



Development of a framework to capture the maturity of food safety regulatory and enforcement agencies: Insights from a Delphi study

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ABSTRACT

Purpose: The purpose of the paper is to present the first stage of work being undertaken to develop and evaluate a maturity framework designed to assess and benchmark the effectiveness, ability to achieve continuous improvement, and optimise processes and functioning of food safety regulatory and enforcement agencies across the world.

Design/Methodology: To achieve this aim, a comparison of global food safety regulations, and Delphi-interviews with stakeholders of food safety regulatory and enforcement agencies from Australia, Canada, Ireland, and USA were carried out. Through inductive, textual data analysis, three dimensions and thirteen sub-dimensions were identified that covered cultural and systems elements influencing the quality and impact of food safety regulations across the world as well as the gaps identified by the stakeholders.

Findings: The conclusions of the paper are that whilst there is broad support by food safety regulators for developing a benchmarking and evaluation framework for food safety regulatory and enforcement agencies, there are also some outstanding challenges such as defining globally applicable measures, buy-in from specialised agencies and senior management to adopt a maturity framework to change the culture within regulatory agencies, and the role played by governments in influencing the efficiency and functioning of regulatory systems.

Limitations/Implications: While more research would be required to further develop a maturity scale to assess food safety regulatory and enforcement agencies, it is concluded that evaluating the maturity of food safety regulatory and enforcement agencies (FSRA) by food safety regulators is a realistic possibility but needs to take account of some of the lessons which could be learnt from guidance frameworks with similar goals (e.g., the Food and Agriculture Organization's Food Control System Assessment Tool). Evaluation of the framework should be carried out by national agencies to develop a user-centred maturity toolkit.

1. Introduction

Food safety is an important issue that affects public health and trade around the world. Food safety incidents cause a larger social and economic toll on low and middle-income countries (Hoffmann, Moser, & Saak, 2019). A report by the World Health Organization (2015) states that approximately 600 million people fall ill (leading to 420,000 deaths) due to the consumption of contaminated food. Additionally, poor food safety practices negatively impact the environment due to factors such as soil, air and water pollution from producer/manufacturer emissions, contamination due to the use of banned pesticides (Tirado-von der Pahlen, 2008), and methane emissions from food discarded

into landfills (Walia & Sanders, 2019). Although not established as an independent Sustainable Development Goal by the United Nations (due to a historic lack of evidence of the social and environmental costs of foodborne diseases), food safety is considered as a key dimension of food security (a key UN SDG) (Grace, 2017). Additionally, the WHO associated 31 foodborne hazards to global burden/health estimates, i.e., data informing death and disability globally (Havelaar et al., 2015). Thus, it can be inferred that foodborne diseases leading to food safety incidents are an unsustainable outcome. Due to such factors, it is important to control the safety of food products through food safety regulations in global food supply chains (Nayak & Waterson, 2019).

While regulations are designed by legislators, the implementation,

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enforcement and communication of these regulations is performed by food safety regulatory and enforcement agencies (FSRA). This is a critical function for the responsible and safe production and consumption of food (FAO & WHO, 2019b; Wilson et al., 2015). FSRA authorities largely aim to improve public health, ensure food security and facilitate domestic and international trade, while achieving specific targets such as: (1) provision of scientific opinions based on risk assessment; (2) promotion and development of risk assessment strategies; (3) commissioning of scientific studies; (4) analysis of scientific data; (5) identification of emerging risks; (6) working with other regulatory agencies domestically and internationally; and (7) providing information of imminent risks transparently to other nations (Hugas & Tsigarida, 2008, pp. 43–44; Varzakas, Tsigarida, Apostolopoulos, Kalogridou-Vassiliadou, & Jukes, 2006).

As per the framework of the Principles and Guidelines for National Food Control Systems (Codex Alimentarius Commission, 2013), individual countries have the autonomy to define their food control systems and implement specific control measures as long as they are able to ensure public health and wellbeing. Irrespective of the structure of national frameworks, measuring effectiveness, the ability to achieve continuous improvement and optimise processes and functions performed is important for all FSRA. This not only helps improve the quality of the services provided, but also: (1) builds stakeholder confidence; (2) strengthens the national food system's global standing; and (3) opens the national food system to new international markets through favourable trade deals (FAO & WHO, 2019b).

Although autonomy in public sector (micro-level i.e., national) organisations is a critical feature in promoting effective and robust national governance mechanisms (Oberg & Wockelberg, 2021; Wynen, Verhoest, & Rubecksen, 2014), it is important to assist such organisations in assessing the effectiveness and maturity of their national food safety auditing and inspection systems. Developing a globally applicable assessment system would aid all relevant organisations in comparing their maturity (i.e., performance) towards the same standards. This will help identify priority areas and the support required (FAO & WHO, 2019b) by these organisations.

This paper presents a globally applicable maturity model designed to assess and benchmark the effectiveness, ability to achieve continuous improvement, and optimise the processes and functioning of food safety regulatory and enforcement agencies across the world. The framework is developed based on: (1) a review of global food safety regulations to map their scope and the role of the respective food safety regulatory and enforcement agency; and (2) expert stakeholders' perspectives of role of FSRA and gaps in current service assessment strategies of FSRA around the world. Current research on food safety regulations and management systems has tended to focus on the characterization of the importance and implementation of food safety regulations and management systems (Mensah & Julien, 2011), evaluation of culture, climate and behavioural change within private food entities (De Boeck, Jacxsens, Kurban, & Wallace, 2020; Jespersen, Griffiths, Maclaurin, Chapman, & Wallace, 2016; Jespersen & Wallace, 2017; Sharman, Wallace, & Jespersen, 2020), and their impact on market price (Mohand, Hammoudi, Radjef, Hamza, & Perito, 2017). We seek to go beyond the scope of current research by investigating how regulators could improve their operations by using a self-assessment tool.

Data was collected using a modified Delphi approach. According to Linstone and Turoff (1975, p. 3), the Delphi is a method for "structuring a group communication process" enabling a group of experts to deal with a complex problem and suggest potential interventions. It is an iterative process used to elicit anonymous perspectives from experts using a series of data collection and analysis techniques combined with feedback (Wu, Ding, Chen, & Fan, 2021). The iterative rounds of data collection allows the research to maximise participants' judgements (McKenna, 1994) due to the ability of participants to review anonymised responses and provide feedback on statements made by peers with diverse perspectives and experiences. Although the process has not

widely been used to promote food safety (Ilic, LeJeune, Ivey Lewis, & Miller, 2017) due to questions about the reliability, the method however, is widely used in the healthcare and sports science fields (e.g., Bell et al., 2021; Pollard, Mathai, & Walker, 2013).

