a normative benchmark against which the maturity of halal-specific governance arrangements can be assessed. A further question that recurs throughout this review, and to which we return in the Discussion and Conclusion, concerns whether artificial-intelligence-assisted certification decisions can satisfy the jurisprudential requirement of human deliberative reasoning (*ijtihad*); this tension between automated verification and Islamic legal epistemology is flagged here as a question requiring sustained, interdisciplinary attention.

2. Methodology

2.1 Research design

A bibliometric review was conducted following the PRISMA protocol as illustrated in Figure 1.

To ensure clarity and methodological transparency, this review differentiates between two overlapping but distinct geographic-political categories: the Gulf Cooperation Council (GCC), which consists of six member states (Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, and the United Arab Emirates), and the broader Arab League, which includes twenty-two member states across the Middle East and North Africa. When the literature search and manual coding (Section 2.2) identified studies relevant to either category, the resulting n = 82 subset is referred to as the 'Arab-region subset' to avoid suggesting that the two terms are interchangeable. Findings specific to GCC states are explicitly noted.

2.1.1 Data source and search strategy

The Scopus database was selected for its comprehensive coverage of food science, management, and Islamic marketing journals. The search was executed on 15 April 2026, covering publications from 2010 to 2025. The following search string was applied to the title, abstract, and keyword fields:

TITLE-ABS-KEY("halal food" OR "halal certification" OR "halal assurance")

Filters applied via the Scopus interface restricted results to peer-reviewed journal articles published in English or Arabic between 2010 and 2025, excluding conference papers, book chapters, and non-journal sources. The inclusion criteria further required an explicit focus on halal food control systems or their components. Initial yield was 1,204 documents.

The inclusion criteria included peer-reviewed articles with an explicit focus on halal food control systems or their components (legislation, management, inspection, laboratory, IECT). Exclusion criteria included conference proceedings, book chapters, non-halal-related studies, and purely consumer behaviour articles without system linkage—initial yield: 1,204 documents. After removing duplicates (n = 67) and exclusions (n = 290), 847 articles were retained for analysis.

2.2 Analysis tools

Two complementary software packages were employed for bibliometric analysis: VOSviewer 1.6.20 for bibliographic coupling, keyword co-occurrence, and cluster identification. (Van Eck & Waltman, 2010) and Biblioshiny (R package): for annual production, source impact, trending topics, and international collaboration (Aria & Cuccurullo, 2017).

A qualitative analysis of the Arab-region subset (n = 82) was also conducted. Articles were manually coded into the five FAO components (plus *fatwa* as a distinct legislative element). Cohen's Kappa for inter-coder agreement was 0.84 (excellent) (Landis & Koch, 1977). Drivers, challenges, and recommendations were extracted thematically.

Manual coding was conducted independently by two coders (Elgharbawy and Al-Saab), with disagreements resolved through discussion; Cohen's Kappa ($\kappa = 0.84$) was calculated on this dual-coded sample, indicating excellent inter-coder agreement (Landis & Koch, 1977).

3. Results

3.1 Growth trajectory

From 2010 to 2025, the global publication record on halal food control systems expanded considerably, registering an annual growth rate of 18.3% and peaking at 156 articles in 2024.

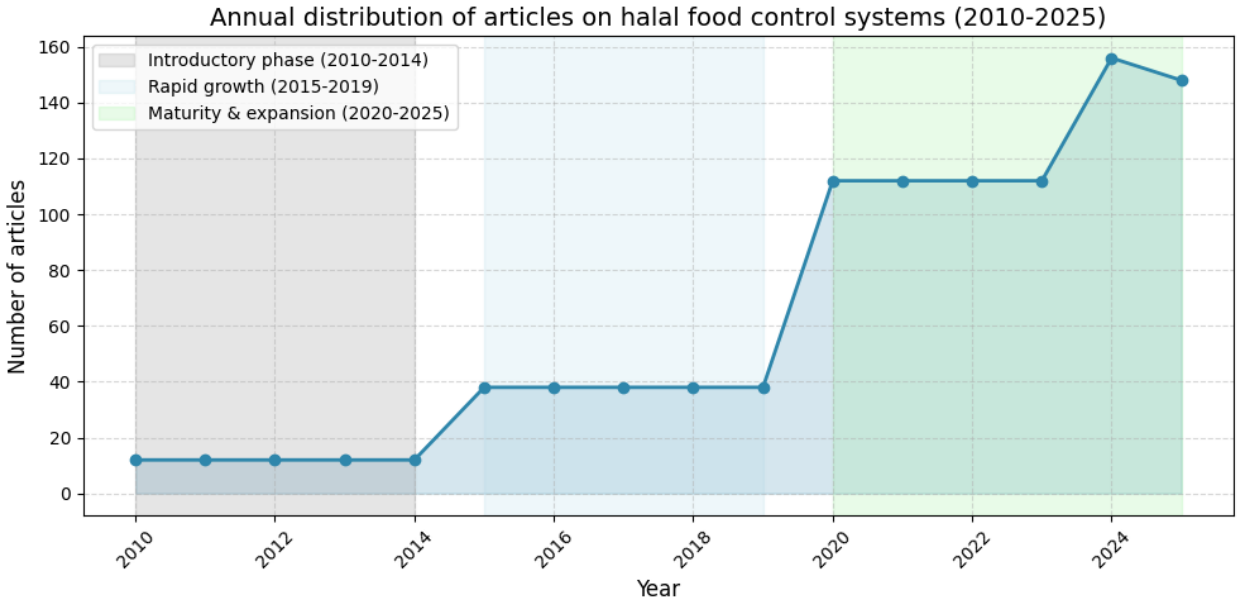

Figure 2: Annual scientific production of halal food control system research (2010–2025).
Source: Authors' analysis from Scopus.

Longitudinal inspection of the corpus reveals three structurally distinct phases of development, summarised in Table 1.

The formative phase (2010–2014) was characterised by a relatively modest annual output of approximately 12 articles, predominantly descriptive in orientation and geographically concentrated in Malaysia. The take-off phase (2015–2019) was precipitated by high-profile fraud events, most notably the detection of porcine DNA in Cadbury products in 2014 (Musa *et al.*, 2016) and the European horsemeat adulteration scandal of 2013 (Brooks *et al.*, 2017), which collectively stimulated research attention and raised the average annual output to 38 articles. The acceleration phase (2020–2025) saw output surge to an average of 112 articles per year, driven by the compounding effects of the COVID-19 pandemic on supply chain vulnerability and a rapidly expanding interest in digital technologies, including blockchain, artificial intelligence, and the Internet of Things (Figure 2).

It is, however, important to critically contextualise this quantitative growth. As Donthu *et al.* (2021) caution, bibliometric expansion does not inherently signify theoretical progress; a substantial proportion of the post-2020 surge comprises applied case studies that replicate similar methods and findings across incrementally different national contexts, suggesting a quantity-quality tension that is characteristic of rapidly internationalizing interdisciplinary fields. (Donthu *et al.*, 2021). Furthermore, an analysis of the emerging technologies cluster reveals that only approximately 4% of blockchain and AI papers present primary empirical data, indicating that conceptual and speculative contributions are currently disproportionately represented, and that technological enthusiasm may be outpacing empirical grounding in this sub-field.

3.2 Most productive countries

The geographical distribution of publications reveals a pronounced concentration in two countries: Malaysia accounts for 43% of global output and Indonesia for a further 28%, together constituting 71% of the corpus. The United Kingdom (7%), Pakistan (5%), and Iran (2%) occupy a modest secondary tier, whilst the entirety of Arab-majority countries collectively contributes only 9%, with Saudi Arabia individually accounting for 4% of the global total (Table 2; Figure 3).

This concentration constitutes a significant geographical bias with substantive epistemological consequences. The near-exclusive reliance on empirical evidence, methodological norms, and policy recommendations drawn from the Malaysian and Indonesian experiences means that cross-cultural transferability has received virtually no systematic attention in the literature. Foundational questions – such as whether Malaysia's JAKIM-centred audit model would be effective in the context of Egypt's fragmented regulatory landscape or Jordan's smaller market economy - remain empirically unresolved. The Saudi Arabian contribution of 4% is particularly striking given the Kingdom's stated ambition under Vision 2030 to develop into a leading global halal logistics hub, suggesting a critical misalignment between policy aspiration and the knowledge production necessary to inform it.

Table 2: Research output by country

Country	Percentage
Malaysia	43%
Indonesia	28%
United Kingdom	7%
Pakistan	5%
Iran	2%
Saudi Arabia	4%
All Arab countries combined	9%

Table 3: Most productive journals

Journal	N	Focus
Journal of Islamic Marketing	128	Islamic marketing, consumer behaviour
Food Control	94	Food safety, regulation
British Food Journal	71	Food science, policy
Trends in Food Science & Technology	35	Reviews
Journal of Halal Product and Research	18	Specialised halal research

Table 4: Top 12 most productive authors by document output and h-index in the halal food control systems corpus (Scopus, 2010–2025; n = 847)

Rank	Author	Institution	Country	Documents	h-index
1	Zailani, S.	University of Malaya	Malaysia	15	59
2	Tieman, M.	Saito University College	Malaysia	13	13
3	Ali, M.H.	UKM Graduate School of Business	Malaysia	12	40
4	Azmi, F.R.	Universiti Teknologi MARA	Malaysia	10	8
5	Zakaria, Z.	Universiti Malaya	Malaysia	9	9
6	Iranmanesh, M.	Taylor's University Malaysia	Malaysia	9	69
7	Vanany, I.	Institut Teknologi Sepuluh Nopember	Indonesia	8	20
8	Tan, K.H.	University of Nottingham	United Kingdom	8	57
9	Mohamed, Z.	Universiti Putra Malaysia	Malaysia	8	29
10	Jamaludin, M.A.	International Islamic University Malaysia	Malaysia	8	8
11	Rezai, G.	Saint Leo University	United States	7	16
12	Kamarulzaman, N.H.	Universiti Putra Malaysia	Malaysia	7	18

3.3 Most productive countries

The Journal of Islamic Marketing (n = 128) emerges as the single most productive outlet, followed by Food Control (n = 94) and the British Food Journal (n = 71) (Table 3). The prominence of the Journal of Islamic Marketing, however, warrants critical scrutiny: its editorial focus is predominantly on consumer trust, brand perception, and certification demand, rather than on the technical and operational dimensions of halal control, such as laboratory analytical methods, inspection protocols, or enforcement mechanisms. Accordingly, the most frequently cited outlet in this field directs scholarly attention disproportionately towards marketing and behavioural constructs, whilst rigorous studies of enforcement infrastructure and laboratory capacity tend to appear in journals with lower disciplinary reach. This structural publication bias may distort the field's perceived research priorities and systematically discourage investment in studies addressing the operational and technical dimensions of halal control, particularly in contexts in the Arab world where such infrastructure remains at an early stage of development.

3.4 Authors and institutions

The bibliometric analysis reveals that the most productive authors by document output do not necessarily correspond to those with the highest h-index — a pattern consistent with bibliometric theory, in which the h-index captures both volume and sustained citation uptake simultaneously, whilst raw document counts reflect only research activity (Donthu *et al.*, 2021). As presented in Table 4, Zailani (University of Malaya; h-index 59) and Tieman (Saito University College; h-index 13) lead the corpus in document output, whilst Iranmanesh (Taylor's University Malaysia; h-index 69) and Tan (University of Nottingham; h-index 57) command the highest h-indices relative to their corpus document counts, indicating that their work exerts disproportionate scholarly influence beyond the halal food corpus specifically. Ten of the twelve authors in Table 4 are affiliated with Malaysian institutions, with Vanany (Institut Teknologi Sepuluh Nopember, Indonesia; h-index 20) and Rezai (Saint Leo University, United States; h-index 16) constituting the sole non-Malaysian contributors in the top tier, confirming the strong concentration of high-productivity authorship within Malaysian higher education.

Figure 3: Geographical distribution of research output on halal food control systems. Source: Scopus analysis. Note: Malaysia + Indonesia = 71%; Arab countries = 9%.

This concentration of authorship within Southeast Asian institutions provides a deep, "insider" contextual perspective but also poses a challenge to the field's global scientific rigor.

Table 5: Research clusters from keyword co-occurrence analysis

Cluster	Theme	Representative Keywords	Approx. Articles
Red	Legislation & *fatwa*	*fatwa, Shari'ah,* MS1500, halal standard	210
Green	Governance	JAKIM, coordination, multi-agency	185
Blue	Inspection & laboratories	porcine DNA, PCR, ISO/IEC 17025	170
Yellow	IECT	awareness, training, consumer trust	140
Purple	Emerging technologies	blockchain, IoT, AI, traceability	95

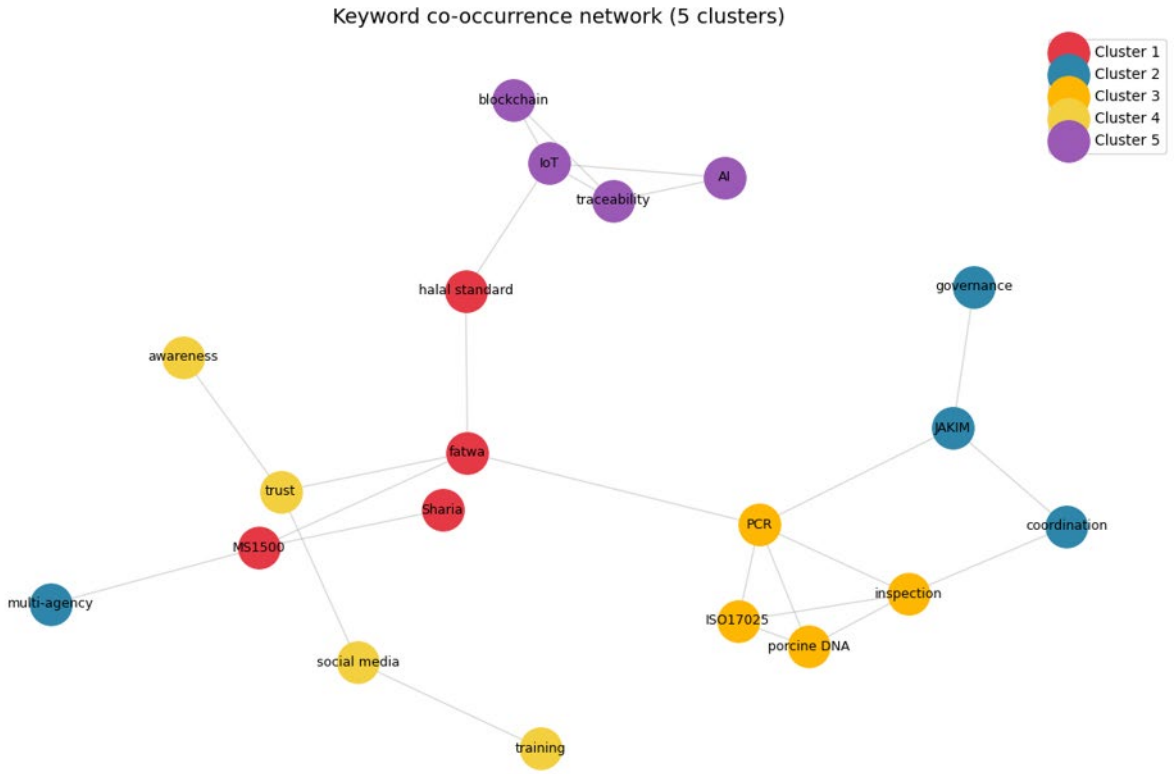

Figure 4: Bibliographic coupling map of keywords (five clusters)—source: VOSviewer analysis.

The dominance of a few key research clusters, particularly those focusing on supply chain integration and regulatory frameworks, indicates that the field's theoretical foundations are being built by a relatively small circle of experts. As Donthu *et al.* (2021) note, high citation counts in an emerging discipline may reflect a scarcity of available frameworks rather than their definitive validation. Consequently, the current literature lacks the independent replication studies necessary for robust knowledge verification. The reliance on a limited number of highly cited frameworks suggests that, while the field has established a strong regional base, it remains provisional, requiring broader external validation and critical scrutiny from the global scientific community to mature.

3.5 Keyword co-occurrence and research clusters

A VOSviewer co-occurrence analysis with a minimum keyword frequency threshold of 5 yielded a network of 124 terms organised into 5 bibliometrically distinct clusters (Table 5; Figure 4).

The five clusters – legislation and *fatwa* (red, ≈210 articles), governance (green, ≈185 articles), inspection and laboratories (blue, ≈170 articles), information, education, communication and training or IECT (yellow, ≈140 articles), and emerging technologies (purple, ≈95 articles), correspond with reasonable fidelity to the five components of a national food control system as articulated by the FAO (2006), providing bibliometric confirmation that the field's intellectual structure broadly reflects policy-relevant categories of analysis.

Notwithstanding this structural correspondence, several inter-cluster deficiencies are noteworthy. Cross-cluster linkages are relatively sparse: few publications examine, for example, how revisions to *fatwa*-based legislation (Cluster 1) propagate into changes to inspection protocols (Cluster 3), or how laboratory analytical capacity shapes consumer trust formation (Clusters 3 and 4). The purple cluster representing emerging technologies is particularly isolated from the remainder of the network, indicating that discourse on blockchain, artificial

Table 6: Distribution of Arab-region studies across the five components (n = 82)

Component	Articles (n)	Percentage (of 82)*
Legislation & *fatwa*	28	34%
Governance	22	27%
Inspection & enforcement	18	22%
Laboratories	12	15%
IECT (education, awareness, training)	24	29%

*Note: each of the 82 articles could be coded into more than one of the five FAO/WHO components; consequently, the percentages reported above sum to more than 100% and should not be read as mutually exclusive shares of the subset.

intelligence, and IoT-enabled traceability has not yet been substantively integrated with the core halal control literature. Most critically, the analysis reveals the complete absence of a cluster addressing economics, cost-benefit analysis, or resource constraints, a silence that reflects a field predominantly driven by the supply-side priorities of researchers and certification bodies, rather than by the budgetary and implementation realities facing governments.

3.6 Results from Arab-region subset (n = 82)

Manual coding of the 82 articles comprising the Arab-region subset revealed an uneven distribution of scholarly attention across the five FAO components, as detailed in Table 6. Legislation and *fatwa* attracted the greatest proportion of coverage (34%), followed by IECT (29%) and governance (27%), whilst inspection and enforcement (22%) and, most markedly, laboratories (15%) received comparatively limited attention.

Thematic analysis of the subset literature revealed three principal motivating factors underpinning the development of halal control in the region. Government Vision programmes, most notably Saudi Vision 2030, were cited as a key catalyst in 68% of relevant articles, indicating the extent to which state-led development strategies shape halal regulatory ambitions in the Gulf. Rising consumer demand for certified halal products was identified in 72% of articles, making it the most frequently referenced driver overall. Corporate export ambitions were cited in 45% of the subset literature as a third major impetus for regulatory investment.

In contrast to these drivers, the Arab and Gulf literature documents a persistent set of endemic challenges. Weak inter-agency coordination was the most frequently reported implementation infrastructure necessary for effectiveness. The concentration of Arab scholarship on legislation and Islamic Economic and Commercial Transactions (IECT), rather than laboratory science and technical enforcement, risks producing systems that are, in practical terms, "law-rich but evidence-poor." The frequent reporting of weak inter-agency coordination (81%) further supports the FAO's (2006) observation that multi-agency governance models are prone to being identified as a structural challenge in 49% of the subset, indicating the fragmented regulatory architectures that characterise much of the Arab world.

These data indicate that Arab halal food control systems exhibit characteristics of the early-stage regulatory systems described by Jia and Jukes (2013), in which legislative structures outpace the implementation infrastructure necessary for effectiveness. The concentration of Arab scholarship on legislation and Islamic Economic and Commercial Transactions (IECT), rather than laboratory science and technical enforcement, risks producing systems that are, in practical terms, "law-rich but evidence-poor." The frequent reporting of weak inter-agency coordination (81%) further supports the FAO's (2006) observation that multi-agency governance models are prone to failure when no single authority holds an overarching regulatory mandate, a structural condition present in most Arab regulatory contexts examined in this corpus (Hopper & Boutrif, 2006).

4. Discussion

The evolution of the global halal food industry from a niche, localised religious market into a significant segment of the global bioeconomy, valued at approximately USD 2.1 trillion and serving nearly 1.9 billion consumers, necessitates a comprehensive re-evaluation of its governance frameworks. Although traditional food safety governance has developed over nearly a century, the Halal Food Control System (HFCS) constitutes a highly complex socio-technical regime. It is required to ensure both technical safety, including toxicology, microbiology, and hygiene, and religious ontological security, such as *Shari'ah* compliance, halal slaughter protocols, and the strict avoidance of *najs* (impurities or contaminants) (Lau *et al.*, 2016). The primary emphasis is on developing new regulatory frameworks in emerging economies and the Arab and Gulf regions.

4.1 Summary of key findings

A bibliometric analysis of 847 articles retrieved from Scopus demonstrates that the field is undergoing rapid and structurally unique evolution. Scientific output increased at a compound annual growth rate of 18.3%, reaching a peak of 156 publications in 2024. This growth follows three development phases: a formative phase (2010–2014) dominated by descriptive, Malaysia-focused administrative studies; a scandal-driven take-off phase (2015–2019) triggered by high-profile fraud events such as the detection of porcine DNA in Cadbury products and the European horsemeat adulteration crisis; and an acceleration phase (2020–2025) driven by COVID-19 supply chain susceptibilities and increased interest in Industry 4.0 digital traceability technologies.

This quantitative expansion remains structurally and geographically concentrated. Malaysia (43%) and Indonesia (28%) together account for 71% of global research output, resulting in a significant geographical bias that limits the generalizability of empirical findings. Although high-level policy initiatives such as Saudi Vision 2030 exist, Arab-majority countries contribute only 9% of the global corpus, with Saudi Arabia representing just 4%. Additionally, a pronounced disciplinary imbalance is evident: the Journal of

Table 7: Socio-Technical and Comparative Matrix of Global Halal Food Control System Models

Structural Component	Established Southeast Asian Benchmark Model (Malaysia/Indonesia)	Early-Stage Arab-Region Subset Regulatory Model	Systemic Implications & Critical Knowledge Gaps
Administrative Governance	Monocentric, centralised state-led audit architecture (e.g., JAKIM, BPJPH) with legally defined divisions of authority	Decentralised, multi-agency models with overlapping municipal, commercial, and religious ministerial portfolios	Multi-agency fragmentation results in severe inter-agency coordination failures (81%) and high transaction costs.
Pillar Alignment	Balanced distribution across legislative standards, laboratory forensics, and mandatory firm-level training	Skewed distribution favouring legislation (34%) and IECT (29%) over laboratory forensics (15%)	Characterises a "law-rich but evidence-poor" pathology where statutory laws outpace physical enforcement capacity.
Analytical & Forensic Capacity	State-funded, ISO/IEC 17025 accredited laboratories equipped for rapid, high-throughput porcine DNA screening	High dependency on private, high-cost laboratories with extended turnaround times for PCR testing	High laboratory costs (58%) act as a barrier to proactive market surveillance, encouraging reactive regulatory responses.
SME Compliance & Internal Controls	Mandated employment of certified Halal Executives and structured Halal Assurance Systems (HAS)	Low compliance literacy and high perceived economic burdens among micro, small, and medium enterprises	Lack of specialised human resources (76%); standard implementation is often decoupled into symbolic compliance.
Digital Infrastructure	Advanced national databases (e.g., MYeHALAL) and integrated supply chain traceability tools	Manual record-keeping and 49% absence of unified national certification databases	Low consumer awareness of applicable laws and reporting systems (54%) leaves systems vulnerable to logo misuse.

Islamic Marketing is the most productive outlet (n = 128), which directs scholarly focus primarily toward consumer trust, brand perception, and behavioural constructs. In contrast, technical, operational, and laboratory enforcement studies remain underrepresented in journals with a wider disciplinary scope.

Keyword co-occurrence mapping indicates that the field's intellectual structure broadly aligns with the five-pillar national food control system framework established by the Food and Agriculture Organization (FAO). These pillars are: legislation and *fatwa*; governance; inspection and laboratories; information, education, communication, and training (IECT); and emerging technologies. Despite this structural alignment, several systemic gaps persist. Cross-cluster linkages are limited, and a sixth critical dimension, namely the economics and cost-benefit analysis of halal control, is absent from the global literature.

Within the Arab and Gulf subset (n = 82), this structural fragmentation is especially pronounced, showing a "law-rich but evidence-poor" condition. Highly developed legislation (34%) and consumer training (29%) coexist with severely underdeveloped laboratory infrastructure (15%) and widespread failures in inter-agency coordination (81%). Table 7 presents a comparative matrix of established and early-stage HFCS regimes to illustrate these structural discrepancies.

4.2. Regulatory maturity and institutional architecture: The Malaysian model as a comparative benchmark

The geographical distribution of the reviewed literature shows a marked imbalance, supplying valuable analytical insight. Arab countries contribute only 9% of total scholarly output on halal governance, whereas Malaysia and Indonesia together account for 71%. This difference goes beyond bibliometric measures and reflects substantive differences in the institutional depth and operational maturity of the regulatory systems examined. Bibliometric analyses indicate that research in this field is mainly concentrated in Muslim-majority Southeast Asian markets, with minimal contributions from Sub-Saharan Africa, Latin America, and the broader Arab world (Changalima, 2025). Within the Arab subset of this review, research themes are primarily focused on legislation (34%) and information, education, communication, and training (IECT) (29%), while laboratory infrastructure (15%) and inspection mechanisms (22%) receive comparatively less scholarly attention. This distribution suggests that halal governance in the Arab and Gulf regions remains in the early, norm-setting stages of regulatory development, prioritising the codification of legal frameworks and public awareness over the technical enforcement and analytical verification characteristic of more mature systems.

This contrast is particularly clear when compared to the Malaysian regulatory architecture, which is the most comprehensively documented and institutionally differentiated halal governance system in the current literature.

According to Ahmad *et al.* (2018), the Malaysian model features a clearly defined division of regulatory authority: JAKIM is responsible for halal certification, the Ministry of Health (MOH) oversees food safety, and the Ministry of Domestic Trade and Consumer Affairs (MDTCC) manages market enforcement. ISO/IEC 17025-accredited testing laboratories support this tripartite structure, standardised certification frameworks such as MS1500:2019, and formalised human capital development through structured programs such as the Halal Executive Program (Ahmad *et al.*, 2018). These elements are integrated within a coherent statutory framework, most notably the Trade Descriptions Act 2011, which criminalises fraudulent halal claims and provides enforcement agencies with the legal tools required for systematic, risk-based market surveillance. Comparative analyses also confirm that Malaysia's system, along with those of Singapore and Indonesia, serves as a model for evaluating other national models (Zhang *et al.*, 2026).

In contrast, the Arab governance landscape, as thoroughly documented by Faour-Klingbeil *et al.* (2022) for the Middle East, is defined by the diffusion of regulatory responsibility across multiple competing administrative bodies, including ministries of Islamic affairs, municipal authorities, and food safety agencies, without a single institution holding an effective coordinating mandate. (Faour-Klingbeil *et al.*, 2022). Saudi Arabia's experience is particularly illustrative: Alrobaish *et al.* (2021) show that, while the Kingdom enforces substantive technical standards for imported food, enforcement is hindered by fragmented oversight, limited inspection capacity at ports of entry, and excessive reliance on documentary rather than analytical verification (Alrobaish *et al.*, 2021). Although the GCC region enforces technical standards, such as those set by the SFDA.FD/GSO 2055-1 and GSO 993 for animal-derived products, effective implementation is undermined by the administrative architecture responsible for enforcement. Hopper and Boutrif (2006) note that distributing regulatory authority across competing ministries without a designated coordinating body is a well-documented source of systemic failure. The finding that 81% of Arab-focused studies in this review report weak inter-agency coordination is a predictable structural outcome of this model (Al Busaidi *et al.*, 2025). A recurring institutional issue is evident: states enact detailed and technically advanced legislation rapidly, yet do not develop the necessary physical, technical, and human infrastructure for efficient monitoring and enforcement (C. Jia & Jukes, 2013). This results in a system that is highly formalistic in its legal structure but operationally vulnerable, showing a persistent gap between de jure regulatory capacity and de facto enforcement performance that the literature consistently documents but seldom examines at the level of institutional design.

Beyond the public sector, the political economy of halal governance in both Southeast Asian and Arab contexts is formed by ongoing negotiations among state authorities, religious bodies, and market actors. Suryawan *et al.* (2022) illustrate in the Indonesian context that halal standards are influenced not only by religious imperatives but also by economic competitiveness, political legitimacy, and industrial policy, thereby complicating cross-regional institutional comparisons. Additionally, the assimilation of minority communities and small enterprises into halal administrative frameworks remains insufficiently examined (Suryawan *et al.*, 2022). Fiteuanto *et al.* (2024) demonstrate that the social effects of halal standardisation in Malaysia and Indonesia can marginalise small religious groups and small firms, raising equity concerns that are often overlooked in regulatory analyses (Fiteuanto *et al.*, 2024).

