National Food Safety Management Systems: An Overview of Selected OECD Country Food Safety Systems (Australia, Canada, European Union, New Zealand & United States)

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ABSTRACT: The purpose of this study is to understand global best practices of modern national food safety systems, with reference to selected Organisation for Economic Co-operation and Development (OECD) countries. This information can inform regulators and managers key stakeholders and donors for the design and development of capacity building of an effective national food control system aligned with international standards. Such systems require a comprehensive, integrated organization of infrastructure, policy and human resources to mitigate and control the evolving complexity of food safety risks. International experiences indicate that establishing risk-based preventive controls and verifiable management systems during primary production, processing and distribution of food proved to be more effective than inspecting possible contamination in final food products along the production chain (end-product testing). The development of an effective national food safety control system requires a comprehensive, integrated and rational organization of regulatory policy, infrastructure and human resources to mitigate and control the complexity of food safety risk. These include border inspection posts, laboratories, information systems and operational resources for monitoring, inspection, surveillance, incident management, traceability and stakeholder engagement for shared responsibility. This report provides a review of the existing risk-based food safety regulatory systems in selected OECD countries and focuses on their systems and approaches for enforcing food safety compliance along the entire food value chain.

1. INTRODUCTION

Demand for a more consistent supply of high quality and safe food is increasing globally and both retailers and agri-food processors are demanding this high quality from their suppliers. Although food safety has traditionally been considered a non-competitive space, it is increasingly becoming a factor in agri-food competitiveness. Rising incomes and consumer awareness of food safety are affecting the domestic marketplace for producers and processors, food exports and opportunities for import substitution.

In many emerging markets, existing food safety programs are regulated by a multitude of government bodies often operating independently with limited coordination. As one of the key steps to increase cohesion of government supervision, governments often create new institutions or undergo institutional reform while at the same time establishing new risk-based food safety laws and regulations aligned with international standards. This is usually accompanied by capacity building to promote on-farm food safety and quality, and upgrade supply chain food safety management, traceability and related information systems.

The development of an effective national food safety control system requires a comprehensive, integrated and rational organization of regulatory policy, infrastructure and human resources to mitigate and control the complexity of food safety risk. These include border inspection posts, laboratories, information systems and operational resources for monitoring, inspection, surveillance, incident management, traceability and stakeholder engagement for shared responsibility.

The purpose of this study is to understand global best practices of modern national food safety systems, with reference to selected countries, including Australia-New Zealand, Canada, European Union and the United States. This information can inform regulators, key stakeholders and donors for the design and development of capacity building of an effective national food control system aligned with international standards. International experiences indicate that establishing risk-based preventive controls and verifiable management systems during primary production, processing and distribution of food proved to be more effective than inspecting possible contamination in final food products along the production chain (end-product testing). The role of the official inspection service has been transitioning to authorities that promote systems of preventive controls and provides training, information and consultation to all stakeholders in contact with the food chain under an umbrella of shared responsibility.

2. FOOD SAFETY MANAGEMENT SYSTEMS

2.1 Australia and New Zealand

Food Standards Australia New Zealand (FSANZ) is an Australian statutory authority established by the Food Standards Australia New Zealand Act (1991)(Food Standards Australia New Zealand 2020). This is a collaboration by policy makers and law makers to ensure implementation and enforcement of food safety measures in both countries (Eleojo 2020). The Authority's mandates are to ensure the protection of public health and safety; to provide adequate information relating to food to enable consumers to make informed choices; to prevent misleading

or deceptive conduct, through the Australia New Zealand Food Standards Code (the Code) (Eleojo 2020; Healy, Brooke-Taylor, and Liehne 2003; Rumble et al. 2003). The Code applies to foods produced and sold in either country and sets joint food standards (e.g. labelling, composition, food additives, processing aids and contaminants) for both countries (Sainsbury et al. 2020).

Both countries require every business within the supply chain to produce a risk management plan, verified by a certified third party, that takes primary responsibility for the safety of the food under their control (Kotsanopoulos and Arvanitoyannis 2017; Powell et al. 2013). FSANZ standards provide the essential requirements and guidance have been developed to provide details around implementation and enforcement of the regulations. These certified plans are required before registration of the business and then monitored and updated on a regular basis (Chousalkar et al. 2018). Enforcement resources inspect high-risk businesses more frequently than low risk businesses (Chousalkar et al. 2018; Zach et al. 2012).

Unique to the joint Australian / New Zealand system is the Home Jurisdiction Rule (Magnuson et al. 2013). The jurisdiction of the Headquarters or the main processing plant is taken as the relevant jurisdiction for enforcement even for its branches in other States or Territories. The home jurisdiction is responsible for investigating potential breaches of food legislation including complaints and undertaking any necessary compliance or enforcement action in relation to the business (Food Regulation Secretariat 2018). Home jurisdiction will also take a lead role in coordinating any investigation that involves other State and Territory enforcement agencies and provides input to businesses on food legislation and food safety issues including whether food needs to be recalled (Food Regulation Secretariat 2018).

In Australia primary responsibility for food safety falls to the Department of Health which advises Ministers regarding overarching food policy and law (Australian Government Department of Agriculture Water and the Environment 2019). The Department of Agriculture and Water Resources has responsibility for import and export standards and biosecurity (Moss 2018). Australia has 8 States and Territories each of which has its own government food agencies. Health usually takes the lead role in food regulation and safety of foods manufactured and sold in the state (Australian Government Department of Agriculture Water and the Environment 2019). In some states such as Victoria and Queensland, there are separate agencies undertaking food safety roles for the primary production sector. The State and Territory agencies are responsible for implementation and enforcement within their local area supported by local municipal authorities (Kotsanopoulos and Arvanitoyannis 2017).