This study is part of a larger examination of the functioning of FSRA across the world, with the aim of developing a globally applicable maturity assessment framework to help agencies improve achieving public health and trade. While this study established the dimensions of the maturity framework, the larger study will aim to develop a maturity scale which will help FSRA measure the effectiveness and efficiency of their existing functions and identify areas for improvement.

2. Methods

2.1. Sample characteristics and participation

In this study, eight experts received invitation letters via email prior to the first round and four FSRA stakeholders participated in the Delphi panel (one each from Australia, Canada, Ireland, and USA) for both rounds. All panel members had a minimum of 20 years of experience of working in and/or with FSRA leading to data saturation for this stage of the study. The genders of the panel members included three members who identified as males and one member who identified as a female - this was kept stable during the two rounds.

2.2. Recruitment

Recruitment philosophy for this study was inspired by the framework proposed by Adler and Ziglio (1996) who state that there are four pre-requisites that panel members must possess in a Delphi study: (1) knowledge and experience of the topic under investigation; (2) capacity and willingness to participate (3) sufficient resources (e.g., time); to take study initial findings; and (4) effective communication skills.

Individuals with over twenty years of experience in the food regulation setting were recruited for this study. Recruitment was through purposive sampling, enabling the inclusion of individuals who were information rich (Patton, 2002) and were able to share information based on experience (Popay, Rogers, & Williams, 1998). As the roles of stakeholders working in the food safety regulatory and enforcement domain are varied, a sampling strategy suggested by Wilson et al. (2015, p. 2131) was adopted – the authors recruited participants with experience in varied but relevant areas such as policy and framework development, establishing new national agencies, improving existing national agencies, standards setting, implementation, inspection, and enforcement.

According to Alizadeh et al. (2020), the outcome of a Delphi study does not depend on the size of a panel, but the experience of the panel members. Additionally, Skulmoski, Hartman, and Krahn (2007, p. 6) highlight the flexibility of sample sizes used in previous Delphi studies, with a range between 3 and 171. Following these principles, the inclusion criteria, and the framework adopted, potential participants were contacted by the second author. Contact was established through emails. Follow-up emails were not required. The purpose of the study was explained through a letter of introduction (which included the *participant information sheet*), following which, they were invited to participate in an online interview as a part of the Delphi study.

2.3. Data collection

Data was collected using a modified Delphi approach. According to Steurer (2011), a Delphi is carried out in three overarching steps: (1) identifying the research subject, specifying the research question, developing an basic understanding of existing theories and practices; (2) identifying and selecting a panel of experts based on defined inclusion criteria; and (3) conducting surveys to assimilate panel members' perspectives involves two or more rounds. To collect sufficient information

a review of global food safety regulations was carried out to map their scope and the role of the respective food safety regulatory and enforcement agency. Following this, a review of existing FSRA improvement tools was carried out. Finally, a two-round analysis was performed (Ilic et al., 2017) using a modified Delphi method. The anonymity provided to participants (i.e., experts) enabled them to share their opinions independently and free from the halo effect (Dalkey & Helmer, 1963). Recent use of this approach has been widespread in agri-food supply chain and operations management research (for examples, see Jespersen et al. (2016); Padel and Midmore (2005); and Wu et al. (2021)). The research process has been illustrated in Fig. 1.

2.3.1. Conduction of the Delphi interviews

Before the first round of Delphi interviews, a pilot was conducted to revise interview design and questions to make it more relevant, practical and to ensure that the questions captured real-world challenges faced by FSRA. Delphi interviews were conducted online (Microsoft Teams) with an interview schedule (Table 1) to keep in-line with the Covid-19 pandemic restrictions and to include panel members from around the world. Interviews lasted between 60 and 90 min. The second author led the interviews while the first author made notes and asked follow-on questions. Both authors met regularly through Microsoft Teams during data collection to ensure consistency and to discuss the need for modifications to the interview schedule. The first round of Delphi interviews was carried out in October 2020 over a two-week period, contingent on the availability of the panel. After the first round, a thematic inductive analysis was completed in two weeks. The results of the first round were

compiled into a *participant feedback report* to inform the panel in the second round. A further interview schedule was designed based on the themes identified in the first round. The second round of Delphi interviews was carried out between December 2020 and January 2021, following which a final report was generated. Interviews were conducted until theoretical saturation of themes was reached (Guest, Bunce, & Johnson, 2006). Overall, the two-round Delphi study, including the time for data analysis and report drafting, lasted five months.

2.4. Data analysis

Microsoft Stream recordings were deidentified and transcribed verbatim. Nonverbal cues, pace and emphasis were deemed less important and were not transcribed as participants had sufficient time, knowledge, experience, and effective communication skills. Transcripts were checked against the respective video recordings by the first author for accuracy. Deidentified transcripts were imported into QSR NVivo (Version 12), a qualitative data analysis software package. Themes were identified from the data using an inductive thematic coding approach (Braun & Clarke, 2006) to identify, analyse, and report patterns within the data (Flick, 2014). A preliminary list of codes was developed by both authors which included the identification of broader themes: *pre-requisites to establish FSRA*; *Role of FSRA*; *Drivers of FSRA*; *Operational challenges*; and *Flaws in the operational structure*. Transcripts were further coded by the first author using the initial list following the six stages identified by Braun and Clarke (2006). Upon completion of coding, the authors reviewed the outputs – any disagreements were resolved