4.3 Operational failure mechanisms

The structural deficiencies outlined above do not function independently; rather, they interact and compound to create specific, identifiable failure pathways within the halal supply chain. A shortage of specialised human resources, including field inspectors, internal auditors, and laboratory technicians, is reported in 76% of the reviewed Arab-focused studies. High laboratory testing costs compound this shortage, noted in 58% of studies, which have major implications for the reliability of analytical verification. Hossain *et al.* (2023) reported that PCR-based species authentication, the analytical gold standard for detecting porcine contamination in halal-certified products, calls for substantial laboratory infrastructure and technical expertise that many regulatory systems in the Arab and Gulf regions have yet to develop at scale (Hossain *et al.*, 2023). When testing is slow and expensive, regulators often replace risk-based analytical surveillance with paper-based audits of imported certificates (Islam *et al.*, 2023), a practice that introduces structural vulnerabilities at critical points in the verification chain.

The result of this substitution is a supply chain vulnerable to what can be described as "certificate laundering": the use of fraudulent or forged halal certificates paired with unverified or cross-contaminated consignments originating from distant locations. El-tahlawy *et al.* (2025) document various sophisticated food fraud mechanisms, including adulteration, ingredient substitution, and deliberate mislabelling, which flourish in regulatory settings where analytical verification is rare and documentary checks are predominant (El-tahlawy *et al.*, 2025). The lack of a centralised national certification registry, reported in 49% of the Arab-focused studies, means that no single authority possesses the traceability infrastructure required to detect or prevent such manipulation systematically. Ensuring halal integrity throughout the supply chain, starting from farm-level production to warehousing, logistics, and retail, demands extensive monitoring capabilities that go beyond certificate issuance (Yunan *et al.*, 2020). However, the necessary physical logistics infrastructure to support this remains underdeveloped in many Arab markets. It should be emphasised that no study within the reviewed corpus directly quantifies the prevalence of certificate laundering; the term is employed here as an analytic descriptor of a plausible structural vulnerability inferred from the reviewed evidence on documentary-reliant verification, rather than as an empirically substantiated estimate of fraud incidence.

Emerging digital technologies present a theoretically promising solution to these verification challenges. Blockchain-based systems, such as the HalalChain model developed by Yakubu *et al.* (2025), aim to provide immutable compliance records, instant monitoring, and automated verification across distributed supply chains (Yakubu *et al.*, 2025). Artificial intelligence-assisted authentication tools have also shown potential for rapid, scalable detection of halal mislabelling in commercial products (Nawaz *et al.*, 2025). Blockchain frameworks piloted in Malaysia have demonstrated technical feasibility for halal supply chain management, and traceability systems using IoT and RFID technologies have demonstrated potential for monitoring logistics integrity. However, the adoption of these technologies in Arab and other emerging-economy contexts confronts significant structural barriers, including high implementation costs, limited digital

infrastructure, interoperability challenges, and, critically, the low technological readiness of small and medium enterprises (SMEs) that make up the majority of actors within halal supply chains (Bayatzadeh & Talaie, 2025; Nawaz *et al.*, 2025).

It is important to acknowledge, however, that these operational failures are not occurring in a context of regulatory stagnation. Saudi Vision 2030 is cited in 68% of Saudi-focused studies as a primary institutional catalyst for reform, whilst consumer demand (72%) and export market ambitions (45%) constitute additional motivating forces. Non-conformance reporting in halal certification, as studied by Abdul Halim *et al.* (2024) in the Malaysian SME context, reveals that even within a relatively mature system, recurring compliance failures are concentrated among smaller firms with limited internal capacity, which accentuates the inherent nature of the challenge rather than its reduction to individual firm behaviour (Abdul Halim *et al.*, 2024). However, the literature's treatment of these drivers is characterised by a persistent tendency to diagnose without prescribing: weak inter-agency coordination is consistently flagged, but no study quantifies the transaction costs of coordination failure; the shortage of specialised personnel is acknowledged, but no study appraises the cost-benefit ratio of training investment relative to expected reductions in fraud incidence; and high laboratory costs are described without proposing the risk-based sampling frameworks, such as pooled testing or rapid screening prior to confirmatory PCR, that might enable regulators to maximise diagnostic value inside constrained resources. This diagnostic-with-prescriptive tendency represents a consistent methodological limitation of the halal governance literature that future research needs to address if it is to serve as a credible basis for policy design.

4.4 Gaps in the literature

The five empirically derived thematic clusters identified in this review: legislation, laboratory systems, inspection and enforcement, IECT, and emerging technologies, correspond closely with the FAO/WHO five-component food control framework. This agreement affirms that effective halal governance requires the simultaneous, integrated functioning of all components, rather than their consecutive or selective development. The convergence between the inductively derived cluster structure and the normative FAO/WHO model improves the methodological credibility of the review's findings. The wider science-mapping literature supports it. Mostafa (2020), in a 30-year visualisation of the knowledge domain of halal food research, identifies certification, supply chain management, safety, and traceability as the field's core intellectual themes. Rejeb *et al.* (2023) traced the main paths of knowledge diffusion in halal food research, confirming that regulatory and supply chain concerns have regularly dominated the field's development. (Rejeb *et al.*, 2023). Recent bibliometric work by Fauzi *et al.* (2024) also identifies a shift from supply-side concerns to consumer-oriented research, specifically about trust and purchasing behaviour. (Fauzi *et al.*, 2024).

However, this agreement also highlights a distinct absence: the literature does not identify a sixth cluster related to economic analysis or cost-benefit evaluation. This gap is conceptually significant, as it suggests that halal governance research remains largely supply-driven, determined by the perspectives of researchers, certifiers, and institutional advocates, rather than policy-driven in addressing budget constraints, resource allocation, and efficiency trade-offs relevant to real-world implementation by governments and regulatory agencies. The unresolved question of whether centralised certification systems empirically outperform decentralised ones, a design issue carrying direct implications for the Arab governance context, where 49% of studies report the absence of a centralised national certification system, illustrates this gap.

Similarly, the potential for cross-regional coordination among emerging halal markets, as explored by Ma and Abdul Hamid (2026) in their study of seven Muslim-minority economies, remains undertheorised with respect to the specific institutional and economic conditions of the Arab world (Ma & Abdul Hamid, 2026). The pursuit of harmonised regional standards, as analysed by Johan and Plana-Casado (2023) in the ASEAN context, provides a partial model. However, the applicability of the ASEAN experience to the more fragmented Arab regulatory environment has not been systematically examined (Johan & Plana-Casado, 2023).

A parallel and equally significant gap exists within the emerging technologies cluster. The adoption of blockchain, artificial intelligence, and the Internet of Things for halal supply chain traceability represents a rapidly expanding area of scholarly interest, as shown by systematic reviews such as Rejeb *et al.* (2021) on IoT integration and Nawaz *et al.* (2025) on AI in halal authentication. However, most contributions in this cluster remain conceptual, proposing technological solutions that lack real-world efficacy, cost-effectiveness, or institutional compatibility at scale. More fundamentally, many techno-optimist contributions overlook the issue of *Shari'ah* compliance in AI-assisted certification decisions. This tension between automated certification and the epistemological requirements of Islamic legal reasoning warrants dedicated interdisciplinary scholarly attention across food science, computer science, Islamic jurisprudence, and governance studies as the field advances.

Operationalising *Maqasid al-Shari'ah* (the higher objectives of Islamic law) as an explicit analytical framework, rather than as a normative reference invoked in passing, would require future studies to map specific halal control mechanisms, such as laboratory verification, supply-chain traceability, or certification audit protocols, onto the five recognised *maqasid* categories (preservation of faith, life, intellect, lineage, and property), and to assess empirically whether existing risk management practices serve these objectives or merely satisfy narrower technical-compliance criteria. The literature reviewed here, including the present study's own bibliometric corpus, does not yet contain studies that undertake this operationalisation; this is therefore identified as a substantive methodological gap rather than a claim that can be resolved within a bibliometric synthesis alone, and is proposed as a priority direction for future doctrinal-empirical collaboration between Islamic jurisprudence scholars and food control specialists.

5. Conclusion, recommendations, and future research

5.1 Conclusion

The application of the FAO/WHO five-component framework as an explicit analytical lens, rather than as a post-hoc descriptive label, yields a structurally grounded diagnosis not previously articulated in halal bibliometrics. In particular, halal governance in the Arab region is defined by under-implementation rather than under-legislation. Three converging findings support this assessment.

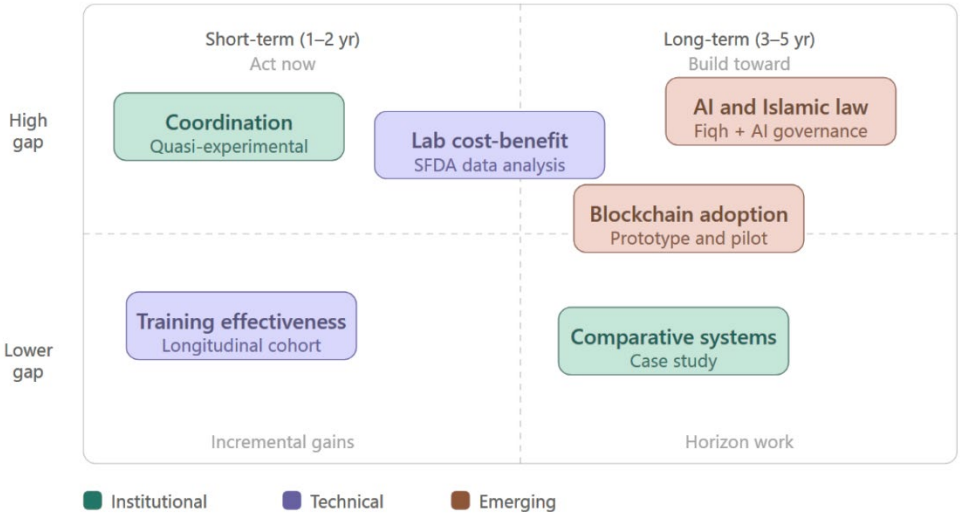

Figure 5: Priority matrix positioning six research directions by implementation horizon (short-term: 1–2 years; long-term: 3–5 years) and evidence gap severity.

The rapid expansion of the field has resulted in significant geographic unevenness, with implications that extend beyond descriptive analysis. A literature corpus centred primarily on Malaysian and Indonesian regulatory contexts does not sufficiently address the enforcement fragmentation, laboratory deficiencies, and inter-agency coordination failures characteristic of the Arab governance context. Moreover, as demonstrated in Section 3.6, the Arab-focused literature has reinforced this imbalance by prioritizing legislation and consumer awareness over the operational and technical dimensions that remain most deficient.

The five-cluster intellectual structure of the global corpus aligns with the FAO/WHO pillars, indicating that halal governance is widely recognised as a multi-component challenge. However, the literature has not yet fully integrated these components, particularly in economic analysis. No cluster addresses cost-benefit analysis or resource allocation, which leaves the field diagnostically adequate but prescriptively limited. Consequently, regulators seeking to prioritise investment lack academic guidance on which interventions yield the greatest systemic benefit per unit of institutional expenditure.

The emerging-technologies cluster presents an additional challenge that the literature has deferred: whether algorithmic halal verification can satisfy the jurisprudential requirement of human deliberative reasoning (*ijtihad*). The resolution of this issue will determine not only scholarly classification but also religious legitimacy and, consequently, the practical adoption of digital certification tools in Muslim markets.
These findings reframe Arab halal food control as a systemic implementation problem that requires investment in enforcement capacity, economic appraisal, and cross-disciplinary governance research, rather than a legislative deficit for which additional *fatwa* production is the primary solution.

5.2 Recommendations

For policymakers in Arab and Gulf countries, four priority actions are recommended. First, a National Supreme Halal Council should be established to integrate food safety, Islamic affairs, commerce, and municipal bodies under a legally binding coordinating mandate. Without this reform, investments in technical capacity will remain fragmented. Second, ISO/IEC 17025-accredited national laboratory networks should be created, funded for proactive risk-based sampling rather than reactive complaint-driven testing, and linked through a unified certification registry with public authentication capabilities. Third, human capital development should be institutionalised through mandatory halal executive training programs evaluated for effectiveness, rather than treated as voluntary awareness activities. Finally, consumer engagement should shift from passive logo recognition to active civic participation, equipping consumers with the knowledge and accessible mechanisms to report suspected violations.

For the research community, the primary need is methodological reorientation. This entails shifting from descriptive country studies to quantitative causal modelling, from conceptual technology proposals to empirically grounded cost-benefit analyses, and from single-discipline investigations to cross-disciplinary collaboration among food science, Islamic jurisprudence, and digital governance, particularly in the context of algorithmic certification.

5.3 Limitations

Three limitations constrain the interpretive scope of this review. The analysis is restricted to Scopus, excluding Web of Science and Arabic-language databases such as *Ma'rifah*, which may contribute to the underrepresentation of Arab scholarship. Bibliometric methods assess knowledge structure rather than the methodological quality of individual studies, although this limitation was partially mitigated through manual coding of 82 Arab-focused articles. The 2010–2025 time window, while appropriate for contemporary analysis, excludes foundational contributions made prior to 2010. Reliance on a single-database design is a significant limitation. Scopus exhibits documented gaps in its coverage of regional, Arabic-language, and non-Anglophone journals compared to Web of Science and discipline-specific Arabic repositories such as *Ma'rifah*. Consequently, the 9% share of Arab-region output

reported in Section 3.2 should be regarded as a lower-bound estimate that may underrepresent the actual volume of Arabic-language halal governance scholarship, rather than serving as a definitive measure of the field's geographic distribution. Furthermore, the citation-based author and journal rankings presented in Sections 3.3 and 3.4 are based on raw citation counts rather than field-normalised indices, such as the h-index or the journal impact factor. These rankings should therefore be interpreted as indicative of relative visibility within this corpus, rather than as calibrated measures of scholarly influence.

5.4 Future research agenda

Six priority directions are identified across three clusters: institutional reform, technical capacity, and emerging frontiers, as illustrated in Figure 5.

At the institutional level, two critical questions remain insufficiently examined despite being consistently identified as weaknesses: whether a unified halal council enhances enforcement, and whether centralised certification is more effective than decentralised models. Both issues could be addressed in the near term.

For technical capacity, laboratory cost-benefit analyses and evaluations of training effectiveness are overdue. Regulators and programme managers currently make investment decisions without robust evaluation. In the emerging frontier, blockchain evaluation should progress from conceptual frameworks to empirical studies, with mutual recognition within the Gulf Cooperation Council serving as a suitable test case. Importantly, whether AI-assisted certification can meet *ijtihad* requirements must be established before the digital agenda in this field can achieve legitimate adoption. Addressing this issue requires collaboration among experts in food science, computer science, and Islamic jurisprudence.

Acknowledgements

The authors thank the anonymous reviewers for their valuable comments. Special thanks to the International Islamic University Malaysia (IIUM) for providing access to Scopus, and to the Ph.D supervisors for their guidance during manuscript preparation.

Conflict of interest

The authors declare no conflict of interest. This research received no external funding.

AI declaration

Artificial Intelligence (AI) tools, including ChatGPT (OpenAI, San Francisco, CA) and Grammarly, were used to assist with language editing, improve sentence structure, and clarify grammar during manuscript preparation. The authors reviewed, verified, and take full responsibility for the accuracy and integrity of the content. No AI tools were used for data analysis, result interpretation, or scientific conclusions.

Author contribution

Al-Saab A.: first coder, investigation, data curation, writing – original draft preparation. Elgharbawy, A. A. M.: conceptualization, formal analysis, writing, reviewing, and editing, second coder.

References

Abdul Halim, N. R., Mutalib, S. A., Abd Ghani, M., & Hashim, H. (2024). Non-conformance report (NCR)on Malaysia halal certification: A case study among small- and medium-scale food enterprises (SMEs) in Malaysia. Food Control, 160, 110298. https://doi.org/10.1016/j.foodcont.2024.110298

Ahmad, A. N., Ungku Zainal Abidin, U. F., Othman, M., & Abdul Rahman, R. (2018). Overview of the halal food control system in Malaysia. Food Control, 90, 352–363. https://doi.org/10.1016/j.foodcont.2018.02.035

Al Busaidi, M. A., Rahman, M. S., & Al Masroori, H. S. (2025). Transitioning from a multi-agency to an integrated food control system: A case study from the Sultanate of Oman. In Foods (Vol. 14, Number 15, p. 2618). https://doi.org/10.3390/foods14152618

Al-Mahmood, O. A., & Fraser, A. M. (2023). Perceived challenges in implementing halal standards by halal certifying bodies in the United States. PLoS ONE, 18(8), e0290774. https://doi.org/10.1371/journal.pone.0290774

Alrobaish, W. S., Vlerick, P., Luning, P. A., & Jacxsens, L. (2021). Food safety governance in Saudi Arabia: Challenges in control of imported food. Journal of Food Science, 86, 16–30. https://doi.org/10.1111/1750-3841.15552

Aria, M., & Cuccurullo, C. (2017). Bibliometrix: An R-tool for comprehensive science mapping analysis. Journal of Informetrics, 11(4), 959–975. https://doi.org/10.1016/j.joi.2017.08.007

Bayatzadeh, S., & Talaie, H. R. (2025). An evaluation of traceability dynamics in dairy supply chains through causal modelling in emerging economies. Supply Chain Analytics, 11, 100156. https://doi.org/10.1016/j.sca.2025.100156

Brooks, S., Elliott, C. T., Spence, M., Walsh, C., & Dean, M. (2017). Four years post-horsegate: An update of measures and actions put in place following the horsemeat incident of 2013. Npj Science of Food, 1(1), 5.

Changalima, I. A. (2025). Halal supply chain management: A bibliometric analysis of the 100 most -cited publications from Scopus-indexed journals. Social Sciences and Humanities Open, 11, 101248. https://doi.org/10.1016/j.ssaho.2024.101248

Donthu, N., Kumar, S., Mukherjee, D., Pandey, N., & Lim, W. M. (2021). How to conduct a bibliometric analysis: An overview and guidelines. Journal of Business Research, 133, 285–296.

El-tahlawy, A. S., Alawam, A. S., Rudayn, H. A., Abd El-Raheem, H., & Alahmad, W. (2025). Advanced analytical and digital approaches for proactive detection of food fraud as an emerging contaminant threat. Talanta Open, 12, 100499. https://doi.org/10.1016/j.talo.2025.100499

Faour-Klingbeil, D., Al-Busaidi, M. A., & Todd, E. C. D. (2022). Legislation for food control in the Arab countries of the Middle East. In Food Safety in the Middle East (pp. 275–322). Elsevier. https://doi.org/10.1016/B978-0-12-822417-5.00007-6

Fauzi, M. A., Saadiah, M. A., Mat Russ, N., Battour, M. M., & Mohd Zaki, N. N. (2024). Halal certification in food products: Science mapping of present and f uture trends. Journal of Islamic Marketing, 15(12), 3564–3580. https://doi.org/10.1108/JIMA-12-2023-0407

Fiteuanto, R., Sofi, F. Bin, & Muzakki, A. (2024). Inclusive halal standards: Societal effects on religious minorities in Indonesia and Malaysia. Islamic Quarterly, 68(4), 451–479.

Helmi Ali, M. H., Chung, L., Kumar, A. V., Zailani, S. H. B. D. M., & Hua Tan, K. (2021). A sustainable blockchain framework for the halal food supply chain: Lessons from Malaysia. Technological Forecasting and Social Change, 170, 120870. https://doi.org/10.1016/j.techfore.2021.120870

Hopper, M., & Boutrif, E. (2006). Strengthening national food control systems: Guidelines to assess capacity building needs. Food & Agriculture Org.

Hossain, M. A. M., Zainal Abidin, S. A. S., Bujang, A., Johan, M. R. Bin, & Nina Naquiah, A. N. (2023). TaqMan multiplex qPCR for detecting animal species in meat and meat products: Development, recent advances, and future prospects. Food Control, 150, 109761. https://doi.org/10.1016/j.foodcont.2023.109761

Islam, M. M., Ab Talib, M. S., & Muhamad, N. (2023). Challenges of halal standards and halal certification for Islamic marketing. Muslim Business and Economics Review, 2(1), 105–124.

Jia, C., & Jukes, D. (2013). The national food safety control system of China–a systematic review. Food Control, 32(1), 236–245.

Jia, X., & Zhang, C. (2021). Turning impediment into attraction: A supplier perspective on halal food in non-Islamic destinations. Journal of Destination Marketing and Management, 19, 100517. https://doi.org/10.1016/j.jdmm.2020.100517

Johan, E., & Plana-Casado, M. J. (2023). Harmonizing halal in ASEAN: Analysis of halal food guidelines under the ASEAN way Approach. Journal of ASEAN Studies, 11(1), 43–67. https://doi.org/10.21512/jas.v11i1.9682

Jose, A., & Venkatesan, S. P. (2023). Traceability adoption in dry fish supply chain SMEs in India: exploring awareness, benefits, drivers, and barriers. Sadhana - Academy Proceedings in Engineering Sciences, 48(19). https://doi.org/10.1007/s12046-023-02077-4

Kohilavani, W.-N., Yang, T. A., Sifat, S. A. D., & Zzaman, W. (2021). Development of safe halal food management system (SHFMS). Food Control, 127, 108137. https://doi.org/10.1016/j.foodcont.2021.108137

Kohilavani, Z., W., F., N. A., W.-N., W. A., & Yang, T. A. (2013). Embedding Islamic dietary requirements into the HACCP approach. Food Control, 34(2), 607–612. https://doi.org/10.1016/j.foodcont.2013.06.008

Landis, J. R., & Koch, G. G. (1977). The measurement of observer agreement for categorical data. Biometrics, 159–174.

Lau, A. N., Jamaludin, M. H., & Mei Soon, J. (2016). Quality assurance and halal control points for the food industry. Nutrition & Food Science, 46(4), 557–570. https://doi.org/10.1108/NFS-03-2016-0026

López Cifuentes, M., & Sonnino, R. (2024). Transforming the food environment: An assemblage-based research approach. Environmental Innovation and Societal Transitions, 52, 100874. https://doi.org/https://doi.org/10.1016/j.eist.2024.100874

Ma, Y., & Abdul Hamid, B. (2026). Strategic coordination in the halal economy: A cross-regional study of seven Muslim-minority emerging markets. International Journal of Emerging Markets. https://doi.org/10.1108/IJOEM-06-2025-1189

Musa, N., Muslim, N., Omar, M. F. C., & Husin, A. (2016). The Cadbury controversy: Blessings in disguise? Contemporary Issues and Development in the Global Halal Industry: Selected Papers from the International Halal Conference 2014, 95–104.

Nawaz, A., Afzal, A., Khatibi, A., Rasheed, M., & Islam, F. (2025). Role of artificial intelligence in halal authentication and traceability: A concurrent review. Food Control, 169, 111003. https://doi.org/10.1016/j.foodcont.2024.111003

Osman, O. A., & Saeed, T. S. (2023). Metrology's importance and application in the halal food assurance system. In Halal and Kosher Food: Integration of Quality and Safety for Global Market Trends. https://doi.org/10.1007/978-3-031-41459-6_3

Rejeb, A., Rejeb, K., Zailani, S. H. B. D. M., & Kayikci, Y. (2023). Knowledge diffusion of halal food research: a main path analysis. Journal of Islamic Marketing, 14(7), 1715–1743. https://doi.org/10.1108/JIMA-07-2021-0229

Suryawan, A. S., Hisano, S., & Jongerden, J. (2022). Negotiating halal: The role of non-religious concerns in shaping halal standards in Indonesia. Journal of Rural Studies, 92, 482–491. https://doi.org/10.1016/j.jrurstud.2019.09.013

Van Eck, N., & Waltman, L. (2010). Software survey: VOSviewer, a computer program for bibliometric mapping. Scientometrics, 84(2), 523–538.

Yakubu, M. M., Hassan, M. F., Danyaro, K. U., Beevi, Z. S., & Aliyu, G. (2025). HalalChain: A decentralized blockchain model for enhanced data integrity, real-time compliance, and automated verification in the halal food supply chain. Results in Engineering, 27, 106591. https://doi.org/10.1016/j.rineng.2025.106591

Yunan, Y. S. M., Helmi Ali, M. H., & Alam, S. S. (2020). Safeguarding halal integrity through halal logistics adoption: A case of food manufacturers. Institutions and Economies, 12(3), 19–41.

Zhang, B., Moon, J., & Park, J. (2026). Comparative review of halal certification frameworks for poultry meat in Malaysia, Singapore, and Indonesia. Foods, 15(14), 659. https://doi.org/10.3390/foods15040659

APPENDICES

Appendix A: Full Search Strategy in Scopus

Date of execution: 15 April 2026

Database: Scopus (Elsevier)

Date of execution: 15 April 2026
Database: Scopus (Elsevier)

Search string applied to TITLE-ABS-KEY fields:
TITLE-ABS-KEY("halal food" OR "halal certification" OR "halal assurance")

The following filters were applied via the Scopus Advanced Search interface after executing the search string: Document type: Article; Source type: Journals; Language: English or Arabic; Publication year: 2010–2025 (records published in 2026 excluded).

Initial yield: 1,204 documents. After removal of 67 duplicates, 1,137 records were screened by title and abstract.

Component	Search Terms (OR)	Purpose
Halal concept	*"halal food", "halal certification", "halal assurance"*	Capture core halal literature
Control system	*"control system", "food control", "regulatory framework"*	Focus on national control systems
Five components	*fatwa, legislation, inspection, enforcement, audit, laboratory, porcine DNA, authentication, training, awareness, IECT*	Ensure coverage of all FAO components

Appendix B: Distribution of Arab-Region Studies Across the Five Components (n = 82)
Each of the 82 articles was manually coded into one or more of the five components. Note: one article could cover multiple components, so the sum of percentages exceeds 100%.

Component	Articles (n)	Percentage	Representative Topics
Legislation & *fatwa*	28	34.1%	National halal laws, fatwas on novel foods, and the role of *fatwa* committees.
Governance	22	26.8%	Division of authority among ministries, inter-agency coordination
Inspection & enforcement	18	22.0%	Field inspection, fake halal logos, penalties
Laboratories	12	14.6%	Porcine DNA testing (PCR), ISO/IEC 17025 accreditation
IECT	24	29.3%	Consumer campaigns, Halal Executive Programme, university roles

HALALSPHERE
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Loop-mediated isothermal amplification for detection of porcine adulteration in meat and gelatine-based products: Analytical performance and potential applications

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Received: 27/6/2026
Accepted: 18/7/2026
Published: 31/7/2026

Keywords:
Food fraud; Porcine DNA; Loop-mediated isothermal amplification; Pork, Gelatine; Lard; Molecular authentication

Abstract

Porcine-derived products, including pork gelatine and lard, are commonly associated with undeclared food additives or contaminants. Deoxyribonucleic acid (DNA)-based approaches are typically considered the most reliable strategy for species authentication in food products due to DNA's stability in processed food matrices and its high specificity. Loop-mediated isothermal amplification (LAMP) has emerged as a viable method for rapid DNA detection in isothermal conditions, requiring minimal instrumentation and offering high sensitivity and robust inhibitor tolerance. This review discusses the past and current literature on LAMP assays for detecting porcine adulteration in meat and gelatine. At the same time, there is still a lack of studies involving the detection of lard adulteration in fat-based products. It also discusses several important factors, such as assay design, target gene selection, detection formats, and matrix-dependent analytical performance. A comparison of LAMP with quantitative polymerase chain reaction (qPCR) demonstrates LAMP's advantages in rapid screening, high specificity, and ease of use. Limitations and possible future avenues for incorporating LAMP into food control initiatives were also discussed.

1. Introduction

The globalisation of food supply chains, combined with complex processing methods and the extensive use of animal-derived substances, has increased the risk of food product mislabelling, substitution, and adulteration (Brooks *et al.*, 2021). Porcine-derived products are especially important, as their use may be limited or prohibited for religious, cultural, ethical, and regulatory reasons (Herdiana *et al.*, 2024). Undeclared porcine contents, whether intentional or unintentional, undermine consumer trust and may constitute food fraud, with economic and public health consequences.

Meat and meat-derived products are prominent sources of food adulteration, with pork frequently used in mixed meat formulations due to its low cost and functional qualities (Hamsar *et al.*, 2024). Gelatine and lard are commonly employed to enhance texture, stability, and sensory quality in processed foods, pharmaceuticals, and confectionery products (Rather *et al.*, 2022; Prihandiwati *et al.*, 2024). Detecting porcine compounds in these matrices is difficult in commercial foods, as protein-based detection methods often fail when proteins are denatured or hydrolysed during processing (Tasrip *et al.*, 2021).

DNA-based technologies are more stable and specific than protein-based approaches, particularly in highly processed matrices like gelatine and fat-rich foods (Barrias *et al.*, 2024). Conventional PCR and qPCR are commonly used for species identification; however, their reliance on heat cycling, controlled laboratory conditions, and trained staff limits their use in quick, on-site, or field-based screening (Yugovich *et al.*, 2025).

Loop-mediated isothermal amplification (LAMP) is an appealing option. LAMP amplifies nucleic acids at a constant temperature using strand-displacing polymerases and multiple primers, enabling rapid, sensitive, and specific detection with minimal equipment requirements (Yang *et al.*, 2026).