The Imported Food Control Act (1992) sets out the powers and authority for controlling imported food, including registration of importers, sampling and inspection rules (Gruber and Panasiak 2011). High risk imported foods, as determined by FSANZ, such as seafood, are inspected at a rate of 100% of consignments (Moir 2009; R.B. Wallace and Oria 2010; Williams, Hernandez-Jover, and Shamsi 2020). Low risk foods are sampled and inspected at 5% of consignments (R.B. Wallace and Oria 2010). FSANZ provides risk advice (e.g. listeria in ready-to-eat-cooked chicken meat) to Agriculture which then decides on inspection measures. Sampling and inspection rates can vary and is dependent on performance (R.B. Wallace and Oria 2010). All

imported foods must comply with FSANZ (Ghosh 2014; Sheridan et al. 2020; Szabo, Porter, and Sahlin 2008).

Food safety responsibilities for food businesses are set by the Code which contains 3 standards relating to food safety programs, food safety practices and general requirements for food premises and equipment (Ghosh 2014). Individual state authorities also issue regulations or codes of practice to assist implementation and compliance. In general, food businesses are required to prepare a food safety scheme or programme covering the key matters of hazard analysis and control in the supply chain through cleaning and sanitation, instrument calibration, traceability and recall, staff health, pest control, plant design and adequate documentation across all activities (Gordon et al. 2020). Regulations and codes support these measures and, in some cases, specify particular conditions to be used in processing (Healy et al. 2003; Magnuson et al. 2013). Registration, audit and verification requirements are established at State levels.

The risk-based model has progressed from product inspection to fully integrated manufacturer designed and operated food safety and quality assurance systems across the broad domestic and export food industries with the government playing a role in registration, implementation, verification and enforcement (R.B. Wallace and Oria 2010). Food law in New Zealand has both enabled and accelerated this move with recent legislation such as the Animal Products Act 1999 and the Food Act 2014 (Ministry of Primary Industries 2020a). These Acts are supported by FSANZ and industry specific regulations and codes of practice. The Food Act, Animal Products Act as well as the Wine Act all require businesses to undertake a review of hazards and risk and to undertake steps to manage, mitigate, eliminate or minimise those risks and produce safe and suitable food. While the terminology used may differ e.g. the Food Act requires a Food Control plan, the Animal Products Act requires a Risk Management Plan and the Wine Act requires a Wine Standards Management Plan, the essential requirements are the same. Hazards must be identified, controlled and monitored, traceability and recall assured, calibration of critical instrumentation achieved, product sampled and tested to assure compliance, and staff trained. Hazard Analysis Critical Control Points (HACCP) is recommended as a strategy to assess hazards and risk and to determine risk mitigation strategies, and a through chain approach is required (Orriss and Whitehead 2000).

The Food Act 2014 focuses on the processes of food production, not the premises where food is made (Act 2014). A key component of the new Act is a sliding scale, under which higher-risk food businesses will be subject to more strict food safety rules and inspections than lower-risk food enterprises (Ministry of Primary Industries 2020b). In practice, food control plans are required for higher-risk activities and national programmes are required for lower-risk activities.

Food industry and regulatory authorities in each country are supported by a range of accredited laboratories and accredited third-party verification (auditing) agencies (Kotsanopoulos and Arvanitoyannis 2017). Generally, laboratories must hold ISO 1725 accreditation to be able to provide food safety data for export certificates that are required to accompany consignments (Ministry of Primary Industries 2020b). Once food safety plans are implemented, there are regular audits and reviews to ensure the plans are operating effectively and that non-compliances are being

acted upon. The National Association of Testing Laboratories Australia (NATA) and International Accreditation New Zealand (IANZ) are the agencies that accredit laboratories in each country for their food industry (Sivakumaran, Huffman, and Sivakumaran 2018).

The Codex Alimentarius Commission (Codex) is the international food standards setting body recognised by the World Trade Agreements on Sanitary and Phytosanitary (SPS) and Technical Barriers to Trade (TBT) as being the reference point for food standards applied in international trade with the objectives of protecting the health of consumers and ensuring fair practices in the food trade (Arpaia 2017; Korada et al. 2018; Pruchniewicz and Srogosz 2020). Both Australia and New Zealand participate in Codex.

Codex Australia coordinates Australia's position on priority Codex standards (Australian Government Department of Agriculture Water and the Environment 2020; Handford, Elliott, and Campbell 2015). It expresses Australian views in Codex Alimentarius Commission fora and distributes documents under consideration to interested members of the food industry for comment (Australian Government Department of Agriculture Water and the Environment 2020). Codex Australia's consultative processes provide the avenue for all stakeholders to provide input to and consider policy, technical and strategic issues relating to Australia's role in Codex (Handford et al. 2015).

For New Zealand, the Ministry for Primary Industries Food Safety Science Group supports standard setting through Codex by providing expert scientific advice on all aspects of standards development and by participating in committees (Smythe 2013). As well, the Ministry provides input into expert groups and other international fora for standards development and leading key areas of work, which include: meat inspection, labelling, fortification of foods for special dietary uses, food additives and contaminants such as melamine and plant toxins.

For Australia, the Department of Agriculture and Water Resources is active in supporting Australia's Market access activities. It works with the Department of Foreign Affairs and Trade (DFAT) to support Australian agricultural and food export interests in bilateral and multilateral trade negotiations (Australian Government Department of Foreign Affairs and Trade 2020). The department is also responsible for technical market access, negotiating with trading partners on arrangements to open, maintain, and improve access, and providing expert advice in negotiations to restore markets when trade is disrupted (Australian Government Department of Foreign Affairs and Trade 2020). For New Zealand, the Ministry for Primary Industries Food Safety Science supports food exports from New Zealand by providing evidence that New Zealand food safety requirements are equivalent to those in destination markets (Ministry of Primary Industries 2020a).