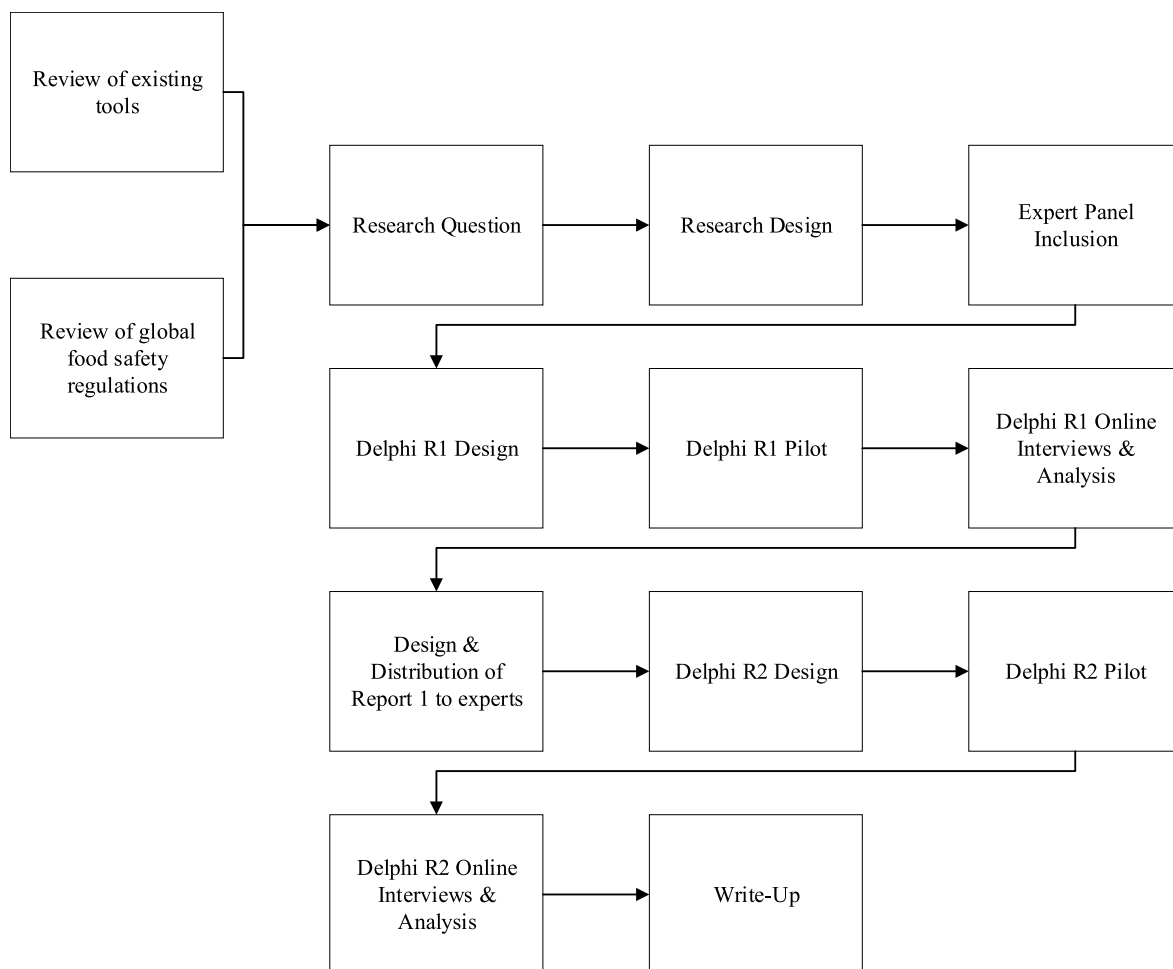


Fig. 1. Research process. Adapted from Wu et al., 2021.

Table 1
Interview schedule used in Round 1 of the Delphi study.

Section 1 – Profile	
You will be asked these questions during the one-to-one interview. The questions will be designed to collect some demographic information.	
Section 2 – Landscape	
The questions listed below are designed to seek your opinion. Responses will be collected for each one during the virtual meeting. Please do not feel limited in the length or style of your answers.	
<u>Questions</u>	<u>Guide</u>
What is your broad opinion of the structure of food safety regulatory bodies?	Panellists may comment on as many regulatory bodies as they have knowledge of
What are the key drivers of food safety regulatory bodies? Are these drivers country-specific?	What impacts the performance of regulatory bodies?
What operational challenges do food safety regulatory bodies encounter on a day-to-day basis? Are these operational challenges country-specific?	Difficulty with compliance Inadequate staffing Communication barriers Governance issues Inadequate policies
If you can, please give examples that demonstrate that food safety regulatory encounter challenges on a day-to-day basis.	
Have you worked in helping establish food safety regulatory bodies? If yes, which country/agencies have you worked with?	<i>Competence check question</i>
Section 3 – Main body	
<u>Questions</u>	<u>Guide</u>
In your opinion, what are the pre-requisites for establishing a regulatory body?	
Are there any pre-requisites that are specific to food safety regulatory bodies?	
What is the role of a food safety regulatory body?	
What is the process of establishing a food safety regulatory body? If you can, please discuss a case to demonstrate the steps taken to establish a food safety regulatory body.	Does this process vary based on the country?
Could you list the flaws (if any) in the operational structure of food safety regulatory bodies that you are familiar with?	

through discussion until consensus was reached in a manner similar to the approach adopted in Underwood and Waterson (2014). Table 2 highlights the coding framework developed from a preliminary list of codes. Names of the four participants were anonymised (i.e., P1, P2, P3 and P4).

Table 2
Coding framework.

Macro-codes	Micro-codes
Environment	Economic Political Public health
Operations management	Agency structure Autonomy Informal markets Management and Leadership Appeals process Resources
Pre-requisites	Equivalence in standards Knowledge Legal authority Ownership

2.5. Ethics approval

This research received ethics approval from the relevant ethics committee where the primary author was employed at the time of data collection. Written informed consent was obtained from all participants.

3. Results

The subsequent subsections present the framework for a maturity assessment tool identified through inductive thematic coding of the data collected from two the Delphi rounds.

3.1. Pre-requisites to establish FSRA

Participants in this study agreed that *pre-requisites* were essential building blocks enabling the functioning of FSRA. They helped to build and maintain coherent and purposeful agencies, which consequently aided the FSRA in defining and achieving its goals, vision, and mission. They defined the duties and responsibilities of the stakeholders, and encourages the establishment of adequate guidelines to ensure inclusivity and effective control of food safety:

“... it’s almost like all pre-requisites have equal importance. Pre-requisites lay out what each agency does, and their responsibilities.” (P2)

“It [pre-requisites] lay out a framework for how all [regulatory] agencies are going to collaborate, whether it is through a central competent authority or through local, regional, and so on. It determines how it all fits together ...” (P1)

3.1.1. Equivalence in standards

There is a need for harmonisation of global food safety and trading standards. Equivalence of standards may occur either at a global or a regional level through partnerships within geographical regions with at least two other neighbouring countries:

“The lack of consistency was the bane of my existence because it is so hard to have a large inspection workforce [across the country], all operating the same way.” (P4)

“The more senior people who produce codes of practice and guidance notes for inspectors on how to do their job should be put together in a room, with representatives from all different regions, to develop guidance or codes of practice by getting everybody to buy into it ... Everybody agrees how it [food inspection] is done, and the mechanism of awarding scores and so on ...” (P2)

Participants agreed on the influence of equivalence on consistency in regulatory enforcement. It was highlighted that the same transnational organization may be held to different standards in different parts of a country, leading to confusion and poor food safety outcomes:

“Consistency is terribly important when it comes to the enforcement of regulations. If you have Company X in the north and south of a country, and they have been inspected by [food safety] inspectors to completely different standards of the legislation, then you [stakeholders] will be in trouble.” (P1)

“Consistency of enforcement is the job of the ... central competent authority. They must ensure consistency to guarantee an oversight of the whole ... food chain, and to make certain that they can look at how food laws are consistently enforced.” (P3)