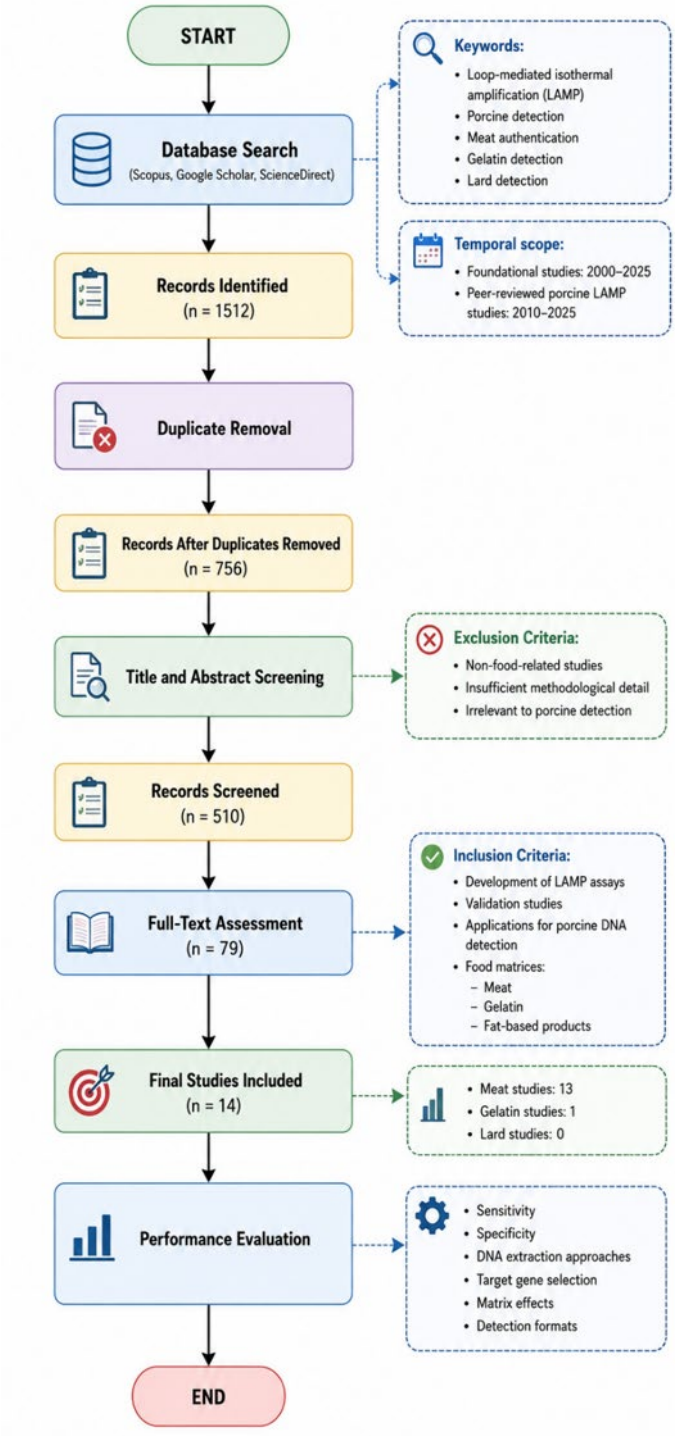

Figure 1: Flow diagram illustrating the literature searching, references, and study selection process in this review article.

Its resistance to inhibitors and capacity for decentralised testing make it appropriate for routine food control, certification audits, and monitoring programs. This review summarises current information on LAMP-based detection of porcine adulteration, focusing on test performance, applicability to complex food matrices, and significance to food additive and contaminant monitoring.

2. Methodology

The literature search methodology employed in this review is illustrated in Figure 1. A comprehensive search strategy was conducted using three major scientific databases: Scopus, Google Scholar, and ScienceDirect. The search combined methodological and application-specific keywords, including *"loop-mediated isothermal amplification"*, *"LAMP"*, *"porcine detection"*, *"meat authentication"*, *"gelatine detection"*, and *"lard detection"*. The search was limited to peer-reviewed articles published between 2010 and 2025 that investigated the detection of porcine DNA in food matrices using LAMP. To provide historical context and capture the development of LAMP technology, foundational studies published between

2000 and 2025 were also included. The initial database search yielded 1,512 records. After removing duplicate publications, 756 records remained for title and abstract screening. Studies unrelated to porcine detection, involving non-food applications, or lacking sufficient methodological information were excluded, leaving 510 articles for further assessment. The remaining publications were evaluated against predefined inclusion criteria, yielding 79 full-text articles focused on the development, optimisation, validation, or application of LAMP assays for detecting porcine DNA in food matrices, particularly meat, gelatine, and fat-based products. Following full-text assessment, 14 studies met all eligibility criteria and were included in the qualitative synthesis. These studies were systematically evaluated based on key analytical parameters, including target gene selection, DNA extraction approach, analytical sensitivity (limit of detection), analytical specificity, sample matrix effects, and detection format. In addition, backward reference searches of selected research articles and relevant review papers were conducted to identify any additional eligible studies that were not captured during the initial database search. This systematic literature screening and evaluation process ensured a comprehensive, transparent, and focused synthesis of the current state of knowledge on LAMP-based methods for detecting porcine adulteration in food products.

3. LAMP as a versatile tool for food authentication and safety monitoring

The use of molecular methods in food authentication requires not only analytical sensitivity and specificity but also resilience to matrix effects, operational simplicity, and adaptability across diverse testing settings. Loop-mediated isothermal amplification (LAMP) has emerged as an alternative to PCR-based technologies, overcoming various practical limitations associated with temperature-cycling-dependent amplification (Table 1).

LAMP has been increasingly used in food analysis, such as species identification, adulterant detection, and food contamination monitoring, since its original description by Notomi et al (2000). Its usefulness for food authentication stems from its unique amplification method, excellent inhibitor tolerance, and ability to perform rapid DNA amplification under isothermal conditions, enabling the authentication of animal DNA in meat and gelatine. (Ran *et al.* 2016; Tasrip *et al.* 2021).

Also, LAMP has been applied for the early detection of DNA derived from processed animal proteins in poultry feed. The developed DNA-based LAMP assays enabled rapid identification of chicken, turkey, duck, goose, and helmeted guineafowl DNA in highly processed feed matrices. One of the major advantages of the approach is its suitability for on-site applications, as the assays can be integrated with simple DNA extraction and amplification devices, allowing the entire workflow to be completed in less than one hour. (Voorhuijzen-Harink *et al.*, 2026).

Furthermore, LAMP has demonstrated strong potential for authenticating aquatic animal species in food products. Li *et al.* (2022) reported the successful application of duplex LAMP for the simultaneous visual detection of rainbow trout (*Oncorhynchus mykiss*) and Atlantic salmon (*Salmo salar*). The assay enabled rapid, species-specific identification without complex instrumentation, highlighting LAMP's capability for multiplex detection and suitability for routine seafood authentication and anti-adulteration monitoring.

LAMP has also been explored for the authentication of traditional medicines and valuable botanical materials susceptible to adulteration. Lee *et al.* (2019) developed a rapid and highly specific LAMP assay for the authentication of edible bird's nest adulterated with white fungus, egg white, and pig skin at different mixing ratios. The assay produced results within 1 hour and successfully distinguished microbial contaminants from animal-derived adulterants, demonstrating its suitability for rapid authenticity screening of high-value traditional products.

In addition, LAMP has shown strong applicability in detecting species adulteration in botanical products. Rodrigues *et al.* (2024) reported a fast, sensitive, and highly specific LAMP assay for the authentication of *Styphnolobium japonicum* in *Ginkgo biloba* products, while Lanubile *et al.* (2024) successfully applied LAMP for the authentication of *Curcuma longa* DNA in turmeric products. The assay achieved optimal amplification at 65°C for 30 minutes and demonstrated approximately 10-fold greater sensitivity than conventional PCR, highlighting LAMP's capability for rapid authentication of plant-derived commercial products.

Furthermore, LAMP has also been used for the screening of genetically modified organisms (GMOs), such as cotton, maize, and soybeans. (Singh *et al.* 2020). In the study, the LAMP assays target the junction between two genetic elements, e.g., a promoter and a transgene. This approach is more specific than targeting individual genes because it identifies the unique way the genetic cassette is put together. They applied visual LAMP, e.g., a colour change from orange to green upon adding Synthetic Yellowish Blue Rosolic acid (SYBR) Green dye, and real-time LAMP, based on detection of fluorescent signals or amplification curves, using a portable real-time instrument, thereby supporting the enforcement of non-GMO labelling and certification schemes. (Liu *et al.* 2023).

While LAMP is best known for its role in food authentication, it has also evolved into a versatile molecular tool used throughout the food supply chain, particularly for food safety and quality monitoring. For instance, in food safety testing, LAMP is commonly used to detect foodborne pathogens rapidly. (Li *et al.*, 2017). It has been successfully used to identify clinically and industrially important bacteria, including *Salmonella* spp., *Listeria monocytogenes*, *Staphylococcus aureus*, and *Vibrio parahaemolyticus*, in complex food matrices containing meat, dairy products, and shellfish. Beyond bacterial pathogens, LAMP assays have been increasingly developed to rapidly detect harmful yeasts, moulds, and toxigenic fungi in food commodities. This application is crucial for identifying spoilage organisms directly on food items (such as blue mould on fruit) and for detecting mycotoxin-producing strains before they enter the consumer market. (Frisch *et al.*, 2021; Mellikeche *et al.*, 2024).

Furthermore, LAMP has enabled the detection of biotoxin-producing bacteria, such as genes encoding enterotoxins produced by S. aureus, and mycotoxin-producing fungi, such as Aspergillus species that produce aflatoxins and ochratoxin A, by providing a faster, less labour-intensive alternative to traditional culture-based or chromatographic techniques. (Niessen *et al.* 2013; Yang *et al.* 2026). Key advantages of LAMP that enable it to detect biotoxins and mycotoxins include the stability of its DNA targets, which allow it to detect specific

Table 1: Applications, functionalities, and analytical advantages of LAMP across the food supply chain

Application category	Application area	Application	Key advantage of LAMP	Reference
Food Authentication	Species identification and adulteration detection in food	Detection of specific animal DNA in porcine identification in meat, gelatine, and processed foods.	Unique amplification method, excellent inhibitor tolerance, and ability to perform rapid DNA amplification under isothermal conditions.	Ran *et al.* (2016); Tasrip *et al.* (2021).
	Early detection of DNA derived from processed animal proteins in poultry feed	Fast detection for chicken, turkey, ducks, geese, and helmeted guineafowl in highly processed feed materials	Applicability on-site: the developed DNA-based LAMP assays were combined with easy-to-use DNA extraction and amplification devices, resulting in a workflow of less than one hour.	Voorhuijzen-Harink *et al.* (2026).
	Authentication of aquatic animals	Visual detection of rainbow trout (*Oncorhynchus mykiss*) and Atlantic salmon (*Salmo salar*) simultaneously	Simultaneously detected two species via duplex LAMP.	Li *et al.* (2022)
	Authenticate traditional medicine	Authenticate edible bird's nest adulterated with white fungus, egg white, and pig skin, in different ratios.	The LAMP assay was specific and rapid, with results available within 1 h, and it differentiated microbes from animal adulterants.	Lee *et al.* (2019)
	Species adulteration of plant substitutes in valuable botanicals	Authenticate the presence of *Styphnolobium japonicum* in *Ginkgo biloba*	Fast, selective, and highly sensitive LAMP conducted at optimal conditions set at 68◦C for 40 min	Rodrigues *et al.* (2024)
		Authentication of *Curcuma longa* DNA for turmeric authentication.	LAMP was conducted at conditions set at 65◦C for 30 min, where LAMP sensitivity was 10-fold higher than that of PCR	Lanubile *et al.* (2024)
	GMO detection	Genetically modified cottons, maize, and soybeans	LAMP assays target the junction between two genetic elements (e.g., a promoter and a transgene). This is more specific than targeting individual genes because it identifies the unique way the genetic cassette is put together.	Singh *et al.* (2020)
	GMO detection	Detection of genetically modified crops, including maize, soybean, cotton, rapeseed, alfalfa, beet, and rice	High specificity through CRISPR-Cas12a-assisted recognition of target LAMP amplicons, enabling rapid and sensitive visual or fluorescence-based detection of GMO-associated genetic elements	Liu *et al.* (2023)

Food Safety	Foodborne pathogen detection	Identification of pathogens such as *Salmonella* spp., *Listeria monocytogenes*, *Staphylococcus aureus*, and *Vibrio parahaemolyticus*	Rapid detection; high specificity in complex food matrices, such as e.g., meat, dairy products, and shellfish	Li *et al.* (2017)
	Detection of toxin-producing microorganisms	Identification of enterotoxin produced by Staphylococcus aureus and aflatoxins and ochratoxin A produced by *Aspergillus* species in food systems	LAMP enables rapid and highly sensitive detection of toxin-associated DNA sequences, even in dead or non-viable cells, while demonstrating strong tolerance to food-derived inhibitors and requiring minimal sample preparation compared to conventional PCR methods.	Niessen *et al.* (2013); Yang *et al.* (2026)
	Antibiotic resistance monitoring	Detection of methicillin-resistant *Staphylococcus aureus* (MRSA) and resistance-associated genes in foodborne bacteria	LAMP targets resistance-associated gene, namely as *femA*, a gene coding for a factor essential for the expression of the methicillin resistance gene (mec) produced by S. aureus	Wong *et al.* (2018)
	Allergen detection	Detection of trace allergenic ingredients (e.g. soy, nuts, celery) in food products	High sensitivity; suitable for trace-level detection.	Schäfer *et al.* (2023).
	On-site and field testing	Application in slaughterhouses, wet markets, food processing plants, and ports of entry	Minimal instrumentation; portable; fast turnaround time	Incili *et al.* (2019; Aglietti *et al.* (2024); Liu *et al.* (2026)
	Traceability and routine inspection	Monitoring authenticity and product integrity across supply chains	Compatible with crude samples; reduces preparation time	Zhang et al (2025)
	Hygiene control	Surface monitoring using loop-mediated isothermal amplification (LAMP) for the rapid detection of key nosocomial pathogens, such as *Pseudomonas aeruginosa, Staphylococcus aureus,* and *Enterococcus spp.*	High-sensitivity, rapid, portable, real-time monitoring methods, such as fluorescence-based detection, reduce the risk of contamination from environmental DNA, thereby enhancing reliability.	Marino *et al.* (2026)
	Microfluidic systems	Integration with lab-on-a-chip platforms for automated and multiplex detection of *Vibrio parahaemolyticus, Escherichia coli* O157: H7, *Yersinia enterocolitica,* and *Bacillus cereus*.	High throughput; reduced reagent consumption; automation; simultaneous detection of multiple pathogens	Lv *et al.* (2025)
	Biosensor integration	Coupling with electrochemical and optical sensors for detection	Real-time monitoring; semi-quantitative capability	Das *et al.* (2022)

Table 2: Overview of the fundamental analytical framework of loop-mediated isothermal amplification (LAMP) for porcine DNA detection in food matrices

Subtopic	Key analytical concept	Major features	Analytical significance	Contribution to analytical performance
Analytical principle	Isothermal strand-displacement amplification	*Bacillus stearothermophilus* (Bst) polymerase, stem-loop formation, continuous amplification	Rapid amplification without thermal cycling	Enables rapid detection in field settings
Target genes and primer design	Multi-primer recognition	4 to 6 primers recognizing 6 to 8 target regions, e.g., Cyt b, D-loop, 12S rRNA, etc.	High analytical specificity and reduced false positives	Determines species specificity
Sample preparation and DNA extraction	DNA extraction strategies	Conventional, rapid, and crude extraction	Determines DNA quality, inhibitor removal, and assay robustness	Influences DNA recovery from processed meat and gelatine
Detection formats	Detection of amplification products	Colorimetric, fluorescent, turbidity, lateral flow assay, CRISPR	Determines sensitivity, portability and instrumentation requirements	Determines laboratory versus field applicability
Analytical performance and validation	Method evaluation	Sensitivity, specificity, LOD, repeatability, reproducibility, inhibitor tolerance	Demonstrates analytical reliability and suitability for routine application	Determines assay reliability for halal authentication

DNA sequences associated with toxin production, even in dead or non-viable cells. This is useful as the toxins themselves, rather than the live cells, may be the primary concern for food safety. Secondly, LAMP's high sensitivity can detect very low levels of target DNA, down to 10-100 genome equivalents in some cases, enabling early identification of potential toxin contamination. The LAMP reactions can be completed in 30-60 minutes, much faster than traditional culture-based or PCR methods. This allows for rapid screening and decision-making. LAMP is also less susceptible to inhibitors in food samples than PCR, reducing the need for extensive sample preparation (Niessen *et al.* 2013).

In addition, LAMP has been used for antibiotic resistance surveillance, targeting resistance-associated genes, including *fem*A, which encodes a factor essential for the expression of the methicillin resistance gene in *S. aureus*. Researchers design a high number of primers, e.g., 4 to 6 primers that recognise 6 to 8 distinct regions of the target resistance gene, ensuring extreme specificity, where if one primer does not match perfectly, the reaction will not occur. (Wong *et al.* 2018). The application of LAMP for targeting these genes enables public health risk assessment within the food chain.

LAMP has also been employed for allergen detection, enabling the identification of trace amounts of allergenic ingredients, such as celery, soy, or nuts, that must be declared under food labelling regulations. (Schäfer *et al.* 2023).

Across the food supply chain, LAMP is particularly advantageous for traceability and on-site operations. Its low equipment requirements, typically limited to a simple heat block or water bath, enable testing at point-of-need locations such as slaughterhouses, wet markets, food processing facilities, and ports of entry. Numerous LAMP protocols are compatible with crude sample inputs, allowing extraction-free or minimal-preparation workflows that significantly reduce analysis time (Aglietti *et al.*, 2024; Incili *et al.*, 2019; X. Liu *et al.*, 2026).

In addition, LAMP is increasingly used for environmental monitoring, including the screening of processing environments to assess hygiene status and potential cross-contamination. For instance, Karanis *et al.* (2007) developed LAMP for the detection of Cryptosporidium in environmental and faecal samples. The method could become a useful diagnostic tool for epidemiologic studies of Cryptosporidium presence, given the specificity and simplicity of the developed LAMP. Beyond conventional assays, LAMP has also been integrated with advanced technological platforms to enhance throughput and analytical performance. Microfluidic lab-on-a-chip systems enable the automation of LAMP reactions and the simultaneous detection of multiple pathogens, including *Vibrio parahaemolyticus, Escherichia coli O157:H7, Yersinia enterocolitica,* and *Bacillus cereus* in a single run (Lv *et al.* 2025). Moreover, coupling LAMP with biosensors, including electrochemical and optical detection systems, has enabled

real-time, semi-quantitative monitoring, further expanding its potential for continuous surveillance of food quality and safety (Das *et al.* 2022).

Given the diverse applications of LAMP in food authentication and food safety, this section reviews its analytical principles, target genes, sample preparation strategies, detection formats, and analytical performance and validation criteria. Table 2 shows the overview of the fundamental analytical framework of loop-mediated isothermal amplification (LAMP) for porcine DNA detection in food matrices.

3.1 Analytical principle of LAMP

Loop-mediated isothermal amplification (LAMP) is an isothermal nucleic acid amplification technique that enables rapid, highly specific DNA amplification at a constant temperature. Unlike conventional polymerase chain reaction (PCR), which relies on repeated cycles of thermal denaturation, primer annealing, and extension, LAMP employs *Bacillus stearothermophilus* (Bst) DNA polymerase possessing strong strand-displacement activity together with a specially designed multi-primer system to achieve continuous DNA amplification without thermal denaturation (Notomi *et al.*, 2000). Consequently, LAMP can be performed at a constant temperature, typically between 60°C and 65°C, using simple heating devices such as water baths, dry blocks, or portable incubators. This unique amplification mechanism underpins LAMP's high analytical sensitivity, specificity, and rapid detection capabilities, making it particularly suitable for food authentication and halal verification.

The amplification process is initiated through transient DNA "breathing", a natural phenomenon in which a few base pairs within double-stranded DNA spontaneously separate under isothermal reaction conditions, temporarily exposing short single-stranded regions (Notomi *et al.*, 2000). These transiently exposed regions provide binding sites for LAMP primers without requiring high-temperature denaturation. Following primer annealing, Bst DNA polymerase initiates DNA synthesis and simultaneously displaces the downstream complementary DNA strand through its intrinsic strand-displacement activity (Yang *et al.*, 2025). Unlike Taq DNA polymerase used in PCR, which requires thermal cycling to generate single-stranded templates, Bst continuously synthesises new DNA while displacing the existing complementary strand, thereby enabling uninterrupted amplification under isothermal conditions.

Following strand displacement, the newly synthesised DNA strand undergoes self-hybridisation because complementary sequences are incorporated into both ends by the inner primers. This process generates a characteristic dumbbell-shaped DNA intermediate, which rapidly converts into a stem-loop DNA structure that serves as the fundamental amplification template throughout the LAMP reaction. These stem-loop structures provide continuously accessible loop regions for repeated primer annealing and strand-displacement DNA synthesis. The continuous recycling of stem-loop templates distinguishes LAMP from conventional PCR and underpins its rapid exponential amplification.

The remarkable specificity of LAMP is primarily attributed to its unique primer architecture (Yang *et al.*, 2024). A standard LAMP assay employs four essential primers comprising the Forward Inner Primer (FIP), Backward Inner Primer (BIP), Forward Outer Primer (F3), and Backward Outer Primer (B3). The FIP, consisting of the F2 and F1c regions, initiates DNA synthesis and facilitates loop formation. In contrast, the BIP, composed of the B2 and B1c regions, performs the corresponding function at the opposite end of the target sequence. The outer primers (F3 and B3) subsequently initiate strand displacement of the DNA strands synthesized by the inner primers. Additional Loop Forward (LF) and Loop Backward (LB) primers are frequently incorporated to accelerate amplification by targeting the loop regions of the stem-loop DNA structures. Collectively, this multi-primer system recognises six to eight independent regions of the target DNA, substantially reducing the probability of non-specific amplification because successful DNA synthesis can only occur when multiple primer-binding sites are correctly matched. Consequently, LAMP generally exhibits higher analytical specificity than conventional PCR, which typically relies on only two primer-binding sites (Yang *et al.*, 2024).

The amplification logic of LAMP is based on continuous recycling of stem-loop templates rather than repeated thermal cycling (Kaur *et al.*, 2020). Once the initial stem-loop DNA structures have formed, primers repeatedly anneal to the exposed loop regions, initiating successive strand-displacement reactions that generate increasingly complex cauliflower-like DNA structures containing multiple inverted repeats. This cyclic, self-sustaining amplification process produces exceptionally large quantities of DNA, often within 30–60 minutes, while maintaining high analytical specificity and sensitivity. From an analytical perspective, the integration of strand-displacement DNA synthesis, self-priming stem-loop formation, and multi-site primer recognition enables LAMP to achieve rapid, high-specificity amplification under isothermal conditions. These mechanistic features distinguish LAMP from conventional PCR and account for its high amplification efficiency, compatibility with inhibitor-rich food matrices, and adaptability to multiple detection formats, as discussed in the following sections.

3.2 Target genes and primer design of LAMP

Table 3 provides an integrated overview of target genes, detection formats, and the analytical performance of LAMP for porcine detection. The choice of appropriate genetic markers is a significant factor influencing analytical performance in species authentication procedures. Because of its high copy number, maternal inheritance, and relatively quick evolutionary divergence across species, mitochondrial DNA (mtDNA) has been the primary target in species authentication using LAMP, especially for porcine detection (Cho *et al.*, 2014). This property improves specificity and sensitivity, especially in processed food matrices where nuclear DNA is frequently damaged. One significant advantage of targeting mitochondrial genes is the high copy number of mtDNA per cell, which can range from hundreds to thousands. This abundance considerably improves detection sensitivity relative to nuclear targets, especially in highly processed or degraded matrices where only trace amounts of template DNA are present (Merheb *et al.*, 2019). In gelatine and fat-rich matrices, where nuclear DNA is frequently undetectable, mitochondrial targets may be the only viable alternative for molecular identification. Nevertheless, the use of mitochondrial targets necessitates careful consideration of specificity. Closely related species may have highly similar mitochondrial sequences, raising the possibility of cross-reactivity if primers are not carefully designed and confirmed. Comprehensive in silico analysis and experimental testing against non-target species are thus critical

Table 3: Integrated overview of target genes, detection formats, and analytical performance of LAMP for porcine detection

Category	Component	Type	Advantages	Limitations	Sensitivity / LOD	Quantitative Capability	Field Suitability / Application	Reference
Target Gene	Cytochrome b	mtDNA	High specificity	Longer sequence (less suitable for degraded DNA)	High (pg level)	No	Meat, gelatine	Yang *et al.*, 2014; Tasrip *et al.*, 2021; Rungruang *et al.*, 2017
	D-loop	mtDNA	Short fragments, high sensitivity	Sequence variability	Very high (pg-fg level)	No	Processed food	Lee *et al.*, 2016; Girish *et al.*, 2020; Cai *et al.*, 2020; Thangsunan *et al.*, 2021; Qin *et al.*, 2022. Zhang *et al.*, 2025
	12S rRNA	mtDNA	Short amplicon, good for degraded DNA	Possible cross-reactivity	Moderate (ng-pg level)	No	Meat	Ahmed *et al.*, 2010
	Nuclear DNA	nDNA	High specificity	Low copy number	Moderate	No	Raw meat	Lee *et al.*, 2016
Sample preparation and DNA extraction	DNeasy Tissue Kit (QIAGEN, Hilden, Germany). DNeasy Tissue kit (Qiagen, USA) DNeasy Blood and Tissue Kit (Qiagen, Hilden, Germany TIANamp	Commercial DNA extraction kits	Fast; often takes 30–60 minutes, depending on the samples Simple; standardized protocols with	High Cost: The convenience of pre-packaged components results in a higher per-sample cost, which can be a barrier for labs with limited budgets.	Depend on the optimization steps involved for the removal of PCR inhibitors in complex	Yes	Meat and gelatine	Ahmed *et al.*, 2010; Cho *et al.*, 2014; Lee *et al.*, 2016; Ran *et al.*, 2016; Abdullahi *et al.* 2017; Rungruang

	Genomic DNA kit (Tiangen, China). Animal tissue DNA isolation and purification kit (Qiagen, Dneasy, Dermastar, Germany) Dneasy Tissue Kit (Qiagen, USA) DNA extraction kit (LabServ, Beijing, China). DNeasy Mericon Food Kit (Qiagen, Germany) DNeasy Blood and Tissue Kit (Qiagen, Germany) GeneAllÒ ExgeneTM kit for Animal Tissue (Gen-eAll Biotechnology Co., Ltd., Seoul, Korea), PorcineTrace Gelatine DNA Extraction Kit (7FoodPillars), DNeasy maricon Food Kit (Qiagen, Hilden, Germany).	pre-mixed reagents. .	Rigid protocols are hard to "tweak." Limited Customisation: Standardised protocols may not be ideal for unique or challenging samples (e.g., degraded DNA or complex food matrices) that require specific modifications to the extraction process Yield & Purity Variations: Depending on the sample type (e.g., human milk or bioaerosols), some kits may yield lower quantities or suboptimal purity (260/280 and 260/230 ratios) compared to manual methods. Manufacturer Dependency: Labs rely on manufacturers for product availability and consistent formulation; discontinued kits or changes in protocol can disrupt ongoing research. Inhibitor Sensitivity: Some kits may not	food matrices.	*et al.*, 2017; Cai *et al.*, 2020; Thangsunan *et al.*, 2021; Jawla *et al.*, 2021, Tasrip *et al.*, 2021)

				effectively remove certain sample-specific inhibitors (e.g., fat in milk or tannins in plants), which can interfere with downstream applications like qPCR				
	CTAB, Phenol/Chloroform, Alkaline Lysis (AL) method superparamagnetic nanoparticles superparamagnetic nanoparticles	In-house DNA extraction method	Maximum Yield: Recovers almost all available DNA. Longer Fragments: Minimal shearing for better structural integrity. Budget-Friendly: Drastically lower cost for high-volume work. Adaptable: Can be modified for any biological matrix.	Slow; it can take several hours to stay overnight. Complex; requires precise reagent prep and technique. Low; bulk chemicals are inexpensive. Hazardous; involves toxic organic solvents (Phenol/Chloroform). Variable; highly dependent on the researcher's skill. Poor manual steps make automation difficult. Moderate; mostly chemical waste.	Variable; can be very high yield but prone to inhibition.	Yes	Meat and gelatine	Yang *et al.*, 2014 Girish *et al.*, 2020 Qin *et al.*, 2022 Zhang *et al.*, 2025
Detection Format	Calorimetric	Visual	Rapid, simple, portable	Qualitative, subjective interpretation	Moderate	No	Excellent (field testing)	Yang *et al.*, 2014; Lee *et al.*, 2016; Ran *et al.*, 2016; Abdullahi *et*

								al., 2017; Girish *et al.*, 2020; Thangsunan *et al.*, 2021; Jawla *et al.*, 2021; Qin *et al.*, 2022; Zhang *et al.*, 2025; Tasrip *et al.*, 2021
	Fluorescent	Instrument-based	High sensitivity, real-time detection	Requires equipment	High	Semi-quantitative	Moderate (lab-based)	Ahmed *et al.*, 2010; Cho *et al.*, 2014; Rungruang *et al.*, 2017; Cai *et al.*, 2020; Tasrip *et al.*, 2021; Qin *et al.*, 2022; Zhang *et al.*, 2025
	Turbidity	Optical	Simple detection	Limited sensitivity, less precise	Moderate	Limited	Laboratory	Saifuddin *et al.*, 2024
	LFA (Lateral Flow Assay)	Strip-based	Easy interpretation, portable	Lower sensitivity than fluorescence	Moderate	No	Excellent (on-site testing)	Jawla *et al.*, 2021
Analytical Performance	LAMP	—	Rapid (30–60 min), minimal equipment, high inhibitor tolerance	Risk of contamination, limited multiplexing	fg–pg	Semi-quantitative (limited)	Field and lab	Muflihah *et al.*, 2023
	qPCR	—	High precision, quantitative	Expensive, requires a thermal cycler	pg–ng	Yes	Laboratory only	Muflihah *et al.*, 2023

elements in LAMP assay development (Tasrip *et al.*, 2021). In addition to mitochondrial genes, other studies have used nuclear DNA targets for porcine identification; however, these targets are often less effective in highly processed matrices due to their lower copy number and greater susceptibility to degradation. As a result, mitochondrial targets remain the preferred option for LAMP-based porcine detection in food authentication.