One of the ways in which the Ministry for Primary Industries facilitates exports of New Zealand food is by making agreements with destination countries about food safety requirements for exported foods (Epps and Wheeler 2020). Destination markets set requirements which producers and manufacturers must meet if they export to that market (Lees and Nuthall 2015). Sometimes these overseas market access requirements (OMARs) do not take account of New Zealand's production processes or food safety requirements (Epps and Wheeler 2020). The Ministry for Primary Industries is alert to OMARs that may not be scientifically justified,

especially where they would add unnecessary production, processing and compliance costs to the industry. The Ministry for Primary Industries Food Safety Science Group works in a number of ways to facilitate bilateral trade through ensuring a risk-based, outcome-focused approach to OMARs and carrying out scientific projects to demonstrate that proposed OMARs are equivalent to New Zealand's standards and systems (Ministry of Primary Industries 2021). In addition, the Ministry prepares equivalence submissions for negotiations with competent authorities in destination markets, provides scientific and technical input to bilateral and multilateral agreements and builds and maintains strategic alliances with key partners.

In 2012, New Zealand Food Safety Authority (now Ministry of Primary Industries) and United States Food and Drug Administration (FDA) announced that a joint review of their respective food safety systems had been finalised with the signing of an arrangement recognising each other's food safety systems as comparable (Buchanan et al. 2015; Halabi 2015). The International Comparability Assessment Tool (ICAT) was used during a review of each country's relevant laws and regulations, inspection programs, response to food-related illness and outbreaks, compliance and enforcement and laboratory support (Buchanan et al. 2015; Halabi 2015). Such recognition opens the way to improved collaboration on matters of food safety science, food safety incidents and inspection arrangements for foods traded between the two countries.

Comprehensive public-private engagement supports new laws, standards or regulations. FSANZ's standards setting process requires at least one round of public consultation usually through issuing documents and inviting submissions (Ridgway, Lawrence, and Woods 2015; Somerset 2005). In many industry sectors, there are ongoing public-private sector working groups and for a to maintain effective communication thereby assisting policy implementation and problem resolution activities.

2.2 Canada

The Food and Drugs Act (F&DA) is the main food safety legislation in Canada and regulates safety, compositional, nutritional, labelling and sanitary manufacturing requirements of food products manufactured domestically and those imported into Canada (Cadieux, Goodridge, and Spink 2019). The legislation also sets out provisions for monitoring the interprovincial transport of food products, inspection and enforcement of the Act and its related Regulations, as well as offences for violations. The Food and Drugs Regulations (F&DR) support implementation of the F&DA by prescribing particular standards for food content and labelling (Cadieux et al. 2019). The Safe Food for Canadians Act (SFCA), along with Safe Food for Canadians Regulations (SFCR) include provisions to enhance food safety requirements and provide additional regulatory powers to the Federal government (Canadian Food Inspection Agency 2020).

The main federal governmental agencies and departments involved in ensuring food safety are Health Canada (HC) and the Canadian Food Inspection Agency (CFIA) (Health Canada 2012). HC sets food safety and nutritional standards, performs risk assessments, and develops the necessary guidance documents to minimize risks associated with food consumption (Health Canada 2020). These are enforced by the CFIA through inspection activities to monitor the whole

food system and validate compliance of all the parties involved in the food supply chain (Canada Food Inspection Agency 2020).

Other federal departments are also involved in overseeing food safety. The Public Health Agency of Canada (PHAC) conducts public health surveillance and responds to interprovincial and national food-borne illnesses and related incidents (Canada 2021). Agriculture and Agri-Food Canada (AAFC) oversees all federal agriculture matters including security of the agricultural food system, trade and marketing of agriculture products, stabilization of farm incomes, and health of the agricultural environment (Government of Canada 2021). Other federal government departments involved include Fisheries and Oceans which manages and protects fisheries, marine and fresh-water environments to ensure the sustainability of the maritime industry, and the Canadian Grain Commission which is responsible for establishing, implementing and inspecting grain grades, as well as monitoring Canada's grain distribution system (Canada 2021).

The SFCR now applies an outcome-based approach to the regulatory framework and, whenever possible, only the required outcome or level of performance are specified in the regulations (Canada Food Inspection Agency 2019a). Process or procedure requirements are not defined in the regulations but are at the discretion of the individual food businesses. As such, producers and processors are primarily responsible for the safety of the food commodities and products they supply and to continuously evaluate whether the outcomes are consistently achieved (Canada Food Inspection Agency 2021). For example, more emphasis is placed on implementing mandatory preventive control plans, in which biological, chemical and physical hazards, that present a risk of contamination of food, are identified and analysed (Canada Food Inspection Agency 2021). Preventive controls are to be put in place to prevent, eliminate or reduce hazards to an acceptable level. This provides the basis for preventive food safety control systems which meet the quality, safety and labelling requirements of Canadian food legislations (Canadian Food Inspection Agency 2020). Preventive control plans, along with the effectiveness of the control measures, must be documented, and be put into place for any foods that will be imported, exported, and moved from one province to another (Canadian Food Inspection Agency 2020). Under the SFCA, registration or licence is mandatory for all food businesses along the food supply chain which are involved in either sending or conveying food from one province to another, importing or exporting.

The SFCA and SFCR require all food businesses to implement a mandatory traceability system which enables them to identify and control ingredients and finished products along the food supply chain, including production, processing and distribution. The National Agriculture and Food Traceability System (2006), provides for the traceability of livestock and poultry as a first priority based on three pillars: animal/product identification, premises identification and movement reporting (Schroeder and Tonsor 2012).

