Final Report

Review of national food control plans in Australia, Canada, New Zealand and United States

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1 Executive summary

Campden BRI was commissioned by the Food Standards Agency (FSA) to complete a desk study reviewing and comparing the sampling systems of four countries of interest – Australia, Canada, New Zealand, and the United States. This report aims to provide a qualitative assessment of how competent authorities in each of these jurisdictions perform sampling and analysis of food and feed, their systems for gathering intelligence and other information which informs the need and structure of any sampling and testing programme.

The review found that the authorities in the four markets do not necessarily use the same terminology as the three types of sampling identified by the FSA. These differences presented a challenge when comparing sampling systems in the four markets.

A substantial level of fragmentation in the development and enforcement of food law in Australia and the United States also added to the complexity of the task. It was demonstrated for the United States and theorised for Australia that sharing the responsibilities between multiple agencies may lead to differences in the extent of regulatory oversight in different parts of the country or between foods, sometimes even with similar associated risks. By contrast, the oversight of the entire food chain from farm to fork, including animal feed and biosecurity, in Canada and New Zealand is predominantly in the hands of a single regulatory authority, which may potentially facilitate the planning of various sampling activities.

The operational arrangements for various sampling activities in all four countries showed significant variation. While samples for official controls and surveillance are mostly collected by government officials, or at least by third-party personnel accredited by government, sampling for a number of programmes is conducted by third-party contracted samplers. In certain cases, food business operators are legally required and therefore are responsible for taking the samples, arranging the testing, and/or submitting data to the authorities.

Government agencies in the United States and especially in Canada benefit from a well-developed government laboratory infrastructure but may use third-party private laboratories as well, if needed. However, the authorities in New Zealand and

Australia predominantly rely on the services of external accredited or government approved laboratories.

The Canadian Food Inspection Agency (CFIA) in Canada and Food and Drug Administration (FDA) in the United States require most food establishments to implement preventive controls and official controls in relation to affected establishments are mostly concerned with verifying the effectiveness of preventive controls in place. In New Zealand, most businesses are required to have appropriate food safety systems in place as well. In Australia, similar requirements on the state/territory level were noted only for higher risk industry sectors. Preventive controls as well as various food safety systems or schemes make use of sampling and testing to monitor the effectiveness of such systems.

A number of programmes were identified where regulated businesses are required to share sampling and testing data with the authorities. In Canada, such information feeds into Establishment-based Risk Assessment models, which then use the cumulative data to calculate the level of risk associated with a specific establishment and determine the level of oversight that it will receive.

As all four countries are major exporters of agri-food products, exporting establishments are subject to additional oversight, including mandatory participation in dedicated sampling and testing programmes, including for microbiological hazards and chemical residues.

The research revealed that in terms of imports, Australia and New Zealand classifies imported foods based on risk to consumers and public health associated with the food, and riskier foods are subjected to a significantly higher level of scrutiny. For instance, “risk food” imported into Australia is initially inspected and tested at a rate of 100% of consignments. The rate later drops to 25% or even 5%, meanwhile “surveillance food” is inspected and potentially tested at a rate of 5% at random. In New Zealand, imported foods presenting a greater risk to consumers and public health known as “High Regulatory Interest Food” and “Increased Regulatory Interest Food” require a food safety clearance, are monitored for specific hazards, and may need to be sampled and tested.

The CFIA in Canada is gradually adopting a risk-based approach, where product inspection and sampling is conducted primarily through the ongoing compliance verification of importer's Preventive Control Plan. Also, the CFIA aims to develop a dedicated Establishment-based Risk Assessment model for importers to automatically determine the frequency of inspection and sampling needed.

All shipments of FDA- and Tax and Trade Bureau (TTB)-regulated products must be notified to the FDA and therefore are electronically screened. Risky products or entries that are incomplete or contain inaccurate data are flagged. Properly notified shipments of lower-risk product are most likely to be allowed to enter without further FDA review. At the same time, all imported Food Safety and Inspection Service (FSIS)-regulated products are subject to reinspection to verify the equivalence of inspection systems in exporting countries. One or more types of inspection are conducted on every lot of product before it enters the United States.

Considering inherent differences in the regulatory systems as well as other aspects such as market size, products on the market, or share of imports/exports, a comparison of the numbers of samples taken by authorities for various purposes was considered subjective. There were challenges in having a comprehensive view of sampling activities due to the fact that not all documents are in the public domain. The enforcement agencies may also publish reports on some past activities with a significant delay. The level of information on sampling activities was particularly inconsistent in the United States.

Authorities in all four countries reviewed periodically conduct nationwide total diet surveys to assess consumers' exposure to certain food safety risks but certain differences in the organisation of such studies were highlighted. These include whether it is an ongoing programme or taking place every 2 or even 5 years, how many kinds of foods and beverages are collected, and which parameters are being tested.

Although we have not identified in the four countries any industry intelligence sampling systems in use that would be similar to Food Industry Intelligence Network, several examples of how authorities leverage the industry sampling and testing data. In certain cases, such sampling, testing and data sharing with the relevant authorities

is mandated, in certain others, sharing of own sampling and testing data is only encouraged.

And finally, ongoing efforts by FSIS and the CFIA to take stock of their sampling activities were noted. A strategic review of sampling resources at FSIS is expected to yield a semi-quantitative method to rank current and future sampling projects, Strategic Assessment of Sampling Resources (PDF).

2 Introduction

Sampling and subsequent analysis is a key tool in maintaining the safety and authenticity of the food supply chain. The FSA distinguishes three main types of sampling: for official controls; as a means of testing hypotheses; and as a source of intelligence data.

"Official controls" are defined in retained Regulation (EU) 2017/625 as "activities performed by the competent authorities, or by the delegated bodies or the natural persons to which certain official control tasks have been delegated…, in order to verify compliance by the operators with this Regulation and with the rules referred to in Article 1(2); and that animals or goods meet the requirements laid down in the rules referred to in Article 1(2), including for the issuance of an official certificate or official attestation". Therefore, sampling for official controls covers all aspects of food and feed safety, labelling, animal and plant health, animal welfare, pesticide use and others.

Hypothesis (surveillance) sampling is defined by the FSA as being "undertaken to test hypotheses identified through the collation of intelligence from the FSA's surveillance programme, or to provide sampling evidence where we have a lack of knowledge around a specific risk or food product". In turn, intelligence sampling refers to access to data generated and shared by organisations beyond central and local government, for instance, by industry.

The specific objectives of this study were to provide an overview of global approaches to the use of these three types of sampling and analysis, how they complement each other, and to also examine the intelligence gathering and other mechanisms which inform the need for, and structure of, sampling and analysis for official control and surveillance purposes.

Despite the efforts to align the findings in the four markets with the three types of sampling as used by the FSA, it was not always possible as the terminology used differs from country to country, from authority to authority within the same country, and sometimes even between similar activities conducted by the same authority. Particularly challenging was the identification of what constitutes "official controls" in four markets.

3 Approach

The aims of the project were addressed by systematically reviewing for each country:

- The underpinning legislative and regulatory basis.
- How official controls and surveys are performed together with methodologies adopted.
- Intelligence gathering together with hypothesis generation and testing.
- Use of third-party data (for example, generated by food or feed businesses) to provide leverage to quality of outputs from regulatory activities.

Primary competent authorities in each of the jurisdictions considered were identified in collaboration with the FSA and are listed in Table 1. The objectives described above were addressed in a three-stage process:

i. Web-based literature review. The websites of these organisations were interrogated using, as terms of reference, Figure 1 (Division of responsibility for official food controls) in the Multi-Annual National Control Plan for the United Kingdom, April 2019 to March 2023, produced by the FSA, and Figure 2 (Proposed FSA sampling data flow) in the FSA report FSA sampling framework: our future approach to sampling. Overviews of the search strategies used for interrogating the websites of primary competent authorities are provided in Annex 1.

ii. Interviews with national representatives. Representatives of the various organisations listed in Table 1 and identified by the FSA agreed to provide additional information and detail through web based structured interviews using a pre-agreed interview aide-memoire (Annex 2).

iii. Review of information in the scientific and technical literature. Literature searches were performed using the publicly available PubMed and the subscription-based Food Science and Technology Abstracts (FSTA) databases. Search ontologies were developed using key words linked by Boolean operators and were used to interrogate titles and abstracts. Final search ontologies used are detailed in Table 2. In the case of New Zealand and the United States, searches were performed twice using slightly different search ontologies to take into account that two separate agencies have

primary responsibility for sample collection and testing. A separate literature search for products under TTB was not conducted as TTB has a very niche product portfolio to oversee with limited sampling activities and also because FDA is responsible for overseeing the safety of ingredients in all products. Coarse outputs were further reviewed and refined to confirm relevance. The results of literature searches are presented Annex 3.

Table 1. Primary competent authorities identified

Country	**Authority**
Australia	Food Standards Australia New Zealand
Canada	Canadian Food Inspection Agency
New Zealand	Food Standards Australia New Zealand
New Zealand	Ministry of Primary Industries
United States of America	Food and Drug Administration
United States of America	Food Safety and Inspection Service
United States of America	Alcohol and Tobacco Tax and Trade Bureau

Table 2. Search ontologies used for literature searches performed on PubMed and FSTA databases

Country	Search ontologies
Australia	(fsanz OR “food standards australia new zealand”) AND (sampl* OR survey OR control OR monitor* OR intelligence)
Canada	(cfia OR "canadian food inspection agency") NOT (fragilis OR "gene cfia" OR "cfia gene OR cfia-gene") AND (sampl* OR survey OR control OR monitor* OR intelligence)
New Zealand	(fsanz OR “food standards australia new zealand”) AND sampl* OR survey OR control OR monitor* OR intelligence) (mpi OR “ministry of primary industries”) AND “new zealand” AND sampl* OR survey OR control OR monitor* OR intelligence)
United States of America	(“food safety inspection service” OR fsis) AND (sampl* OR survey OR control OR monitor* OR intelligence) ("center for food safety and applied nutrition") AND (sampl* OR survey OR control OR monitor* OR intelligence)

Each country considered is discussed in a separate chapter. All chapters follow a similar structure and begin with a brief description of the country. This is then followed by three sections using similar headings as in Figure 1 of the FSA’s Multi-Annual National Control Plan, except that the last of the three is broader as it is not limited to sampling for official controls. The last section for each country aims to cover aspects addressed under Figure 2 (Proposed FSA sampling data flow) in the FSA’s report FSA sampling framework: our future approach to sampling.

4 Comparative overview

The outcome of the study suggests that there is no one size that fits all as considerable differences in terms of planning and conducting various sampling activities were observed between the four countries reviewed and sometimes even between the authorities within the same country.

4.1 Terminology

The first observation is that authorities in Australia, Canada, New Zealand, and the United States tend to use slightly different terms compared to the United Kingdom. While the FSA documents distinguish sampling for official controls, hypothesis/surveillance sampling, and intelligence sampling, these are not necessarily the terms used in other countries. This is especially problematic when considering what constitutes “official controls” in specific countries. The terminology used may also differ between the authorities within the same country, as in the United States, or even between specific programmes. This complicates a direct comparison of sampling activities for official controls between the four countries to a certain extent.