3.1.2. Knowledge

FSRA stakeholders must make use of information generated by official controls with the agency acting as a body that supports interaction between various stakeholders, contributing to the drafting of policy and legislation leading to improved and targeted food control activities. This

would help eliminate assumptions and false expectations:

“... the absence of something does not assume that something is correct. It is the role of regulatory agencies to ensure that correct knowledge is freely disseminated within the system to make things clearer in the market. We need a system to get rid of assumptions and unwanted expectations and manage the number of expectations.” (P1)

3.1.3. Legal authority

Regulatory agencies must have legal authority based on a well-defined legislative framework and policy drafted from both, a legal and technical perspective. The framework should mandate legal responsibilities of the various agencies including details around frequency of inspections and actions to be taken in the event of non-compliance:

“A clear policy guidance is required for food safety and quality, and not just food control as it in across most countries.” (P2)

“The legislative framework should lay out what each agency does, and their responsibilities. One day there might be ten people selling in your market, another time there might be a hundred. The number should not make a difference as long as the FSRA is able to deal with it and provide factual evaluations – this can be achieved through a well-defined and consistent regulatory framework.” (P4)

“If they [food businesses] have a history of non-compliance, FSRA inspectors must have some guidance to decide the frequency with which to inspect said food business. They should be able to increase inspections if required, and once sustained compliance has been reached, they should also be able to reduce the frequency of inspections.” (P1)

Participants believed that FSRA must be provided with an evaluation framework that they have been involved in co-designing to evaluate effectiveness of interventions. Co-design was deemed as important to ensure optimal scope of the regulatory framework:

“It is important to be able to and know how to measure success of interventions inspectors may put in place ... you need something like program logic to define the outcome or intent. The tool needs to be consistent and transparent to the people. The evaluation framework must be applicable for between three and five years.” (P2)

“Regulatory frameworks must have a specific scope. The number of operations eligible within the scope must be clearly defined. This would act as an effectiveness measure for regulatory agencies. We must ensure, for example, that our exports are not bypassing the Commonwealth systems as otherwise we risk making the system redundant.” (P3)

FSRA must be able to provide licenses, prosecute and charge fees. To do this, there needs to be a legal framework to ensure transparency regarding the amount charged, and efficiency in the utilisation of the money received:

“Nuancing and sophistication is extremely important. FSRA, and inspectors by extension, must be able to license, audit, report, charge a fee and prosecute food businesses. They must be able to show that they money they collected as being used to inform education and/or training, and to develop differential systems [the ability to develop additional customised options to the ones mentioned in the guidance]. If they are unable to do so, it could be a sign of an immature organisation.” (P2)

However, there was an acceptance among participants about the existence of unregulated food markets. The common consensus was that FSRA must be able to work with such markets to ensure the trade of safe and high-quality food:

“You will always have a regulated and non-regulated aspect to food supply. People may sell various products through these markets, which is why it is important for FSRA to have oversight of all such establishments ... Not regulated does not mean bad – it just means that something is not being captured.” (P2)

“In country X, un-regulated markets are allowed to setup shop at the basement levels of malls. This means food businesses are given a chance to setup shop in a legal manner through the issuing of licenses in a defined [closed] setting [environment]. This is beneficial for food businesses operators, public health outcomes as well as consumers as businesses owners can trade, inspectors are able to ensure the trade of safe and high-quality food in hygienic environments, and consumers are able to access **traditional street food**. Licensing is surely one of the building blocks of a mature regulatory culture.” (P4)

Overly prescriptive regulations were seen to be tedious and more of a hindrance in effectively managing food safety. Participants felt the need for there to be flexibility in regulatory design to allow businesses and regulators adopt a proactive approach to food safety, and the ability to design supportive policies.

“I am a big proponent of making sure that the law has flexibility built in so that an agency has the ability to interpret it according to the case they are dealing with. For example, a law stating that a business cannot sell unsafe food is better than a law stating that a business cannot sell food stored at room temperature for X number of days. Hence, the less prescriptive, the more flexibility it provides in terms of being proactive and coming up with supportive policies.” (P4)

3.1.4. Ownership

Participants agreed food safety was a collaborative effort and not just the food safety regulators' responsibility, but also of food businesses.

“Collaborative working between regulators, food business operators, the central competent authority, and local/regional authorities is really important. Only in an immature setup would agencies be working independent of each other and prioritise protecting their turf. The role of the food control agency should be ... about assisting.” (P1)

“It is important for stakeholders to be able to have defined roles and responsibilities, with the ability to communicate with each other openly. It would be essential for them to share and understand how a problem was overcome, and how it affected the business. This would help them get ownership of food safety-related issues.” (P2)

Participants stated that food businesses that owned food safety were able to proactively identify risks (with oversight from food safety inspectors). Further, this enabled allocation of the required resources to mitigate identified risks.

“If a business has the education to perform its own risk assessment activities, they would then be able to identify in advance where more resources are required, even if this was not possible immediately. This would help them mitigate against the risks through detailed planning.” (P2)

There was an emphasis on using the FAO and WHO's (2019) shared model of ownership to allocate responsibilities to various stakeholders – responsibility of food safety lay with food businesses while food safety inspectors were responsible for providing guidance to help food businesses achieve their food safety targets, and regulating food safety.

“I would be a fan of a more independent oversight role for regulatory agencies, with [food businesses] having more of a responsibility regarding managing food safety. The framework mentioned in the FAO's 2019 report must be used to share ownership of food safety. This is the only way food safety could be managed in a sustainable manner.” (P3)

“The role of the regulatory agency should be to provide industry guidance, support industry practice, help trade associations, and form [successful] public-private partnerships. Successful [public-private] partnerships have in the past led to higher rates of industry compliance because they feel educated in their own industry and by their own trade associations.” (P4)

Ownership of food safety at the political level was identified as an essential criterion to reduce the number of food safety incidents.

Political institutions were deemed to be reactive in their approach to food safety as they were usually insensitive to issues surrounding managing food safety until it became a national incident.