The F&DA and SFCA govern food labelling in Canada (Cadieux et al. 2019; GFSR 2021). The SFCR provide a uniform method of labelling and packaging consumer goods, prevent misrepresentation and deception and ensure all mandatory labelling is in both official languages in Canada, English and French. The CFIA has developed an Industry Labelling Tool, which

consolidates all current requirements in a single online platform (Canada Food Inspection Agency 2019b). The Industry Labelling Tool also serves as a reference for inspectors to apply a more standardized approach to inspection and to assist industry stakeholders in complying with labelling legislation (Canada Food Inspection Agency 2019b).

Canadian food laws and regulations include lists of permitted food additives (e.g., anti-caking agents, colouring agents, sweeteners, preservatives, etc.) and their maximum allowable quantity (Canadian Food Inspection Agency 2019). If a food additive is not included in the current regulations, the manufacturer can request an amendment to have it approved as a new food additive (Canadian Food Inspection Agency 2019). Lists of permitted vitamins, minerals and amino acids which can be used for the purpose of food fortification and enrichment are also included, along with their recommended daily intake. Also included is a description of novel foods, including genetically-modified foods, and details of the pre-market notification process necessary to have the novel food approved for use in Canada. Finally, food laws and regulations include various requirements regarding food packaging materials

The CFIA is responsible for conducting compliance monitoring and verification activities and assesses the level of compliance through routine inspections, risk-based inspections, and audits (Canada Food Inspection Agency 2020). The CFIA will also conduct risk-based inspections of food and/or establishments which have a history of higher risk or probability of representing a public health risk (i.e. ready-to-eat deli meat which could be contaminated with *Listeria monocytogenes*) (Racicot et al. 2020; Zanabria et al. 2018, 2019). Regular audits are also performed by the CFIA to examine the establishment, the processing method, the food safety system, and the control mechanisms in place to minimize the potential risk the product may present to consumers (Rhouma et al. 2021).

The CFIA has developed the Integrated Agency Inspection Model, which focusses on a systems-based approach and recognized preventive risk management concepts (Andree, Ballamingie, and Coulas 2021). The industry is responsible for its products and processes and must demonstrate ongoing compliance with legislative requirements (Canada Food Inspection Agency 2020). The system is flexible to accommodate the complexity and size of an operation, as well as advancements in technology and will target food commodities that represent a higher risk for public health or companies that have previously been identified as being non-compliant. This inspection model enables both the CFIA and regulated parties to more readily adapt to emerging risks, as well as global and scientific trends. Moreover, the model is both scientific and risk-based and aligns with international standards to facilitate access to international markets (Belanche, Flavián, and Pérez-Rueda 2020).

The CFIA continues to perform regular inspections of food manufacturers. However, the inspection program is now the same for all food commodities and the frequency of inspections will depend on the risks associated with the types of food being produced and the compliance history of a particular establishment (Rhouma et al. 2021). Areas of the food supply chain which are at highest risk for public health hazards and establishments demonstrating any non-compliance will be targeted with a higher frequency of inspections.

The CFIA responds to non-compliance by applying a range of tools such as issuing a notice of violation and/or non-compliance; requesting a corrective action; additional inspections; conducting further directed sampling; seizure, detention or forfeiture of non-compliant products; suspension, revocation or refusal to renew licenses, registrations, certifications or permits; refusal of product entry into Canada or an order to remove the product from Canada; request of a voluntary recall or order of a mandatory recall; and referral for prosecution (Canada Food Inspection Agency 2020). The enforcement approach follows a continuum to support the regulated party to comply with applicable legislation, and guide them back into compliance, as needed.

Foods samples collected by inspectors to monitor regulatory compliance are either analysed by CFIA's network of laboratories or by private laboratories accredited by the CFIA (Canadian Food Inspection Agency 2021). These monitor regulatory compliance, including chemical, microbiological and physical analytical services related to foods; technology development; scientific advice; inspection services; and responding to consumer complaints. All laboratories are accredited to ISO 17025 standards (Canadian Food Inspection Agency 2021).

Maintaining and improving Canada's food safety system requires collaboration between the government and the food industry. Their collaboration is apparent as funding opportunities are given by the government to industries, and relevant associations, to work on food quality and safety issues, including traceability, whether on-farm or further down the food supply chain. These funding projects are provided by the federal government to support projects on regional, provincial, and national levels and they encourage improving food safety systems by constantly referring to the HACCP principles or other risk management systems. Public advisory committees have been established by HC as an initiative to directly work in collaboration with consumers on policy-making.

2.3 European Union

The European Union (EU) has a single legal framework for Food Safety which is binding on all 27 Member States. Yet, implementation of the framework has considerable diversity across the Member States. One of the products of Regulatory Delivery has been a practice known as Primary Authority. Under Primary Authority, businesses obtain expert advice from a local government regulator on compliance and this advice becomes legally binding on all enforcement bodies. For the business, the advice is tailored to its specific operations, turning a broad abstract regulatory system into a personalised compliance plan designed for the business and authorized in law.

The EU Food Safety Authority (EFSA) is the leading source of expertise for the whole of the EU for risk assessment (Food Standards Agency (FSA) et al. 2020). This approach is founded in the network of reference laboratories, which specialize in a specific disease or pathogen.

EU regulations require on food product labels list shelf life expectancy in the form of "Use By" date or a "Best Before" date (Samotyja and Sielicka-Różyńska 2021). Products that lose quality after a date, such as crispness or other texture, which does not affect the safety of the food are labelled "Best Before" date to indicate that change in quality. Food products must also include a list of ingredients in order to highlight allergens.

The EU traceability system was set out in Article 18 of the General Food Law (Regulation (EC) 178/2002) (Mania et al. 2018; Zhang and Bhatt 2014). Food businesses must identify end-to-end supply chain points for products. The EU system does not require forward traceability either to end customers by retailers or for suppliers to third countries. It does require traceability to apply to imports from third countries although the traceability may start at the stage of import (Charlebois et al. 2014).