4.2 Authorities

Competent authorities in Canada, New Zealand, and the United States play both regulation setting and enforcement roles. By contrast, the main competent authority for Australia (FSANZ) sets standards and coordinates responses to food safety and related incidents but does not have an enforcement function. This means that enforcement of food and feed laws in Australia is done on two levels – control of imports and exports as well as biosecurity aspects on the national level is conducted by the national government while most other aspects of food and feed law are left to state and territory governments to implement, monitor, and enforce under local enabling legislation. It is not impossible that this fragmentation may lead to slight differences in the extent of oversight in different parts of the country.

Similar observation can be raised for the United States where federal oversight of all food is divided between three main authorities. Two of the agencies (FSIS and TTB) oversee a narrow range of foods but the rest, which constitutes ~80% of all food, is regulated by the FDA, which effectively serves as a safety net. States also play a significant role, especially for retail and catering industries, and for foods in intrastate commerce.

In Canada and New Zealand, the oversight of the entire food chain, including animal feed and biosecurity, is largely concentrated in the hands of a single regulatory authority. Although provincial/territorial authorities in Canada also play a role, this is mostly limited to businesses trading within the province or territory. Having a single

central authority may potentially facilitate the planning and implementation of official controls and surveillance activities.

By contrast, in Australia, official controls can be prompted by national and state/territorial agencies, while surveillance activities can also be instigated by binational bodies such as FSANZ and ISFR where state/territory governments indirectly play a considerable role as well.

4.3 Who does the sampling?

While samples for official control and surveillance purposes in all four countries are mostly collected by authorised officials, especially in establishments with stationed government officers, or at least by third-party personnel accredited by the government as in Australia, arrangements for sampling sometimes provide for the use of third-party contracted samplers, especially where samples need to be collected from restaurants or retail, in remote areas, or on a regular basis. In certain situations, employees may be asked to take official samples, although under the direction of the authorised officer.

4.4 Laboratories

Government agencies in the United States and especially in Canada have a well-developed government laboratory infrastructure, whereas the authorities in New Zealand and Australia do not. Instead, authorities in New Zealand fully rely on external independent laboratories such as the ones accredited under the MPI's Recognised Laboratory Programme or approved by the MPI to test imported food. Some reports indicate that Australian authorities tend to have a primary contracted laboratory for certain tasks but also use additional accredited laboratories as needed.

North American authorities may use third-party accredited private laboratories as well. For example, in instances where there is a need to test the samples near the sampling site to reduce the time between sample collection and the reporting of test results to minimise economic losses associated with products that test negative for pathogens. In the United States, some testing required by law or under agreements with the industry associations may only be conducted at either official laboratories or at one of the laboratories approved under laboratory approval programmes.

4.5 Approach to food and feed sampling

In the United States, the surveillance of food/feed and enforcement is effected by various federal and/or state agencies. Since products under FSIS jurisdiction are relatively riskier, FSIS-regulated establishments are subject to a much more comprehensive oversight. This includes not only pre-market label approvals, but also continuous inspection by FSIS, active participation of the inspection personnel in the everyday operation of the plant, such as taking official samples for pathogen reduction performance standards purposes, microbiological or residue control, and conducting other verification activities, for instance, reviewing establishment's SOPs, HACCP plans, test results, and corrective actions. FSIS-regulated establishments may be required by law to conduct various types of sampling and testing and share results with the authorities. Some of the sampling conducted is for establishment categorisation purposes only and does not necessarily prevent the contaminated food to be sold.

While FSIS-regulated establishments producing meat, poultry, and egg products in the United States are regulated separately. This higher level of scrutiny when it comes to riskier foods is noticeable in all three other markets as meat, poultry, dairy, and certain other establishments tend to be subject to an extra layer of regulatory oversight which usually includes participation in a number of dedicated monitoring programmes. Export-oriented establishments are usually subject to an even greater level of oversight to ensure access to key export markets.

Considering the tax implications of products overseen by TTB, most TTB-regulated alcoholic beverages are subject to pre-market label and/or formula approval before a product could be produced or imported. For certain products, especially imported, this also involves submitting a sample for laboratory analysis. As such, TTB has a substantial level of visibility regarding potential issues associated with the products it oversees. At the same time, FDA oversees the safety aspects of alcoholic beverages under TTB.

The FDA oversees the vast majority of foods, including game meat and certain alcoholic beverages, but has somewhat disproportional resources. Therefore, FDA's approach to ensuring the safety of human and animal food is based on substantially different principles from the FSIS. Instead of more frequent inspections and wider

use of sampling for “official controls”, most food businesses are required to implement appropriate preventive controls, which may involve sampling and testing.

In Canada, most establishments trading interprovincially are also required to implement preventive controls. To reflect that, the CFIA is gradually adopting a new risk-based approach to inspection where product inspection and sampling is conducted through the ongoing compliance verification by inspectors of establishment’s preventive controls. This risk-based approach is reflected in Establishment-based Risk Assessment (ERA) models being developed and implemented by the CFIA. Under these models, the frequency of inspection will be guided by the risk associated with a specific establishment, meaning that higher risk establishments will be subject to more oversight. As of April 2021, the automated calculation and delivery of risk results and profiles under ERA-Food was implemented in dairy, maple, honey, egg, processed fruits and vegetables, and fish sectors.

Agri-food businesses in New Zealand are required to have appropriate food safety managements systems in place and depending on the nature and size of the business may be required to collect and test samples to verify the continuing efficacy of their food safety management systems. In the case of meat processing businesses, samples collected are used to generate a ranked list that shows establishment’s performance against the national benchmark.

In Australia, the oversight of most aspects of food law is in the hands of state/territory governments. In New South Wales, which served as an example of systems on the state/territory level for the purposes of this report, food businesses in higher risk industry sectors operate under the corresponding state’s Food Safety Scheme. Among other things, the schemes specify minimum sampling and testing requirements for food businesses licensed under these schemes. The compliance is then verified by the state authority through its verification programmes.

4.6 Sampling of foods for export

All four countries are important exporters of agri-food products and, as a result, have systems in place to ensure continuing access to foreign export markets. Australia and New Zealand have a particularly strong focus on exports. For this reason,

exporting establishments must not only meet all applicable requirements of the importing country but may also need to take part in the statutory test and sampling programmes such as AEMIS and National Residue Survey in Australia or Independent Verification Programme in New Zealand. This is less pronounced in Canada as most exports are destined for the United States. Therefore, food industry is mostly concerned with meeting the specific requirements for one market.

Industry sampling and testing for microbiological hazards is also required under a number of export certification programmes. As an example, establishments exporting raw beef manufacturing trimmings to the United States from Australia, Canada, and New Zealand will all be required to participate in the corresponding national sampling and testing programmes for *E. coli* STEC.

4.7 Sampling of imported foods

All food imported into Australia is classified as either a “risk food” (medium to high risk to public health and safety) or “surveillance food” (low risk) following an imported food risk assessment conducted by Food Standards Australia New Zealand (FSANZ) to determine the risk factors associated with the food. While all imported food may be inspected and potentially sampled for analytical testing by the Australian Department of Agriculture, Water and the Environment (DAWE), “risk food” is initially inspected and tested at a rate of 100% of consignments, with inspection rate potentially dropping later to 25% or even 5%, meanwhile “surveillance food” is inspected and potentially tested at a rate of 5% at random. Information such as the importer, producer, or the country of origin has no effect on the random selection and referral for inspection for “surveillance food”. For “risk food”, a compliance history is built upon a specific combination of producer, country of origin, and tariff code but not on individual importer’s compliance history. “Surveillance food” may be distributed following the inspection and before test results are received, but “risk food” is subject to a “test and hold” directive.

New Zealand uses a similar targeted approach to monitoring imported food based on risk, where imported foods presenting a greater risk to consumers and public health known as “High Regulatory Interest Food” and “Increased Regulatory Interest Food” require a food safety clearance, are monitored for specific hazards, and may need to be sampled and tested, with the exception of imports from Australia. Whether

sampling and testing or some other form of evidence is required depends on the food, associated hazards, and the country or geographic region of origin.

For most foods imported into Canada, the CFIA is adopting a risk-based approach to inspection, where product inspection and sampling is conducted primarily through the ongoing compliance verification of importer's Preventive Control Plan by CFIA inspectors. Under this approach, imports are only held if inspector suspects an issue. For the purposes of planning inspections of imports, the CFIA aims to develop a dedicated Establishment-based Risk Assessment model.

Canadian inspection and monitoring systems for imported meat products are not yet updated and would subject the first shipments of meat products from a newly authorised foreign establishment to full organoleptic import inspection which, by the way, would be conducted in a Canadian third-party establishment licensed to conduct such inspection. Depending on the results, the establishment is either automatically placed into the reduced or intensified inspection mode. In case of adverse test result from monitoring sampling of imported meat products for microbiological and chemical contaminants, the CFIA will apply a targeted sampling plan for 15 consecutive shipments of at least 15 times the total weight of the original non-compliant shipment of meat products originating from the same establishment.

All shipments of FDA-regulated products imported or offered for import into the United States are electronically screened, and risky products or entries that are incomplete or contain inaccurate data are flagged. If prior shipment notice is properly submitted, a lower-risk product may be allowed to enter without further FDA review. Any entry that does not receive a release by FDA's automatic system is routed for manual review. This could happen for products identified as higher-risk, prior notice entries with incomplete or inaccurate data, or products identified for examination or sampling, either on a surveillance basis or specifically targeted. Sampling under FDA's surveillance programmes takes into account the volume of the target food that is imported and produced domestically and the number of states/countries that produce the target food.

TTB-regulated alcoholic beverages are not exempt from FDA's prior notice requirement and may be flagged by the FDA.

In connection with imports, it is important to mention Import Alerts, a tool used by the FDA to block imports of foods associated with specific known risks as well as foods coming from specific companies, countries, or geographical regions. The FDA does not need to inspect foods covered by an Import Alert – such products are automatically refused entry.

For foods under FDA's jurisdiction, certain risk-based verification activities are performed by importers rather than the FDA as they are required to verify that food imported into the United States has been produced in a manner that meets applicable safety standards. In addition to inspecting the importers, the FDA also conducts an increasing number of inspections at food facilities based abroad, which may involve sampling and testing.

The FDA aims to leverage the expertise of foreign food safety systems by signing Systems Recognition Arrangements with foreign regulatory counterparts. Such arrangements currently signed with Australia, Canada, and New Zealand allow the FDA to prioritise resources in a more risk-based manner as foods produced under comparable but not necessarily identical food safety systems could be deemed relatively safer. FDA intends to adjust its risk-based screening and targeting criteria for import entries of foods covered by System Recognition Arrangements as well as limit inspections in these countries.

By contrast, all imported FSIS-regulated products are subject to reinspection under a monitoring program conducted to verify the equivalence of inspection systems in exporting countries. One or more types of inspection are conducted on every lot of product before it enters the United States. The reinspection includes chemical residue testing and can be done through normal random sampling, increased sampling (at the discretion of FSIS management), or intensified sampling (additional samples taken after a previous failed sample). The estimated annual amount of product imported into the United States is used to assign the number of samples.