The LAMP assay uses four key primers, which are two inner primers (FIP and BIP) and two outer primers (F3 and B3) to recognise six different locations on the target DNA and two loop primers (LF and LB), which are frequently used to speed the reaction, bringing the total number of identified areas to eight (Notomi *et al.*, 2000). This multi-site recognition mechanism significantly improves specificity compared to qPCR, which typically recognises two primer-binding sites to amplify a single target region. During the earliest phases of the reaction, the outside primers cause strand displacement, allowing the inner primers to form self-priming loop structures. These structures act as templates for continuous amplification, leading to exponential DNA buildup without temperature cycling. The resulting amplicons comprise diverse inverted repeat structures and cauliflower-like DNA products with many loops, which help explain the extraordinarily high yield of amplified DNA (Gill *et al.*, 2011).

Among mitochondrial targets, the cytochrome b gene has been routinely used to identify porcine origin. Cytochrome b comprises conserved regions favourable for primer binding, interspersed with variable regions that allow species differentiation. LAMP assays for cytochrome b have reliably detected porcine DNA in meat and gelatine, even after heat or chemical processing (Tasrip *et al.*, 2021). However, due to the considerably larger length of cytochrome b, primer design is crucial to ensure compatibility with fragmented DNA and successful DNA amplification.

The mitochondrial D-loop region is also becoming a more popular target for detection in porcine samples. Because of its high variability and limited amplifiable regions, LAMP assays targeting the D-loop have demonstrated high specificity and sensitivity, especially in matrices with very low DNA concentrations (Natonek-Wiśniewska *et al.*, 2022). The D-loop's non-coding nature provides greater flexibility in primer design, making it easier to construct assays optimised for fragmented DNA.

Ribosomal RNA genes, such as 12S rRNA and 16S rRNA, are also commonly targeted due to their high abundance and species-specific regions. These genes are particularly advantageous for LAMP assays because they enable the design of short target regions, thereby improving amplification efficiency in degraded samples. Several studies have reported that LAMP assays targeting 12S rRNA outperform PCR-based methods in gelatine and highly processed meat products, where DNA fragmentation is severe (Cho *et al.*, 2014; Tasrip *et al.*, 2021).

Targeting mitochondrial regions such as cytochrome b and the D-loop in LAMP offers significant advantages for samples with DNA fragmentation, owing to their high copy numbers, sensitivity, and ability to amplify degraded DNA. These features make them indispensable in fields like forensics, epidemiology, and food safety.

3.3 Sample preparation and DNA extraction

Sample preparation and DNA extraction are crucial for reliable porcine DNA detection in processed foods using LAMP, as food processing methods such as heating, pressure, enzymatic hydrolysis, and chemical treatment can degrade DNA and introduce amplification inhibitors. Effective preparation involves proper homogenization and representative sampling, often using mechanical grinding and additional pretreatment steps for complex matrices such as meat, gelatine, emulsified products, and lard. DNA extraction methods must efficiently remove inhibitors such as lipids and polysaccharides while recovering fragmented DNA suitable for amplification. Although phenol–chloroform extraction provides high-quality DNA, commercial silica column- and magnetic-bead-based methods are preferred for their safety, reproducibility, and compatibility with automation. Optimisation of lysis conditions, including the use of proteinase K and detergents, is essential to maximise DNA recovery from highly processed samples. Since processed foods often contain fragmented DNA, extraction protocols must ensure adequate yield, purity, and integrity while minimising contaminants that may inhibit amplification. Quality assessment and internal amplification controls are important to prevent false-negative results. In halal authentication, where trace-level porcine detection is required, efficient sample preparation and validated extraction methods are essential to ensure accurate, sensitive, and reproducible detection across different food matrices.

In previous studies, alkaline lysis was used for DNA extraction from processed meat, demonstrating robustness in detecting porcine DNA by LAMP, even in thermally treated samples. This method allows effective amplification of porcine mitochondrial DNA when samples are heated to 121 °C (Girish *et al.*, 2020). The sensitivity of LAMP assays can be influenced by the extraction method used. The alkaline lysis method demonstrated high sensitivity, detecting as low as 0.5 ng/μL of porcine DNA, which is critical for food authenticity testing (Girish *et al.*, 2020). Besides alkaline lysis, Qin *et al.* (2022) reported DNA extraction from pork using nanoparticles. Most studies used commercial DNA extraction kits to obtain DNA from meat (Ahmed *et al.*, 2010; Cho *et al.*, 2014; Lee *et al.*, 2016; Ran *et al.*, 2016; Abdullahi *et al.* 2017; Rungruang *et al.*, 2017; Cai *et al.*, 2020; Thangsunan *et al.*, 2021; Jawla *et al.*, 2021, Tasrip *et al.*, 2021).

However, the degradation of DNA in processed products such as gelatine has complicated its detection using conventional methods, although LAMP has shown promise in overcoming these limitations (Tasrip *et al.*, 2021). LAMP can sometimes yield non-specific amplification, leading to false positives. This issue necessitates careful primer design and optimisation of reaction conditions to enhance specificity (Yang *et al.*, 2024; Girish *et al.*, 2020; Tasrip *et al.*, 2021). DNA from thermally processed meat samples (e.g., heated to 121°C) can be degraded, posing challenges for extraction and amplification. However, LAMP has been shown to work effectively even with such degraded DNA, provided the extraction method is robust (Girish *et al.*, 2020).

Recent advancements in LAMP have included real-time monitoring techniques that enable immediate analysis of amplification products without electrophoresis. This feature significantly streamlines the detection process.

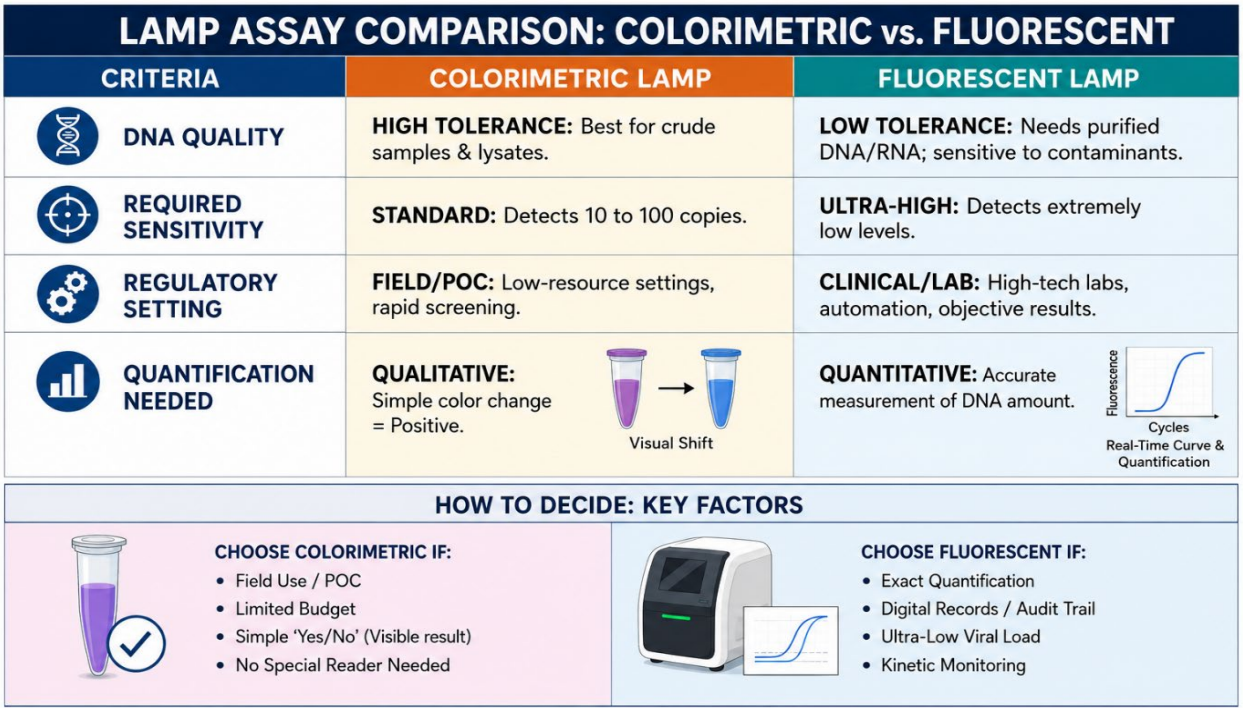

Figure 2: A LAMP assay comparison and a decision framework for selecting LAMP in halal food authentication based on specific laboratory or field needs.

The methodologies used for sample preparation and DNA extraction in LAMP applications for porcine tissues are diverse and evolving. Variations in protocols can significantly impact the efficiency and yield of DNA extraction, while challenges such as sample degradation and non-specific amplification remain pertinent. However, advancements in integration with other technologies continue to enhance LAMP's effectiveness across various applications, particularly in food safety and authenticity testing.

3.4 Detection formats of LAMP

Colourimetric LAMP tests use pH-sensitive dyes or metal-ion indicators to produce visible colour changes during amplification. The colourimetric LAMP provides rapid interpretation without requiring additional tools, making it excellent for field screening, preliminary inspections, and certification audits (Figure 2). Despite their qualitative nature, they provide reliable preliminary results and can reduce laboratory workload by prioritising suspected samples (Saifuddin *et al.*, 2024). Fluorescent dyes and turbidimetry enable real-time monitoring of LAMP reactions, yielding semi-quantitative data with greater sensitivity than ocular detection. Although these processes require specialist tools, they are effective for laboratory-based testing and for regulatory applications that require greater precision (Wong *et al.*, 2018). Combining LAMP with lateral flow immunoassays (LFAs) yields rapid, easy-to-read results while retaining molecular specificity. This technique encourages decentralised testing while meeting regulatory requirements for speedy screening (Holz *et al.*, 2024).

Because of their high amplification efficiency, LAMP reactions can be observed using a variety of readout formats, including turbidity generated by magnesium pyrophosphate precipitation (Mori *et al.*, 2001), fluorescence-based detection (Fang *et al.*, 2025), and visible colourimetric changes (Sridapan *et al.*, 2024). The ability to analyse data visually, without electrophoresis or specialised instruments, is particularly interesting for food authentication applications that require quick decision-making.

LAMP has emerged as a powerful tool for rapid, instrument-free detection, particularly suitable for field-based applications such as halal food authentication. The detection mechanism is based on the release of protons (H^+) during nucleotide incorporation, thereby lowering the reaction pH (Chen *et al.*, 2024). This pH shift can be visualised using pH-sensitive dyes such as phenol red, hydroxy naphthol blue (HNB), or neutral red, which undergo distinct colour changes in response to acidification. For instance, phenol red transitions from red to yellow, while HNB changes from violet to sky blue upon successful amplification. These visual readouts enable "naked eye" interpretation without the need for specialised instrumentation, making colourimetric LAMP highly suitable for on-site screening, border inspections, and rapid food testing scenarios. However, the method is generally qualitative and may be influenced by reaction buffer composition or intrinsic sample properties, thereby affecting pH stability.

3.5 Analytical performance and validation criteria

Based on analytical performance, LAMP demonstrates exceptional sensitivity, often detecting DNA at very low concentrations. For example, it can identify porcine DNA at levels as low as 0.0001 ng in gelatine products (Tasrip *et al.*, 2021) and up to 0.000001 ng pork in meat matrices (Zhang *et al.*, 2025). This sensitivity is comparable to or exceeds that of PCR methods. LAMP assays are highly specific because they use species-specific primers. For instance, porcine-specific primers targeting mitochondrial DNA regions (e.g. Cytochrome b and D-loop) showed no cross-reactivity with other species (Tasrip *et al.*, 2021). LAMP is a rapid technique, with results often available within 30–60 minutes. This makes it suitable for point-of-care (POC) applications and field settings.

Crucially for food forensics, *Bst* is highly tolerant of inhibitors. The inhibitor tolerance of Bst enzymes is primarily enhanced through fusion protein strategies and targeted structural modifications. These approaches improve the enzyme's ability to function in the presence of various inhibitors, making it more effective for applications such as LAMP (Xiang *et al.*, 2024; Yang *et al.*, 2025).

Based on validation criteria, a wide range of non-target species will be tested to confirm the absence of cross-reactivity. For example, porcine-specific LAMP primers were tested against 14 other meat species and showed 100% specificity. Sensitivity is validated by testing serial dilutions of target DNA. LAMP consistently demonstrates low LODs, such as 1 pg/µL for porcine DNA (Tasrip *et al.*, 2021). Repeatability is assessed by analysing the coefficient of variation (CV) across multiple runs. For instance, a CV of 0.53% was reported for real-time PCR with porcine-specific primers (Salamah *et al.*, 2021). Reproducibility is confirmed through inter-laboratory comparisons, which have shown no significant differences in results. LAMP has been validated across various sample types, including raw and processed foods, gelatine products, and clinical samples, demonstrating its versatility (Tasrip *et al.*, 2021). LAMP is equipment-independent and can be performed in resource-limited settings. Visual detection methods, such as colour changes induced by dyes, further simplify its application (Sari *et al.*, 2026).

One of the most distinguishing characteristics of LAMP is its amplification efficiency. Large amounts of DNA can be generated in 30-60 minutes, typically exceeding the yield obtained by PCR in the same time frame. Sensitivity is another distinguishing feature of LAMP. The continuous amplification method, along with high primer redundancy, enables the detection of very low DNA copy numbers. Numerous investigations have shown that LAMP can detect target DNA at levels comparable to, or even lower than, those achieved by qPCR, especially in inhibitor-rich or degraded samples (Wu *et al.*, 2022; Soroka *et al.*, 2021). This sensitivity is especially important in food matrices, where DNA is often fragmented or present at trace levels due to processing. LAMP's resistance to amplification inhibitors is crucial for food analysis. Food matrices frequently contain polysaccharides, salts, phenolic chemicals, lipids and heme derivatives, which can interfere with PCR by reducing DNA polymerase activity. LAMP is more resistant to these inhibitors, allowing for consistent amplification even when DNA extraction is inadequate or simplified (Zhang *et al.*, 2025). This characteristic enables the use of rapid or crude DNA extraction procedures, which reduce analysis time and cost.

4. Application of LAMP for the detection of porcine adulteration

The application of LAMP to various food matrices exemplifies its practical value for food authenticity (Table 4). The subsections examine how LAMP was developed and applied to various matrices, including meat and gelatine, for detecting porcine adulteration, with an emphasis on analytical performance, methodological challenges, and comparative advantages over common molecular methods. The variability of limits of detection (LOD) across the studies summarised in Table 3 reflects methodological heterogeneity rather than intrinsic inconsistencies in the LAMP approach. Key contributing factors include differences in target gene selection, with mitochondrial regions such as cytochrome b, COI, and the D-loop exhibiting varying amplification efficiencies due to differences in sequence characteristics and amplicon length. DNA extraction methods also play a critical role, with commercial kits generally yielding higher-purity DNA and lower LODs than in-house or crude extraction methods, which may retain amplification inhibitors. In addition, the complexity and processing level of the sample matrix, ranging from raw meat to highly processed products such as gelatine, can significantly affect DNA integrity and, in turn, detection sensitivity. Variability is further compounded by differences in LOD definitions and reporting formats across studies, with some expressing LOD in absolute DNA quantities and others reporting percentage adulteration thresholds. Moreover, primer design and optimisation in LAMP, which relies on multiple primers, directly influence amplification efficiency. At the same time, variations in reaction conditions, enzyme systems, and detection formats (as opposed to fluorescent readouts) introduce additional layers of variability. The use of enhancement strategies such as nanoparticle-assisted extraction or DNA concentration steps in certain studies can further lower LOD values. Collectively, these factors underscore the need for standardised protocols and reporting criteria to enable more meaningful cross-study comparisons of LAMP-based halal authentication assays.

4.1 Meat and meat-based products

Meat and meat-based products are among the most often investigated matrices for porcine adulteration due to their susceptibility to species substitution and economic fraud. Sausages, burgers, minced meat, meatballs, and similar products are frequently subjected to extensive processing, such as grinding, curing, heating, and the addition of spices or preservatives, all of which may degrade DNA quality and interfere with amplification reactions (Sajali *et al.*, 2018).

LAMP is widely considered an effective innovation for detecting porcine DNA in raw and processed meat matrices. One of its main advantages is its high sensitivity, with previous studies reporting detection limits as low as 3×10^{-8} gram (Abdullahi *et al.*, 2017) and 0.01% (w/w) pork in beef admixtures (Yang *et al.*, 2014). Such sensitivity is significant in regulatory surveillance, where trace-level contamination or intentional low-level adulteration might not be detected using the less sensitive methods.

Table 4: Representative LAMP assays reported for the detection of porcine adulteration in meat and gelatine products. ND: not determined

Food matrices	Target gene	DNA extraction method	LOD	Sensitivity	Detection format		References
					Colorimetric-LAMP	Fluorescent LAMP	
Meat	Mitochondrial 12S rRNA	DNeasy Tissue Kit (QIAGEN, Hilden, Germany).	20.33 ng for pork	ND	X	√	Ahmed *et al.*, 2010
Meat	cytochrome oxidase subunit II (CO II)	DNeasy Tissue kit (Qiagen, USA)	0.001 ng for raw and cooked pork	ND	X	√	Cho *et al.*, 2014
Meat	mtDNA cytochrome b	In-house method	0.001 ng for pork	0.01% (w/w) pork in beef admixture	√	X	Yang *et al.*, 2014
Meat	the mitochondrial D-loop regions, and eukaryotic primers based on the 18S rRNA gene	DNeasy Blood and Tissue Kit (Qiagen, Hilden, Germany	0.001 ng for raw and heated pork	0.1% (w/w) of pork in a beef admixture	√	X	Lee *et al.*, 2016
Meat	mitochondrial DN1	TIANamp Genomic DNA kit (Tiangen, China).	0.0005 ng pork	0.01% (w/w) pork in beef or mutton admixtures	√	X	Ran *et al.*, 2016
Meat	segments of porcine mitochondrial, tRNA lys gene, and ATPase subunit 8 genes	Animal tissue DNA isolation and purification kit (Qiagen, Dneasy, Dermadst Germany)	3×10^{-8}ng pork	0.5% (w/w) of pork in beef admixture	√	X	Abdullahi *et al.*, 2017
Meat	cytochrome b(cyt b) mtDNA	Dneasy Tissue Kit (Qiagen, USA)	1 ng pork	ND	X	√	Rungruang *et al.*, 2017
Meat	D-loop	Alkaline Lysis (AL) method	2.5 ng pork	0.1% (w/w) pork in beef admixture	√	X	Girish *et al.*, 2020

Meat	D-loop	DNA extraction kit (LabServ, Beijing, China).	0.00088 ng pork	ND	X	√	Cai *et al.*, 2020
Meat	D-loop	DNeasy Mericon Food Kit (Qiagen, Germany)	0.1 ng pork	ND	√	X	Thangsunan *et al.*, 2021
Meat	mitochondrial COI	DNeasy Blood and Tissue Kit (Qiagen, Germany)	1x 10^{-8} ng pork	1% (w/w) pork in meat admixture	√	X	Jawla *et al.*, 2021
Meat	CO II and D-loop	superparamagnetic nanoparticles	0.001 ng pork	0.01% (w/w) pork in beef meat powder admixture	√	√	Qin *et al.*, 2022
Meat	mitochondrial D loop	superparamagnetic nanoparticles	0.000001 ng pork	0.1% (w/w) pork in beef and mutton admixture	√	√	Zhang *et al.*, 2025
Gelatine	mitochondrial DNA of Cytochrome b	GeneAllÒ ExgeneTM kit for Animal Tissue (Gen-eAll Biotechnology Co., Ltd., Seoul, Korea), PorcineTrace Gelatine DNA Extraction Kit (7FoodPillars), DNeasy maricon Food Kit (Qiagen, Hilden, Germany).	0.001 ng porcine gelatine	ND	√	√	Tasrip *et al.*, 2021

LAMP's robustness in meat matrices stems mostly from its tolerance to common PCR inhibitors such as heme compounds, fats, salts, and spices (Cai *et al.*, 2020). qPCR usually requires extensive DNA purification to remove these inhibitors, which increases extraction time and chemical costs. In addition, LAMP works effectively even with unpurified DNA, resulting in faster procedures and less reliance on complex laboratory infrastructure. This function is especially beneficial for routine screening in food analysis laboratories or for on-site testing during audits and enforcement operations.

Another important element in meat authentication is the variability generated by different processing conditions. Thermal treatments such as boiling, roasting, frying, and autoclaving can fragment DNA, reducing the effectiveness of amplification methods. LAMP assays designed to target short mitochondrial DNA fragments consistently outperformed standard PCR in heat-treated meat products, which usually target bigger amplicons (Cho *et al.*, 2014; Kumar *et al.*, 2017). The high copy number of mitochondrial DNA enhances the reliability of detection in processed foods. Several studies have investigated the usage of LAMP in quantitative or semi-quantitative applications (Qin *et al.*, 2022; Zhang *et al.*, 2025; Tasrip *et al.*, 2021). Although LAMP is generally regarded as a qualitative technique, time-to-positivity and real-time fluorescence monitoring have been employed to quantify relative pork content in meat mixtures. While such approaches cannot fully replace qPCR for precise quantification, they can give useful screening-level results that will guide further confirmatory investigation. Overall, previous studies from 2010-2026 suggest that LAMP is a reliable and practical method for detecting porcine adulteration in meat and meat products, particularly when speed, simplicity, and robustness are critical.

4.2 Gelatine-based products

Gelatine-based products are among the most analytically challenging classes for species authenticity (Nhari *et al.*, 2012). It is produced by prolonged heating, acidic or alkaline treatment, and enzymatic hydrolysis of collagen, resulting in significant DNA breakdown and extremely low residual DNA content. As a result, certain protein-based (ELISA, SDS-PAGE, HPLC, IEF) and common DNA-based (conventional PCR, PCR-RFLP) analytical methods failed to reliably identify species in gelatine-containing foods and pharmaceutical foods.

LAMP has emerged as a particularly promising technique for detecting porcine gelatine. The technique's ability to amplify extremely small DNA fragments makes it suitable for severely damaged matrices. Currently, there is still a lack of studies involving the detection of porcine gelatine using LAMP. Specifically, one study directly addresses the detection of porcine gelatine using LAMP, highlighting its effectiveness in identifying porcine traces in gelatine-based products. Tasrip *et al.* (2021) have developed a porcine-specific LAMP assay to detect porcine DNA in highly processed gelatine-based products. The LAMP assay was designed using porcine-specific primers targeting the mitochondrial cytochrome b gene. Two different LAMP reaction mixtures, GENIE and MYRM, were evaluated for their sensitivity and specificity in detecting porcine DNA. The LAMP assay detected porcine DNA as low as 1 pg/µL, with no cross-reactivity to 14 other animal species. Analysis of 32 gelatine-based products showed that 5 samples contained porcine DNA, including 3 that were not labelled as containing porcine gelatine. The LAMP assay demonstrated excellent specificity, sensitivity, and rapidity in detecting porcine DNA in gelatine products. However, due to the limited number of positive samples in this study and limited information on the gelatine's origin and manufacturing process, further assessments using a larger number of samples with known characteristics and robust validation measures are highly recommended to establish the method further.

Another advantage of LAMP in gelatine analysis is that it can be used with basic DNA extraction methods for highly processed foods like gelatine. Given gelatine's low DNA yield, extensive purification often results in significant DNA loss. LAMP's tolerance to impurities allows for the use of minimal extraction procedures, thereby retaining valuable DNA and reducing overall analysis time. This feature is particularly beneficial for high-throughput screening of gelatine-containing products in food and pharmaceutical supply chains. The application of LAMP for gelatine authentication has far-reaching consequences for regulatory compliance and consumer safety. Undeclared porcine gelatine is a common concern in food fraud investigations, and rapid screening technologies are necessary to ensure compliance. LAMP-based assays offer a practical method for preliminary testing, allowing authorities and manufacturers to identify non-compliant products before they reach customers.

Despite these benefits, challenges remain. Even with enhanced LAMP tests, the extremely low DNA levels in some gelatine products may prevent detection. Furthermore, changes in gelatine processing conditions may result in varied DNA fragmentation patterns, necessitating rigorous test validation across product types. Nonetheless, an expanding body of evidence indicates that LAMP can be one of the most effective molecular approaches for identifying porcine gelatine. Compared with qPCR, four studies specifically address the detection of porcine gelatine using qPCR, with applications ranging from halal food authentication to testing in processed foods and cosmetic products. These studies highlight the sensitivity and specificity of qPCR for detecting porcine DNA across various matrices (Rahma *et al.*, 2025; Rumiyati *et al.*, 2026; Sultana & Azlan, 2025; Volkandari *et al.*, 2025).

4.3 Lard and fat-rich matrices

Fat-rich matrices such as lard pose distinct analytical challenges for DNA-based species identification. Lard contains very little recoverable DNA, and the presence of lipids exacerbates extraction by impeding enzymatic

reactions and DNA purification. (Dabrowski *et al.*, 2024). Lipid contamination can reduce DNA purity and may require additional steps, such as ethanol washes or lipid-removal techniques, to improve extraction efficiency. For example, in studies involving lard-adulterated food products using qPCR, DNA extraction was challenging, and optimisation steps did not significantly improve DNA yield (Rosman *et al.*, 2016). Cocoa powder was also identified as a component that inhibits DNA extraction from lard in chocolate, suggesting that lipid interactions can form complexes that further hinder DNA recovery (Rosman *et al.*, 2016).

To date, no studies have reported detecting lard using LAMP. Previously, several analytical methods, in addition to DNA-based techniques, have been developed to detect lard in food products. These methods leverage chemical, spectroscopic, and machine learning approaches (Table 5). However, these methods struggle to detect lard in processed or multi-ingredient foods. Some techniques fail to detect low concentrations of lard (e.g., FTIR in certain matrices). Advanced methods such as NMR and Raman spectroscopy are expensive and require specialised equipment. Many methods rely on chemometric or machine learning models, which require expertise to interpret accurately through statistical analysis.

Given the current absence of LAMP-based studies for lard authentication, a robust analytical framework is proposed to overcome the inherent challenges of low DNA yield and lipid-mediated inhibition. Future research should prioritise an optimisation strategy: first, the implementation of a 'low-volume, high-purity' extraction protocol, such as a modified CTAB method coupled with silica-column purification to ensure the removal of residual triacylglycerols. Additional steps, such as chloroform washes, ethanol precipitation, and mechanical disruption (e.g., bead beating), have been shown to improve nucleic acid recovery from lipid-rich samples (Roy *et al.*, 2020; Gullicksen *et al.*, 2004). Second, the LAMP assay should target short mitochondrial D-loop or cytochrome b fragments (<150 bp) to account for the high degree of DNA fragmentation typical in rendered fats. To ensure field-deployment ability, this framework recommends using Bst DNA polymerase, which offers enhanced reverse transcriptase activity and superior tolerance to lipid carryover compared to earlier generations. By combining these optimized extraction buffers with a pH-sensitive readout, a rapid 'Yes/No' screening tool for halal compliance can be established, providing a cost-effective alternative to the expensive spectroscopic methods currently used for fat-rich matrices.

5.0 Challenges and Future Perspectives of LAMP

Despite the benefits of LAMP for detecting porcine adulteration, several challenges may limit its widespread use in routine food authentication and regulatory laboratories. Addressing these issues is critical for ensuring analytical robustness, repeatability, and long-term adoption of LAMP alongside existing PCR-based technologies.

5.1 Primer design complexity and specificity control

One of the main constraints of LAMP is the complexity of primer design. Unlike qPCR, which typically uses a single primer pair, LAMP requires six primers that recognise eight distinct regions of the target sequence (Notomi *et al.*, 2000). While this multi-primer architecture contributes to LAMP's high specificity, it also significantly raises the possibility of primer-primer interactions, secondary structure formation, and non-specific amplification if primer sets are not carefully designed. The high concentration of multiple primers increases the risk of primer-dimer formation, which can trigger false-positive signals in non-porcine samples (Kim *et al.*, 2023). For field-based porcine screening, it is therefore critical to optimise the reaction temperature (typically 60–65 °C) to suppress these non-templated reactions, which would otherwise lead to the wrongful rejection of halal-compliant products. The significant sequence similarity among mitochondrial genomes of closely related mammalian species can make it difficult to detect porcine. Poor primer evaluation can lead to cross-reactivity, especially in complex food matrices with various animal species. Thus, primer validation against a large panel of non-target species is critical and must be completed to ensure high specificity and minimise non-specific amplification or cross-reactivity. Validating against non-target species confirms that the primers bind only to the intended porcine DNA sequence, preventing false positives and ensuring accurate results, especially in complex food matrices.