There is no standard institutional structure nor single government institution in any country that deals with all aspects of food safety. The EU has the European Food Safety Authority as a source of scientific advice and communication on risks associated with the food chain (Authority et al. 2019; Bánáti 2014; Smith, Terry, and Detken 2012). It is not a policy body (which is made up of the main EU Institutions – the Council, Parliament and Commission) nor is it an enforcement body. The Food and Veterinary Office (FVO) of the agricultural Directorate General is an enforcement body that inspects the enforcement agencies of each Member State (Borraz et al. 2020; Chen, WANG, and SONG 2015). These are the Central Competent Authorities, responsible for implementing the system of Official Controls. Within the EU, there are more than 28 bodies that specialize in Food Safety because some Member States have more than one.

Although an EU-level regulatory system overrides any conflicting national regulation, implementation and enforcement of that regulatory system can allow significant variations in different Member States (Bach and Ruffing 2018). There can also be very large differences in requirements for permits and licenses.

The Commission has an inspection arm for food safety and agricultural matters through the Food and Veterinary Office (FVO) of Directorate-General Health and Food Safety (European Commission 2021). These are inspectors who inspect the enforcement systems of the Member States (and also of third countries if there are trade reasons for investigating). Each Member State has to appoint Central Competent Authorities for various regulatory systems, including food safety (Majone 2002). Each Member State has to have a Multi-Annual Control Plan which sets out its priorities for enforcement over a three year period (Borraz et al. 2020). It also has to have an annual sampling plan, in order to assess the overall level of safety. In addition to the formal enforcement systems, in many Member States it is the large retailers who control safety and quality through proprietary standards. Suppliers have to meet the retailers' requirements and these are usually higher than the formal regulatory standards.

The EU has a Rapid Alert System for Food and Feed (RASFF) which is a network of focal points in each Member State (usually the Central Competent Authority). RASFF shares information on food safety incidents and dangers both internally within the EU and also potential dangers from external sources (Esteki, Regueiro, and Simal-Gándara 2019; Lorenzen et al. 2021). Traceability is a cornerstone of the EU food safety system and businesses are expected to be able to recall products efficiently (Mania et al. 2018). The operation of managing a crisis remains a matter for each Member State's internal organization. If the crisis has a potential impact beyond the Member State, the Food and Veterinary Committee (part of the comitology system) may be convened to operate at the EU level.

2.4 United States

In the United States there are two main federal agencies which regulate food nationally: The Food Safety and Inspection Service (FSIS) under the US Department of Agriculture (USDA) and the US Food and Drug Administration (USFDA) which is part of the Department of Health and Human Services (HHS) (Grossman 2017). The type of products determine the regulating body. Meat, poultry, catfish and egg products are all regulated by USDA, while all other foods are regulated by FDA. The regulatory requirements vary by the type of food product. A HACCP certification is required for companies producing meat, juice and seafood products (Gehring and Kirkpatrick 2020). Shelf stable thermally processed low-acid and acidified foods follow thermal processing regulations, under both FDA and USDA products to ensure public health safety (Ceylan et al. 2021). Majority of the products follow the requirements of Food Safety Modernization Act (FSMA), enacted in 2011, and follows a risk based preventive approach to food safety. FSMA resulted in an overhaul of the US food regulations with mandatory controls for food facilities, produce safety standards, authority to prevent intentional adulteration, inspection frequency, record access, laboratory testing requirements, importer accountability and enhanced partnerships to name a few(United States Food and Drug Adminsitration 2021a) . More recently, FDA launched the New Era of Smarter Food Safety, to focus efforts on four core elements, 1) tech-enabled traceability 2) smarter tools and approaches for prevention and outbreak response 3)new business models and retail modernization and 4) food safety culture (United States Food and Drug Adminsitration 2021b). Collectively, these tools along with a move to predictive methods, all work to support changing consumer needs using advancements in technology.

The US is also an active participant in Codex Alimentarius, which provides a mechanism to work on a global scale and support dynamic two-way trade in the agri-food sector (Pruchniewicz and Srogosz 2020). The international networks of both the USDA and USFDA are critical to US food security and food safety since it has been estimated by the USFDA that more than 250,000 suppliers from 15 countries provide food products to the US market (United States Food and Drug Adminsitration 2019b).

The FDA relies on records review, as opposed to sampling and testing on-site and end product testing, to determine if a facility is in compliance with regulations (Kotsanopoulos and Arvanitoyannis 2017). In the absence of an outbreak or other for-cause investigation, the FDA rarely conducts finished product testing (Robert B. Wallace and Oria 2010). States may also conduct testing and sampling, which is very dependent on the priorities of the state and the resources they have available to test products.

The FDA and USDA FSIS inspect the production facilities of the products they regulate, although in very different ways. FSMA requires that the FDA inspects “high risk” facilities once every 3 years and other facilities once every 5 years (Crawford 2019). In contrast, USDA FSIS inspectors are present in most meat, poultry, and processed egg facilities on a daily basis. USDA FSIS does, however do more in-depth inspections (called Food Safety Assessments) using specially trained staff on the basis of risk (Robert B. Wallace and Oria 2010).

USDA FSIS requires much more testing of their products than the FDA (Clemens and Kadharmestan 2018). For FSIS regulated products, there is some testing that is required to be done by the manufacturing facility (such as testing for *Escherichia coli* O157:H7 in ground beef, and non-O157:H7 Shiga toxin-producing *Escherichia coli* (STEC)s in beef trim) (Bucknavage and Campbell 2020; Martino, Stone, and Ozadali 2020).

The US has the resources to separate the functions of risk assessment, risk management, and risk communication. Risk managers are generally government officials who pose questions to designated scientific risk assessors (Wu Felicia and Rodricks 2020). Both the FDA and USDA employ scientists who are risk assessors, and there is a network of well-recognized university-based food safety experts who also conduct risk assessments (United States Food and Drug Adminsitration 2021c). Risk managers make policy decisions based on the risk assessments.