4.8 Numbers of samples

Considering inherent differences in the regulatory systems as well as other aspects such as market size, products on the market, or share of imports/exports, a comparison of the numbers of samples taken by authorities for various purposes can

be quite subjective. It does not help that some enforcement agencies do not make their sampling planning documents publicly available and often publish reports on activities conducted in the past with a significant delay. Once published, reports tend to provide a good level of detail regarding methodology and rationale but definitely not always. The level of information on sampling activities was particularly inconsistent in the United States.

Some authorities (for example FSIS) have made their sampling planning documents publicly available, providing a useful insight into the processes used to plan activities, including sampling for surveillance, compliance verification, or other purposes, and reasoning behind each. Certain others (i.e. CFIA, MPI, FDA) limit which documents are publicly available as some information is deemed potentially sensitive as it might reveal, for example, inner workings of the authorities, which is not always helping the authorities in their mission to ensure the safety and compliance of products on the market. Information on specific programmes, projects, activities, action plans may sometimes be limited as well.

Since the information on sampling for “official controls” purposes is not always available, especially for domestically produced foods, the information below on the numbers of samples primarily focuses on sampling for hypothesis/surveillance purposes.

The FDA’s current strategy for microbiological surveillance sampling is to collect a large number of samples of targeted foods over a relatively short period (about 18 months) focusing on specific emerging issues or addressing a specific knowledge gap rather than sampling a relatively small number of samples of many different commodities over many years as was the case before 2016. The sampling design for each food usually aims to represent what U.S. consumers are likely to find in the marketplace (for example in terms of country or state of origin, variety, product form, season etc.). Sampling plans for targeted surveys are designed such that if contamination of 1% or greater was present in the commodity, the agency would be likely to detect it. In most cases, this meant aiming to collect 1,600 samples of each commodity. Depending on the results, sampling can be decreased (if few positive samples are obtained) or retargeted (if trends are identified). Information on FDA’s

sampling design for other purposes such as compliance verification or chemical contaminant monitoring was not as informative.

By contrast, FSIS publishes an annual sampling plan clearly detailing the numbers of routine samples and tests planned for each product class. The numbers planned for each commodity are based on current FSIS plans, policies, and industry practices. Obviously, positive routine samples, or other unpredicted events, may trigger additional non-routine sample collections. In FY 2021, planned numbers of samples for chemical residue analyses were between 100 and 788 per product class. The same for microbiological contaminants ranged from 660 for raw catfish to 47,892 for raw poultry. The plans for import samples are driven by expected shipment frequency and volume-based “Type of Inspection” (TOI) tasks. TOI tasks are assigned to imported product from each foreign country/product combination based on the number of imported shipments received. The numbers of samples in FSIS’s programs other than microbiological and chemical residue sampling (for example label verification for allergens, antibiotic or hormone free, species identification) are mostly planned around 200-400 per sampling project.

Since the TTB no longer publishes the results of its Alcohol Beverage Sampling Program, it is difficult to estimate the current numbers of samples taken by TTB. The last available report shows that 450 products were randomly sampled in 2016 but does not provide further information on the sampling methodology.

The CFIA’s surveillance sampling for microbiological contaminants and chemical residues is designed to provide a statistical estimate of the compliance rate of the food production system and therefore aims to collect at least 300 samples per commodity, although it is not always possible. The samples selected are unbiased, random, and collected throughout the fiscal year or when available based on production times or seasonality. The number of samples to be collected for chemical residue surveillance is determined taking into account past compliance data, the volume of food produced, country of origin, consumption information, and changes in import or production locations and practices, and additionally targets the commodities that historically have limited CFIA-generated chemical residue data. The number of samples for microbiological surveillance taken for each product depends on various factors, including the number of establishments producing the food product, whether

the food product would be consumed directly or would undergo further preparation, historical compliance levels, market access requirements, and others. As could be expected, sample numbers taken for targeted surveys depend on many factors and therefore vary greatly.

In Australia, the number of samples taken for a particular survey planned for by FSANZ or ISFR tends to be on a lower side. This could potentially be due to the fact that most such sampling tasks focus on current and emerging issues. On the other hand, Australian primary producers are required by law to participate in national residue monitoring programmes. As a result, the number of samples tested under one of the programmes run by the National Residue Survey at the DAWE is higher (10,476 samples of animal origin and 4,842 of plant origin tested in 2019/2020). Higher numbers were also noted under the Imported Food Inspection Scheme – 42,889 lines of imported food were inspected and potentially analysed, although the report indicates only the number of tests conducted (54,486 label and composition assessments, 25,084 analytical tests, and 52,432 other tests) rather than the number of samples taken for analysis. The number of samples taken by the NSW Food Authority was at 4,540 in 2019/2020. It included 3,622 samples taken for the purposes of food safety compliance verification, 663 samples taken under one of the three verification programmes, and 255 samples for research and targeted surveillance purposes.

For some programmes, New Zealand uses statistically based sample sizes. For instance, in the raw milk monitoring component of the National Chemical Contaminants Programme, the number of samples taken aims to provide 95% confidence of being able to detect an incidence of non-compliance in the sampled population of 1% or greater (i.e. at least 300 official random monitoring samples taken each year for analysis of the core substances monitored). For substances with a proven history of conformance fewer samples may be collected each season, with on-going conformance assessed over multiple seasons. In 2020/2021, the targeted surveillance component of the programme was limited to 5 directed colostrum samples. Under the National Chemical Residues Programme, sampling plans for the monitoring part of the programme are issued on a two-monthly or annual basis. If maximum levels are exceeded, the supplier may be placed on a surveillance list. In 2018/2019, 1,834 samples were taken for monitoring purposes as well as 98

surveillance samples. For surveys, a smaller number of samples is typically taken. The plan for the MPI's Food Residues Survey Programme involved acquiring 60 samples from each ten Codex classified groups of plant food over the period of two years (2017/2019). Although no info was found on sampling numbers under the National Microbiological Database Programme as this is arranged by the operators, it is worth mentioning that only certified trainers or approved samplers can take samples for this programme.

4.9 Total Diet Studies

Authorities in all four countries periodically conduct nationwide total diet surveys to assess consumers' exposure to certain food safety risks, although there are some differences in the organisation of such studies.

In the United States, Total Diet Study is an ongoing programme that monitors levels of about 800 contaminants and nutrients in the average U.S. diet. Samples of about 280 kinds of foods and beverages are collected from representative areas of the country, combined to form one composite sample ("market basket"), and analysed 4 times a year.

Under the Canadian Total Diet Study, levels of priority chemicals are measured in food samples either annually, on a pre-determined cycle, or in response to a specific food safety issue. Approximately 2,100 food samples from one of the nine Canadian cities are collected each year and prepared to form approximately 160 composite samples. The list of contaminants sees significant variation each year.

The Australian Total Diet Study is conducted approximately every two years. The latest report indicates that only 88 food types were sampled and that the composite samples were prepared for a single state or territory rather than for the whole country.

In turn, New Zealand Total Diet Study is conducted only approximately every 5 years. Its focus is on approximately 300 agricultural chemical analytes in ~130 most common foods in the New Zealand diet that make up 90% of the population's intake.

4.10 Data exchange with the industry

We have not identified any specific industry intelligence sampling systems similar to the ones in use by the FSA, such as Food Industry Intelligence Network. This does not mean that the authorities in the four countries have no means of obtaining and leveraging additional sampling data from the regulated establishments. For example, to one degree or another (based on risk), all four countries require certain businesses not only to collect and test samples but also to share the resultant data with the competent authorities. In some cases, test data are generated in sufficient quantity for enforcement agencies to exercise forms of statistical process control which enables enforcement agencies to analyse trends and identify outliers.

In most cases, the details of how industry sampling data is used by the authorities are not publicly available. A notable exception is Canada, where we know that data shared by food businesses on a mandatory and voluntary basis via additional establishment information questionnaire, feeds into the Establishment-based Risk Assessment (ERA) models.

The National Microbiological Database programme in New Zealand is another example of how authorities can leverage sampling and testing conducted by the industry. In 2009/2010, the MPI used specimens routinely sampled from freshly dressed carcasses of very young calves, pigs and broiler poultry and submitted by the industry as part of the National Microbiological Database programme to conduct additional testing to determine a baseline of antimicrobial resistance in bacteria. The outcomes of the National Microbiological Database programme also have helped in developing MPI's *Campylobacter* risk management strategy, which involved setting *Campylobacter* performance target as well as subsequent monitoring to ensure processors are producing food within safe limits.

4.11 Strategic reviews of sampling activities

Lastly, it should be noted that some authorities recently decided to take stock of their sampling activities. For instance, FSIS recently organised a strategic review of sampling resources aimed at maximising the efficiency, effectiveness, and value of sampling projects. The underlying premise for the assessment was that sampling only fulfils its purpose when the data it generates is used by the authority. The assessment took inventory of all current sampling projects and the reasons behind

each and developed weighted categories and criteria for scoring and ranking the potential benefits of each. A semi-quantitative method to rank current and future sampling projects is still under development.

The CFIA has also initiated a review of its surveillance activities, with a focus on sampling and testing, risk identification and analysis. An action plan for the implementation of risk-based decision-making, regular surveillance reviews, and expanded CFIA's data sharing capabilities is expected.

5 Australia

The Commonwealth of Australia is a federation, comprising six states (New South Wales, Queensland, South Australia, Tasmania, Victoria, Western Australia) and ten territories which are to one degree or another directly controlled by the national government.

5.1 Development and implementation of food law

Food safety is a national competency addressed by the Food Standards Australia New Zealand Act 1991. This Act authorised the establishment and operation of a joint body to be known as Food Standards Australia New Zealand (FSANZ). The joint body came into being as a result of Australia New Zealand Joint Food Standards Agreement, which in turn was an outcome of the Australia-New Zealand Closer Economic Relations Trade Agreement (CER Agreement).

Although food safety law is a national competency, the execution of a number of functions (often including sampling and testing) devolves to the state and territorial governments. For the purposes of this exercise, activities within New South Wales (NSW) will be considered where appropriate.

An overview of authorities with key responsibilities for developing and implementing food law in Australia is presented in Figure 1.