To successfully implement a LAMP assay, the validation workflow must include both bioinformatic checks and empirical laboratory testing. Using tools such as PrimerExplorer or the NEB LAMP Design Tool, researchers can screen all six primer sequences against genetic databases to ensure that no single pair initiates amplification in a non-target genome (Yang *et al.*, 2024). Experimentally, this is followed by monitoring the Time to Positive (TTP) and performing real-time LAMP melt curve analysis. A specific reaction will show a sharp, consistent melting peak, whereas cross-reactivity or non-specific noise often results in delayed, inconsistent signals. This comprehensive validation process is the only way to guarantee the diagnostic reliability required for point-of-care or field-based applications.

Despite these benefits, the analytical principle of LAMP still poses several challenges. The LAMP primer design is far more complicated than for PCR, since many primers must be carefully optimised to avoid non-specific amplification and primer-dimer formation. Furthermore, high amplicon yields increase the risk of carryover contamination if laboratory workflows are not managed effectively (Warmt *et al.*, 2022). These problems highlight the importance of comprehensive assay validation and contamination control when using LAMP for routine food verification.

Table 5: Non-DNA-based analytical methods to detect lard in food and their limitations

Method	Studies	Limitation	References
GC-MS	Analyse fatty acid methyl esters derived from lard. Chemometric techniques such as Principal Component Analysis (PCA) and Random Forests can classify lard-adulterated samples.	Requires extensive sample preparation and expertise in data interpretation	Azizan *et al.* (2021); Fadzillah *et al.* (2016)
FTIR Spectroscopy	Detects lard based on its unique infrared fingerprint. It is often combined with chemometric models like PCA and Soft Independent Modelling of Class Analogy (SIMCA) for classification.	Limited sensitivity in complex matrices may fail to detect low concentrations of lard in certain food products.	Ramli *et al.* (2015); Rohman & Che Man (2012)
Raman Spectroscopy	Effective for quantifying lard in butter and monitoring its adulteration and storage time. Advanced machine learning models, such as Adaptive Residual Attention networks, improve accuracy.	Requires sophisticated data processing and may be cost-prohibitive for routine use	Rohman & Che Man (2012). Taylan *et al.* (2020)
Electronic Nose (E-Nose)	Discriminates lard from other fats based on aroma profiles. PCA is used to group lard-containing samples	Limited to volatile compounds and may not work well for processed or complex food matrices.	Nurjuliana *et al.* (2011)
Nuclear Magnetic Resonance (NMR) Spectroscopy	Differentiates lard from other fats in butter using PCA and Discriminant Analysis (DA)	High cost of equipment and limited accessibility	Fadzillah *et al.* (2019)
UV Spectrophotometry	Utilizes chemometric techniques like Linear Discriminant Analysis (LDA) to classify fats based on their spectral properties	Limited to specific fat types and may not detect lard in complex mixtures.	Syahputra *et al.* (2024)
Volatilomics (SPME-GC/MS)	Analyses volatile compounds to detect lard in mixtures with other animal fats	Requires specialized equipment and expertise	Putri *et al.* (2024)
Dielectric Sensing	Measures impedance changes in lard using interdigitated electrodes (IDE)	Limited application scope and sensitivity to environmental factors	Khamil & Yin (2016)

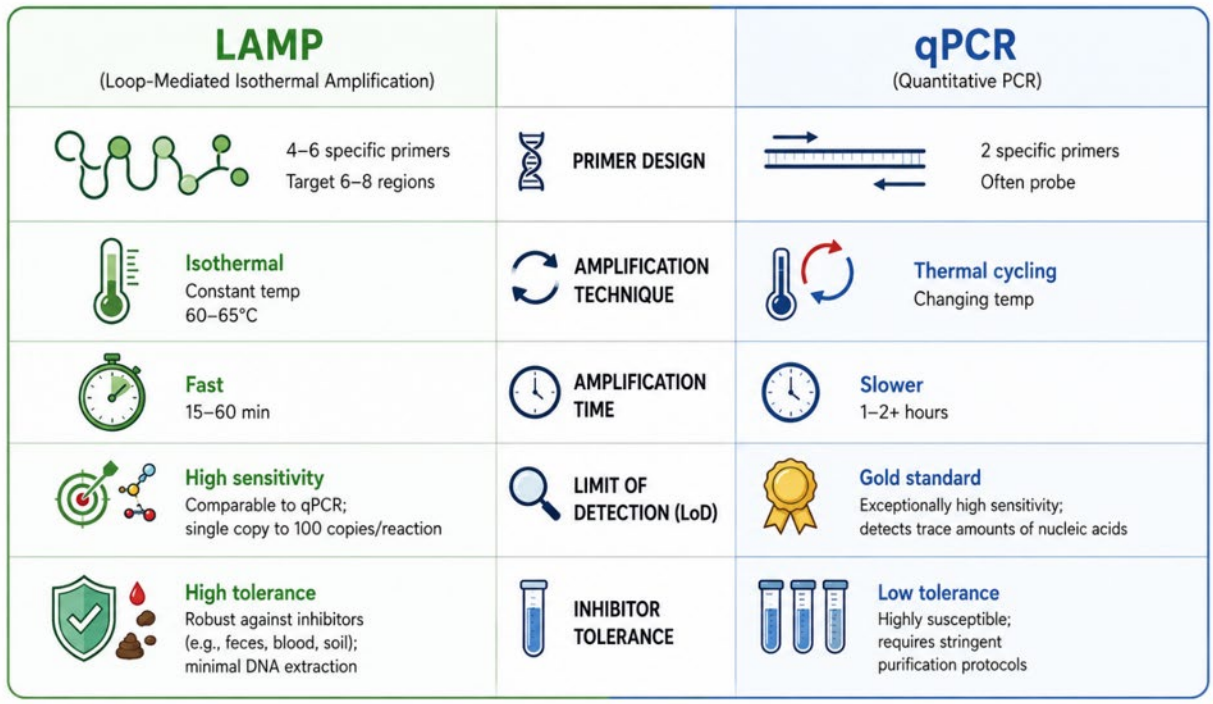

Figure 3: A comparative infographic between LAMP and qPCR based on primer design, amplification techniques, amplification time, limit of detection, and inhibitor tolerance.

The primary distinction between LAMP and PCR is in primer architecture and amplification method. A comparative infographic between LAMP and qPCR based on primer design, amplification techniques, amplification time, limit of detection, and inhibitor tolerance is shown in Figure 3.

5.2 Contamination risk and workflow management control

Despite its advantages, LAMP is highly susceptible to carryover contamination due to its high amplification efficiency and the large number of amplicons generated during the reaction. Amplified products can easily aerosolise and contaminate laboratory surfaces or reagents, leading to false-positive results in subsequent assays (Zhang *et al.*, 2025). This limitation is particularly critical in halal authentication, where false detection of porcine DNA may have significant regulatory, economic, and ethical consequences. To overcome the issue of aerosolised amplification products, several contamination control strategies have been proposed, including the use of a closed-tube detection system (Karthik *et al.*, 2014), a nano capture system which uses magnetic nanoparticles functionalised with specific probes that can capture and remove contaminating amplicons from reaction mixtures (Liu *et al.*, 2025); modified polymerases and UTP substitution, the incorporation of uracil-DNA glycosylase (UDG) to degrades carryover amplicons (Liu *et al.*, 2025); CRISPR-based amplicon depletion and aerogel materials (Zhang *et al.*, 2025). Implementing such options is essential to ensure the reliability and robustness of LAMP assays for clinical, field, and point-of-care applications. Without consistent contamination-control procedures, regulatory agencies may be hesitant to trust LAMP-based assays.

5.3 Limited multiplexing and quantitative capability

Compared with qPCR, LAMP has limited multiplexing capacity. While multiplex PCR and qPCR techniques may detect multiple species simultaneously in a single reaction, LAMP multiplexing is limited by primer complexity, competition among amplification reactions, and challenges in signal discrimination (Crego-Vicente *et al.*, 2024). This constraint limits LAMP's use in scenarios that require complete species profiling, such as screening for multiple illegal or undeclared animal products in processed foods. Furthermore, LAMP is most used as a qualitative or semi-quantitative technique. Although time-to-positivity and turbidity measurements have been used as approximations for target concentration, they lack the precision and dynamic range of qPCR quantification. As a result, LAMP is now best suited for quick screening, whereas confirmatory and quantitative analysis continue to rely on qPCR or sequencing-based approaches. This complementary role is consistent with the comparative performance patterns of LAMP, PCR, and qPCR in detecting porcine adulteration across different food matrices, as presented Table 6.

Table 6: Comparative performance of LAMP, PCR, and qPCR for detection of porcine adulteration in different food matrices

Matrix	Major Analytical Challenges	LAMP	Conventional PCR	qPCR
Meat and meat-based products	• PCR inhibitors (heme, fats, spices) • DNA degradation due to cooking and curing • Complex mixed-meat formulations	• High inhibitor tolerance (Muflihah *et al.*, 2023) • Rapid amplification (≤60 min) (Muflihah *et al.*, 2023) • Sensitive trace detection • Minimal equipment required (Muflihah *et al.*, 2023)	• Reliable for moderately processed samples • Reduced sensitivity in inhibitor-rich matrices • Requires thermal cycling	• High sensitivity and specificity (Munir & Inayatullah, 2021) • Quantitative capability (Munir & Inayatullah, 2021) • Sensitive to inhibitors • Requires specialised instrumentation
Gelatine-based products	• Extensive DNA fragmentation • Extremely low DNA yield • Harsh chemical processing	• Efficient amplification of short mitochondrial targets (Tasrip *et al.*, 2021) • Superior robustness in degraded DNA • Effective as a screening tool	• Often fails due to long amplicon requirements • Low amplification efficiency	• Improved sensitivity over PCR • Performance depends on amplicon size (Rahma *et al.*, 2025) • Inconsistent results at very low DNA levels
Lard and fat-rich matrices	• Very low DNA content • Co-extracted lipids and inhibitors • DNA loss during purification	• Greater tolerance to residual inhibitors • Effective with optimised extraction • Can be adapted to complex fat matrices	• Frequently inhibited • Low amplification success without extensive purification	• High analytical sensitivity • Strongly affected by inhibitors • Requires high-quality DNA extracts (Muflihah *et al.*, 2023)

5.4 Matrix-dependent variability and sample preparation challenges

Although LAMP is more tolerant of inhibitors than PCR-based technologies, sample preparation remains a significant driver of test performance, especially for difficult matrices such as gelatine and fat-rich products. DNA extraction from highly processed or lipid-rich foods often yields fragmented DNA in low quantities, requiring matrix-specific modifications. Variability in extraction efficiency can lead to inconsistent sensitivity across laboratories, affecting inter-study comparisons and procedure standardisation. Future research should focus more on integrated sample-preparation procedures, such as rapid extraction buffers, direct amplification methods, and inhibitor-resistant polymerases. The integration of optimal extraction processes with LAMP detection is critical for obtaining accurate results in on-site testing circumstances where laboratory-grade purification methods may not be practicable.

5.5 Reliability issues (false positives/negatives)

LAMP reliability is often compromised by false positives and false negatives, which pose significant challenges to its broader adoption. LAMP is prone to non-specific amplification, such as primer dimerisation or template-independent amplification, leading to false-positive results. This issue is exacerbated by the complex nature of LAMP amplicons and by indirect detection methods

such as colourimetric or turbidity-based readouts (Bakthavathsalam *et al.*, 2018; Kim *et al.*, 2023). Carryover contamination during amplification can also result in false positives. This is particularly problematic in open-tube systems where amplified products can contaminate subsequent reactions (Kim *et al.*, 2023). Conventional detection methods, such as intercalating dyes or colourimetric changes, are subjective and prone to misinterpretation, further increasing the risk of false positives.

False negatives can occur when inhibitors in clinical or environmental samples interfere with amplification. This is particularly relevant in point-of-care (POC) settings, where sample preparation is minimal (Sritong *et al.*, 2024). The design of LAMP primers is intricate, and poorly designed primers can fail to amplify the target sequence, leading to false negatives (Yang *et al.*, 2024).

5.6 Standardisation and regulatory acceptance

Broader adoption of LAMP faces several challenges related to standardisation and regulatory acceptance. LAMP assays often suffer from variability in primer design, reaction conditions, and detection methods, leading to inconsistent results across laboratories. Non-specific amplification and false positives remain significant technical hurdles, which can undermine the reliability of LAMP-based diagnostics (Yang *et al.*, 2024). Regulatory frameworks for LAMP-based diagnostics are still evolving. For example, while some LAMP assays have received FDA Emergency Use Authorisation (EUA), broader regulatory acceptance remains limited. The absence of harmonised international guidelines for laboratory-developed tests (LDTs), including LAMP, creates uncertainty for developers and regulatory bodies (Spitzenberger *et al.*, 2022). Validation of LAMP assays across diverse applications (e.g., infectious diseases, food safety) requires rigorous testing to meet regulatory standards, which can be resource-intensive (Ge *et al.*, 2025). Quality management systems, such as those outlined in ISO 15189, are not uniformly implemented for LAMP, complicating its integration into clinical and diagnostic workflows (Dorn-Beineke & Sack, 2016). Limited clinical trials and real-world validation data hinder the widespread adoption of LAMP, especially in high-resource settings where qPCR remains the gold standard. The lack of clear guidelines for health provider acceptance and reimbursement further delays its adoption (Feddema *et al.*, 2024).

5.7 Future perspectives

LAMP is gaining traction in food authentication, particularly for detecting porcine DNA in food products. Several technological advancements are anticipated to enhance the analytical performance and usability of LAMP in this context. One of the key areas of development is enhanced sensitivity and specificity. Advances in bioinformatics tools will facilitate the design of highly specific primers that minimise cross-reactivity with non-target species, thereby improving the sensitivity and specificity of LAMP assays for detecting porcine DNA in complex food matrices. Additionally, the development of multiplex LAMP assays will enable simultaneous detection of multiple targets (e.g., porcine and other species) in a single reaction, streamlining testing processes and reducing costs. Another significant advancement involves the integration with advanced detection methods. Incorporating real-time fluorescence detection systems will enable continuous monitoring of LAMP reactions, providing immediate results using fluorescent dyes or probes that emit signals during amplification. Furthermore, combining LAMP with CRISPR technology can enhance specificity and sensitivity, as CRISPR-based detection systems can confirm positive LAMP results, providing a robust method for porcine detection (Sun *et al.*, 2025).

The development of portable and user-friendly devices is also on the horizon. Future LAMP devices are expected to facilitate point-of-care testing for porcine DNA in food products, be easy to use, and allow non-experts to perform tests with minimal training. Additionally, integrating these devices with smartphones for data analysis and result interpretation will enable users to receive instant feedback and share results easily. Automation and high-throughput screening are set to revolutionise LAMP applications as well. Automating LAMP processes will increase throughput and reduce human error by having robotic systems handle sample preparation, reaction setup, and result analysis, making it suitable for large-scale food testing. The use of microfluidic technology will enable miniaturised LAMP reactions, reducing reagent consumption and enabling high-throughput screening of food samples. Innovation in enhanced sample preparation techniques will further streamline the LAMP workflow. Rapid DNA extraction methods, such as magnetic bead-based extraction or novel lysis buffers, will enable faster and more efficient extraction of porcine DNA from food matrices. Moreover, developing direct LAMP methods that eliminate the need for DNA extraction will simplify the workflow and reduce testing time.

Lastly, advancements in data management and traceability will play a crucial role in the future of LAMP technology. Implementing blockchain for data management will enhance traceability in food supply chains by securely storing and making LAMP test results easily accessible, thereby improving transparency in food authentication. Additionally, cloud computing can facilitate the storage and analysis of LAMP data, allowing for large-scale data collection and sharing among stakeholders in the food industry.

6. Conclusion

This review underscores the transformative potential of LAMP as a robust, field-deployable alternative to laboratory-bound qPCR for detecting porcine DNA. While significant strides have been made in identifying porcine derivatives in meat and gelatine-based products, a critical technological blind spot remains in the authentication of lard. The high-heat rendering processe

and low DNA yield characteristic of animal fats have historically prevented these matrices from being used in rapid molecular screening. To bridge this gap, the researchers should perform lard detection using qPCR with optimized DNA extraction for lard and develop LAMP by focusing on highly tolerant Bst DNA polymerases and short-fragment mitochondrial targets specifically optimized for degraded lipid environments. Implementing the proposed "dual-stage" extraction and amplification strategy using qPCR will move lard authentication from a reactive, lab-dependent process to a proactive, point-of-need reality. By prioritizing the development of these specialized assays, the global food industry can ensure total supply chain integrity, providing consumers with the transparency and religious assurance they require in an increasingly complex global market. In conclusion, the future of LAMP technology for food authentication, particularly for porcine detection, is promising. With advancements in sensitivity, detection methods, portability, automation, sample preparation, and data management, LAMP is poised to become a vital tool in ensuring food safety and authenticity. These innovations will not only enhance LAMP's analytical performance but also improve its usability across settings, from laboratories to point-of-care testing environments.

7. Acknowledgement

This study was supported by the Malaysia Research University Network (MRUN) Research Officer Grant Scheme (Grant number MROGS/2023/UPM-17) and Nexabiotech Sdn Bhd. PhD candidate of INHART, Raja Mohd Hafidz Raja Nhari, thanks the Ministry of Higher Education (MOHE) of Malaysia for awarding him the PhD sponsorship through the *Hadiah Latihan Persekutuan bagi Staf Bukan Akademik* (HLPSBA 2025).

8. Declaration of generative AI in scientific writing

The authors declare that they have used a generative artificial intelligence tool (Grammarly) specifically to improve the readability and language of the manuscript. After using this tool, the author(s) reviewed and edited the content as needed and take(s) full responsibility for the content of the published article.

References

Abdullahi, U. F., Igwenagu, A., Azu, M., Naim, & Wan-Taib. (2017). A rapid and sensitive Loop-mediated isothermal amplification assay for the detection of pork DNA based on porcine tRNA lys and ATPase 8 genes. In International Food Research Journal, 24(4): 1357–1361. https://ifrj.upm.edu.my/24 (04) 2017/.pdf

Aglietti, C., Benigno, A., Cacciola, S. O., & Moricca, S. (2024). LAMP Reaction in Plant Disease Surveillance: Applications, Challenges, and Future Perspectives. In Life, 14(12):1549. https://doi.org/10.3390/life14121549

Ahmed, M. U., Hasan, Q., Mosharraf Hossain, M., Saito, M., & Tamiya, E. (2010). Meat species identification based on loop-mediated isothermal amplification and an electrochemical DNA sensor. Food Control, 21(5), 599–605. https://doi.org/10.1016/j.foodcont.2009.09.001

Bakthavathsalam, P., Longatte, G., Jensen, S. O., Manefield, M., & Gooding, J. J. (2018). Locked nucleic acid molecular beacon for multiplex detection of loop mediated isothermal amplification. Sensors and Actuators, B: Chemical, 268, 255–263. https://doi.org/10.1016/j.snb.2018.04.081

Barrias, S., Ibáñez, J., Fernandes, J. R., & Martins-Lopes, P. (2024). The role of DNA-based biosensors in species identification for food authenticity assessment. In Trends in Food Science and Technology (Vol. 145). Elsevier Ltd. https://doi.org/10.1016/j.tifs.2024.104350

Brooks, C., Parr, L., Smith, J. M., Buchanan, D., Snioch, D., & Hebishy, E. (2021). A review of food fraud and food authenticity across the food supply chain, with an examination of the impact of the COVID-19 pandemic and Brexit on food industry. Food Control, 130, 108171. https://doi.org/10.1016/j.foodcont.2021.108171

Cai, S., Kong, F., & Xu, S. (2020). Detection of porcine-derived ingredients from adulterated meat based on real-time loop-mediated isothermal amplification. Molecular and Cellular Probes, 53. https://doi.org/10.1016/j.mcp.2020.101609

Chen, Q., Zhang, L. J., Song, T. Y., & Ge, J. Q. (2024). Development of a loop-mediated isothermal amplification (LAMP) assay for rapid and visual detection of *Anguillid herpesvirus* 1. Journal of Virological Methods, 330. https://doi.org/10.1016/j.jviromet.2024.115014

Cho, A. R., Dong, H. J., & Cho, S. (2014). Meat species identification using loop-mediated isothermal amplification assay targeting species-specific mitochondrial DNA. Korean Journal for Food Science of Animal Resources, 34(6), 799–807. https://doi.org/10.5851/kosfa.2014.34.6.799

Crego-Vicente, B., del Olmo, M. D., Muro, A., & Fernández-Soto, P. (2024). Multiplexing LAMP Assays: A Methodological Review and Diagnostic Application. In International Journal of Molecular Sciences, 25(12). https://doi.org/10.3390/ijms25126374

Dabrowski, P., Rasmus, M., Jundzill, A., Drewa, T., & Pokrywczynska, M. (2024). A comparison of five methods to maximize RNA and DNA isolation yield from adipose tissue. PeerJ, 12. https://doi.org/10.7717/peerj.17071

Das, D., Lin, C. W., & Chuang, H. S. (2022). LAMP-Based Point-of-Care Biosensors for Rapid Pathogen Detection. In Biosensors 12(12):1–39. https://doi.org/10.3390/bios12121068

Dorn-Beineke, A., & Sack, U. (2016). Quality control and validation in flow cytometry. LaboratoriumsMedizin, 40(2). https://doi.org/10.1515/labmed-2016-0016

Feddema, J. J., Fernald, K. D. S., Keijser, B. J. F., Kieboom, J., & van de Burgwal, L. H. M. (2024). Commercial Opportunity or Addressing Unmet Needs—Loop-Mediated Isothermal Amplification (LAMP) as the Future of Rapid Diagnostic Testing? Diagnostics, 14(17). https://doi.org/10.3390/diagnostics14171845

Frisch, L. M., Mann, M. A., Marek, D. N., & Niessen, L. (2021). Development and optimization of a loop-mediated isothermal amplification (LAMP) assay for the species-specific detection of Penicillium expansum. Food Microbiology, 95. https://doi.org/10.1016/j.fm.2020.103681

Ge, B., Domesle, K. J., Young, S. R., McDonald, R. C., & Pamboukian, R. Y. (2025). Independent laboratory validation of a Salmonella loop-mediated isothermal amplification assay in 27 human and animal food matrices of 9 ISO food categories. Food Microbiology, 132. https://doi.org/10.1016/j.fm.2025.104821

Girish, P. S., Barbuddhe, S. B., Kumari, A., Rawool, D. B., Karabasanavar, N. S., Muthukumar, M., & Vaithiyanathan, S. (2020). Rapid detection of pork using alkaline lysis- Loop Mediated Isothermal Amplification (AL-LAMP) technique. Food Control, 110. https://doi.org/10.1016/j.foodcont.2019.107015

Gullicksen, P. S., Dean, R. G., & Baile, C. A. (2004). Detection of DNA fragmentation and apoptotic proteins, and quantification of uncoupling protein expression by real-time RT-PCR in adipose tissue. Journal of Biochemical and Biophysical Methods, 58(1), 1–13. https://doi.org/10.1016/S0165-022X(03)00151-9

Hamsar, M. N., Sazili, A. Q., & Md Tohid, S. F. (2024). Chemical probe as a specific detector of porcine protein or peptide in meat and meat-based products: Potential applications, challenges, and the way forward. In Journal of Agriculture and Food Research (Vol. 15). Elsevier B.V. https://doi.org/10.1016/j.jafr.2024.101026

Herdiana, Y., Sofian, F. F., Shamsuddin, S., & Rusdiana, T. (2024). Towards halal pharmaceutical: Exploring alternatives to animal-based ingredients. In Heliyon (Vol. 10, Number 1). Elsevier Ltd. https://doi.org/10.1016/j.heliyon.2023.e23624

Holz, N., Wax, N., Illarionov, B. A., Iskhakova, M., & Fischer, M. (2024). Food Authentication: The Detection of Arbutus unedo and Olea europaea Leaves as an Admixture of Oregano Using LAMP- and Duplex LAMP-Based Test Systems with Lateral-Flow Assays. Agriculture (Switzerland), 14(4). https://doi.org/10.3390/agriculture14040597

Incili, G. K., Koluman, A., Aktüre, A., & Ataşalan, A. (2019). Validation and verification of LAMP, ISO, and VIDAS UP methods for detection of Escherichia coli O157:H7 in different food matrices. Journal of Microbiological Methods, 165:105697. https://doi.org/10.1016/j.mimet.2019.105697

Jawla, J., Kumar, R. R., Mendiratta, S. K., Agarwal, R. K., Singh, P., Saxena, V., Kumari, S., Boby, N., Kumar, D., & Rana, P. (2021). On-site paper-based Loop-Mediated Isothermal Amplification coupled Lateral Flow Assay for pig tissue identification targeting mitochondrial CO I gene. Journal of Food Composition and Analysis, 102. https://doi.org/10.1016/j.jfca.2021.104036

Karanis, P., Thekisoe, O., Kiouptsi, K., Ongerth, J., Igarashi, I., & Inoue, N. (2007). Development and preliminary evaluation of a loop-mediated isothermal amplification procedure for sensitive detection of Cryptosporidium oocysts in fecal and water samples. Applied and Environmental Microbiology, 73(17), 5660–5662. https://doi.org/10.1128/AEM.01152-07

Karthik, K., Rathore, R., Thomas, P., Arun, T. R., Viswas, K. N., Dhama, K., & Agarwal, R. K. (2014). New closed tube loop mediated isothermal amplification assay for prevention of product cross-contamination. MethodsX, 1, e137–e143. https://doi.org/10.1016/j.mex.2014.08.009

Kaur, N., Thota, N., & Toley, B. J. (2020). A stoichiometric and pseudo kinetic model of loop mediated isothermal amplification. Computational and Structural Biotechnology Journal, 18, 2336–2346. https://doi.org/10.1016/j.csbj.2020.08.020

Kim, S. H., Lee, S. Y., Kim, U., & Oh, S. W. (2023). Diverse methods of reducing and confirming false-positive results of loop-mediated isothermal amplification assays: A review. In Analytica Chimica Acta (Vol. 1280). Elsevier B.V. https://doi.org/10.1016/j.aca.2023.341693

Kumar, Y., Bansal, S., & Jaiswal, P. (2017). Loop-Mediated Isothermal Amplification (LAMP): A Rapid and Sensitive Tool for Quality Assessment of Meat Products. In Comprehensive Reviews in Food Science and Food Safety (Vol. 16, Number 6, pp. 1359–1378). Blackwell Publishing Inc. https://doi.org/10.1111/1541-4337.12309

Lanubile, A., Stagnati, L., Marocco, A., & Busconi, M. (2024). DNA-based techniques to check quality and authenticity of food, feed and medicinal products of plant origin: A review. In Trends in Food Science and Technology. 149:104568. https://doi.org/10.1016/j.tifs.2024.104568

Lee, S. Y., Kim, M. J., Hong, Y., & Kim, H. Y. (2016). Development of a rapid on-site detection method for pork in processed meat products using real-time loop-mediated isothermal amplification. Food Control, 66, 53–61. https://doi.org/10.1016/j.foodcont.2016.01.041

Lee M-S, Huang J-Y, Lien Y-Y, Sheu S-C. (2019). The rapid and sensitive detection of edible bird's nest (Aerodramus fuciphagus) in processed food by a loop-mediated isothermal amplification (LAMP) assay. Journal of Food and Drug Analysis, 27(1):154–163. https://doi.org/10.1016/j.jfda.2018.08.003

Li, Q., Xue, H., Fei, Y., Cao, M., Xiong, X., Xiong, X., Yang, Y., & Wang, L. (2022). Visual detection of rainbow trout (Oncorhynchus mykiss) and Atlantic salmon (Salmo salar) simultaneously by duplex loop-mediated isothermal amplification. Food Chemistry: Molecular Sciences, 4. https://doi.org/10.1016/j.fochms.2022.100107

Li, Y., Fan, P., Zhou, S., & Zhang, L. (2017). Loop-mediated isothermal amplification (LAMP): A novel rapid detection platform for pathogens. In Microbial Pathogenesis. 107: 54–61. Academic Press. https://doi.org/10.1016/j.micpath.2017.03.016

Liu, H., Hu, X., Zeng, H., He, C., Cheng, F., Tang, X., & Wang, J. (2023). A rapid and high-throughput system for the detection of transgenic products based on LAMP-

CRISPR-Cas12a. Current Research in Food Science, 7. https://doi.org/10.1016/j.crfs.2023.100605

Liu, X., Zhang, J., Hua, K., & Cui, Y. (2025). Both aerosol and primer dimer breakdown for straightforward genotyping based on an integrated immunochromatographic biosensor. Talanta, 285. https://doi.org/10.1016/j.talanta.2024.127300

Liu, X., Zheng, Y., Chen, Z., Wang, S., Liao, H., Jia, J., Wang, G., Wang, J., Yuan, C., Guo, X., Yin, Y., & Hu, Q. (2026). Rapid and visual detection of Listeria monocytogenes by combining one-pot LAMP–CRISPR/Cas12b with lateral flow assay. Food Microbiology, 135. https://doi.org/10.1016/j.fm.2025.104977

Lv, J., Liu, W., Wang, F., Xiong, L., Yang, H., Yao, X., Liu, H., & Zheng, J. (2025). Multi-target microfluidic loop-mediated isothermal amplification technology for the detection of foodborne pathogens in various food matrices. Analytica Chimica Acta, 1346:343751. https://doi.org/10.1016/j.aca.2025.343751