FSMA requires the FDA to inspect facilities based on evaluated risk. All high risk facilities need to be inspected once within 7 years of the passage of FSMA, whereas lesser risk facilities need to be inspected within 5 years (Page 2018). After the first round of inspections, the frequency will increase to every 5 years for high risk facilities and every 3 years for lower risk facilities (Robert B. Wallace and Oria 2010). Given the complexity of today's supply chain, FDA is working to ensure policy decision are based on sound science. One such example is the development of FDA's iRISK tool by FDA CFSAN that applies the concept of risk analyses to prioritize risk and calculate optimal interventions (United States Food and Drug Adminsitration 2019b).

Routine inspections may be carried out by an FDA employee, or the FDA may contract with the individual state's food inspectors to perform an inspection on the FDA's behalf (United States Food and Drug Adminsitration 2019a). Although the minimum inspection frequencies apply, states that have more resources may conduct inspections more frequently. States also have the authority to conduct inspections on their own in addition to the work they might conduct on behalf of the FDA (Clemens and Kadharmestan 2018).

When serious violations are found, the agencies work with the US Department of Justice to determine if a legal case (criminal or civil) might be brought against a firm (Sanchez 2018). Within the past couple of years there has been a dramatic increase in criminal charges being brought against firms including their executives, as well as individuals with a role in quality/food safety.

Both the FDA and USDA have investigators that enforce the regulations or rules (Van Loo 2019; Stevens 2019). The FDA can suspend a facility's registration, making it illegal for the establishment to ship or sell food products (Rasco 2017). USDA FSIS has a similar tool in that they can cancel or suspend an establishment's official registration. The agencies have the authority to levy fines but in the US this is uncommon for food safety violations (Arsi and Donoghue 2017). Fines are more common for violations related to worker safety or environmental pollution which are regulated by different agencies. The FDA also has the authority to mandate a recall (Martino et al. 2020).

The Food Emergency Response Network (FERN) is a network of organized labs in the US designed to provide surge capacity in the event of a major event (Meigs, Merrick, and Hinrichs 2020). FERN consists of federal, state and local governmental labs. Third party, primarily private, laboratories are not integrated into this system (Inhorn et al. 2010). FERN is composed of four components: the FERN Steering Committee, the FERN National Program Office (NPO), FERN Support Programs, and the FERN Regional Coordination Centers (RCC's) (Inhorn et al. 2010; Meigs et al. 2020). Organizations with representatives on the FERN Steering Committee include state agriculture, environmental, public health, and veterinary diagnostic laboratories as well as federal partners from HHS (Food and Drug Administration, Centers for Disease Control), United States Department of Agriculture (Food Safety and Inspection Service, Animal and Plant Health Inspection Service, Agricultural Marketing Service, Grain Inspection, Packers, and Stockyard Administration), US Customs, Department of Defense, Federal Bureau of Investigation, Environmental Protection Agency, and Department of Homeland Security (Food Emergency Response Network 2021). The FERN Steering Committee is co-chaired by senior executives from the USDA FSIS and HHS FDA and the day to day operations of FERN are a joint venture between the USDA FSIS and the FDA (Food Emergency Response Network 2021).

The FSMA process ensures industry support and commitment to the rules and guidance which will ensure the law is supported by programs on the ground. Farmers, industry associations and consumers contributed to the process and submitted comments which were considered and incorporated by the FDA into subsequent iterations of the regulations.

3. RESULTS AND DISCUSSION

In many countries the traditional regulatory approach to food safety has been end product testing (Kotsanopoulos and Arvanitoyannis 2017). Testing a food product provides information about that specific product but it does not provide any guarantees about the safety of other products in the system. It is a static test of a point in time and not necessarily an indicator of the future risks. If the test is positive, it may indicate that other products from the same source may have the same contamination but testing negative may not be an indication that further products will also be safe.

Testing is most effective when the results can be used in future production. For example, testing raw materials at source may show dangerous levels of contaminants. Testing samples during a processing operation is a check on whether the processing system is working properly but environmental testing in a processing plant provides much better information of the risks for all products in the operation. Testing products at the retail stage is the least effective use of testing. By the time that the product has been harvested / slaughtered, transported, processed, packaged, transported again and stored, testing of the end product may not indicate where the problem occurred in the chain and may not even indicate whether other batches from the same producer will also have the same problem.

The food safety system applied in the jurisdictions outlined above is based on risk and applied along the entire food chain – from "farm to fork". The level of safety of a food product

may change at different points in the chain, from safe to dangerous and back to safe, depending on how it is managed. Feeding urban populations has complicated the food chain and changed the nature of food safety management in order to deal with that complexity. The entire chain needs to be understood and managed. We cannot go back to living off the land, with short food chains. Understanding and managing the dangers of modern food production and management involves assessing risks and managing them. The "farm to fork" approach shifts the focus from the product to the sequence of operations along the food chain that the product is subjected to, and to the systems applied at each stage to manage the risks.

A risk-based approach allows (limited) management of future risks, anticipating what dangers may arise, in what circumstances and how these dangers can be reduced or removed. It is based on science and evidence but also on experience and judgement. It applies to the design of the regulatory system, to the laws and the regulations, and to the implementation of the regulatory system in day-to-day activities. But above all, it has to apply to the people who are directly managing food. Food business operators and farmers are responsible to analyse the dangers in their operation and take steps to control them. This may seem too sophisticated for many small businesses but there are ways of simplifying it for them that have proved successful in other countries. For larger businesses, systems exist that can be tailored to their operations.