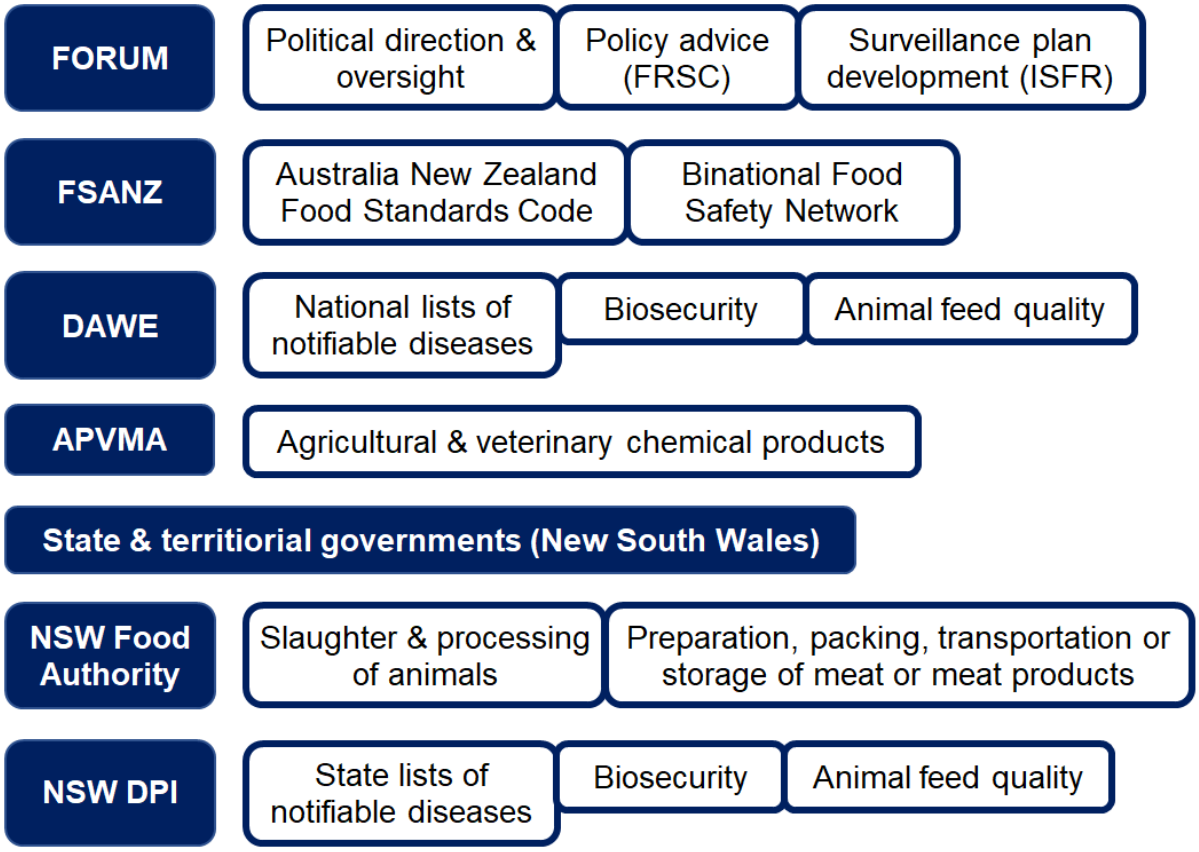
5.1.1 Australia and New Zealand Ministerial Forum on Food Regulation

Political direction and oversight are provided by the Australia and New Zealand Ministerial Forum on Food Regulation (Forum), which is responsible for developing domestic food regulation policy in the form of policy guidelines. Membership of the Forum consists of ministers from the New Zealand and Australian national governments, Australian state/territorial health ministers as well as ministers from related portfolios (for example Primary Industries and Consumer Affairs) where they have been nominated by their jurisdictions and the Australian Local Government Association as an observer.

Policy advice to the Forum is coordinated by the Food Regulation Standing Committee (FRSC). Some of these functions are undertaken by the Implementation Subcommittee for Food Regulation (ISFR), which has been described as “a subcommittee where Australian and New Zealand food regulators meet to discuss

and determine common approaches to implementing food standards which are then agreed and produced as guidelines". Of relevance to this exercise is the ISFR Coordinated Food Survey Plan, which describes "Tier 1 national and binational co-ordinated surveillance and monitoring activities".

Figure 1. Overview of authorities with responsibilities for enacting food laws and regulations in Australia



- **Forum:** political direction and oversight, policy advice (FRSC) and surveillance plan development (ISFR).
- **FSANZ:** Australia New Zealand Food Standards Code and Binational Food Safety Network
- **DAWE:** National lists of notifiable diseases, biosecurity and animal feed quality.
- **APVMA:** Agricultural and veterinary chemical products

State and territorial governments (New South Wales):

- **NSW Food Authority:** Slaughter and processing of animals and preparation, packing, transportation or storage of meat or meat procuts.

- **NSW DPI:** State lists of notifiable diseases, Biosecurity and Animal feed quality.

5.1.2 Food Standards Australia New Zealand

Food Standards Australia New Zealand (FSANZ) is an independent statutory agency. Its responsibilities include establishing standards that regulate the use of ingredients, processing aids, colourings, additives, vitamins and minerals in the Australia New Zealand Food Standards Code. The Food Standards Code also covers the composition of some foods such as dairy, meat, and beverages as well as foods developed by new technologies such as genetically modified foods. FSANZ is also responsible for labelling requirements for packaged and unpackaged food, for example, specific mandatory warnings or advisory labels. FSANZ also develops Australia-only primary production and processing standards.

5.1.3 Other national authorities

On the national level, the Department of Agriculture, Water and the Environment (DAWE), among other things, has responsibility for agricultural, fishing, and food industries, export and import controls, biosecurity, in relation to animals and plants.

DAWE also hosts the Australian Pesticides and Veterinary Medicines Authority (APVMA), which is responsible for the approval of agricultural and veterinary chemicals as well as the establishment of maximum residue limits.

5.1.4 State authorities (New South Wales)

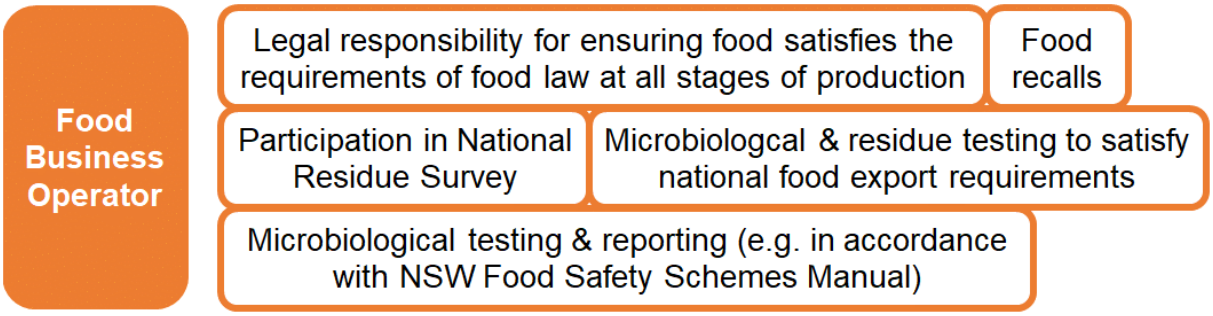
Individual states and territories are responsible for laws in connection with the slaughter and processing of animals as well as the preparation, processing, storage and transportation of meat products. They also have responsibility for industry specific food safety schemes.

In New South Wales, food safety regulations are enacted and enforced by the NSW Food Authority. This organisation also contributes to national surveys organised under ISFR and FSANZ auspices as well as conducting its own. Biosecurity is the responsibility of the NSW Department of Primary Industries, which addresses plant and animal diseases, identified at both national and state levels, as well as animal feed quality.

5.2 Ensuring that food satisfies the requirements of food law

As summarised in Figure 2, food business operators have a legal obligation to comply with relevant food legislation. Depending on the commodity or food as supplied to the consumer, food businesses also have an obligation to submit samples for testing to both microbiological and chemical end-points in order to meet the requirements of national or state legislation. Examples at a national level, which are considered here, are the National Residue Survey and the Australian Export Meat Inspection System. At a state level, Food Safety Schemes Manual of the NSW Food Authority is discussed.

Figure 2. Australian food businesses' responsibilities (New South Wales)



Food Business Operator:

- Legal responsibility for ensuring food satisfies the requirements of food law at all stages of production
- Food recalls
- Participation in National Residue Survey
- Microbiological and residue testing to satisfy national food export requirements
- Microbiological testing and reporting (for example, in accordance with NSW Food Safety Schemes Manual)

5.3 Sampling activities in respect of food

An overview of roles played by different competent authorities in Australia in relation to food is provided in Figure 3. Key sampling surveys and programmes are summarised in Table 3. More specific information on some of these can be found in Annex 4.

To help monitor and enforce standards implementation across jurisdictions, the ISFR develops a Coordinated Food Survey Plan, which identifies and prioritises the survey

activities. Surveys are usually coordinated by FSANZ but operationally can be managed by other (state) government bodies.

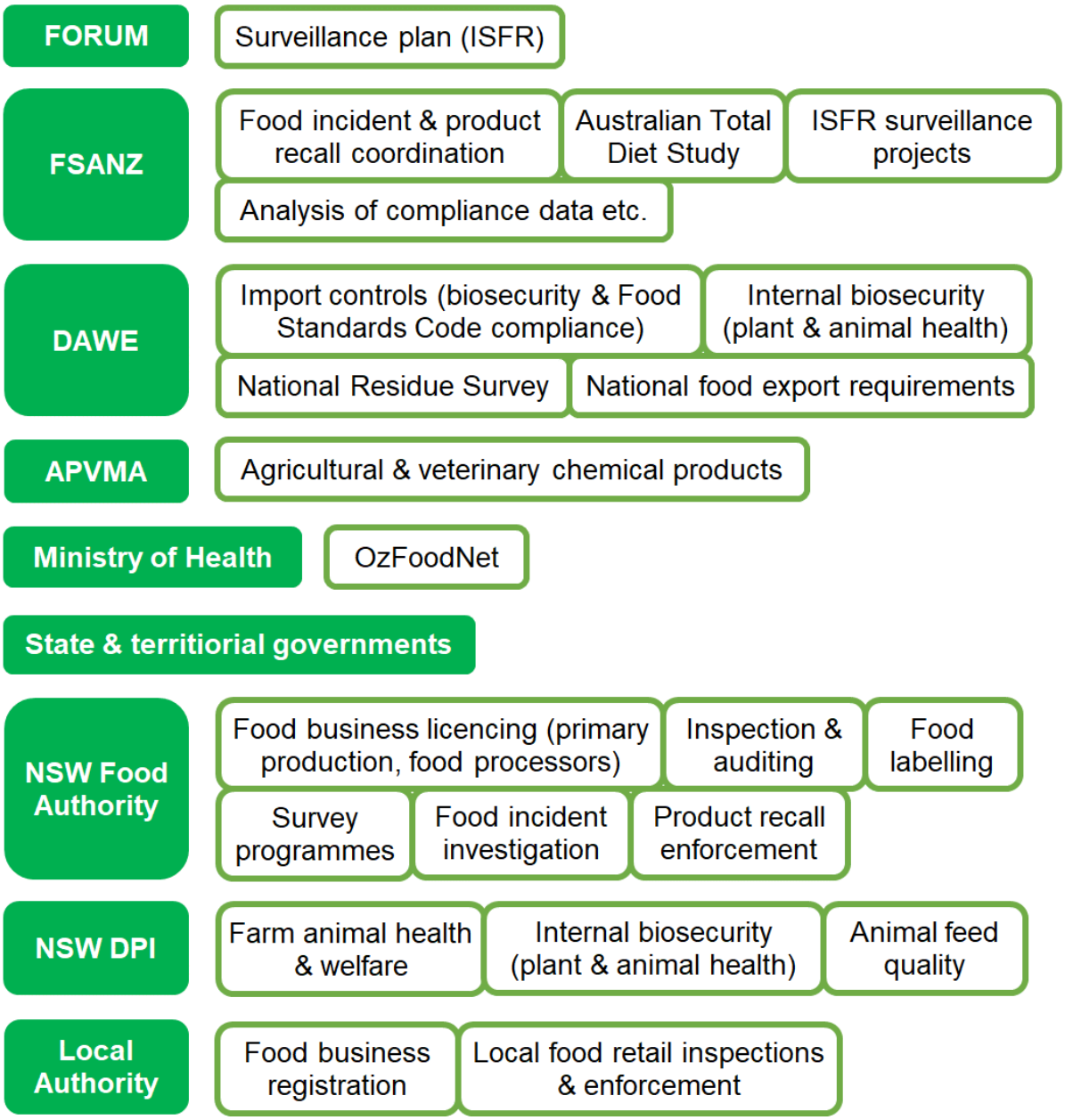
FSANZ coordinates and manages surveys instigated under the ISFR's Coordinated Food Survey Plan. It also coordinates and manages the Australian Total Diet Study and conducts *ad hoc* surveys in support of its activities to maintain the Food Standards Code.