Rodrigues, V., Honrado, M., Santos, J., Pinto, M. A., & Amaral, J. S. (2024). Development of a loop-mediated isothermal amplification assay for the rapid detection of Styphnolobium japonicum (L.) Schott as an adulterant of Ginkgo biloba (L.). Phytomedicine, 128: 155322. https://doi.org/10.1016/j.phymed.2023.155322

Marino, F., Bonincontro, C., Caligaris, L., Carlo, D., Girolamini, L., & Cristino, S. (2026). Improving Microbiological Monitoring of Hospital Surfaces: Loop-Mediated Isothermal Amplification (LAMP) as a New Approach for Rapid Nosocomial Pathogens Detection. International Journal of Environmental Research and Public Health, 23(2).174. https://doi.org/10.3390/ijerph23020174

Merheb, M., Matar, R., Hodeify, R., Siddiqui, S. S., Vazhappilly, C. G., Marton, J., Azharuddin, S., & Zouabi, H. A. L. (2019). Mitochondrial DNA, a powerful tool to decipher ancient human civilisation from domestication to music, and to uncover historical murder cases. In Cells (Vol. 8, Number 5). MDPI. https://doi.org/10.3390/cells8050433

Mellikeche, W., Ricelli, A., Casini, G., Gallo, M., Baser, N., Colelli, G., & D'Onghia, A. M. (2024). Development of Loop-Mediated Isothermal Amplification (LAMP) Assays for the Rapid Detection of Toxigenic Aspergillus flavus and A. carbonarius in Nuts. International Journal of Molecular Sciences, 25(7). https://doi.org/10.3390/ijms25073809

Mori, Y., Nagamine, K., Tomita, N., & Notomi, T. (2001). Detection of loop-mediated isothermal amplification reaction by turbidity derived from magnesium pyrophosphate formation. Biochemical and Biophysical Research Communications, 289(1), 150–154. https://doi.org/10.1006/bbrc.2001.5921

Muflihah, H. A., K., P., Prabowo, S., & Hartati, Y. W. (2023). DNA-based detection of pork content in food. In Heliyon, 9(3). Elsevier Ltd. https://doi.org/10.1016/j.heliyon.2023.e14418

Munir, M. A., & Inayatullah, A. (2021). Comparison of real-time PCR and conventional PCR by identifying genomic DNA of bovine and porcine. Jurnal Kimia Terapan Indonesia, 23, 63–71. https://doi.org/10.14203/inajac.v23i2.491

Natonek-Wiśniewska, M., Piestrzynska-Kajtoch, A., Koseniuk, A., & Krzyścin, P. (2022). Current Analytical Methods and Research Trends Are Used to Identify Domestic Pig and Wild Boar DNA in Meat and Meat Products. In Genes (Vol. 13, Number 10). MDPI. https://doi.org/10.3390/genes13101825

Nhari, R. M. H. R., Ismail, A., & Che Man, Y. B. (2012). Analytical methods for gelatine differentiation from bovine and porcine origins and food products. Journal of Food Science, 77(1). https://doi.org/10.1111/j.1750-3841.2011.02514.x

Niessen, L., Luo, J., Denschlag, C., & Vogel, R. F. (2013). The application of loop-mediated isothermal amplification (LAMP) in food testing for bacterial pathogens and fungal contaminants. In Food Microbiology 36(2):191–206. https://doi.org/10.1016/j.fm.2013.04.017

Notomi, T., Okayama, H., Masubuchi, H., Yonekawa, T., Watanabe, K., Amino, N., & Hase, T. (2000). Loop-mediated isothermal amplification of DNA. In Nucleic Acids Research 28(12):63e–663. https://doi.org/10.1093/nar/28.12.e63

Prihandiwati, E., Rohman, A., Fadzillah, N. A., Betania, K., Nurani, L. H., Ahda, M., Irnawati, E., Y., S., Y., & Febrianti, D. R. (2024). A review of the developed methods for the analysis of lard and pork in food and pharmaceutical products for halal authentication. In Food Research (Vol. 8, Number 3, pp. 14–27). Rynnye Lyan Resources. https://doi.org/10.26656/fr.2017.8(3).095

Qin, P., Li, Y., Yao, B., Zhu, Y., Xu, J., Yao, L., & Chen, W. (2022). Rational incorporating of loop-mediated isothermal amplification with fluorescence anisotropy for rapid, sensitive, and on-site identification of pork adulteration. Food Control, 137. https://doi.org/10.1016/j.foodcont.2022.108863

Rahma, A. A., Meilani, N. D., Sulistiawati, A., A. S., D., D. S., & Malau, J. (2025). Development of a Gelatine-Based Genomic Reference Material for Halal Authentication Using Real-Time PCR. Science and Technology Indonesia, 10(1), 27–42. https://doi.org/10.26554/sti.2025.10.1.27-42

Ran, G., Ren, L., Han, X., Liu, X., Li, Z., Pang, D., Ouyang, H., & Tang, X. (2016). Development of a Rapid Method for the Visible Detection of Pork DNA in Halal Products by Loop-Mediated Isothermal Amplification. Food Analytical Methods, 9(3), 565–570. https://doi.org/10.1007/s12161-015-0246-z

Rather, J. A., Akhter, N., Ashraf, Q. S., Mir, S. A., Makroo, H. A., Majid, D., Barba, F. J., Khaneghah, A. M., & Dar, B. N. (2022). A comprehensive review on gelatine: Understanding impact of the sources, extraction methods, and modifications on potential packaging applications. In Food Packaging and Shelf Life (Vol. 34). Elsevier Ltd. https://doi.org/10.1016/j.fpsl.2022.100945

Rosman, N. N., Mokhtar, N. F. K., Ali, M. E., & Mustafa, S. (2016). Inhibitory Effect of Chocolate Components Toward Lard Detection in Chocolate Using Real Time PCR. International Journal of Food Properties, 19(11), 2587–2595. https://doi.org/10.1080/10942912.2015.1137936

Rumiyati, R., Sari, M. N., Nawwaruddin, H. H., Laksitorini, M. D., & Rohman, A. (2026). Optimisation and validation of the real-time polymerase chain reaction protocol for porcine gelatine detection in processed food and cosmetic products. Open Veterinary Journal, 16(1), 478–491. https://doi.org/10.5455/OVJ.2026.v16.i1.45

Rungruang, N., Phapugrangkul, P., & Kaewpa, D. (2017). Science and Technology RMUTT Journal Identification of pig DNA using loop-mediated isothermal amplification. Sci. & Tech. RMUTT J, 7(1), 34–42. www.sci.rmutt.ac.th/stj

Saifuddin, S. A., Rashid, R., Nor Azmi, N. J., & Mohamad, S. (2024). Colorimetric strategies applicable for loop-mediated isothermal amplification. In Journal of Microbiological Methods (Vol. 223). Elsevier B.V. https://doi.org/10.1016/j.mimet.2024.106981

Sajali, N., Wong, S. C., Hanapi, U. K., Abu Bakar @ Jamaluddin, S., Tasrip, N. A., & Mohd Desa, M. N. (2018). The Challenges of DNA Extraction in Different Assorted Food Matrices: A Review. Journal of Food Science, 83(10), 2409–2414. https://doi.org/10.1111/1750-3841.14338

Salamah, N., Erwanto, Y., Martono, S., & Rohman, A. (2021). The employment of real-time polymerase chain reaction using species-specific primer targeting on d-loop mitochondria for identification of porcine gelatine in soft candy. Indonesian Journal of Chemistry, 21(4), 852–859. https://doi.org/10.22146/ijc.60413

Sari, F. R., Adhiyanto, C., Ferania, M., Wulandari, R. J., Inayah, N., Harini, S., Tazi, I., Zamhari, A., Suryani, S., W., & Muthmainnah. (2026). A Qualitative Rapid Detection of Sus scrofa DNA using Loop-Mediated AMPlification (LAMP) Isothermal Assay for Halal Food and Drug Detection at the Point-of-Care. Bangladesh Journal of Medical Science, 25(2), 518–525. https://doi.org/10.3329/bjms.v25i2.88736

Schäfer, L., Allgöwer, S., & Holzhauser, T. (2023). Rapid DNA extraction and colorimetric amplicon visualisation speed up LAMP-based detection of soybean allergen in foods. European Food Research and Technology, 249(11), 2875–2886. https://doi.org/10.1007/s00217-023-04334-6

Singh, M., Pal, D., Sood, P., & Randhawa, G. (2020). Construct-specific loop-mediated isothermal amplification: Rapid detection of genetically modified crops with insect resistance or herbicide tolerance. Journal of AOAC International, 103(5), 1191–1200. https://doi.org/10.1093/jaoacint/qsaa043

Soroka, M., Wasowicz, B., & Rymaszewska, A. (2021). Loop-mediated isothermal amplification (Lamp): The better sibling of pcr? In Cells (Vol. 10, Number 8). MDPI. https://doi.org/10.3390/cells10081931

Spitzenberger, F., Patel, J., Gebuhr, I., Kruttwig, K., Safi, A., & Meisel, C. (2022). Laboratory-Developed Tests: Design of a Regulatory Strategy in Compliance with the International State-of-the-Art and the Regulation (EU) 2017/746 (EU IVDR [In Vitro Diagnostic Medical Device Regulation]). Therapeutic Innovation and Regulatory Science, 56(1), 47–64. https://doi.org/10.1007/s43441-021-00323-7

Sridapan, T., Jaturapaktrarak, C., Rujirawat, T., Jiaranaikulwanich, A., Yurayart, C., & Krajaejun, T. (2024). A colorimetric loop-mediated isothermal amplification assay (c-LAMP) for rapid detection of Pythium insidiosum. Heliyon, 10(22). https://doi.org/10.1016/j.heliyon.2024.e40478

Sritong, N., Ngo, W. W., Ejendal, K. F. K., & Linnes, J. C. (2024). Development of an integrated sample amplification control for salivary point-of-care pathogen

testing. Analytica Chimica Acta, 1287. https://doi.org/10.1016/j.aca.2023.342072

Sultana, S., & Azlan, A. (2025). Development and validation of TaqMan qPCR assay for porcine DNA detection in gelatine-based foods for halal authentication. International Food Research Journal, 32(3), 800–807. https://doi.org/10.47836/ifrj.32.3.14

Sun, Y., Zhong, K., Nie, L., Xu, Y., Wang, Y., Yuan, J., Jiang, S., Li, X., Zhang, Z., Li, X., & Jiang, L. (2025). State-of-the-art in food safety: The potential of CRISPR/Cas-based lateral flow assay technology in the field of food analysis. In Food Safety and Health (Vol. 3, Number 2, pp. 155–171). John Wiley and Sons Inc. https://doi.org/10.1002/fsh3.12082

Tasrip, A., Nasir, M., Desa, M., Fadhilah, N., Mokhtar, K., Sajali, N., Mohd Hashim, A., Ali, M. E., Cheah, K. Y. (2021). Rapid porcine detection in gelatine-based highly processed products using loop mediated isothermal amplification. J Food Sci Technol, 58(12):4504–4513. https://doi.org/10.1007/s13197

Volkandari, S. D., Jenie, S. N. A., Rohman, A., Ridwanuloh, A. M., Dewantoro, A., Cahyadi, M., Chin, K. B., & Erwanto, Y. (2025). Validation of NADH dehydrogenase 4 L (ND4L) primers for porcine detection using qPCR analysis on commercial food products. European Food Research and Technology, 251(11), 3807–3820. https://doi.org/10.1007/s00217-025-04847-2

Warmt, C., Yaslanmaz, C., & Henkel, J. (2022). Investigation and validation of labelling loop mediated isothermal amplification (LAMP) products with different nucleotide modifications for various downstream analysis. Scientific Reports, 12(1). https://doi.org/10.1038/s41598-022-11320-7

Wong, Y. P., Othman, S., Lau, Y. L., Radu, S., & Chee, H. Y. (2018). Loop-mediated isothermal amplification (LAMP): a versatile technique for detection of microorganisms. In Journal of Applied Microbiology (Vol. 124, Number 3, pp. 626–643). https://doi.org/10.1111/jam.13647

Wu, Y., Bai, L., Ye, C., Yuhong Guan, K. Y., Chen, H., & Jiang, Z. (2022). Novel miniaturised fluorescence loop-mediated isothermal amplification detection system for rapid on-site virus detection. Frontiers in Bioengineering and Biotechnology, 10. https://doi.org/10.3389/fbioe.2022.964244

Xiang, R., Liu, G. Y., Hou, Y., Xie, L. X., Wang, Q. S., & Hu, S. Q. (2024). Double domain fusion improves the reverse transcriptase activity and inhibitor tolerance of Bst DNA polymerase. International Journal of Biological Macromolecules, 274. https://doi.org/10.1016/j.ijbiomac.2024.133243

Voorhuijzen-Harink, M. M., Saggiomo, V., Fronen, B. J., Prins, T. W., van der Vorst, V., Bovee, T. F. H., Velders, A. H., & Salentijn, G. I. (2026). Easy, on-site applicable DNA extraction in combination with LAMP analysis for the early detection of DNA derived from processed animal proteins in poultry feed. Animal Feed Science and Technology, 333. https://doi.org/10.1016/j.anifeedsci.2025.116616

Yang, L., Fu, S., Peng, X., Li, L., Song, T., & Li, L. (2014). Identification of pork in meat products using real-time loop-mediated isothermal amplification. Biotechnology and Biotechnological Equipment, 28(5), 882–888. https://doi.org/10.1080/13102818.2014.963789

Yang, N., Zhang, H., Han, X., Liu, Z., & Lu, Y. (2024). Advancements and applications of loop-mediated isothermal amplification technology: a comprehensive overview. In Frontiers in Microbiology (Vol. 15). Frontiers Media SA. https://doi.org/10.3389/fmicb.2024.1406632

Yang, R., Li, X., Wang, X., Jing, W., Xu, C., Jiang, J., Lin, Y., Yin, H., Gui, P., & Ma, F. (2025). Engineering and enhancement of Bst DNA polymerase variants toward improved diagnostic applications: A review. In International Journal of Biological Macromolecules (Vol. 332). Elsevier B.V. https://doi.org/10.1016/j.ijbiomac.2025.148691

Yang, Y., Yang, R., Luo, C., Wang, X., & Ma, F. (2026). Loop-Mediated Isothermal Amplification (LAMP): Current Progress and Future Directions in Rapid Nucleic Acid Detection. Sensors and Actuators Reports, 11:100440. https://doi.org/10.1016/j.snr.2026.100440

Yugovich, O., Bunce, M., & Harbison, S. A. (2025). Point-of-need species identification using non-PCR DNA-based approaches to combat wildlife crime. In Forensic Science International: Genetics (Vol. 78). Elsevier Ireland Ltd. https://doi.org/10.1016/j.fsigen.2025.103278

Zhang, D., Abubaker, M. A., Jiao, Y., & Liu, Y. (2025). Removal of aerosols from the air by seaweed cellulose nanofibers: To improve the authenticity of loop-mediated isothermal amplification for detection of pork adulteration. Food Control, 172. https://doi.org/10.1016/j.foodcont.2025.111205

Zhang, J., Hua, M. Z., Chen, H., Hou, H., Hu, Y., & Lu, X. (2025). Food authentication using the loop-mediated isothermal amplification (LAMP) method: Current trends and prospects. In Trends in Food Science and Technology, 156:104874. https://doi.org/10.1016/j.tifs.2025.1048

HALALSPHERE

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MS 2424:2019: A mini review on contemporary issues and challenges of halal pharmaceuticals in Malaysia

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Received: 19/6/2026
Accepted: 27/7/2026
Published: 31/7/2026

Keywords:
Pharmaceutical; Halal pharmaceutical; Challenges; Integrity; Regulatory; Contemporary issue

Abstract

The demand for halal pharmaceutical products has increased significantly due to growing consumer awareness and the need for medicines that comply with *Shari'ah* principles while ensuring safety, quality, and efficacy. Despite the introduction of the Malaysian Standard MS 2424:2019, implementing halal pharmaceutical requirements remains challenging due to complex supply chains, diverse raw material sources, and sophisticated manufacturing processes. Although previous studies have focused on specific issues such as animal-derived ingredients and halal certification, limited attention has been given to the broader implementation challenges addressed by MS 2424:2019. Therefore, this review examines the contemporary implementation challenges affecting Malaysia's halal pharmaceutical industry and analyses the role of MS 2424:2019 in safeguarding halal integrity. A qualitative literature review was conducted by systematically analysing peer-reviewed articles, conference papers, industry reports, regulatory documents, and MS 2424:2019, followed by thematic analysis. The review identified three major challenges: raw material traceability, cross-contamination during manufacturing, and limited halal knowledge and competency among industry stakeholders. The findings further highlight the importance of Halal Assurance Systems, supplier verification, documentation, and personnel competency in maintaining halal integrity. Overall, MS 2424:2019 provides a comprehensive framework for addressing these challenges. However, its effective implementation requires transparent supply chain management, competent personnel, and collaborative efforts among industry, regulatory authorities, and other stakeholders to strengthen the sustainability and global competitiveness of Malaysia's halal pharmaceutical industry.

1. Introduction

The halal pharmaceutical sector has become a crucial component of the global halal industry due to increasing demand for medicines and healthcare products that comply with Islamic principles. Statistics show that its valuation increased from US$ 94 billion in 2019 to US$ 105 billion in 2024 (Naimat *et al.*, 2023). Compared with halal food, halal pharmaceuticals require more complex formulations, advanced manufacturing technology, and various sources of raw materials, including both animal-derived and biotechnology-based ingredients (Herdiana *et al.*, 2024). This complexity indeed increases both issues regarding the halal status of pharmaceutical products and problems such as ingredient verification, contamination in processing facilities (Naimat *et al.*, 2023), and a lack of human capital (Amid *et al.*, 2024).

In Malaysia, the halal pharmaceutical industry plays an important role in supporting the country's goal to become a global halal hub. Moreover, under the New Industrial Master Plan 2030 (NIMP 2030), halal pharmaceuticals are a priority for advancing Malaysia into high-value, advanced manufacturing. To be able to support the country's target, a strong halal assurance is required within the pharmaceutical sector, and that is the reason for the Department of Standards Malaysia to introduce the Malaysian Standards (MS) 2424: 2019 – Halal Pharmaceuticals, which contains comprehensive guidelines to ensure compliance with the *Shari'ah* requirements throughout the production of pharmaceutical products (Department of Standards Malaysia, 2019). The standard highlights that compliance with the Shari'ah requirements covers all steps from the beginning until the end of the production of pharmaceutical products.

Recent studies have highlighted several challenges affecting the halal pharmaceutical industry, including the use of animal-derived ingredients, raw material traceability, cross-

contamination during manufacturing, and inadequate halal knowledge among industry personnel (Naima *et al.*, 2023; Herdiana *et al.*, 2024). While these studies have improved understanding of the operational and regulatory challenges faced by the industry, they primarily discuss these issues independently or from broader perspectives on halal pharmaceuticals and supply chains. Limited attention has been given to critically examining how the provisions of MS 2424:2019 address these contemporary implementation challenges within the Malaysian pharmaceutical industry. Furthermore, as MS 2424:2019 serves as the primary standard governing halal pharmaceutical compliance in Malaysia, there is a need to reassess its relevance in addressing current industry challenges, particularly in light of increasingly complex global supply chains and the continued growth of the halal pharmaceutical sector. Therefore, this review seeks to bridge this gap by examining contemporary implementation challenges alongside the requirements of MS 2424:2019 to provide a comprehensive understanding of its role in safeguarding halal integrity.

2. Challenges in the implementation of halal pharmaceuticals

2.1 Halal pharmaceutical

Recently, consumer preferences have shifted significantly towards products that align with religious beliefs, ethical values, and quality standards, driving increasing global demand for halal pharmaceutical products. This trend reflects not only the growth of the Muslim consumer market but also broader concerns regarding product safety, transparency, ethical sourcing, and sustainability in healthcare. Previous studies have reported that multiple factors, including religious obligations, confidence in product quality, ingredient traceability, and trust in halal certification systems, influence consumers' acceptance of halal pharmaceuticals. Consequently, halal pharmaceuticals have emerged as an important segment of the global pharmaceutical industry rather than merely a niche market for Muslim consumers.

The concept of halal pharmaceuticals extends beyond the prohibition of specific ingredients. It encompasses the entire pharmaceutical value chain, including raw material selection, manufacturing processes, storage, packaging, transportation, and quality management to ensure compliance with *Shari'ah* principles while maintaining product safety, efficacy, and quality. Halal Food Council USA (2023) defines halal pharmaceutical products as medications manufactured in accordance with Islamic principles, ensuring that both their ingredients and production processes comply with Islamic dietary laws and ethical standards. Similarly, the Malaysian Standard MS 2424:2019 (Halal Pharmaceuticals General Requirements) defines halal pharmaceutical products as pharmaceutical products that contain ingredients permitted under *Shari'ah* law and *fatwa*, free from prohibited animal-derived substances, *najs* (filth or impurities), human body parts and their derivatives, while being safe, efficacious, and physically segregated from non-halal materials throughout processing, preparation, handling, storage, and distribution (Naimat *et al.*, 2023)

Although these definitions establish the fundamental principles of halal pharmaceutical products, previous literature emphasizes that achieving halal integrity is considerably more complex than complying with ingredient requirements alone. Pharmaceutical manufacturing commonly involves numerous raw materials, excipients, processing aids, shared production facilities, and complex global supply chains, all of which increase the risk of contamination, cross-contamination, or the incorporation of non-halal substances. Consequently, maintaining halal integrity throughout the pharmaceutical supply chain has become one of the most critical challenges facing the halal pharmaceutical industry, necessitating comprehensive regulatory standards, effective halal assurance systems, and robust traceability mechanisms (Herdiana *et al.*, 2024).

2.2 Common contamination risks in halal pharmaceuticals

Despite the establishment of comprehensive definitions and regulatory requirements for halal pharmaceuticals, ensuring halal compliance in practice remains a significant challenge. The complexity of modern pharmaceutical manufacturing, characterised by diverse raw material sources, sophisticated production processes, and global supply chains, increases the potential for halal integrity to be compromised. Previous studies have highlighted that contamination and cross-contamination with non-halal substances can occur at multiple stages of the pharmaceutical value chain if appropriate control measures are not implemented. Consequently, understanding the sources and pathways of contamination is essential for maintaining halal integrity and strengthening consumer confidence in halal pharmaceutical products.

According to the Institute for Foods, Drugs, and Cosmetics LPPOM (2025), contamination in halal pharmaceuticals refers to the presence or involvement of non-halal (haram or doubtful) substances at any stage of drug development, production, or distribution. One of the most common risks arises from raw materials, especially active ingredients and excipients derived from animal sources such as gelatine, enzymes, glycerine, or stearates. When these substances are sourced from pigs or from animals not slaughtered according to Islamic law, the halal status of the medicine becomes compromised. Another major contamination risk occurs during manufacturing and processing. Pharmaceutical facilities often produce both halal and non-halal products using the same equipment. If proper cleaning (*taharah*) and segregation procedures are not strictly followed, cross-contamination may occur. This includes shared mixers, pipelines, storage tanks, or packaging lines that previously handled non-halal substances, particularly porcine-based materials (Zaimy *et al.*, 2025).

2.3 Raw material in pharmaceutical products

Previous reviews have consistently identified the use of animal-derived pharmaceutical ingredients, particularly porcine excipients such as gelatine, glycerine, and magnesium stearate, as one of the most significant challenges in halal pharmaceutical development, as their origin is often difficult to verify. Suitable halal alternatives may not always provide equivalent technological and functional properties (Herdiana *et al.*, 2024). A Malaysian study on the halal pharmaceutical industry identified raw material traceability and documentation as important considerations for halal assurance, noting that complex supply chains and variations in certification practices can pose challenges during verification. (Nasihah, *et al.*, 2023). Although regulatory frameworks for halal pharmaceuticals continue to evolve, enhancing transparency in raw material sourcing remains an important consideration for strengthening halal verification and ensuring

consistent halal integrity (Alzeer, 2025). Consequently, these challenges may compromise compliance with Clause 4.4.2(i) of MS 2424:2019, which requires pharmaceutical products to be produced using ingredients that comply with *Shari'ah* requirements and are supported by appropriate verification and documentation.

2.4 Contamination in the processing facility

Cross-contamination remains a critical operational challenge in halal pharmaceutical manufacturing because many facilities use shared production equipment for multiple products to optimize efficiency and reduce costs. While this practice is common under Good Manufacturing Practice (GMP), it presents additional challenges for halal-certified production when equipment has previously been used to process materials containing *najis mughallazah*, particularly porcine-derived ingredients. In such cases, maintaining halal integrity requires not only compliance with conventional sanitation procedures but also adherence to *Shari'ah*-specific cleansing (*sertu* or *taharah*), validated cleaning protocols, equipment segregation, and documented verification procedures to prevent contamination throughout the manufacturing process. However, studies have reported that implementing these requirements can be challenging due to the need for dedicated production facilities, additional operational costs, specialized personnel training, and integration of halal requirements into existing pharmaceutical quality management systems. (Rahman *et al.*, 2024)

To address these risks, MS 2424:2019 requires pharmaceutical manufacturers to implement preventive controls rather than relying solely on end-product inspection. In practice, compliance with Clause 4.4.2(ii)(c) and Clauses 4.9.6–4.9.7 is achieved through the establishment of dedicated halal production lines or validated conversion procedures for equipment previously exposed to *najis mughallazah*, supervised *sertu* cleansing, physical segregation of halal and non-halal production areas, comprehensive cleaning validation records, and routine monitoring under a Halal Assurance System (HAS). These measures are intended to minimize the risk of cross-contamination while providing documented evidence of halal compliance during regulatory inspections and halal certification audits. Failure to implement these controls may compromise the halal integrity of pharmaceutical products and affect compliance with MS 2424:2019 (Yana, 2025; MS 2424:2019).

2.5 Lack of halal-based knowledge

Beyond technical and operational challenges, the effective implementation of halal pharmaceutical requirements also depends on the competency of personnel responsible for maintaining halal compliance throughout the pharmaceutical value chain. Previous studies have identified limited halal-related knowledge and a shortage of qualified personnel as important barriers to the sustainable development of the halal pharmaceutical industry. Amid (2024) reported that insufficient knowledge among manufacturers, suppliers, regulators, and prospective industry participants regarding halal requirements, certification procedures, and regulatory expectations may hinder industry development and market expansion. Similarly, Lowe (2010) noted that consumers and some healthcare stakeholders often have limited awareness of the ingredients used in medicines and their corresponding halal status, which may affect informed decision-making and confidence in halal pharmaceutical products.

The knowledge gap extends beyond general awareness and includes specialized competencies in *Shari'ah* requirements for pharmaceutical ingredients, halal risk assessment, raw material verification, halal assurance system (HAS) implementation, traceability, documentation, and the application of *sertu* (*taharah*) procedures where applicable. Without personnel possessing these competencies, pharmaceutical manufacturers may encounter difficulties in consistently implementing halal control measures throughout procurement, manufacturing, storage, and distribution processes. Consequently, the availability of trained halal professionals is essential to support compliance with Clauses 4.2.3, 4.2.4, 4.4.2(ii)(a), 4.6.1, and 4.7 of MS 2424:2019, which require organizations to establish competent halal management personnel, provide appropriate training, implement effective halal control measures, and maintain a documented Halal Assurance System.

3. Analysis and discussion

3.1 Issue 1: Use of non-halal raw materials and unclear ingredient origin

Halal pharmaceutical production is a reality in which, unfortunately, porcine-based excipients are still used among animal-derived raw materials due to their good availability, functional reliability, and cost-effectiveness. Apart from porcine-derived ingredients, halal verification also extends to other pharmaceutical materials such as active pharmaceutical ingredients (APIs), processing aids, solvents, synthetic materials, and biotechnology-derived materials, including cell culture media, growth media, cell banks, and seed lots used in the production of biological products and vaccines. The halal status of these materials must also be verified because they may originate from animal-derived or other non-halal sources. However, pharmaceutical companies usually buy raw materials through a complex global supply chain with many suppliers and negotiators, making it hard to trace the true origin of ingredients and increasing reliance on supplier declarations.

Apart from that, a Malaysian study on the halal pharmaceutical industry found that verifying the origin and documentation of raw materials remains complicated due to complex supply chains and inconsistent certification practices, raising consumer concerns about halal compliance (Nasihah *et al.*, 2023). Although Malaysia has established MS 2424:2019 as a comprehensive standard for halal pharmaceutical production, implementing halal verification remains challenging because pharmaceutical manufacturers often source raw materials from multiple countries with different halal certification systems and varying levels of transparency. These challenges are not limited to conventional pharmaceutical ingredients but also involve specialized materials used in biotechnology and vaccine production, where complete documentation and traceability are required to maintain halal integrity (Alzeer, 2025).

Thus, these challenges may compromise compliance with Clause 4.4.2 (i) of MS 2424:2019, which requires all raw materials used in halal pharmaceutical products to originate from halal sources and be properly verified and documented. Therefore, manufacturers are required not only to verify porcine-derived excipients but also to establish effective traceability and supplier verification systems for all pharmaceutical materials used throughout the production process to ensure continuous halal compliance.