The fundamental principle underpinning the risk-based systems is that people and businesses add risk to food through their operations and the key to safe food is how well these risks are managed by these same people. The safety of the raw materials remains an issue but is only one factor in safe management of food along the supply chain. Testing alone cannot help with the other factors which involve the operations that add risk to the food – harvesting, slaughtering, cutting, packaging, transporting, processing, storing, cooking, displaying and home food preparation. Processing alone is an operation that can be extremely complex as different food products are mixed with multiple ingredients and these may themselves simply be new materials for further processing along the supply chain. That chain may be global, with products crossing half the world twice in their route to market.

A focus on prevention suggests that governments are being more proactive in delivering safety. Enforcement becomes a matter of monitoring results rather than actively delivering public benefits. The onus for following laws becomes the responsibility of practitioners. This changes the dynamic of the regulatory system. Punishing a food business for non-compliance does not deliver safer food. Supporting a food business in improving its compliance does deliver safer food.

3.1 Enforcement Models - Responsive Regulation

There is a widespread approach to the enforcement of regulatory systems called Responsive Regulation (Ajwang 2020). This approach recognizes that compliance support requires an understanding of the barriers to compliance, including the factors that stop these businesses from being more compliant. The cost of compliance will always be a major factor and one that has to be taken into account in designing the regulatory system. Businesses will also need to be convinced that if they bear the compliance costs then their competitors will also bear the same

costs: this is an obligation on the enforcement agencies to create a "level playing field" where enforcement is applied equally across the sector. There is also a recognition that how well businesses are treated by the enforcement system also helps improve compliance, referred to as "Procedural Legitimacy". If the business sees the system as fair and evenly applied, it is more likely to accept penalties when they are deserved and try harder to work with the system to get it right.

3.2 Applying risk at the operational level

There are many different operations involving food which can each present dangers. Transporting food is not an activity that involves changing the nature of the food, compared with processing or cooking for example, but the activity of transporting may actually change the nature of the food unintentionally. The most important factor is maintaining the correct temperature that the food needs in order to prevent growth of pathogenic microorganisms that could pose a public health concern. The time spent in transport may also affect the food even if properly stored, as can altitude if the food is being transported by air. For this operation, the likely hazards are well known and the ways of controlling them are also straightforward and well understood. It should be possible to transport food in complete safety by maintaining adequate temperatures but the transport stage can be a weak link in the chain.

For each operation, the starting point is analyzing the hazards inherent in the operation, including the hazards in the raw materials themselves, as well as in each step in the operation. The most commonly used approach is the HACCP method (Kuo and Hsiao 2021). The analysis identifies the key points in the operation where something can go wrong, which become the control points at which specific action is taken to avoid or reduce the risk. The overall approach is simple but its application to particular situations can be extremely complex; there is an enormous body of learning developed across the world and experts can be hired to assist in setting up a HACCP system. Getting full HACCP certification can be expensive because of hygiene standards for the physical environment in which the food business operates, which can involve rebuilding the premises if they are not suitable. But the importance of HACCP is in the system rather than the premises. The state of the premises is a basic requirement but HACCP is a dynamic system that needs to be applied constantly. An inspection of a food business running a HACCP system involves observing the system in operation to ensure all key points have been identified and adequate control points have been put in place, and checking documentary records.

For small businesses, however, engaging consultants is not feasible yet they also need advice. In the EU, it is mandatory for all food businesses to apply HACCP principles, including small businesses (Trafialek and Kolanowski 2017). Most small food businesses have fairly basic operations and HACCP principles can be applied generically. There is a growing body of expertise on how to provide practical advice on good food safety management systems to small food businesses in a way that will benefit businesses.

3.3 Risk profiling of businesses

The risk-based approach sees the business as the main focus of attention for enforcement, not the product (Borraz et al. 2020). It is the business that adds risk and can also manage risk.

There may be risks inherent in specific products but that is only one factor. The enforcement agency needs a database of all food businesses under its control, including a risk profile for that business. The normal spread of risk is across three levels but some split Medium into Upper and Lower. In some countries, catering businesses have been rated from A to D or with a red/orange/green stoplight designation and that system is spreading now to production and distribution.

The risk profile of the business should determine the frequency of inspection, with higher risk businesses receiving more frequent inspections (Borraz et al. 2020; Kaskela et al. 2019). Frequency will also depend on the resources available to the agency. Risk is a combination of the severity of the hazard and the likelihood of its happening. Severity is a combination of seriousness and extent. This applies directly to assessing the risk level of a business, with a combination of two factors: The nature of the materials and the processes as some foods are more dangerous than others and some processes add more danger than other processes.

The severity of possible damage: this includes both the seriousness of the possible illness and the number of people who could be affected. Seriousness can also include the vulnerability of the people affected, such as hospitals or schools. Because of this factor, most small businesses tend to be Low Risk because they are unlikely to affect many people, compared with something like a bottling plant that may affect thousands of people.

Typically, jurisdictions use a scoring system that gives scores for each of the elements mentioned above and allows an overall score to be given, which then translates into a risk level. Devising a scoring system requires expertise but the actual scores will be influenced by the risk criteria. That means that scores may change from one year to another if the risk criteria also change. This three factor approach places a very high importance on the ability of the business to manage its risks well since that covers the element of likelihood. The ability of the business to manage its risks is at the heart of the system.

3.4 Risk Communication

A further component of risk is Risk Communication. The EU regulatory system recognizes this as a third element of the overall Risk Analysis package – Risk Assessment, Risk Management and Risk Communication (Flynn et al. 2019). At one level, this is mainly a requirement for transparency and joint working across the different agencies involved in risk assessment and risk management. At another level, it is about raising awareness of risks with the general public, consumers and businesses. Food safety is a sensitive issue in any society because everyone is vulnerable to becoming ill from unsafe food. Food safety can also be a confusing issue because there are many ingredients that are harmless in small doses but possibly fatal in large doses and it is easy for a “food scare” to escalate over the discovery of a substance that is unlikely to do any damage to anyone eating a normal amount. When the media escalate an issue into a “food scare”, it is helpful if the public has trust in a particular institution and will follow advice on whether there is any danger and, if so, what to do about it. Building that trust is another challenge for an enforcement agency but is part of the risk-sharing strategy mentioned earlier. In the EU system, there is no single enforcement agency because it is a collection of 27 Member States but there is

the European Food Safety Authority (EFSA), created as an integral part of the EU food safety system (Mantovani 2018). EFSA is responsible for the scientific risk assessment of emerging risks and also has a role in risk communication with the public.