The DAWE is responsible for the administration of a number of schemes relating to sampling and testing. These include the Imported Food Inspection Scheme, the Australian Export Meat Inspection System, and the National Residue Survey.

State governments can require food businesses in certain sectors to use sampling and testing as part of the process both to verify their food safety management systems and demonstrate that remedial actions in the event of a non-compliance have been effective.

State authorities themselves also collect and test samples. For instance, the NSW Food Authority regularly conducts testing of food products to ensure compliance with regulatory requirements, as part of foodborne illness investigations and to gather information to identify and respond to food safety issues. It also undertakes scientific surveillance projects to identify and better understand food safety issues and risks in the state.

Figure 3. Sampling activities in respect of food law in Australia



- **Forum:** Surveillance plan (ISFR)
- **FSANZ:** Food incident and product recall coordination, Australian Total Diet Study, ISFR surveillance projects and Analysis of compliance data.
- **DAWE:** Import controls (biosecurity and Food Standards Code compliance), Internal biosecurity (plant and animal health), National Residue Survey and National food export requirements.
- **APVMA:** Agricultural and veterinary chemical products
- **Ministry of Health:** OzFoodNet

State and territorial governments:

- **NSW Food Authority:** Food business licencing (primary production and food processors), inspection and auditing, food labelling, survey programmes, Food incident investigation and product recall enforcement.
- **NSW DPI:** Farm animal health and welfare, internal biosecurity (plant and animal health), animal feed quality.
- **Local Authority:** Food business registration and local food retail inspections and enforcement.

Table 3. Key sampling surveys and programmes in Australia

Activities	**Description**
Coordinated Food Survey Plan	The ISFR plan detailing national and binational coordinated surveillance and monitoring activities, including the Australian Total Diet Study. Lead agency/participants may differ and can include DAWE, FSANZ, MPI NZ, and state/territory agencies.
Australian Total Diet Study (ATDS)	Monitoring programme conducted approximately every two years to assess consumers' dietary exposure. Coordinated by FSANZ. A particular focus may be set by the ISFR. Samples collected by state/territory agencies. Testing is outsourced.
Surveys to support development and implementation of the Food Standards Code	Surveys commissioned by FSANZ or instigated by ISFR under its Coordinated Food Survey Plan. Data is evaluated by FSANZ. Sampling and testing are outsourced.
National Residue Survey (NRS)	A set of monitoring programs designed in consultation with industry and the Exports Division of the DAWE, aimed at monitoring Australian animal and plant products for chemical residues and environmental contaminants. Testing is conducted by contracted laboratories. Includes targeted residue testing programs as well.

Activities	Description
Imported Food Inspection Scheme (IFIS)	Monitoring scheme administered by the DAWE to assess compliance of imported foods with the Food Standards Code and biosecurity requirements. Inspection is conducted by DAWE authorised officers.
Australian Export Meat Inspection System (AEMIS)	The system managed by the DAWE requires exporting processors to collect and submit samples for testing in approved laboratories for a number of key performance indicators such as microbiological quality of carcasses, finished products, and the environment (product hygiene index). It also requires participation in the NRS.
NSW Food Safety Schemes Manual	Specifies mandatory minimum sampling and testing requirements for food businesses licenced by NSW Food Authority under particular food safety scheme. Microbiological testing must be done in a NATA approved laboratory. Adverse results must be notified to NSW Food Authority and FSANZ.
NSW Food Authority verification programs, research and targeted projects, and food safety compliance testing	Verification programs for RTE products under Food Safety Schemes, raw poultry, and kJ menu labelling. Research and targeted projects to inform the Food Authority's future risk assessment work. Food safety compliance sampling. Testing is conducted by contracted laboratories.

5.4 Intelligence gathering and data integration

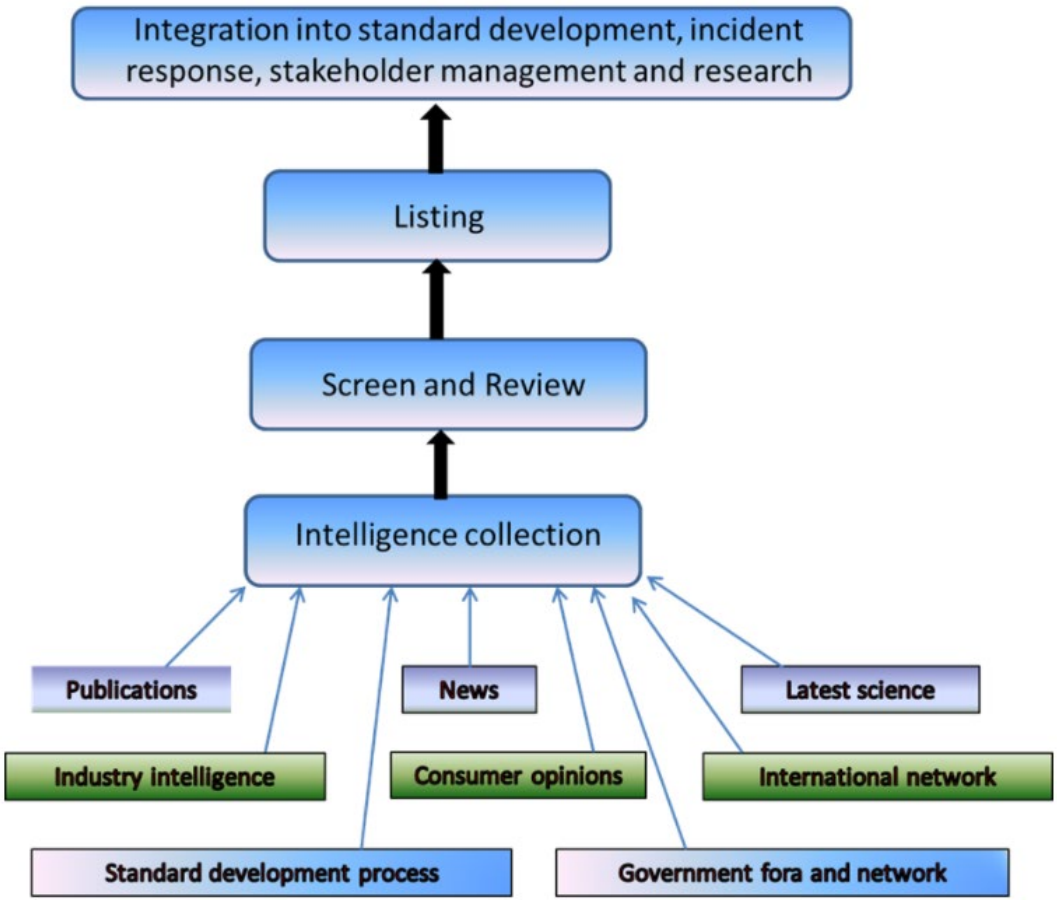
5.4.1 Food Standards Australia New Zealand

Two of the principle roles of FSANZ are to maintain the Food Standards Code and coordinate incident investigations/food recalls. It does not have enforcement powers which are a state/territory competence with the exception of imported foods. In order to maintain an appropriate level of situational awareness, a necessary prerequisite, for both those involved in risk assessment and management as well as enforcement,

is provision of appropriate intelligence either through consideration of emerging and ongoing issues or through efficient transfer of data.

Development of the strategy to inform surveys and other activities is undertaken in accordance with a structured process. Issues are identified by FSANZ officers from a range of sources including the scientific literature, traditional and social media, international organisations and agencies, public and industry consultations (see Figure 4 for the workflow). This includes consulting expert advisory groups formed to focus on specific issues, academia, research institutions. Issues cease to be considered under this process when their management is subsumed within another process, for example, development of a standard or when no further action is required following the issue's investigation.

Figure 4. FSANZ distributed system for identifying and managing emerging and ongoing issues



Source: FSANZ, 2019

Under this workflow, FSANZ actively engages with stakeholders, and its latest annual report on emerging and ongoing food safety issues describes consultations with two key stakeholder committees, the Consumer and Public Health Dialogue (CPHD) and the Retailers and Manufacturers Liaison Committee (RMLC), as well as its own board in the identification of emerging issues and future trends impacting on the food regulatory system.

A summary of the outputs from the consultations regarding emerging issues is provided in Table 4. Arsenic in rice, 3-monochloropropandiol (3-MCPD), glycidyl esters (GE), caffeine, hepatitis A virus in ready-to-eat berries, intense sweeteners, microplastics in the food supply chain, per- or polyfluoroalkyl substances (PFAS), and pyrrolizidine alkaloids were recognised as ongoing issues in 2019. Meanwhile, antimicrobial resistance, glutamates in food, and *Salmonella* in raw fish were identified for archiving or to be managed through other processes. Identified issues are likely to be "hazards" needing further investigation. Investigations may require acquisition of further information through the conduct of bespoke surveys or additional testing of samples collected in other surveys such as the Australian Total Diet Study.

Table 4. Emerging issues identified in 2019/2020 FSANZ stakeholder consultations

CPHD	**RMLC**	**FSANZ Board**
Sustainability and climate change	Plant-based and synthetic meat	Innovation and food technology
Information for consumers	Packaging	Public health and diet
Innovation & changes in the food supply	Climate change	Disruptions

CPHD	RMLC	FSANZ Board
Governance and process	Agility	Climate change and sustainability
Obesity and overweight	Legislative review	Consumer and social changes
Food hazards (in particular impacts of microplastics, antibiotic use in food, food additives and gut microbiome, food fraud)	Consumer and stakeholder confidence	Globalisation
Food fraud	-	-

Source: FSANZ, 2020

5.4.2 OzFoodNet

OzFoodNet was established by the Australian Department of Health in 2000 as a collaborative initiative with Australia's state and territory health authorities. Its function is to provide both a national capacity to identify and respond to outbreaks of foodborne diseases as well as providing information on foodborne disease. It works in collaboration with FSANZ, DAWE, state and territory food authorities, as well as the Public Health Laboratory Network. It provides intelligence on the incidence foodborne diseases which can then be acted on by relevant state agencies to investigate and implement appropriate corrective actions. Case reports of significant incidents are published in Communicable Diseases Intelligence (CDI), which is a peer-reviewed scientific journal published by the Australian Office of Health Protection, Department of Health. Relevant reports for the period 2016-2020 are listed in Table 5. Most of the incidents reported relate to microbiological incidents;

however, a number relate to outbreaks relating to phycotoxins (ciguatera fish poisoning and paralytic shellfish poisoning).