3.2 Issue 2: Cross-contamination during manufacturing processes

One of the main reasons for cross-contamination in halal pharmaceuticals is their common production alongside non-halal products. This risk is posed by contamination of pharmaceutical products through the use of shared equipment with improper purification techniques (*samak* or *taharah*). This poses a significant risk of contamination when pharmaceutical products come into contact with *Najis*, such as porcine-derived materials. Besides contamination from shared manufacturing equipment, halal risks may also arise during the handling of processing aids, biological materials, cell culture media, growth media, and cell banks used in the production of vaccines and other biotechnology-based pharmaceutical products. Therefore, effective segregation and verification are required throughout the manufacturing process to ensure these materials remain free of contamination. Malaysian standards like MS 2424:2019, through Clauses 4.4.2(ii)(c), 4.9.6, and 4.9.7, would control this risk by requiring proper segregation, validated cleaning procedures, and efficient contamination control measures. However, difficulties in fulfilling these requirements arise from the high financial burden of establishing dedicated halal facilities, the limited halal-cleansing know-how of staff, constraints on production scheduling, and the lack of comprehensive halal-specific cleaning validation guidelines. Thus, manufacturers might accidentally fall short of halal-specific contamination control standards while adhering to general GMP requirements.

3.3 Issue 3: The lack of halal knowledge and expertise among industry stakeholders

Beyond technical issues related to raw materials and manufacturing processes, the sustainable implementation of halal pharmaceutical practices also depends on the availability of competent personnel with interdisciplinary expertise in both pharmaceutical sciences and *Shari'ah* requirements. Unlike conventional pharmaceutical production, halal pharmaceutical manufacturing requires professionals to understand not only pharmaceutical quality, safety, and efficacy, but also halal-specific requirements, including ingredient verification, halal risk assessment, traceability, documentation, supplier qualification, and implementation of the Halal Assurance System (HAS). However, previous studies have identified a shortage of personnel possessing these combined competencies, particularly among manufacturers, suppliers, quality assurance personnel, and regulatory stakeholders (Amid, 2024; Herdiana *et al.*, 2024). The limited availability of halal expertise presents broader implications than a simple knowledge gap. In practice, inadequate understanding of halal requirements may affect decision-making during supplier selection, verification of animal-derived ingredients, management of shared manufacturing facilities, and documentation required for halal certification. These challenges become more pronounced as pharmaceutical supply chains increasingly involve multinational suppliers, contract manufacturers, and complex sourcing networks, requiring personnel to interpret both pharmaceutical regulations and halal requirements simultaneously. Furthermore, previous studies have highlighted that organizational commitment, continuous professional training, and management support remain important determinants of successful halal implementation, yet these aspects are not consistently prioritized across the pharmaceutical industry (Mohezar *et al.*, 2016; Khan *et al.*, 2023). The contemporary challenges facing Malaysia's halal pharmaceutical industry extend beyond regulatory compliance and reflect broader operational, technical, and human capital constraints. While issues relating to animal-derived ingredients, cross-contamination risks, and limited halal expertise have been widely reported in the literature, they are closely interconnected rather than occurring independently. For example, difficulties in verifying raw material origins are compounded by increasingly complex global supply chains. In contrast, effective contamination control relies not only on infrastructure but also on competent personnel who can consistently implement halal assurance procedures. Similarly, the shortage of halal expertise may affect manufacturers' ability to integrate halal requirements into existing pharmaceutical quality management systems.

Rather than merely prescribing compliance requirements, MS 2424:2019 provides a structured framework to address these interconnected challenges through requirements on ingredient verification, contamination prevention, personnel competency, documentation, and the implementation of a Halal Assurance System. Nevertheless, the continued growth of the halal pharmaceutical industry requires complementary efforts beyond regulatory compliance, including greater investment in halal competency development, stronger collaboration between regulatory authorities and industry, harmonization of halal standards across international supply chains, and wider adoption of digital traceability technologies to improve transparency and supply chain integrity. Addressing these areas will be essential for enhancing the global competitiveness and long-term sustainability of Malaysia's halal pharmaceutical industry.

4. Implications

The findings of this review indicate that contemporary challenges in halal pharmaceutical manufacturing extend beyond technical compliance with halal requirements and have broader implications for pharmaceutical governance, supply chain management, healthcare practice, and consumer confidence. As pharmaceutical supply chains become increasingly globalised, ensuring the halal integrity of raw materials, manufacturing processes, and finished products requires greater transparency, traceability, and collaboration among manufacturers, suppliers, certification bodies, and regulatory authorities. Consequently, halal compliance should be viewed as an integrated quality management approach rather than solely a certification requirement. From an industrial perspective, pharmaceutical manufacturers are increasingly expected to incorporate halal considerations into existing pharmaceutical quality management systems throughout the product life cycle. This includes strengthening supplier qualification procedures, improving ingredient traceability, validating cleaning and segregation protocols, implementing robust Halal Assurance Systems (HAS), and maintaining comprehensive documentation to support halal verification. Such measures not only facilitate compliance with MS 2424:2019 but also enhance operational transparency, strengthen consumer confidence, and improve the competitiveness of Malaysian halal pharmaceutical products in international markets. The review also highlights that strengthening halal governance requires coordinated efforts among multiple stakeholders rather than relying solely on halal certification authorities. Regulatory agencies, halal certification bodies, pharmaceutical manufacturers, professional associations, academic institutions, and training providers each have complementary roles in developing industry competency. Continuous professional education, interdisciplinary training that integrates pharmaceutical

sciences with *Shari'ah* principles, and closer collaboration between academia and industry are essential to developing a workforce capable of consistently implementing halal requirements across increasingly complex pharmaceutical supply chains. Such collaborative initiatives are likely to improve organizational readiness for halal certification while supporting long-term industry sustainability. For healthcare professionals, greater transparency regarding the halal status of pharmaceutical ingredients is important for supporting patient-centred care, particularly when advising Muslim patients on treatment options. Improved access to reliable information on ingredient sources and halal certification can facilitate informed clinical decision-making, strengthen communication between healthcare providers and patients, and enhance confidence in prescribed medications without compromising therapeutic effectiveness. From a societal perspective, maintaining halal integrity is fundamental to protecting consumer trust and upholding the ethical principles underpinning halal pharmaceutical products. Public confidence depends not only on the availability of halal-certified medicines but also on transparent supply chains, credible certification systems, and consistent regulatory oversight. Therefore, strengthening halal pharmaceutical governance through improved traceability, digital documentation systems, competency development, and stakeholder collaboration will be critical for supporting the sustainable growth and international competitiveness of Malaysia's halal pharmaceutical industry.

While MS 2424:2019 provides a comprehensive framework for safeguarding halal integrity, its effectiveness depends on consistent implementation supported by competent personnel, robust Halal Assurance Systems, transparent supply chain management, and effective collaboration among industry, regulatory authorities, healthcare professionals, and academic institutions. Future efforts should therefore focus on strengthening integrated halal governance, enhancing workforce competency, improving traceability technologies, and promoting international harmonization of halal pharmaceutical standards. Addressing these priorities will contribute to a more resilient, transparent, and globally competitive halal pharmaceutical industry while reinforcing consumer confidence in halal-certified medicines.

5. Conclusion and recommendations

In conclusion, this review demonstrates that the implementation of halal pharmaceutical requirements in Malaysia is influenced by a combination of technical, operational, and organizational challenges rather than by isolated compliance issues. The review identified three interrelated implementation challenges: verification and traceability of halal raw materials, prevention of cross-contamination during pharmaceutical manufacturing, and limited availability of halal-specific knowledge and expertise among industry stakeholders. As pharmaceutical products increasingly involve complex formulations, biotechnology-derived ingredients, multinational supply chains, and multiple manufacturing partners, maintaining halal integrity requires a comprehensive, integrated approach across the entire pharmaceutical value chain.

The findings further suggest that MS 2424:2019 provides a comprehensive regulatory framework for safeguarding halal integrity by establishing requirements for ingredient verification, contamination control, personnel competency, documentation, and the implementation of a Halal Assurance System. Nevertheless, the effectiveness of the standard depends not only on regulatory compliance but also on consistent implementation by pharmaceutical manufacturers, transparent supplier verification, robust quality management practices, and effective collaboration among regulatory authorities, halal certification bodies, industry, academic institutions, and healthcare professionals. Therefore, the successful implementation of halal pharmaceutical requirements should be viewed as a shared responsibility that requires coordinated governance and continuous capacity-building across the pharmaceutical ecosystem.

This review contributes to the current body of knowledge by synthesizing contemporary implementation challenges within the Malaysian halal pharmaceutical industry and highlighting the practical role of MS 2424:2019 in supporting halal integrity. Moving forward, greater attention should be directed towards strengthening halal competency development, enhancing digital traceability and supply chain transparency, harmonizing halal verification practices across international supply chains, and investigating emerging issues associated with biotechnology-derived pharmaceuticals and advanced pharmaceutical manufacturing technologies. Addressing these priorities will strengthen the resilience, credibility, and global competitiveness of Malaysia's halal pharmaceutical industry while supporting the sustainable implementation of halal pharmaceutical standards.

References

Amid, A. (2024). Halal industry and issues. In solving halal industry issues through research in halal sciences (pp. 1-14). Singapore: Springer Nature Singapore.

Department of Standards Malaysia. (2019). MS 2424:2019 Halal pharmaceuticals – general requirements (First revision).

Herdiana, Y., Sofian, F. F., Shamsuddin, S., & Rusdiana, T. (2024). Towards halal pharmaceuticals: Exploring alternatives to animal-based ingredients. Heliyon, 10(1), https://doi.org/10.1016/j.heliyon.2023.e23624.

Latiff, J. A., Zakaria, Z., & Man, S. (2024). Advancing halal vaccine certification in Malaysia: Exploring the legal status criteria of Islamic principles through Fiqh rules. Journal of Ifta and Islamic Heritage, 3(1), 1-24,

Lowe, A. (2010). Steady demand drives the halal cosmetics industry. Gulf News.

Malaysian Standard (MS) 2424 Halal Pharmaceuticals, 2019. Retrieved from Department of Standards Malaysia: https://www.jsm.gov.my/announcement/781-kelulusan-malaysian-standards-ms-bil-5-2024

Musa, S. F. P. D., Sumardi, W. H., & Idris, P. D. S. R. P. H. (2025). The halal pharmaceutical supply chain traceability system: Malaysia, Brunei, Japan, and Brunei Darussalam. 382–383. 10.1007/978-981-96-0393-0_19.

Naimat, N., Mustafa, M. S. A., Nasrijal, N. M. H, & Mahat, I. R. (2023). Challenges and opportunities in the halal pharmaceutical industry in Malaysia. Information Management and Business Review, 15(4), 73-78, https://doi.org/10.22610/imbr.v15i4(I).3565

Nazar, Z., Ali, B., Rutter, P. M., & Barnes, N. (2025). Islamic reasoning and the use of prohibited medicines among Muslim patients: A qualitative study. International Journal of Clinical Pharmacy, 47(6), 10.1007/s11096-025-02046-3.

Rahman, S. A., Omar, F. Z., & Mohd Nor, S. B. (2024). A qualitative study on the implementation of *sertu* in pharmaceutical industry: Processes, issues and challenges. Current Trends in Biotechnology & Pharmacy, 18.

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Understanding the Malaysian halal certification framework for medical devices

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Received: 27/7/2026
Accepted: 30/7/2026
Published: 31/7/2026

Keywords:
Halal medical devices; Halal certification; MPPHM 2020; MHMS 2020; MS 2636:2019; Medical device authority

Abstract

This short communication analyses Malaysia's halal certification framework for medical devices using document analysis of the *Manual Prosedur Pensijilan Halal Malaysia (Domestik) 2020* (MPPHM), as amended in 2026, the Malaysian Halal Management System 2020 (MHMS), MS 2636:2019, and relevant medical-device legislation. The analysis shows that halal certification functions as an additional assurance layer built upon regulatory compliance. Within this framework, MPPHM establishes regulatory eligibility through registration with the Medical Device Authority (MDA) or an exemption, and through establishment licensing. MHMS provides halal management through the Halal Assurance System (HAS) or Internal Halal Control System (IHCS). At the same time, MS 2636:2019 defines technical requirements for materials, manufacturing, premises, contamination control, packaging, traceability, and internal audit. Collectively, these documents integrate regulatory, certification, management, and technical controls to safeguard the halal integrity, safety, and quality of medical devices.

1. Introduction

Medical devices comprise a broad range of instruments, implants, reagents, materials, software, and related articles intended for purposes such as diagnosis, prevention, monitoring, or treatment (Medical Device Act 2012, 2012). A specialised regulatory system governs their safety, quality, and performance. In Malaysia, this system is established principally through the Medical Device Act 2012 (Act 737), the Medical Device Regulations 2012, and subsequent subsidiary legislation issued under the Act. The Medical Device Authority (MDA), established under the Medical Device Authority Act 2012 (Act 738), administers and enforces the medical-device regulatory framework (Medical Device Authority Act 2012, 2012).

Halal considerations arise when a device contains, incorporates, or is manufactured using materials whose origin or processing may be uncertain from a Shariah perspective. Examples identified under the Malaysian halal certification procedure include sutures, humidifiers, dental floss, selected solutions, grafts, implants, and prosthetic products. The concern is not limited to the visible finished device. Raw materials, components, processing aids, manufacturing equipment, packaging materials, storage, and distribution may also affect halal integrity (Department of Islamic Development Malaysia [JAKIM], 2026).

Malaysia addresses these concerns through a framework that combines medical device regulation, halal certification procedures, internal halal management, and product-specific technical requirements. However, the functions of the relevant documents are sometimes discussed separately, which may create uncertainty among manufacturers and halal practitioners. The legal basis for the certification and marking of products as halal is provided by the Trade Descriptions (Certification and Marking of Halal) Order 2011, which recognises JAKIM and the respective State Islamic Religious Councils or Departments as competent authorities for halal certification (Trade Descriptions (Certification and Marking of Halal) Order 2011).

This short communication therefore explains the complementary roles of the *Manual Prosedur Pensijilan Halal Malaysia (Domestik) 2020* (MPPHM 2020), as amended by *Pekeliling Pensijilan Halal Malaysia Bilangan 1 Tahun 2026*, the Malaysian Halal Management System 2020 (MHMS 2020), and MS 2636:2019 Halal Medical Device - General Requirements. It also positions these halal requirements within the regulatory foundation provided by Act 737, the Medical Device Regulations 2012, and ISO 13485:2016.

2. Methodology

A descriptive document analysis was conducted using the primary documents governing the halal certification and regulatory control of medical devices in Malaysia. The analysis included the Medical Device Act 2012 (Act 737), the Medical Device Regulations 2012, the Medical Device (Duties and Obligations of Establishments) Regulations 2019, the Medical

Device (Exemption) Order 2024, the Medical Device (Compounding of Offences) Regulations 2024, the Medical Device (Amendment) Regulations 2025, the Medical Device (Designated Medical Device) Order 2026, the Trade Descriptions (Certification and Marking of Halal) Order 2011, the second edition of MDA Guidance Document MDA/GD/0027 on establishment licensing, MPPHM 2020 as amended in 2026, MHMS 2020, MS 2636:2019 and ISO 13485:2016. The documents were examined according to four functional dimensions reflected in the structure of the following discussion: (i) medical-device regulatory eligibility, (ii) halal certification procedures under MPPHM 2020 as amended in 2026, (iii) internal halal governance under MHMS 2020, and (iv) technical and operational controls under MS 2636:2019. The objective was not to compare the documents clause by clause, but to show how their different functions combine into a coherent certification framework.

3. The regulatory foundation for medical devices

The Medical Device Authority (MDA), established under the Medical Device Authority Act 2012 (Act 738), is responsible for regulating medical devices, the medical device industry, and related activities in Malaysia (Medical Device Authority Act 2012, 2012). Halal certification does not replace compliance with medical device regulations. Section 5 of the Medical Device Act 2012 (Act 737) establishes the requirement for medical-device registration, while Section 15 addresses establishment licensing (Medical Device Act 2012, 2012).

The Medical Device Regulations 2012 provide further requirements for conformity assessment, device registration, establishment licensing, and labelling. Conformity assessment covers the quality management system, post-market surveillance system, technical documentation, and declaration of conformity. These regulatory controls are principally directed at the safety, quality, and performance of medical devices (Medical Device Regulations 2012).

Post-market responsibilities are further governed by the Medical Device (Duties and Obligations of Establishments) Regulations 2019, which prescribe requirements for complaint handling, distribution records, mandatory problem reporting, field corrective action, and medical-device recall (Medical Device (Duties and Obligations of Establishments) Regulations 2019, 2019).

More recent subsidiary legislation has refined specific aspects of the medical-device regulatory framework. The Medical Device (Exemption) Order 2024 specifies exemptions from selected regulatory requirements and revokes the previous 2016 order. This instrument is relevant to halal certification because MPPHM 2020, as amended in 2026, permits an exemption letter from the MDA for devices that do not require device registration. The Medical Device (Compounding of Offences) Regulations 2024 identify offences that may be compounded. The Medical Device (Amendment) Regulations 2025 revise the application and registration fees for Class A medical devices with effect from 1 January 2026. The Medical Device (Designated Medical Device) Order 2026 specifies designated medical devices and their permitted uses. These instruments refine particular aspects of medical-device regulation but do not alter the principal halal certification requirements (Medical Device (Exemption) Order 2024, 2024; Medical Device (Compounding of Offences) Regulations 2024, 2024; Medical Device (Amendment) Regulations 2025, 2025; Medical Device (Designated Medical Device) Order 2026, 2026).

The second edition of the establishment licensing guidance further distinguishes the regulatory roles of manufacturers, authorised representatives, importers, and distributors (MDA, 2022). It specifies that a manufacturer must obtain quality management system certification to MS ISO 13485:2017 or ISO 13485:2016. In contrast, an authorised representative, importer, or distributor must obtain a certificate of conformity to Good Distribution Practice for Medical Devices (GDPMD) (MDA, 2022). For a local manufacturing premise seeking halal certification, the validity and appropriate scope of the MDA establishment licence are therefore important.

Taken together, these requirements establish the regulatory foundation for medical devices before halal certification is considered. Device registration, establishment licensing, conformity assessment, quality management, and post-market controls primarily address the safety, quality, and performance of medical devices. However, regulatory compliance alone does not confirm halal status. Halal certification, therefore, introduces an additional assurance layer that addresses material sources, manufacturing practices, contamination control, and ongoing halal integrity, as discussed in the following section.

4. Components of the halal certification framework

4.1 MPPHM 2020 as amended in 2026: Certification eligibility and procedure

MPPHM governs the application and administration of Malaysian halal certification. For the medical-device scheme, it links halal certification directly to regulatory status. Each device must possess a valid Medical Device Registration Certificate issued by the MDA or a letter confirming exemption from registration. In addition, the premises that process and manufacture the device must possess a valid MDA establishment licence (JAKIM, 2026).

The procedure also identifies the types of devices that may be considered under the scheme. These include devices for which the source of manufacturing materials or ingredients creates halal uncertainty, particularly materials associated with animals or alcohol. The listed examples include sutures, humidifiers, and dental floss, as well as liquid products such as dialysis or haemodialysis solutions, saline solutions, lubricants, wound-irrigation solutions, contact-lens solutions, and eye lubricants. Other examples include skin or surgical mesh, bone and vascular grafts, heart valves, stents, cochlear implants, intraocular lenses, and prosthetic devices. Eligibility remains subject to approval by the halal competent authority (JAKIM, 2026).

MPPHM requires compliance with MS 2636:2019, Act 737, the Medical Device Regulations 2012, and other current legislation enforced by the relevant authorities. It also specifies Muslim personnel and halal management requirements according to industry size. Large and medium industries must permanently appoint at least two Malaysian Muslim employees to the processing area during operations or shifts, appoint a Halal Executive at each branch, establish an Internal Halal Committee where required, and implement a Halal Assurance System (HAS). A small industry must appoint at least one such Muslim employee, appoint a Halal Supervisor, and implement an Internal Halal Control System (IHCS). A micro industry must appoint at least one such Muslim employee and

implement an IHCS (JAKIM, 2026).

4.2 MHMS 2020: Maintaining internal halal assurance

MHMS explains how a certified company develops, implements, and maintains internal halal control. It provides two levels of management system: IHCS for small and micro industries and HAS for large and medium industries. The distinction allows the depth of documentation and organisational control to be proportionate to the scale of the operation while maintaining essential halal safeguards.

IHCS represents the minimum internal control arrangement and includes a halal policy, a raw-material control or halal-risk control procedure, and a traceability procedure. HAS is more comprehensive. It includes a documented HAS manual, halal policy, Internal Halal Committee, halal internal audit, halal risk control, raw-material control, halal training, traceability, and management review. The company is responsible for ensuring that these controls remain effective throughout the validity of the Malaysian Halal Certification Certificate (JAKIM, 2020).

For medical-device manufacturing, the MHMS approach is especially relevant because material and component supply chains can be complex. Traceability should allow the company to identify materials and products through receiving, processing, storage, and distribution. Halal risk control requires identifying Halal Control Points, control mechanisms, responsible personnel, monitoring frequency, corrective actions, and records. Thus, MHMS converts the certification requirements into continuing organisational responsibilities.

4.3 MS 2636:2019: Technical and operational requirements

MS 2636:2019 specifies requirements for the manufacturing and handling of medical devices eligible for halal certification. The standard adopts a halal-built-in approach, whereby halal requirements are incorporated into product development and the overall management and control system, rather than assessed only at the end of production. The standard states that its requirements are to be incorporated with Act 737 and MS ISO 13485 as enforced by the relevant authority (Department of Standards Malaysia, 2019).

The standard requires that the medical device submitted for halal certification be registered with the competent medical device authority. It also requires a documented halal management system, appropriate Muslim personnel or an Internal Halal Committee, continuing halal training, adequate resources, and maintained records. The main Halal Control Points include sources of materials, equipment, and utilities used during manufacturing. Evidence of material origin may include recognised halal certificates, specifications describing the materials and processing methods, and manufacturing formulae or processing instructions (Department of Standards Malaysia, 2019).

All materials used in manufacturing must comply with halal requirements and be free from *najis*. The standard addresses synthetic materials, natural materials, and genetically modified sources, as well as manufacturing premises, equipment, manufacturing and storage areas, transportation, quality-control activities, packaging, and labelling. Controls are intended to prevent contact or cross-contamination with non-halal materials. Where a facility or equipment has previously been used for *najis mughallazah*, cleansing by *sertu* is required under the stated conditions before conversion to a dedicated halal line (Department of Standards Malaysia, 2019).

MS 2636:2019 also extends halal assurance beyond production. Distribution must minimise risks to halal integrity; outsourced activities must be defined, agreed and controlled through written arrangements; and a post-market halal surveillance mechanism should be established. Complaints involving halal non-conformity must be investigated and corrective action taken. An internal audit is required annually to monitor compliance with halal requirements and MS ISO 13485 (Department of Standards Malaysia, 2019). These requirements connect halal integrity with the established quality management practices in the medical device sector.

5. An integrated framework

The three halal documents perform different but complementary functions. MPPHM determines whether the product and applicant meet the certification conditions and prescribes the administrative and scheme-specific requirements. MHMS establishes the internal governance needed to maintain halal assurance. MS 2636:2019 provides the technical requirements for materials, facilities, and operations. Their complementary functions are summarised in Table 1.

Collectively, these documents form a complementary and layered framework. The applicable MDA requirements provide the regulatory foundation for device registration, establishment licensing, safety, quality, and performance. MPPHM 2020, as amended in 2026, establishes the eligibility and procedural requirements for halal certification, while MHMS 2020 and MS 2636:2019 provide the internal governance and technical controls required to demonstrate and maintain halal compliance. Following certification, traceability, internal audit, complaint handling, and post-market controls support continuing halal assurance.

6. Practical implications, challenges, and future directions

MDA registration confirms regulatory compliance relating to the medical-device registration framework, but it does not confirm that the device is halal. Conversely, halal certification should not be interpreted as a substitute for regulatory assessment of safety and performance. The two systems address distinct but related expectations. This distinction is important in product communication so that a halal mark is not presented as a general regulatory endorsement.

Within this complementary framework, material documentation becomes a central halal control point. Medical devices may contain several layers of materials, including primary components, coatings, adhesives, lubricants, solvents, processing aids, and packaging materials. The halal status of a finished product, therefore, depends on sufficient information from the supply chain. The manufacturer should be able to identify the original material producer, the material composition, the processing method, and relevant supporting evidence. Changes in suppliers, formulations, or manufacturing processes should trigger an assessment of their potential effects on both product quality and halal integrity.

Halal controls may be integrated with the existing medical device quality management system. ISO 13485 requires documented quality processes, purchasing controls, traceability where applicable, internal audits, corrective actions, and record retention (International Organization for Standardization, 2016). These structures can support halal assurance when halal-specific criteria are incorporated. For example, supplier approval may include verification of halal-critical materials, while change control may include an assessment of halal impact. Quality and halal audits may also be coordinated when examining related evidence, while preserving their distinct objectives, criteria, and required records.

Table 1: Complementary functions of the principal documents in the Malaysian halal medical-device framework

Document	Primary function	Key contribution
MPPHM 2020, as amended in 2026	Certification procedure and scheme eligibility	Requires valid MDA device registration or exemption, a valid establishment licence, an eligible product scope, Muslim personnel, and implementation of MHMS.
MHMS 2020	Internal halal management and control	Provides HAS for large and medium industries and IHCS for small and micro industries, including risk control, traceability, training, audit, and records.
MS 2636:2019	Technical manufacturing and handling requirements	Controls materials, components, premises, equipment, manufacturing, contamination, packaging, storage, distribution, outsourcing, and post-market halal issues.
Act 737, Medical Device Regulations 2012, post-market regulations, MDA/GD/0027, and ISO 13485:2016	Regulatory and quality foundation	Addresses device registration, conformity assessment, establishment roles and licensing, post-market obligations, and quality management for safety and performance.

However, a uniform assessment may not be appropriate for all medical devices. A dialysis solution, an animal-derived bone graft, and a synthetic prosthetic component may involve different materials, processes, and halal risks. Product assessment should therefore consider the intended purpose, material and component origins, processing aids, manufacturing processes, outsourced operations, and potential contamination pathways. Potential implementation challenges include obtaining sufficient evidence from international suppliers, addressing differences in certification requirements across jurisdictions, and developing personnel with combined expertise in halal requirements and medical device regulations (Astiwara, 2023; Jailani & Jezani, 2024).

Recent studies indicate growing interest in halal medical devices for religious assurance, medical tourism, and international market opportunities (Jamal & Jamaludin, 2024; Sarisae *et al.*, 2023). Nevertheless, empirical research involving medical-device manufacturers remains limited. Future research should examine supplier documentation practices, product-specific Halal Control Points, coordination with ISO 13485, and multidisciplinary human talent development. Comparative studies across jurisdictions may also support clearer guidance and greater international harmonisation of halal medical-device certification.

7. Conclusion

Malaysia's halal certification framework for medical devices is not based on a single document. It is formed through the interaction of medical-device legislation and four complementary functions: regulatory eligibility, halal certification procedure, internal halal governance, and technical control. MPPHM 2020, as amended in 2026, links certification to valid MDA device registration or exemption and to establishment licensing, defines eligible products, and specifies scheme requirements. MHMS 2020 provides the HAS or IHCS needed to maintain internal control, while MS 2636:2019 translates Shariah requirements into controls for materials, facilities, manufacturing, packaging, distribution, and post-market activities. Reading these documents together clarifies that halal assurance complements rather than replaces safety, quality, and performance requirements. Effective implementation, therefore, depends on coordinated regulatory compliance, traceable material evidence, competent halal personnel, and integration of halal controls into the existing medical-device quality management system.

Conflict of interest

The authors declare no competing interests.

AI declaration

Artificial Intelligence (AI) tools, including ChatGPT (OpenAI, San Francisco, CA), were used to assist with language editing, improve sentence structure, and clarify grammar during manuscript preparation. The authors reviewed, verified, and take full responsibility for the accuracy and integrity of the content. No AI tools were used for data analysis, result interpretation, or scientific conclusions.

Author contribution

Author 1: project administration, conceptualization, methodology, formal analysis, investigation, data curation, writing original draft preparation, writing, reviewing, and editing. Author 2: writing, reviewing, and editing. Author 3: writing, reviewing, and editing.

References

Astiwara, E. M. (2023). Halal certification regulation on health products: A global comparative study. International Journal of Science and Society, 5(3), 470–483. https://doi.org/10.54783/ijsoc.v5i3.1422

Department of Islamic Development Malaysia. (2020). Malaysian Halal Management System 2020 (MHMS 2020).

Department of Islamic Development Malaysia. (2026). *Pekeliling Pensijilan Halal Malaysia Bilangan 1 Tahun 2026: Pindaan Manual Prosedur Pensijilan Halal Malaysia (Domestik) 2020*.

Department of Standards Malaysia. (2019). Halal medical device - General requirements (MS 2636:2019).

International Organisation for Standardisation. (2016). Medical devices - Quality management systems -Requirements for regulatory purposes (ISO 13485:2016).

Jailani, M. D. A., & Jezani, S. N. (2024). Halal in the medical and pharmaceutical sector: Recent issues, standard guidelines, and state-of-the-art. In: Rahman, N.A.A., Ali, M.H. (eds) Emerging Technology and Crisis Management in the Halal Industry. Springer, Singapore. https://doi.org/10.1007/978-981-97-1375-2_14

Jamal, A. Z. A., & Jamaludin, M. A. (2024). Halal medical tourism and reproductive care and services: An overview of the Malaysian marketplace. Journal of Halal Industry & Services, 7(1). https://doi.org/10.36877/jhis.a0000528

Medical Device (Amendment) Regulations 2025 (Malaysia).