“Politicians get a bit insensitive to food safety issues. They wait for something big to happen, which leads to them being dragged into it and being made to feel vulnerable, to take measures such as increase funding temporarily for the responsible agency to deal with the incident.” (P3)

“Politicians are often choosing between food safety programs and health governance policies. This leads to lesser funding being allocated to food safety programs as a lot of governments swing to the health side.” (P2)

“You need champions at the ministerial level who are willing to stick their necks out and support food safety and be able to discuss the technical details of endorsing and supporting to provide the required resources.” (P2)

3.2. Operations management

Participants believed efficient and well-designed operations management systems were essential for the everyday functioning of FSRA:

“It is important for there to be robust operations management systems to carry out essential functions such as reviews, assessments, authorisations, inspections, enforcement, and the development of regulations and guidelines.” (P1)

3.2.1. Agency structure

Participants opined that an integrated operations structure would allow for conflict resolution to take place in a timely and systematic manner. Additionally, an integrated structure would allow stakeholders to work together and carry out function across the ‘farm-to-retailer’ chain, allowing for risk assessments based on a systems and cooperative approach:

“Some ministries might not have any food safety authorities in certain areas of the food system (e.g., farms). However, there is always an agency that works with farms. It would then be useful for the FSRA to work with such an agency/ministry to help put programs in place for farmers to carry out risk assessments collaboratively with food safety inspectors ... you can never get away from the fact that agencies will have to deal with internal dynamics to get buy-in ... there will always be a need for some type of integration.” (P3)

“By law, some ministries such as ministries of agriculture are not allowed to take food safety regulatory actions on farms. However, it would be helpful for the safety and sustainability of the food system to involve and incentivise an agency that is able to assess food safety, and educate stakeholders (e.g., farmers) to look for best practices. Another role of FSRA in this context could be to put pressure along the entire [food] system.” (P2)

3.2.2. Autonomy

Autonomy, which is ‘the right to self-govern through integrated functioning without coercion from external bodies’ (Carver & Scheier, 2000), was deemed to be a key requirement for FSRA to not be controlled and/or heavily influenced by prevailing geopolitical climates. Participants argued that central political authorities should not have the power to influence the functioning and decision-making ability of FSRA:

“... it is not very mature of a political authority to control the job roles of a [food] safety inspector. Quite often, changing political parties leads to a change in the senior leadership within FSRA. This is not a sign of a mature national food safety governance system as every new politically appointed leader brings with them their own views on how the agency should run, and the powers granted to each individual.” (P3)

Co-design of “best practice” and stakeholder buy-in was viewed as a key component of an autonomously operating FSRA:

“It is crucial that regulations are not implemented in a vacuum ... it is useful to get stakeholder buy-in to develop best practice guidance through a system of co-design. You have got to have a wide range of people in the room with a diverse set of expertise while writing the policy. Co-design also helps with effective communication as when multiple stakeholders have been a part of the policy design, they will be more effective at communicating [the message].” (P3)

3.2.3. Informal markets

Participants opined that while informal markets comprised of a diverse group of stakeholders, it was important to work with all stakeholders to codesign codes of practice to ensure food safety as polices designed in siloed systems struggle to garner buy-in and compliance:

“You have ... informal markets which comprise of market traders’ associations, people making food at home and all the other people who own stalls and work in informal [food] markets. There are also policy and regulatory people who put codes of practice in place to ensure food and consumer safety ... The way forward is for policy and regulatory stakeholders to work with all the other stakeholders.” (P2)

Additionally, participants felt that codesign would lead to identification of training needs:

“By working together, it would help people in leadership and management roles identify training needs and the support required for people selling in informal markets.” (P1)

“Previous work done by various governments has led to the development of effective training programmes on hygiene and food safety. The aim of these programmes was to create an awareness of the basics of food safety, washing in clean water, not contaminating cooked and non-cooked foods ...” (P3)

As opposed to penalising informal markets, it was deemed to be necessary to accept their operations and aid in their establishment within an easy-to-inspect environment:

“Singapore is a good example where street traders have been given space within closed markets at the basement level of large shopping centres. The basements of these stores is usually full of traditional street stalls. This is a good way of first giving them hygiene and food safety training, and slowly bringing them within the remit of the regulatory world.” (P2)

An alternative to shopping centres included charging street traders a licencing fee as a means of self-regulation within this sector. Additionally, licensing was viewed as a method of being able to locate various street traders:

“... start by having a street traders fee, making it mandatory for these operations to be registered. This would not only lead to inspectors not having to shut down these businesses, but also create a level-playing field where traders will self-regulate. Self-regulation would involve them ensuring that other operations such as their having a license too. Providing licenses would help inspectors know the location of these operations.” (P4)

3.2.4. Management and leadership

A robust structure to manage collaborative operations between food safety and regulatory departments and government bodies was deemed to be critical to food safety governance:

“... there is always a healthy tension between the departments and government bodies that have responsibility for food control. They will always exist, but a mature system would be one in which they operate together through some form of a management structure.” (P2)

Enthusiasm and commitment from high level management was viewed as essential to get buy-in from other stakeholders. Active involvement by senior leaders was also identified as a critical factor to promote a positive and strong culture of food safety within FSRA:

“You need your high-level management team to be able to motivate you, and to be able to talk to other stakeholders such as ministers to manage change effectively. Things will not work out if senior leaders are hesitant to take part in implementing a culture of owning food safety and its impact on public health.” (P1)

“Once a concept or an approach has been discussed, it is important for senior leaders to develop it further by viewing it as a project that is close to their heart. This then needs to be conveyed to the rest of the team.” (P4)

Career development and making the field of food safety inspections appealing was deemed to be an essential role of the leadership team. Continuous professional development was viewed as key to retaining staff:

“... employees should be able to identify where working for an agency will take them, and the opportunities they will get along the way. It is also important to provide them with career development opportunities to improve their resume and get practical experience. Having a mentor to learn from is essential to be able to recruit high-quality staff.” (P1)

“Consistency in staffing is important as otherwise the number of food businesses increases while the number of inspectors reduces, adding pressure on employees.” (P3)

Participants opined that senior leadership needed to comprise of a diverse set of stakeholders, i.e., not just those who had management degrees as this would help the management team understand multiple perspectives prior to implementing policy change:

“... I liked the idea of the appointment of senior people from a diverse background in these agencies. Senior leadership teams should include scientists, food safety specialists, medical doctors, and other people that are knowledgeable in science and have good management leadership skills.” (P3)

Budget constraints were identified as common issues across the world, leading to a reduction in the number of food safety inspectors and the amount of resources allocated per inspection team. Borrowing of resources, including personnel, was seen as an effective and tried-and-tested method to overcome this limitation. There were two advantages to adopting such as approach: (1) the FSRA would not have to recruit more employees while having to stay operational; and (2) people from multiple agencies would develop transferable skills which is a key to their career development:

“Staff sharing is quite common as it is impossible to have all the expertise within one department with a limit budget. This also gives the staff to get a change of environment and gives them the opportunity to learn something new. Quite often, it helps to keep them on their toes. In essence, you borrow them and let the other department borrow your staff [when required], and at the end of task, they can go back to working for their parent department.” (P1)

“FSRA often borrow epidemiologists, even if it just to go out for lunch. This time lunchtime meeting and knowledge exchange programme leads to other teams learning about epidemiologists’ work and their areas of concern. This helps all teams stay vigilant.” (P3)

Hiring people for leadership positions should not be based solely on their degrees, but also on their experience:

“Looking at people’s backgrounds often acts as a limitation while hiring someone in a leadership position. Mature FSRA often have people with experience in leadership roles as opposed to only people who have a Masters degree. There needs to be a balance between level of education and experience.” (P3)

3.2.5. Appeals process

A system that was found to be lacking in FSRA across the world was a robust and transparent process for appealing prosecutions. Participants stated that it was important for there to be an appeals system for food businesses to defend themselves in court:

“... this is where the food regulatory system has been found to be non-compliant. When businesses are going to be prosecuted, there seldom is a known process of appeal. An immature food system will not have a process in place for food business operators to defend themselves in court.” (P2)

“A dispute resolution system is a must. This must be a government-mandated requirement so that all disputes are able to be resolved with an independent arbitrary inspector. If the business wins the appeal, the regulatory agency should pay the ‘dispute resolution process’, and if not, the food business operator.” (P4)

3.2.6. Resources

Engagement tools available to regulators needed to offer a certain degree of autonomy and ownership. Existing tools were viewed to be blunt and a tick-box exercise:

“... regulators have very few engagement tools and they are blunt. Most tools provide you with too many instructions which ends up with businesses always getting licenses, despite inspectors picking up on non-compliances. However, they are unable to act on this as they must stick to the instructions provided to them by the tool. Most of them fail to allow the inspector to engage the food business operator and can be quite unfriendly.” (P3)

“Tools that enable education, training and promote engagement must be used by regulators and inspectors.” (P3)

Training provided by regulators for inspectors was viewed as critical in shaping the quality of inspections carried out:

“... because money is an issue, regulatory bodies always try to find training that is cheaper. However, it is important that a regulatory body thinks about what and why they are launching training before they launch it. If the training is not relevant, it shows in the nation’s public health outcomes.” (P1)

“The quality of training shows the culture within the FSRA. Inspection bodies have struggled with providing adequate and relevant training – this makes the outcomes of these inspections poor in reliability and validity. As a lot of the work involves managing risk, there needs to be more than an internal audit form. It is important to develop training programmes after observing inspections and audit results.” (P4)

There was a consensus about the need for a robust IT system and a strategy for innovation. It was deemed to be an area that was often found lacking in many countries. Missing or faulty IT systems were seen to act as barriers to effective inspections. One of the participants felt that IT was as important as developing training programmes:

“... IT systems are very important. Up until five years ago, IT was not a priority area for many FSRA. However, the culture is changing slowly. IT might be as important as training as it makes the inspection more effective.” (P4)

Innovation was deemed to be important to help eliminate monotony. Additionally, this would help inspectors to be vigilant for new non-compliance behaviours and patterns:

“... this is applicable for frontline staff where they look at the same processes which makes the audit process quite monotonous. Modernisation of inspection system through innovation is key, especially in the meat sector. This would enable inspectors to watch out for new non-compliance behaviour patterns.” (P3)

Inspector salaries were viewed to be menial compared to equivalent jobs in other industries. This was associated with inspectors moving to the private sector as consultants:

“... funding needs to take account of how much staff are paid. FSRA must make a case based on competency to show that inspectors are not ‘low-skilled’ workers, and that this must be reflected in their salaries and benefits. They must be paid as much as scientists. There are instances where a robust case presented to the civil services has led to a higher pay category.” (P3)

In addition to government funding, licensing was perceived to be an efficient method of generating a revenue for the FSRA. Money collected from such programs needed to go to the FSRA and not the government:

“... in one of the initial models, the government was paying 97% of the budget to oversee and inspect the dairy industry and the industry was paying about 3% through fees. This was out of balance for the type of inspections being carried out. When the leadership changes, another model was adopted where 76% was government funding and 24% was licensing fees and other add-ons. This made the operations more sustainable.” (P1)

“... money should be collected in the form of licensing fees, service fees or through a registration program. Money collected from here should not go to the government but stay with the regulatory agency. If not, the agency would either end up losing the money to the healthcare sector or fighting with the federal government [or its equivalent] for allocation fair allocation of money collected by them.” (P3)

Resource allocation must be carried out based on the outcomes of risk assessments. This would help efficient management of limited resources and would prohibit overspending on low-risk activities:

“You identify where your high risks are, and you make sure that you are not wasting resources on low-risk activities.” (P3)

Education at university through a process of curriculum co-design was seen to be an important resource for FSRA:

“An immature system would be burdened with providing basic education on food safety and hygiene to food safety inspectors, while a mature system would be able to recruit highly educated staff.” (P1)

“To be able to access educated staff, it is important for the FSRA to be able to work with higher education providers. Curriculum and programmes must be developed through a method of co-design. this would reduce the amount of time spent providing training after recruiting inspectors. Additionally, it would benefit national public health outcomes.” (P3)

3.3. Environmental factors

Factors that were external to the FSRA were perceived to heavily influence the operations of regulatory agencies:

“It is almost like any of the other drivers that influence the functioning of FSRA – they are of equal importance. It is important to account for these factors and adopt a systems perspective while auditing and improving the maturity of FSRA and national food systems.” (P4)

“The most mature FSRA would be able to navigate the science, the industry, the political masters, and get to good food safety outcomes and decision-making outcomes ...” (P1)

3.3.1. Economic

Robust food control systems were viewed as a requirement for investment by trading partners as it determined the level of confidence in a nation’s food safety management system:

“... if your trading partners do not have confidence in your overall food control system, the nation will find it hard to trade.” (P2)

“... food control agencies ensure food safety control in the entire agri-food system – this includes foods of animal origin. Hence, investors judge the safety of the food they agree to trade based on an audit of the exporting nation’s food safety management system.” (P4)

3.3.2. Political

Participants agreed that FSRA and politics were closely linked. The relationship was such that the government influenced the goals and approach adopted by the FSRA as the former funded the latter (i.e., FSRA depended on the government for its survival):

“... when governments are paying for this service, you cannot avoid politics ... it is naïve to think that FSRA are not going to be influenced by politics. Hence, FSRA often have food policy shops within them where scientific content is twisted into material that politicians can understand.” (P4)

However, the need for politicians to stay independent of scientific proceedings and activities was highlighted as a critical factor in the success/failure of FSRA:

“... politicians must stay out of the science, and they have to exclude themselves from the risk-based decision-making process. Most politicians prefer this as they like to stay out of trouble. However, it is also important to keep them in the loop and provide them with regular updates.” (P3)

3.3.3. Public health

Collaborative working with the public health sector was deemed as an important pathway for managing foodborne illnesses during an outbreak:

“Working with the public health sector with respect to foodborne illnesses is critical for effective management of public health. This includes active participation in outbreak control teams where during a national outbreak, the team along with actors from the public health unit, sit at the table and provide multiple perspectives on methods of protecting people.” (P2)

“Usually, the public health unit fail to understand the food sector well enough. This is something that needs working on as a cohesive and open-minded approach will help to protect the people better.” (P4)

4. Discussion

This paper presents the first stage of work being undertaken to develop and evaluate a maturity framework designed to assess and benchmark the effectiveness, ability to achieve continuous improvement, and optimise processes and functioning of food safety regulatory and enforcement agencies across the world. The following section presents an overview of the framework for the maturity model identified and establishes two of the five stages of maturity for each dimension: (a) Stage 1 – building blocks of an immature FSRA; and (b) Stage 5 building blocks of a mature FSRA.