Table 5. Overview of case reports of significant Australian food poisoning incidents published in Communicable Diseases Intelligence journal (2016-2020)

Year	Title
2020	A fatal case of Shiga toxin-producing *Escherichia coli* linked to a private drinking water supply
2019	• An outbreak and case-control study of *Salmonella* Havana linked to alfalfa sprouts in South Australia, 2018 • An outbreak of *Bacillus cereus* toxin-mediated emetic and diarrhoeal syndromes at a restaurant in Canberra, Australia 2018 • A protracted outbreak of *Salmonella* Hessarek infection associated with one brand of eggs—South Australia, March 2017 – July 2018 • Four recent ciguatera fish poisoning incidents in New South Wales, Australia linked to imported fish • Free range eggs does not mean safe eggs: an outbreak of *Salmonella* Typhimurium linked to free range eggs
2018	An Outbreak of Paralytic Shellfish Poisoning in Tasmania
2017	• An outbreak of *Salmonella* Saintpaul gastroenteritis after attending a school camp in the Northern Territory, Australia • An outbreak of salmonellosis associated with duck prosciutto at a Northern Territory restaurant • An outbreak of *Salmonella* Muenchen after consuming sea turtle, Northern Territory, Australia, 2017
2016	• Clinical diagnosis and chemical confirmation of ciguatera fish poisoning in New South Wales, Australia • Epidemiology of bacterial toxin-mediated foodborne gastroenteritis outbreaks in Australia, 2001 to 2013

5.4.3 Data exchange

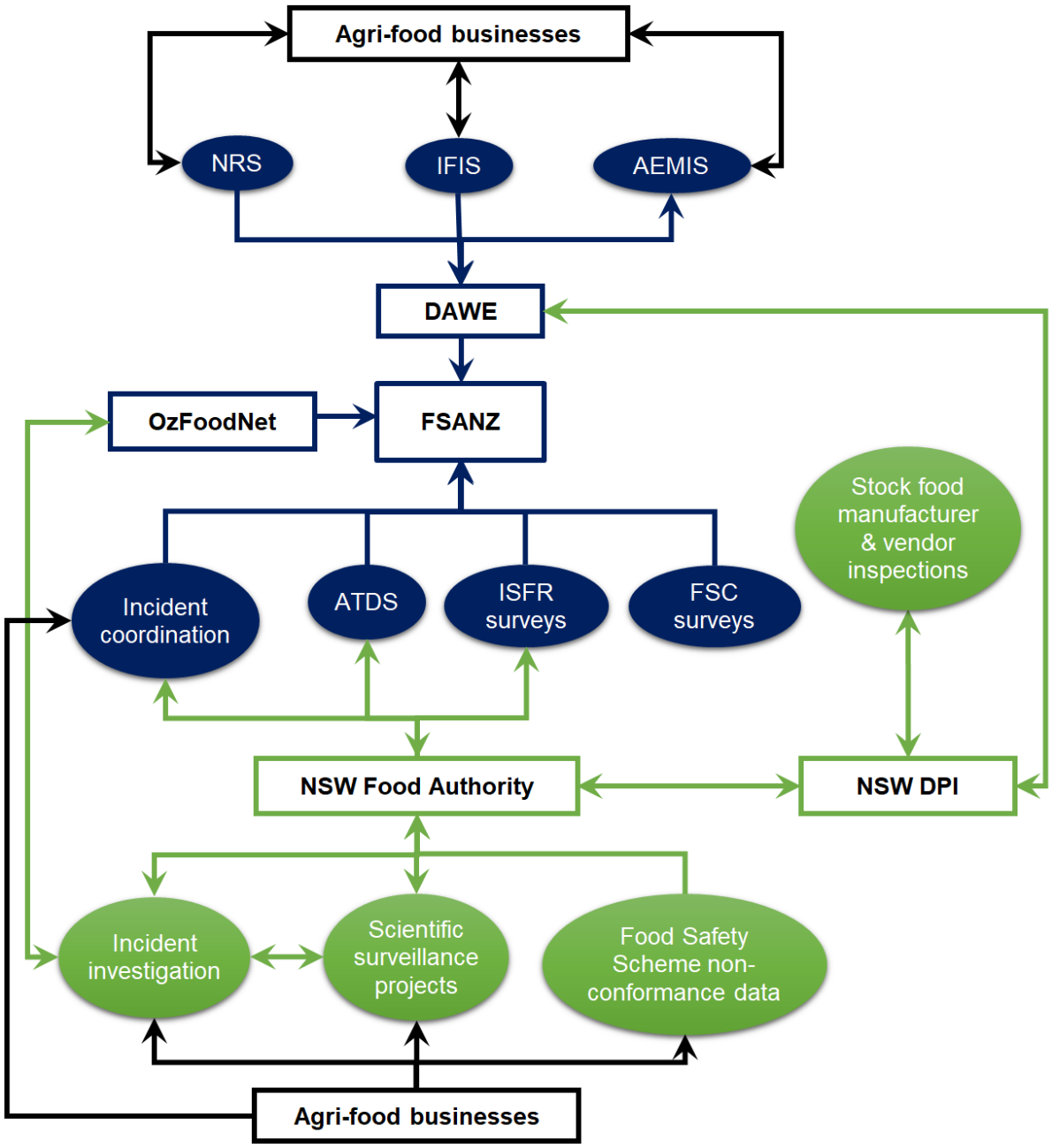
Data exchange has to be seen within the background of:

- The contribution made by agri-food businesses to the Australian national economy and in particular exports. Approximately 65% of Australia's total agricultural production is exported. In 2016, these were valued at AUD 44.7 billion and represented of 14% of all goods and services exported (Department of Foreign Affairs and Trade).

- Legislative requirements at national and/or state/territory levels for agri-food businesses to commission laboratory analyses, which provide evidence contributing to verifying the efficacy of their food safety management systems. Information is either directly shared with relevant government departments (irrespective of outcome) as in the cases of the National Residue Survey or when it suggests that a process is nonconforming as in the case of food businesses located in New South Wales and subject to a specific food safety scheme.

The term "data" is taken to include the provision of physical samples, test results and/or other relevant information. An overview of data flows is presented in Figure 5. Sampling and testing by industry are often integrated within legislative framework.

Figure 5. Analytical data and other data flows between various stakeholders in Australia and New South Wales



Depending on the program, resultant data may be used to provide:

- A form of statistical process control (for example AEMIS) directly accessible to regulators;
- Quality control data (for example IFIS);
- Evidence of verification of food safety management systems. This either can be through statutory test and sampling programs (for example AEMIS and NRS) or through supporting surveys in the maintenance and development of the Food Safety Code (for example On-farm food safety practices survey of strawberry growing in Victoria).

Critical to the process of data exchange and integration is FSANZ. Although it does not have an enforcement role, FSANZ co-ordinates responses to food safety incidents, ensuring a consistent response across all states and territories. Where necessary, it liaises with relevant public health officials through OzFoodNet. Data generated through surveys managed or commissioned by other national departments (for example DAWE) and state government agencies (for example NSW Food Authority) are also shared with FSANZ. These data contribute to the situational awareness of FSANZ, both operationally as well as strategically in helping to inform its own survey activities.

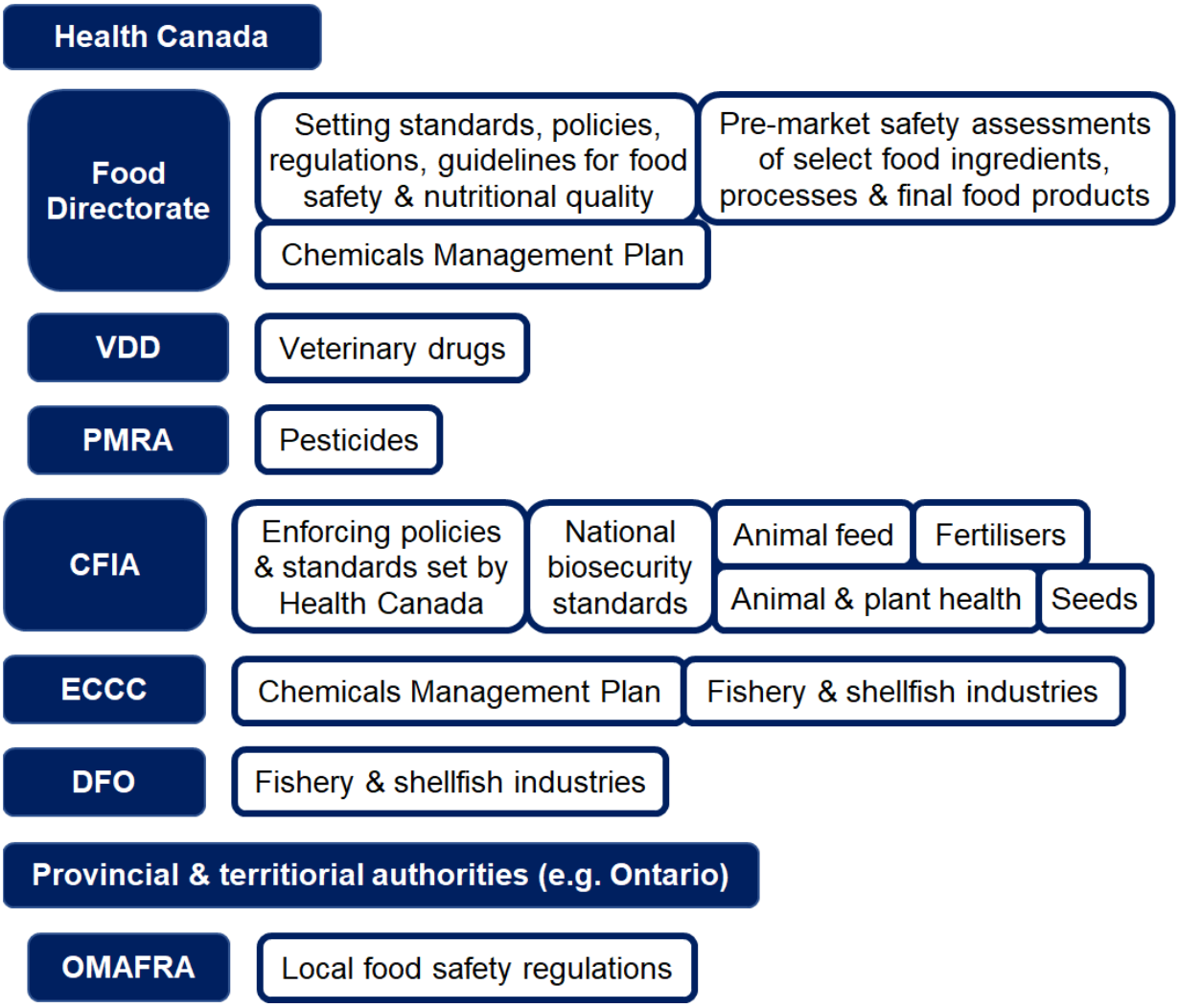
6 Canada

Canada is a federation, comprising ten provinces and three territories. Provinces are to one degree or another considered to be co-sovereign with the federal government with divisions of responsibility based on the constitution. Territories derive their authority from the federal government.

6.1 Development and implementation of food law

The prohibition of selling unsafe food is established in the Food and Drugs Act (FDA). Specific requirements (for example in terms of labelling, composition, adulteration, food additives, irradiation, novel foods) are established in Food and Drug Regulations (FDR). The interprovincial (and some within province) manufacture and sale of food, as well as the import and export of food is legislated for by the Safe Food for Canadians Act (SFCA). Food business obligations under the Act are set out in the Safe Food for Canadians Regulations (SFCR). Provincial and territorial governments may also regulate the production and sale of food. An overview of authorities with key responsibilities for developing and implementing food law in Canada is presented in Figure 6. Most of the legislation setting bodies are part of the Health Portfolio and ultimately report to the Minister of Health.