Medical Device (Compounding of Offences) Regulations 2024 (Malaysia).

Medical Device (Designated Medical Device) Order 2026 (Malaysia).

Medical Device (Duties and Obligations of Establishments) Regulations 2019 (Malaysia).

Medical Device (Exemption) Order 2024 (Malaysia).

Medical Device Act 2012 (Act 737) (Malaysia).

Medical Device Authority Act 2012 (Act 738) (Malaysia).

Medical Device Authority. (2022). Licensing for establishment (MDA/GD/0027, 2nd ed.).

Medical Device Regulations (2012). (Malaysia).

Sarisae, S., Benrit, P., & Salaeh, N. (2023). The need for halal certification of medical devices: A case study of Thailand. Journal of Halal Science and Technology, 2(1), 32–39. https://doi.org/10.59202/jhst.v2i1.664

Trade Descriptions (Certification and Marking of Halal) Order 2011 (Malaysia).

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Operationalizing halal assurance within the quality-by-design pharmaceutical development lifecycle: A conceptual framework for biopharmaceutical development

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Received: 14/7/2026
Accepted: 20/7/2026
Published: 31/7/2026

Keywords:
Quality-by-Design (QbD); Halal assurance; Biopharmaceuticals; Pharmaceutical development; Conceptual framework; Pharmaceutical quality system

Abstract

Halal assurance is increasingly recognized as an important consideration in biopharmaceutical development. However, existing halal assurance and regulatory frameworks remain largely focused on organizational governance, material compliance, certification, traceability, and risk management, without explicitly operationalizing halal assurance within the Quality-by-Design (QbD) pharmaceutical development lifecycle. This Short Communication proposes a conceptual framework that operationalizes halal assurance across each stage of the QbD lifecycle, from the Quality Target Product Profile (QTPP) through Product Lifecycle Management. Rather than introducing a separate halal management framework, the proposed framework complements existing halal governance by embedding halal assurance within established pharmaceutical quality principles, thereby providing a practical foundation for systematic, proactive, and lifecycle-oriented halal biopharmaceutical development.

1. Introduction

Biopharmaceuticals, including vaccines, recombinant proteins, monoclonal antibodies, gene therapies, cell-based therapies, and other advanced biological products, have become increasingly important in the prevention and treatment of a wide range of diseases (Radenković, 2025). Unlike conventional pharmaceuticals, which are small-molecule pharmaceuticals, these products are developed and manufactured using complex biological systems involving living cells, culture media, biological processing aids, and multistage purification processes, rendering them inherently susceptible to process variability that may affect product quality, safety, and efficacy (Yeop *et al.*, 2025). Consequently, a systematic and science-based approach to pharmaceutical development is essential to ensure robust process performance and consistent product quality. The Quality-by-Design (QbD) paradigm has therefore become a cornerstone of modern pharmaceutical development by emphasizing predefined quality objectives, product and process understanding, science- and risk-based decision-making, and lifecycle management to achieve the desired product quality consistently (International Council for Harmonisation (ICH), 2009; ICH, 2023; Lee *et al.*, 2022).

Alongside advances in biopharmaceutical development, increasing attention has been directed toward ensuring that the products comply not only with regulatory requirements for quality, safety, and efficacy but also with halal principles. The expanding halal pharmaceutical market drives this growing interest, evolving regulatory frameworks, and increasing consumer expectations for medicines that satisfy both scientific and religious requirements (Herdiana *et al.*, 2024; Naimat *et al.*, 2024). In biopharmaceutical manufacturing, halal assurance extends beyond the assessment of active ingredients to include the halal integrity of cell substrates, culture media, recombinant materials, processing aids, and/or ancillaries, downstream purification processes, and the prevention of cross-contamination throughout the entire manufacturing lifecycle (Deliaz *et al.*, 2025; Zulkarnain *et al.*, 2021). Consequently, halal assurance is increasingly recognized as an integral consideration in biopharmaceutical development, highlighting the need for systematic approaches that can embed halal considerations throughout the product development lifecycle rather than relying solely on end-product certification.

Despite these advances, current approaches to halal assurance remain largely centred on ingredient permissibility, halal certification, halal management systems, traceability technologies, and halal risk assessment (Herdiana *et al.*, 2024; Pehin Dato Musa *et al.*, 2025; Tan *et al.*, 2023). In Malaysia, these elements are operationalized through the Malaysian Halal Management System (MHMS), which establishes organizational requirements for Halal Assurance Systems

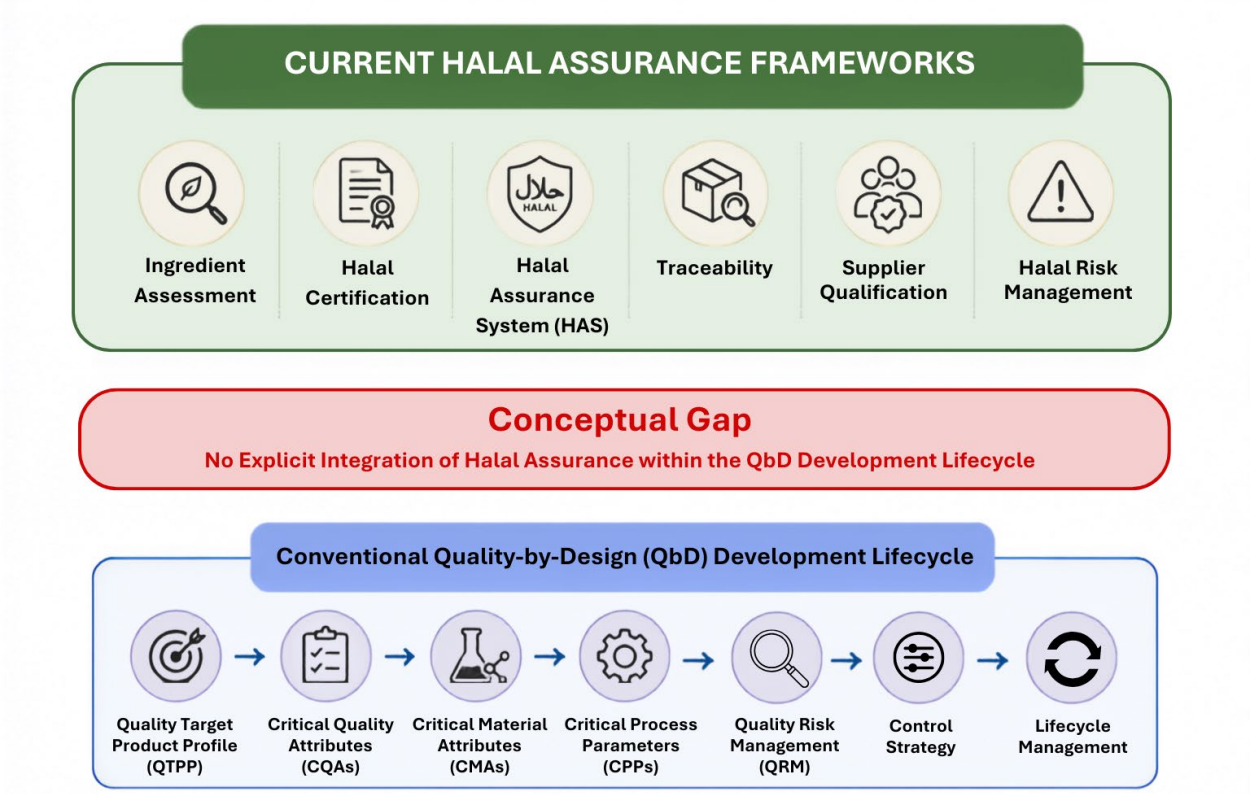

Figure 1: Conceptual comparison between the principal operational components of existing halal assurance frameworks and the conventional Quality-by-Design (QbD) pharmaceutical development lifecycle. The halal assurance components are conceptually synthesized from the Malaysian Halal Management System (MHMS 2020), Malaysian Standard MS 2424:2019, and the contemporary halal pharmaceutical literature, highlighting the absence of explicit operational integration of halal assurance across development-stage activities.

(HAS), including halal risk control, raw material control, traceability, internal halal audits, training, and other governance mechanisms to maintain halal integrity throughout manufacturing (Jabatan Kemajuan Islam Malaysia (JAKIM), 2020). Complementing MHMS, Malaysian Standard MS 2424:2019 establishes the general requirements for halal pharmaceuticals, including provisions applicable to biopharmaceutical products, by addressing materials, manufacturing, quality systems, documentation, personnel, and Halal Management Systems while including general requirements applicable to biopharmaceutical products (Department of Standards Malaysia, 2019). Nevertheless, the standard primarily emphasizes material compliance, manufacturing controls, and halal management requirements, while providing limited guidance on how halal assurance can be systematically operationalized within the Quality-by-Design (QbD) pharmaceutical development lifecycle, particularly for biopharmaceutical products.

Collectively, these regulatory frameworks have substantially strengthened halal governance and compliance within biopharmaceutical manufacturing. However, they primarily provide organizational and operational requirements for maintaining halal assurance and do not explicitly integrate halal considerations into the scientific decision-making processes that underpin product and process development within the QbD paradigm (Figure 1). The six components presented under the "Current Halal Assurance Frameworks" in Figure 1 represent a conceptual synthesis of the principal operational elements consistently reflected across the Malaysian Halal Management System (MHMS 2020), Malaysian Standard MS 2424:2019, and the contemporary halal pharmaceutical literature (Department of Standards Malaysia, 2019; JAKIM, 2020; Herdiana *et al.*, 2024; Tan *et al.*, 2023; Pehin Dato Musa *et al.*, 2025). These elements comprise ingredient assessment, halal certification, Halal Assurance Systems (HAS), traceability, supplier qualification, and halal risk management, collectively characterizing the current operational focus of halal pharmaceutical governance. While these frameworks establish comprehensive organizational and compliance requirements for maintaining halal integrity, they do not explicitly align halal assurance activities with the scientific stages of pharmaceutical development described in the Quality-by-Design (QbD) paradigm (Department of Standards Malaysia, 2019; JAKIM, 2020; ICH, 2009; ICH, 2023). Consequently, halal assurance considerations are predominantly addressed through organizational governance and operational compliance mechanisms rather than being systematically integrated into development-stage activities such as defining product quality objectives, identifying critical material and process attributes, and performing Quality Risk Management (QRM) (Department of Standards Malaysia, 2019; JAKIM, 2020; ICH, 2009; ICH, 2023). This conceptual separation highlights an opportunity to operationalize halal assurance within the established QbD lifecycle while complementing, rather than replacing, existing halal governance frameworks.

In contrast, Quality-by-Design (QbD) is a systematic, science- and risk-based approach to pharmaceutical development that emphasizes building quality into a product from the earliest stages of design rather than relying solely on end-product testing (ICH, 2009; ICH, 2023). First introduced through the International Council for Harmonisation (ICH) Guideline Q8(R2) on Pharmaceutical Development and supported by

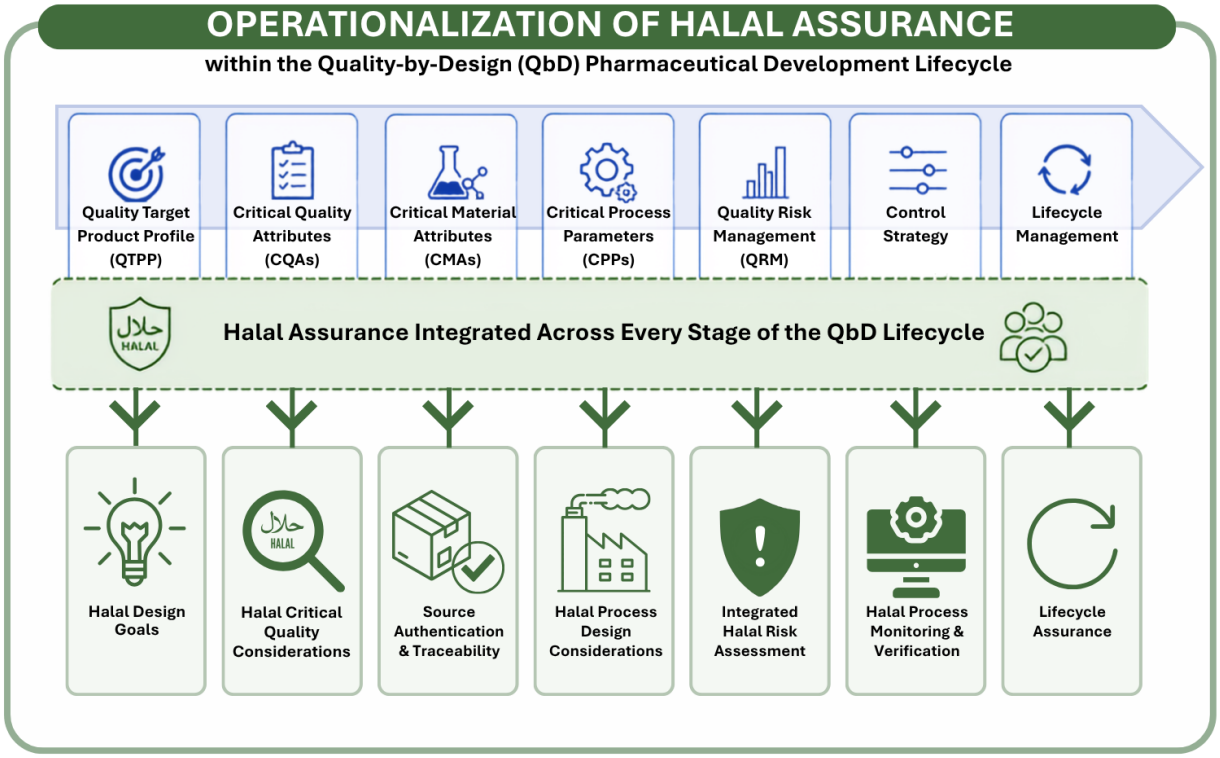

Figure 2: Proposed conceptual framework illustrating the systematic integration of halal assurance considerations across each stage of the Quality-by-Design (QbD) pharmaceutical development lifecycle, from Quality Target Product Profile (QTPP) definition to lifecycle management.

complementary guidelines on Quality Risk Management (Q9(R1)) and Pharmaceutical Quality Systems (Q10), QbD provides a structured framework for designing robust manufacturing processes that consistently deliver products meeting predefined quality requirements (ICH, 2008; ICH, 2009; ICH, 2023). The QbD paradigm is underpinned by several interconnected principles, including the definition of the Quality Target Product Profile (QTPP), identification of Critical Quality Attributes (CQAs), evaluation of Critical Material Attributes (CMAs) and Critical Process Parameters (CPPs), application of Quality Risk Management (QRM), establishment of an appropriate control strategy, and continual lifecycle improvement (ICH, 2008; ICH, 2009; ICH, 2023; Simões *et al.*, 2024). Together, these elements enable systematic, science- and risk-based decision-making throughout pharmaceutical product and process development.

Accordingly, this Short Communication proposes an operational conceptual framework that systematically aligns halal assurance principles with the established Quality-by-Design (QbD) lifecycle for biopharmaceutical development (Figure 2). Rather than introducing a new halal assurance system or modifying existing QbD principles, the proposed framework serves as a translation layer that operationalizes halal assurance considerations within each stage of the QbD lifecycle. By integrating halal assurance considerations from the QTPP through Lifecycle Management, the framework promotes a proactive approach in which halal requirements are considered alongside quality, safety, and process development throughout the product lifecycle.

The proposed framework begins with the QTPP, which defines the intended characteristics of the final product and serves as the foundation for subsequent product and process development decisions (ICH, 2009; Lee *et al.*, 2022). Within the proposed framework, halal assurance is incorporated at this stage by incorporating halal requirements as predefined design objectives. These objectives subsequently inform decisions on material selection, process design, risk assessment, and manufacturing controls throughout the development lifecycle, consistent with the central role of the Quality Target Product Profile (QTPP) in guiding downstream pharmaceutical development activities (Rustandi *et al.*, 2026; Simões *et al.*, 2024). In the proposed framework, halal assurance is treated as a predefined design objective rather than solely as an end-product certification requirement. This approach enables proactive planning, supports risk-informed decision-making, and minimizes the need for corrective measures during later stages of development.

Following the establishment of the QTPP, the framework systematically identifies the Critical Quality Attributes (CQAs) and Critical Material Attributes (CMAs) that may influence both product quality and halal assurance. CQAs define the physical, chemical, biological, and microbiological characteristics that should be maintained within appropriate limits to ensure the desired product quality, whereas CMAs describe the critical physical, chemical, biological, or microbiological properties of raw materials and process inputs that may affect these quality attributes (ICH, 2009; Rustandi *et al.*, 2026; Simões *et al.*, 2024). Within the proposed framework, material evaluation is extended beyond conventional quality specifications to include source authenticity, halal status, traceability, supplier qualification, and the consistency of material attributes relevant to halal assurance. This is particularly important for biologically derived materials, including cell substrates, culture media,

recombinant materials, and processing aids, where variability in source and material characteristics may influence both product quality and the robustness of halal assurance (Herdiana *et al.*, 2026; Yeop *et al.*, 2025). Accordingly, materials that satisfy conventional quality specifications, but present unresolved halal concerns would be identified as requiring further evaluation during the CMA assessment stage, where they become inputs to subsequent halal risk assessment and process optimization.

Building upon the identification of Critical Quality Attributes (CQAs) and Critical Material Attributes (CMAs), the proposed framework next evaluates Critical Process Parameters (CPPs) through the application of Quality Risk Management (QRM) to identify manufacturing steps that may influence both product quality and halal assurance. CPPs are process variables that should be monitored and controlled to ensure that the desired product quality is consistently achieved, while QRM provides a systematic process for identifying, assessing, controlling, communicating, and reviewing risks throughout product development and manufacturing (ICH, 2009; ICH, 2023; Simões *et al.*, 2024). Within the proposed framework, the existing QRM process is expanded to explicitly evaluate risks that may compromise halal assurance during manufacturing while complementing existing organizational halal risk management requirements. Although the Malaysian Halal Management System (MHMS) requires organizations to establish dedicated halal risk control as part of the Halal Assurance System (HAS), these requirements primarily support organizational governance and operational compliance (JAKIM, 2020). By contrast, QRM within the QbD paradigm serves as the established framework for evaluating risks associated with product and process development. Accordingly, the proposed framework complements the organizational halal governance established by MHMS by operationalizing halal assurance within the established QRM process of the QbD pharmaceutical development lifecycle, rather than introducing a separate development-stage halal risk management framework. These risks include the use of non-halal processing aids and/or ancillaries, shared manufacturing facilities, inadequate cleaning validation, cross-contamination, changes in raw material suppliers, and process modifications that may compromise halal integrity (Herdiana *et al.*, 2024; Naimat *et al.*, 2023). Integrating these considerations into routine QRM facilitates the early identification and mitigation of risks to halal assurance during process development. Consequently, appropriate risk control measures can be implemented before process optimization, technology transfer, or commercial manufacturing, thereby embedding halal assurance as a proactive component of process development and control throughout the QbD lifecycle.

Finally, the Control Strategy, which traditionally establishes a comprehensive set of controls to ensure consistent product quality throughout manufacturing, is expanded to incorporate halal assurance measures that preserve both product quality and halal integrity throughout the product lifecycle. In addition to conventional quality controls, the proposed framework

Table 1: Operational halal assurance considerations associated with each stage of the Quality-by-Design (QbD) pharmaceutical development lifecycle

QbD Lifecycle Stage	Primary QbD Function	Operational Halal Assurance Considerations
Quality Target Product Profile (QTPP)	Define intended product quality objectives.	Incorporate halal assurance as a predefined product objective, including intended market requirements, halal expectations, and overall product design considerations.
Critical Quality Attributes (CQAs)	Identify product quality attributes critical to safety, efficacy, and quality.	Evaluate critical quality attributes from both quality and halal assurance perspectives to ensure compatibility with predefined halal design goals.
Critical Material Attributes (CMAs)	Identify material characteristics that may influence product quality.	Assess material origin, halal status, source authentication, supplier qualification, traceability, and the suitability of biologically derived materials, excipients, and processing aids.
Critical Process Parameters (CPPs)	Identify and control process parameters affecting product quality.	Evaluate halal-sensitive manufacturing processes, including segregation, cleaning validation, cross-contamination prevention, and process modifications that may affect halal integrity.
Quality Risk Management (QRM)	Systematically identify, evaluate, control, communicate, and review quality risks.	Integrate halal assurance into routine risk assessments by identifying and mitigating risks that may compromise halal integrity throughout product development and manufacturing.
Control Strategy	Establish planned controls to achieve predefined product quality consistently.	Implement process monitoring, documentation, verification, supplier qualification, end-to-end material traceability, and complementary Halal Assurance System (HAS) activities to maintain halal integrity throughout manufacturing.
Lifecycle Management	Maintain product quality through continual monitoring, change management, and continuous improvement.	Evaluate changes in materials, suppliers, processes, facilities, analytical methods, and technologies from both quality and halal assurance perspectives to ensure sustained halal integrity throughout the product lifecycle.

integrates halal-specific activities, including supplier qualification, end-to-end material traceability, process monitoring, documentation, and verification mechanisms to ensure that halal-critical materials, processing aids, and ancillaries, and manufacturing operations maintain halal integrity throughout manufacturing (ICH, 2009; Herdiana *et al.*, 2024; Pehin Dato Musa *et al.*, 2025). This integrated control approach complements existing Halal Assurance Systems (HAS) by strengthening transparency, facilitating regulatory compliance, reducing the risk of cross-contamination, and supporting the continuous verification of halal integrity from raw material sourcing to the finished product (Pehin Dato Musa *et al.*, 2025). Furthermore, Lifecycle Management extends halal assurance beyond initial product development by ensuring that changes in raw materials, suppliers, manufacturing processes, facilities, analytical methods, or technologies continue to be evaluated from both quality and halal assurance perspectives throughout the product lifecycle. Consistent with the Pharmaceutical Quality System described in ICH Q10, continual monitoring, change management, and continual improvement ensure that halal assurance is maintained as manufacturing processes evolve, thereby supporting sustained compliance with both regulatory and *Shari'ah* requirements (ICH, 2008). Consequently, halal assurance becomes embedded within the pharmaceutical quality system as a continuous lifecycle activity rather than a standalone certification exercise. The operational considerations associated with each stage of the proposed framework are summarized in Table 1.

The proposed framework, summarized in Table 1, provides a conceptual architecture for operationalizing halal assurance within the established Quality-by-Design (QbD) lifecycle for biopharmaceutical manufacturing. Rather than proposing a separate halal management framework, it demonstrates how halal assurance can be systematically embedded into existing pharmaceutical development activities, from defining product objectives and evaluating critical quality and material attributes to managing process risks, establishing control strategies, and enabling continual lifecycle improvement. By aligning halal assurance with internationally recognized pharmaceutical quality principles, the framework complements existing Halal Assurance Systems while promoting proactive risk prevention, transparency, and regulatory consistency throughout product development. Furthermore, the framework extends existing halal pharmaceutical guidance by providing a systematic approach for operationalizing halal assurance within the QbD pharmaceutical development lifecycle, particularly for biopharmaceutical products, where current standards primarily provide general requirements. Although conceptual in nature, the proposed framework provides a foundation for future validation using representative biopharmaceutical products, manufacturing platforms, and industrial case studies to assess its feasibility, adaptability, and practical application in halal pharmaceutical development. Beyond experimental validation, the framework may also provide a conceptual foundation for future supplementary guidance supporting the implementation of Quality-by-Design principles in halal biopharmaceutical development. If successfully validated, this framework may facilitate the systematic integration of halal assurance within established pharmaceutical quality systems, supporting the development of biopharmaceutical products that satisfy both regulatory quality expectations and *Shari'ah* requirements.

2. Acknowledgement

The authors gratefully acknowledge the support provided by the International Institute for Halal Research and Training (INHART), International Islamic University Malaysia (IIUM), in facilitating this work.

3. Conflict of interest

The authors declare no competing interests.

4. AI declaration

Artificial Intelligence (AI) tools, including ChatGPT (OpenAI, San Francisco, CA), were used to assist in language editing, improving sentence structure, and clarifying grammar during the manuscript preparation stage. The authors reviewed, verified, and take full responsibility for the accuracy and integrity of the content. No AI tools were used for data analysis, result interpretation, or scientific conclusions.

6. Author contribution

Yumi Zuhanis Has-Yun Hashim: conceptualization, methodology, writing, reviewing and editing, supervision. Phirdaous Abbas: project administration, conceptualization, methodology, formal analysis, investigation, original draft preparation, writing, reviewing, and editing. Nurhusna Samsudin: reviewing and editing. Mohammad Aizat Jamaludin: reviewing and editing. Mohd Hafidz Mahamad Maifiah: reviewing and editing.

References

Deliaz, M., Kurniawan, A., Sari, F., & Setiadi, F. (2025). Halal alternative raw materials for pharmaceutical and cosmetic applications: A systematic review. Journal of Halal Product and Research, 8, 171–179. https://doi.org/10.20473/jhpr.vol.8-issue.2.171-179

Department of Standards Malaysia. (2019). MS 2424:2019: Halal pharmaceuticals— General requirements (1st rev.). Selangor: Department of Standards Malaysia.

Herdiana, Y., Mahmood, S., Halimah, E., & Sofian, F. F. (2026). Translational barriers to pharmaceutical excipient readiness in marine-derived polymers. Polymers, 18(10), 1179. https://doi.org/10.3390/polym18101179

Herdiana, Y., Sofian, F. F., Shamsuddin, S., & Rusdiana, T. (2024). Towards halal pharmaceutical: Exploring alternatives to animal-based ingredients. Heliyon, 10(1), e23624. https://doi.org/10.1016/j.heliyon.2023.e23624

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. (2008). ICH harmonised tripartite guideline: Pharmaceutical quality system Q10. https://database.ich.org/sites/default/files/Q10_Guideline.pdf

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. (2009). ICH harmonised tripartite guideline Q8(R2): Pharmaceutical development. https://www.ich.org/page/quality-guidelines

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. (2023). ICH harmonised guideline Q9(R1): Quality risk management. https://www.ich.org/page/quality-guidelines

Jabatan Kemajuan Islam Malaysia. (2020). Malaysian Halal Management System (MHMS) 2020 / Sistem Pengurusan Halal Malaysia (MHMS) 2020. Putrajaya: Jabatan Kemajuan Islam Malaysia.

Lee, S.-H., Kim, J.-K., Jee, J.-P., Jang, D.-J., Park, Y.-J., & Kim, J.-E. (2022). Quality by design (QbD) application for the pharmaceutical development process. Journal of Pharmaceutical Investigation, 52(6), 649–682. https://doi.org/10.1007/s40005-022-00575-x

Naimat, N., Mustafa, M. S. A., Nasrijal, N. M. H., & Mahat, I. R. (2024). Challenges and opportunities in the halal pharmaceutical industry in Malaysia. Information Management and Business Review, 15(4(I)). https://doi.org/10.22610/imbr.v15i4(I).3565

Pehin Dato Musa, S. F., Sumardi, W. H., & Idris, R. (2025). The halal pharmaceutical supply chain traceability system: Malaysia, Japan and Brunei Darussalam. In R. Idris, M. A. Tareq, S. F. Pehin Dato Musa, & W. H. Sumardi (Eds.), The Halal Industry in Asia: Perspectives from Brunei Darussalam, Malaysia, Japan, Indonesia and China (pp. 371-387). Springer Nature Singapore. https://doi.org/10.1007/978-981-96-0393-0_19

Radenković, M. (2025). Biopharmaceuticals—current information and new challenges. Scientia Pharmaceutica, 93(4), 59. https://doi.org/10.3390/scipharm93040059

Rustandi, T., Andri, D., & Hayati, F. (2026). Application of failure mode effect analysis (FMEA) in the traditional medicine Industry: A case study on spirulina capsule production. Borneo in Pharmacology. https://doi.org/10.21203/rs.3.rs-2740070/v1

Simões, A., Veiga, F., & Vitorino, C. (2024). Question-based review for pharmaceutical development: An enhanced quality approach. European Journal of Pharmaceutics and Biopharmaceutics, 195, 114174. https://doi.org/10.1016/j.ejpb.2023.114174

Tan, K.-L., Othman, A., Mohd Subri, I., Zulkifli, N., Mahyeddin, M., Yahaya, N., Sulaiman, M. (2023). The incorporation of the halal management system (HMS) by the pharmaceutical industry. Generics and Biosimilars Initiative Journal, 12, 87–94. https://doi.org/10.5639/gabij.2023.1203.014

Yeop, K.-w., Nam, H.-j., Shim, C.-j., Yang, S.-m., Kim, H.-w., Park, C. I., Mok, Y. (2025). Optimizing clarification processes in biopharmaceutical manufacturing through quality by design: Strategies, implications, and future prospects. Biotechnology Progress, 41(6), e70063. https://doi.org/10.1002/btpr.70063

Zulkarnain, N. N., Anuar, N., Abd. Rahman, N., Sheikh Abdullah, S. R., Alias, M. N., Yaacob, M., Ding, G. (2021). Cell-based influenza vaccine: Current production, halal status assessment, and recommendations towards Islamic-compliant manufacturing. Human Vaccines & Immunotherapeutics, 17(7), 2158–2168. https://doi.org/10.1080/21645515.2020.1865044