4.1. Summary of findings

Overall, food safety regulators were in strongly in favour of developing a benchmarking and evaluation framework for food safety regulatory and enforcement agencies. Challenges such as defining globally applicable measures, buy-in from specialised agencies and senior management, and the influence of politics were identified as some of the barriers in assessing the maturity of FSRA. The findings from the study are summarised in [Table 3](#) in terms of the challenges and future opportunities of assessing the maturity of FSRA.

4.2. Pre-requisites to establish FSRA

Pre-requisites are essential building blocks that need to be achieved

Table 3
Opportunities and challenges of assessing the maturity of food safety regulatory and enforcement agencies.

Opportunities and positives	Challenges
Participants agreed for the need to help national food safety regulatory and enforcement agencies evaluate their maturity and move towards becoming more mature organisations.	Potential resistance from national and international bodies who identify themselves as <i>mature</i> based on the outcomes of evaluations from other (more basic) tools.
Harmonisation of global food safety and trading standards was seen as a priority to enable efficient trade and protection of public health.	Conflicting priorities (trade vs public health) and resource limitations may make it harder to secure buy-in from senior leadership.
Collaborative working between departments was already a core part of various regulatory and enforcement agencies, including food, although it might be occurring unofficially.	Existence of multiple tools aiming to assess food control systems could lead to confusion and selective participation – participants felt the need for collaborative working between authors of existing tools to develop one comprehensive and practically applicable tool.
Successful operational models existed where informal markets were being regulated and evaluated for food safety and hygiene practices. It would therefore be easier to adopt and/or further develop such models in other parts of the world.	Mitigating the influence of politicians/politics on FSRA operations was viewed as a critical challenge across most regulatory and enforcement agencies at a global scale.

to enable basic functioning of FSRA.

4.2.1. Equivalence in standards

The principle of equivalence enjoys broad consensus among international health organisations (Lines, 2006). However, the lack of harmonisation of standards across the world has enabled governments, traders, and certification bodies to develop complex pathways to facilitate trade at the international (macro-) and national (meso-) levels (Pekdemir, 2018; Winickoff & Klein, 2011). Although this model has not yet been experimented with in the food safety domain, the model has been met with success in the organic standards domain as it has helped countries manage complex regulatory realities (Bowen & Hoffman, 2015). The *equivalence in standards* dimension accounts for micro-(-local)/meso-level food system standards, regulations and audits which are not in cohesion with wider requirements (at the meso- or macro-levels) (stage 1) or food systems with identical standards, technical regulations, and conformity assessment requirements (audits) based on the principles of the Codex Alimentarius (stage 5).

4.2.2. Knowledge

Knowledge in the regulatory world comprises of: (1) scientific soundness; (2) ability to incorporate risk analysis principles; and (3) keeping up-to-date with new scientific developments and innovations with the aim of continuous improvement (FAO & WHO, 2019b). The *knowledge* dimension accounts for a food safety regulatory system where stakeholders may or may not attend regular training sessions and continuous professional development courses (stage 1) or a food safety regulatory system which makes use of information generated by official controls, supports interactions between stakeholders, contributing to the drafting of policy an legislation leading to an improved targeted food control activities (FAO & WHO, 2019b) (stage 5).

4.2.3. Legal authority

The degree of clarity of a nation's law and legal framework determines the extent of implementation and compliance with it. Poorly drafted laws gives rise to ambiguity in interpretation and poor implementation (FAO & WHO, 2019a). The Codex Alimentarius states that legislation must clearly distribute obligations and rights to the responsible stakeholders with clearly defined goals and objectives (Ref. para 38 of CAC/GL 82–2013 Codex Alimentarius Commission, 2013). The *legal*

authority dimension accounts for erroneously designed statements of legislation providing inaccurate interpretations and a lack of representation (stage 1) or legislation drafted from a legal and technical perspective through constant review and amendments with equal distribution between primary and secondary legislation meeting the CAC/GL 82–2013 requirements (stage 5). Primary legislation encompasses establishments of mandates and functions relating to fundamental rights, whereas secondary legislation encompasses operational, administrative, and technical details which build on and remain within the *remit* of the primary legislation. A mature legislative framework is one which evolves with time without having to be re-examined by Parliament (FAO & WHO, 2019a).

4.2.4. Ownership

Food safety is not just the responsibility of food safety regulators but also of food businesses. The FAO and WHO report (2019) places emphasis on the need for a shared model of ownership of food safety - one in which food businesses are responsible for food safety, while food safety inspectors are responsible for providing guidance to help food businesses achieve this target. Ownership also has other benefits such as a positive attitude towards food safety by staff, a greater uptake of new food safety initiatives, and correct reporting of food safety incidents. It also leads to an increase in accountability. The *ownership* dimension accounts for a food system in which food safety is the sole responsibility of FSRA (stage 1) or a food system in which there is active collaboration, commitment towards food safety, open communication, planning, transparency and accountability by industry and regulatory stakeholders (stage 5).

4.3. Operations management

Operations involve the administration and everyday functioning of FSRA which leads to the creation of a high level of efficiency of functions such as reviews and assessments, authorisations, inspections, enforcement, and the development of regulations and guides. Operations in the FSRA world involves both clerical as well as strategic functioning roles, and in most cases, involves a transition from clerical to strategic functioning due to the adoption of technology and management of centralised processes.

4.3.1. Agency structure

Structure within regulatory agencies is important to carry out the functions (i.e., goals) assigned by governments in ensuring public health and trade efficiency. A well-defined structure also allows for conflict resolution in a timely and a systematic manner. In an ideal world, it would be highly efficient if responsibilities for two or more goals is assigned to one agency (Wall & Eisenbeis, 2000). However, limited resources and increased bureaucracy within centralised governance systems means that it is difficult to assign multiple goals to one regulatory agency. The *agency structure* dimension accounts for agri-food supply chain-related regulatory agencies within countries that do not work in cohesion with each other to achieve food security related targets (stage 1) or those which work in cohesion with each other, codesign policies based on a systems thinking philosophy, and resolve conflicts through open conversations, while working towards a common goal of food security (stage 2).