Figure 6. Overview of authorities with responsibilities for enacting food laws and regulations in Canada



6.1.1 Health Canada

The Food Directorate within the Health Products and Food Branch of Health Canada is the federal health authority responsible for assessing health risks and benefits, setting standards, policies and regulations, and providing advice and information regarding the safety and nutritional quality of all foods sold in Canada. It is composed of six bureaus, three of which (Chemical Safety, Nutritional Sciences, and Microbial Hazards) are science-based and implement the Directorate's core program in food risk analysis and research, standard setting, and market authorisation. The other three are horizontal in nature and are responsible for policy (Policy Intergovernmental and International Affairs), science (Food Surveillance and Science Integration), and operations integration (Business Systems and Operations).

The Health Canada's Pest Management Regulatory Agency (PMRA) is responsible for pesticide regulation in Canada while the Veterinary Drugs Directorate (VDD) of

Health Canada's Health Products and Food Branch performs a similar function for veterinary drugs.

6.1.2 Canadian Food Inspection Agency

The Canadian Food Inspection Agency (CFIA) is a science based regulator, whose mandate encompasses food safety, animal health, plant health, and international market access. Its scope therefore extends beyond food safety and also addresses sanitary and phytosanitary controls including animal feed. As the name of the organisation implies, and, given its scope, the CFIA has primary responsibility for inspection and food law enforcement across the food chain from farm to retail. The CFIA enforces the food safety policies and standards that Health Canada sets.

Current CFIA strategy for development into the mid 2020's is built on five pillars ("Modern regulatory tool kit", "Integrated risk management", "Consistent and efficient inspections", "Digital-first tools and services", and "Global leader"). Objectives to be met in any financial year are detailed in the CFIA's departmental plan.

6.1.3 Other federal authorities

Environment and Climate Change Canada (ECCC) collaborates with the Food Directorate's Bureau of Chemical Safety in effecting the Chemicals Management Plan. The plan includes a number of proactive measures to ensure that chemical substances are managed properly. These include monitoring and surveillance of levels of harmful chemicals in the population and their environment.

The CFIA and ECCC share the oversight of fish and seafood products with Fisheries and Oceans Canada (DFO).

6.1.4 Provincial/territorial authorities (Ontario)

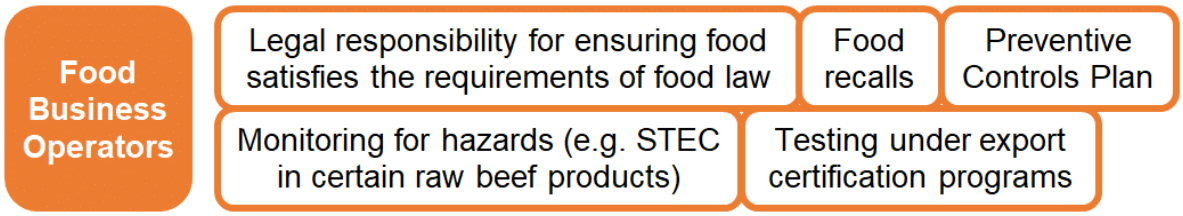
Provinces and territories also enact legislation concerning food safety. For example, the Ontario Ministry of Agriculture, Food and Rural Affairs (OMAFRA) administers provincial legislation concerning the licensing and inspection of certain food businesses whose activities are restricted to the province.

6.2 Ensuring that food satisfies the requirements of food law

An overview of food business responsibilities is provided in Figure 7. Food businesses which trade across provincial boundaries, together with those that import or export food, must meet their legal obligations under federal legislation, including

the SFCA and SFCR. Businesses trading within a single province or territory must comply with regulations established under provincial or territorial law but some provisions of the federal law will apply as well.

Figure 7. Canadian food businesses' responsibilities



Food Business Operators:

- Legal responsibility for ensuring food satisfies the requirements of food law
- Food recalls
- Preventive Controls Plan
- Monitoring for hazards (for example, STEC in certain raw beef products)
- Testing under export certification programs

The CFIA has produced a handbook providing guidance to food businesses in terms of compliance to SFCR. All businesses subject to the SFCR must be licensed and under certain circumstances have a documented Preventive Control Plan (PCP). Developing a PCP requires food businesses to identify and analyse the biological, chemical and physical hazards that present a risk of contamination of a food and use control measures that are shown by evidence to be effective.

Within this context, food businesses may have a legal obligation to collect samples and commission tests to verify the effectiveness of the PCP. The CFIA has produced guidance on the general practicalities of sampling and testing by food businesses as well as their role in monitoring and verification. For certain hazards (for example the presence of *Listeria monocytogenes* in ready-to-eat foods), Health Canada has produced policy documents concerned with risk management issues which need to be addressed in a PCP and which includes recommendations concerning sample collection and testing. Food businesses are encouraged to share with the CFIA details of sampling test results and their use in statistical process control. These data contribute to the CFIA's establishment-based risk assessment model for food establishments (ERA), which is used along with other factors to inform where

inspectors should spend more or less time and inform program planning in order to focus efforts on areas of highest risk.

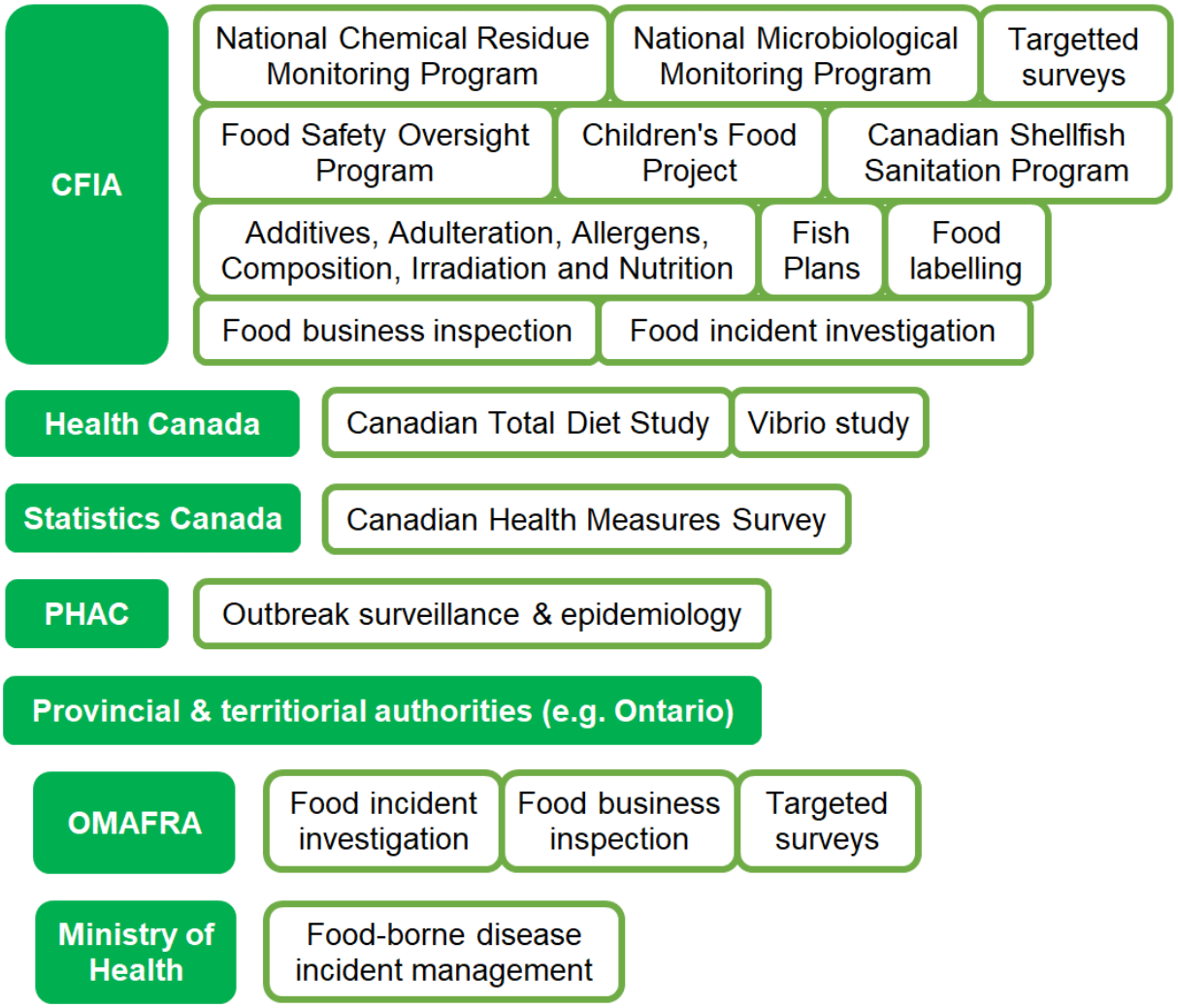
In some cases, sampling and testing methods as well as associated responsibilities are prescribed in law. An example of this is provided in Annex 5.

Industry sampling and testing for microbiological hazards is also required under a number of export certification programs. For example, testing for Shiga toxin-producing *E. coli* is required for abattoirs exporting raw beef manufacturing trimmings to the USA. Abattoirs registered for this purpose must collect samples under the CFIA's supervision using defined procedures at prescribed frequencies. Sampling frequencies are determined by export volume, time of year, and whether or not the abattoir has had a recent adverse finding. Samples are sent to private laboratories (either accredited for the applicable testing method or in the process of obtaining such accreditation in Canada) and tested using methods identified in the requirements document. Test are performed at the food businesses' expense. In addition to submitting results to the abattoir, testing laboratories are also required to submit them directly to the CFIA Food Safety Division. The CFIA inspector must also be advised within 24 hours of receipt of both negative and presumptive positive results.

6.3 Sampling activities in respect of food

An overview of roles played by different competent authorities in Canada in relation to sampling is provided in Figure 8.

Figure 8. Sampling activities in respect of food law in Canada



The CFIA inspects, samples and tests a variety of food products either for official control purposes or in connection with various surveillance programmes. Whenever possible, samples are assessed against food safety standards that have been established by Health Canada and various international organisations, such as the Codex Alimentarius Commission. Detailed food inspection guidance on the collection of samples both generically and for specific foods is provided to inspectors. These cover collection of samples for both official control purposes and surveillance programmes. Notably, some CFIA sampling information, including sampling planning documents, is marked for internal use and was not available for review.

6.3.1 Surveillance sampling

Guidance document on harmonised food sampling and testing terminology used by the CFIA and Health Canada distinguishes monitoring sampling, directed sampling, compliance testing, special/pilot surveys, blitzes, and legal sampling. As indicated in

the document, directed (targeted) sampling, compliance testing, and legal sampling can lead to follow-up actions by the authorities. Some monitoring programs have an element of verifying compliance and can also trigger follow-up actions as well. Follow-up actions may include follow up inspections, additional investigative sampling, product disposal, corrective action requests, food safety investigations, product recalls, etc.