4. LESSONS LEARNED

Businesses add risks by their operations along the food chain but they are also in a position to manage these risks successfully. Consequently, the focus of regulatory systems is on ensuring that food businesses manage their risks well. The "farm to fork" approach means supervising all stages in the food chain and checking systems rather than products. Given this, the success of regulatory systems relies on raising compliance levels across the whole sector and not on reducing cases of violations, which has a profound effect on enforcement policies and strategies. Most businesses are willing to be compliant and will work with the authorities to improve their compliance levels. An enforcement model based on coercion is less likely to increase compliance levels than one based on support. Testing of products is rarely done by enforcement agencies in the study countries and, apart from an annual monitoring plan, it is usually done to confirm suspicions in individual cases. Testing is done by the businesses themselves as part of their own food safety management systems.

The enforcement agency needs to build trust from the public and consumers, especially in a time of crisis, when the enforcement agency can reduce public anxiety through good risk communication. It is also important to raise awareness amongst the public of basic food safety issues so that consumers can make better buying choices and act as another driver in improving the compliance of businesses. All jurisdictions in this study place responsibility for the safety of food on the bodies which have the food under their control, at any point in the supply chain "from farm to fork". These bodies can add risk to the food they control, even if only temporarily, e.g. in transporting it, but they can also ensure safety through applying good practices. Governments set standards for safety, through application of science and following international standards as well as provide guidance and support to food businesses and to consumers on good practices for managing food safety risks. Ultimately, governments must take robust action against anyone who deliberately endangers consumers.

The relationship between food businesses and the government is more one of co-governance in trying to manage food safety risks rather than being adversarial. That co-governance also extends to consumers, with governments ensuring provision of information through labelling and with consumers demanding safety and quality from the businesses. In all the countries, but especially Canada and the US, the leading food businesses are following private sector standards that exceed official standards and have become de facto international standards for parts of the global trade in food. These are enforced by large businesses themselves, requiring their suppliers to meet these standards.

The jurisdictions presented here have complicated and distributed institutional structures for food safety, even where there has been significant streamlining at the very top. Some have multiple laws at different levels of a federal structure, some have a single law but have devolved responsibility for implementation and all have a range of government bodies with specialized

functions relating to food safety. Implementation and enforcement of the food safety systems in each of the countries studied (apart from New Zealand because of its size) is carried out by a range of enforcement bodies, sometimes determined by the type of food product but more often determined by the level of government. The EU and the USA have the most broadly distributed enforcement.

Yet there are major challenges remaining for these countries with emerging economies in applying international standards for food safety. Training, awareness-raising and capacity-building is needed in each of the countries. This applies to the enforcement staff, to food businesses and to consumers. A Law does not give sufficient information to show how good practices can be applied and even Guidance can be limited in its application. Educating small businesses remains particularly challenging, although effective good practices are emerging.

Traceability and recall will never be perfect, despite sophisticated systems being developed and applied. The *E. coli* outbreak in the EU in 2011 which killed 53 people took many months to be traced back to sprouting seeds in Germany and during that time it was mistakenly attributed to Spanish cucumbers, causing drastic economic damage to cucumber growers across the whole EU (Meagher 2021).

4.1 General Recommendations for emerging economies

Many countries still face major challenges in making national food safety control systems work. Change is needed on the part of (a) enforcement personnel, (b) food businesses and (c) consumers if the full potential of any new food safety Law is to be delivered.

Under national or federal guidance, preferably a unified single food safety agency, there needs to be a common and consistent approach to implementation of food safety laws at all levels of government. There still needs to be room for responding to genuine local differences but significant differences in approach to implementation across local government boundaries will present expensive burdens to large businesses which trade across these boundaries. Confusion about what the Law is intended to achieve will itself be a real barrier to achieving these intended results. To counter this requires capacity-building within government at all these levels, backed by good science.

Many individual food businesses could already be applying HACCP or similar food safety risk management systems but a holistic view across individual food chains that links these systems where they exist should be developed in order to optimize the impact. A chain is only as strong as its weakest link so capacity-building at the level of the food chain needs that holistic view. Capacity-building should also look for links with capacity-building on the enforcement side to ensure both sides move forward in a collaborative and consistent manner. It should also look for opportunities to support small producers in that holistic view of the whole food chain.

Consumers and the public more generally need to engage with these changes, as intended in the Law, so that their trust can start to be built in both the regulatory institutions and in the businesses in the food chains. This calls for better communication by government of the actual risks involved in food safety, to replace the occasional “food scares” as the main source of education of the public.

Changing public attitudes and assumptions takes time but engagement in the changes taking place in the way the food chains operate and are enforced should support that change in attitudes.

The construction of an effective national food safety control system demands a comprehensive, integrated, and rational organization of regulatory policy, infrastructure, and human resources to restrict and regulate the complexity of food safety risk. Stations for border inspection, laboratories, information systems, and operational resources for monitoring, inspection, surveillance, and incident response are only a few of them. In emerging markets, food safety is overseen by a myriad of government organizations, many of which work independently and with little cooperation. As one of the main steps to increase the cohesion of government monitoring, governments regularly construct new institutions or undergo institutional change while simultaneously enacting new risk-based food safety rules and regulations that are compatible with international standards. The data offered in this study can assist regulators, key stakeholders, and donors in the design and development of a national food control system that is compliant with international standards.

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