4.3.2. Autonomy

Autonomy, which is the right to self-govern through integrated functioning without coercion from external bodies (Carver & Scheier, 2000), is a key requirement in regulatory agencies as it promotes horizontal coordination between the various stakeholders of these agencies. Regulatory agencies, including the FSRA, often seek enhanced autonomy from political leadership and market actors within the framework defined by central political authorities (Christensen & Læg Reid, 2007). The *autonomy* dimension accounts for both, FSRA whose day-to-day

activities are heavily managed by central political authorities and market actors, as well as political authorities who despite abstaining from individual cases strengthen their role as general regulators through the formulation of excessive laws (leading to confusions in defining tasks, objectives, and responsibilities) (stage 1) or FSRA and political authorities with good governance structures where practice is consistent with the administrative model leading to a balance between accountability and autonomy (stage 5).

4.3.3. Informal markets

Informal food markets are often comprised of small-scale owner operated enterprises (e.g., street traders and hawkers) who sell a variety of food products (Wegerif, 2020). These enterprises often have a small workforce (as small as one employee who might be the owner of the business) and are often managed by relatives of the owner. Informal markets are often frequented by marginalised communities in developing countries due to factors such as: (1) favourable geography of stores; (2) longer operating hours; (3) lower prices compared to retailers; and (4) provision of interest-free credit to frequent customers (Kazembe, Nickanor, & Crush, 2019; Wegerif & Hebinck, 2016). The *informal markets* dimension accounts for FSRA which forcefully shut such markets through blanket regulations for all street vendors and hawkers (stage 1) or FSRA who enable the legal and safe functioning of informal markets within regulated environments or through formalised licensing procedures (stage 5).

4.3.4. Management and leadership

Organisational hierarchy is often viewed as a necessity due to the ability of a central decision maker to speed up the decision-making process, although this might be at the expense of the quality of the solution (Mihm, Loch, Wilkinson, & Hubermna, 2010). Consequently, hybrid systems are an area of investigation to overcome the challenges of centralised and decentralised systems. Regardless of the management model implemented, a robust management structure is essential to help FSRA function efficiently, both as an independent as well as a collaborative agency. The *management* dimension accounts for FSRA with poorly defined management structures with neither any guidance/support for stakeholders along its hierarchical structure (stage 1) or FSRA with management that actively looks for promoting knowledge development and management within its ranks, as well as effective collaborations and resource sharing opportunities with other agencies (e.g., public health) (stage 5).

4.3.5. Appeals process

The appeals system is an important procedural mechanism in any system as it is used to challenge rulings, leading to the system being viewed as fair and accountable (Common, 2019). The right to appeal to a higher tribunal, present evidence and perspectives, and the right to receive a decision based on facts from a tribunal are important aspects of the rule of law (Waldron, 2011). The *appeals process* dimension accounts for food systems where food businesses are unable to appeal FSRA's rulings in court (stage 1) or food systems with an established dispute resolution system, either through a tribunal process or through opportunities for rebuttals with independent arbitrary food safety inspectors (stage 5).

4.3.6. *Resources*. Availability of adequate resources as well as effective resource management is fundamental to enable efficient and effective governance (Thatcher, Nayak, & Waterson, 2020). In addition to financial resources, it is also important to have education and training design, development and management, and resources for promoting and adopting technological interventions. The *resources* dimension accounts for FSRA with resource asymmetries (stage 1) or FSRA with equal and adequate distribution of resources (i.e., resources identified in the ISO 21500:2021 for effective project management – people, facilities,

equipment, training and education materials, infrastructure, and tools) (stage 5).

4.4. Environmental factors

Environmental factors are those drivers of food safety that are external the regulatory bodies, i.e., while FSRA might not have any influence on these drivers, the drivers heavily influence the functioning of FSRA. FSRA aim to improve food safety-related outcomes of large, medium, small, and micro food businesses all over the world by reducing unwarranted variation and providing high quality food to all consumers. Additionally, they aim to reduce the number of non-compliances, increase trade at the local and international levels, and improve overall public health within and across borders.

4.4.1. Economic

An increase in trade within and between nations leads to globalisation of economies (Pace & Gephart, 2017). The need for trade at a global, national, and local level is an economic driver which has the potential to influence the mission, vision, and goals of regulatory bodies. Trading partners play a key role in determining the success and failure of trade deals between countries. It is essential for trading partners to have confidence in a nation's overall food control system. Confidence plays a key role in determining the degree of trust and accountability within the importing/exporting nation's food control system. The *economic* dimension accounts for FSRA which are not transparent and with no clear communication plans with trading nations (stage 1) or FSRA that account for the importance of trade to a nation's economy and promote open communication with trade partners (stage 5).

4.4.2. Political

Governments, comprising of politicians and lobbyists, often pay for the services offered by FSRA. Hence, governments possess the ability to influence the governance models adopted by these regulatory bodies. The *political* dimension accounts for FSRA which are completely influenced by and under the control of governments, without any degree of autonomy (stage 1) or FSRA with an autonomous governance model, and one that feeds back to and takes on board suggestions from the government (stage 5).

4.4.3. Public health

Public health is defined as the science and art of improving the quality of life by preventing disease and prolonging life through organised efforts and informed decisions made by (public and private) organisations, societies, communities and individuals (Acheson et al., 1998; Winslow, 1920). FSRA are a part of public organisations and are largely responsible for ensuring the production and distribution of food that is safe for human consumption. The *public health* dimension accounts for FSRA that work in siloes on matters concerning food safety while not interacting with public health authorities (stage 1) or FSRA that collaborate with other national and local public health authorities and work actively with outbreak control teams to ensure food and feed safety, supply chain resilience and public health (stage 5).

5. Conclusions

This study presents regulators' perspectives on the building blocks of food safety regulatory and enforcement agencies (FSRA), and the actions required to help these agencies evolve into mature organisations. The findings establish the current diverse regulatory and enforcement practices of FSRA across the world. The study also highlights current challenges faced by FSRA, and steps taken to overcome their impact on public health and trade. The study is significant as it provides a framework to assess and benchmark the effectiveness, ability to achieve continuous improvement, and optimise the processes and functioning of FSRA across the world. Additionally, it provides insights into how FSRA

can effectively manage conflicting priorities such as trade and public health. As the tool is to be used by national FSRA, in future research, it is vital to evaluate the applicability of the framework through collaborative working with a food safety regulatory and enforcement agency. This will aid in the development of a maturity scale which can be used by FSRA to self-evaluate their maturity and identify areas for improvement.

CRedit authorship contribution statement

Rounaq Nayak: Conceptualization, Methodology, Investigation, Formal analysis, Resources, Visualization, Writing – original draft. **Lone Jespersen:** Conceptualization, Methodology, Investigation, Resources, Validation, Writing – review & editing.

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