CFIA's operational procedures for planned (monitoring) food sample collection include prescribed annual surveys as well as *ad hoc* targeted surveys to address a specific issue. Besides sampling for own purposes, the CFIA also collects samples for two Health Canada's surveillance programmes under a Memorandum of Understanding between Health Canada and the CFIA.

Key sampling surveys and programmes for food on the federal level are listed in Table 6. Further information on these is available in Annex 5.

Table 6. Key sampling surveys and programmes in Canada

Activities	Description
National Chemical Residue Monitoring Program (NCRMP)	Annual CFIA regulatory surveillance program aimed at verifying compliance of foods to Canadian standards and guidelines for chemical residues and contaminants, identifying trends, collecting baseline data, and supporting international trade. Food products are sampled by CFIA inspectors and tested at CFIA and contracted private laboratories. Sampling is mostly done at federally registered establishments or importers but can also be done at warehouses, distribution centres, or wholesalers.
National Microbiological Monitoring Program (NMMP)	Annual food surveillance program managed by the CFIA to assess for potential health risks, monitor trends, perform risk assessments, and verify industry compliance with food microbiological safety and quality standards. Food product and environmental samples are collected by CFIA inspectors and tested at CFIA laboratories. Sampling is mostly done at

Activities	Description
	federally registered establishments but can also be done at warehouses, distribution centres, or wholesalers.
Food Safety Oversight (FSO) Program	A CFIA program complementary to surveillance under NCRMP and NMMP aimed at increasing oversight for chemical residues/contaminants and microbiological parameters in the non-meat food sectors. Some FSO samples are collected at federally registered establishments or importers by CFIA inspectors, but majority are collected at retail by contracted third-party samplers. Testing is performed at CFIA and contracted private laboratories.
Children's Food Project (CFP)	A CFIA project complementing NCRMP by focusing on levels of pesticide residues and metals in foods frequently consumed by and targeting children. Sampling is conducted at retail. Testing is performed at contracted private laboratories.
Additives, Adulteration, Allergens, Composition, Irradiation and Nutrition (AAACIN)	CFIA's annual surveillance program. Random sampling conducted by CFIA inspectors to assess for potential health risks, perform risk assessments, monitor trends, and verify industry compliance with the Canadian standards. Publicly available information is limited.
Fish Plans	CFIA's annual surveillance programme. Random sampling conducted by either CFIA inspectors or contracted third-party samplers to assess for potential health risks, perform risk assessments, monitor trends, and verify industry compliance with the Canadian standards. Available information is limited.
Targeted surveys	Conducted by the CFIA to focus its surveillance activities on the identified areas of highest health risk and to inform the

Activities	Description
	allocation and prioritisation of the CFIA's activities. Sampling and testing arrangements depend on the survey.
Canadian Shellfish Sanitation Program (CSSP)	As part of CSSP, the CFIA maintains a marine biotoxin surveillance program, in which molluscan shellfish harvest area samples are collected by CFIA inspection personnel and contracted third-party samplers and tested for various microbiological and chemical contaminants.
Canadian Total Diet Study (TDS)	Health Canada's food surveillance program that monitors the concentrations of chemical contaminants in foods that are typically consumed by Canadians. Levels of priority chemicals are measured in food samples either annually, on a pre-determined cycle, or in response to a specific food safety issue. Samples are collected by the CFIA and sent to Health Canada for laboratory analysis.
Vibrio study	Study on *Vibrio* spp. conducted by Health Canada. Samples are collected within Canada from May to October every year by the CFIA and sent to Health Canada for laboratory analysis. No further information is available.

Targeted surveys are used by the CFIA to focus its surveillance activities on areas of highest health risk. The information gained from these surveys provides support for the allocation and prioritisation of the CFIA's activities to areas of greater concern. Sample collection is performed either in accordance with national guidance or on a case-by-case basis, depending on the nature of the survey.

The CFIA has a network of 13 reference and research laboratories across Canada. Depending on the project needs, testing can also be conducted by contracted accredited private laboratories. In turn, testing for the Canadian Total Diet Study and Vibrio study is conducted by Health Canada's own laboratories.

As indicated in the CFIA's departmental plan for 2020-2021, the CFIA is currently undergoing a review of its surveillance activities for food safety, animal health, and plant health to ensure that these meet the performance outcomes for CFIA's programs. The review will focus on sampling and testing, risk identification and analysis, and will inform an action plan for the implementation of risk-based decision-making, regular surveillance reviews, and future work to expand CFIA's data sharing platform.

Provincial/territorial governments have responsibility for the control of food businesses which trade solely within that province or territory and do not export/import food. Within the province of Ontario, this is effected by the Ontario Ministry of Agriculture Food and Rural Affairs (OMAFRA). In addition to food control responsibilities, OMAFRA also conduct targeted surveys which can involve collaboration with Agri-food business stakeholders. One example being the Ontario Grain Corn Ear Mould and Deoxynivalenol (DON) Mycotoxin Survey, which is undertaken in collaboration with Grain Farmers of Ontario and members of the Ontario Agri-Business Association and in 2020 was based on 245 ear corn samples collected across the province.

6.3.2 Verification (official) controls

One of the responsibilities of CFIA is to inspect licensed operators who sell foods across provincial/territorial boundaries. An objective of these inspections is to verify the efficacy of food business operators' food safety management systems. CFIA inspectors and veterinarians conduct random, risk-based, and directed sampling. In all cases, samples are collected in accordance with documented procedures.

Random sampling and testing is conducted to identify trends and gather information on the occurrence and levels of contaminants in food and on equipment. Examples of random sampling include monitoring of *L. monocytogenes* and *Salmonella* in RTE meat and poultry products, and sampling for *E. coli* O157:H7 in uncooked dry or semi-dry fermented products containing beef. The random plans are not dependent upon the risk level of the product and are applicable regardless whether or not the products are exposed to the environment after being processed. In multi-lined operations, a production line is randomly selected on the day of sampling. Random

sampling of products can be conducted with or without a linked random food contact surface environmental sampling plan.

By contrast, risk-based sampling relies on the use of risk-based algorithms and is dependent upon the risk level of the products. As a result, in multi-lined operations, on the day of sampling, the highest risk product being produced will be selected for sampling. An example of targeted risk-based verification sampling plan would be a monitoring of *L. monocytogenes* in RTE products exposed in the post lethality environment which would be also linked to the risk-based food contact surface environmental sampling plan. License holders are assigned a relative risk level (RRL) according to the RTE product risk categories and the types of control interventions that they use. The RRL will determine the frequency of sampling under the risk-based plan.

Another example of using a risk-based approach is the sampling plan for license holders producing domestic beef/veal precursor materials intended for use in raw ground beef/veal to verify the effectiveness of their control measures for *E. coli* O157:H7. This sampling plan takes into account factors such as seasonality, production volume, historical testing, and inspection data.

Directed ("as required") sampling and testing is conducted to investigate suspected problems. For example, as part of the follow-up inspection to support the assessment of the regulated party's corrective actions.

Notably, data from verification controls feeds into both the NMMP and NCRMP.

6.4 Intelligence gathering and data integration

6.4.1 Canadian Food Inspection Agency

As a science-based regulatory agency, the CFIA conducts scientific research to support evidence-based decisions. Scientific research is considered to include any research that supports sound, risk-based decision-making, policy development, and program design and delivery. Current strategy document for 2018-2021 sets the following objectives:

- advancing science and innovative scientific research;
- enabling evidence-based decision-making;
- strengthening collaborative opportunities and partnerships;

- maximising the impact and value of research investments.

Under this strategy, the CFIA intends to expand the use of Establishment-based Risk Assessment (ERA) models. The ERA-Food model uses scientific data and establishment specific information gathered from the additional establishment information questionnaire provided to regulated parties in order to evaluate a facility and determine an establishment's level of risk. How often an inspection occurs will be guided by where a facility falls in the four categories of risk assigned by the ERA-Food model. Higher risk establishments will require more oversight while lower risk establishments will require less oversight. The CFIA has also developed a similar Establishment-based Risk Assessment model for feed mills (ERA-Feed Mill model) as well as for hatcheries (ERA-H model) and is working on adapting the ERA algorithm for food importers (Importer Risk Assessment model).

The Canadian Food Safety Information Network (CFSIN) is a new CFIA-led federal initiative delivered in collaboration with the Public Health Agency Canada (PHAC) and Health Canada together with provincial and territorial partners. It is aimed at better anticipating, detecting, and responding to food safety events and emergencies, by connecting and coordinating federal, provincial, and territorial food safety and public health authorities.

It is anticipated that CFSIN will create an enhanced network of food safety authorities and food testing laboratories across Canada. Participants will thus be able to use digital tools to respond in a more coordinated way across provincial and territorial borders, to predict and respond to foodborne illness incidents. The enhanced functionalities (Table 7) anticipated by CFSIN will also allow the sharing of data, expertise, analysis, scientific techniques, and rapid alerts and communication.

Table 7. Enhanced functionalities to be provided by CFSIN

Function	**Enhanced functionality**
Laboratory mapping	Online geographical mapping of partner laboratories to identify their capacity and capabilities
Scanning and Intelligence	Tools to identify and analyse local or global food safety issues, track new scientific findings, and perform innovative capture of

Function	Enhanced functionality
	food safety concerns found on social media, or other open sources
Collaboration	A secure online environment for network partners to collaborate and communicate through news postings, shared scientific research, data, and working groups
Food safety event management	Tools to manage foodborne illness outbreaks across provinces and jurisdictions
Early warning	Predictive analytics of food safety data from all partners to better predict food safety issues before they happen
Alerting	Automated or manually triggered food safety alerts and warnings distributed to partners

Besides the use of ERA models and CFSIN, the CFIA is also looking into the use of blockchain technology as it has significant potential to trace long and complicated supply chains. A blockchain-based data exchange platform could allow the information exchange between organisations while ensuring security and confidentiality and could be used to share compliance, surveillance, and scientific information.

6.4.2 Public Health Agency of Canada

Public Health Agency of Canada (PHAC) is an agency within the Health Portfolio, which is responsible for public health, emergency preparedness and response, and infectious and chronic disease control and prevention. It operates three programmes for monitoring foodborne infectious disease which are discussed below.

National Enteric Surveillance Program (NESP) is designed to provide timely analysis and reporting of laboratory confirmed enteric disease cases in Canada. Its remit includes the major enteric bacterial pathogens (for example *Salmonella*, *Campylobacter*, *Shigella*, *Vibrio*, verotoxigenic *E. coli*, and *Yersinia*), intestinal parasitic organisms (for example *Giardia*, *Cryptosporidium*, *Entamoeba*, and *Cyclospora*) as well as enteric viruses such as norovirus and rotavirus. For this

purpose, each provincial public health laboratory provides the National Microbiology Laboratory with weekly aggregate totals of new laboratory confirmed enteric diseases for centralised analysis for detection of emerging and priority disease trends. Weekly report is then shared with the laboratories and other stakeholders such as federal and provincial epidemiologists, researchers, and public health professionals. The program also integrates data and information with national (i.e. PulseNet Canada) and international efforts to identify and respond to clusters of foodborne disease.

PulseNet Canada is the national real-time molecular subtyping network for foodborne disease surveillance, tasked with collecting molecular and genomic subtyping data from cases of bacterial foodborne disease from all provincial public health laboratories, and from bacterial pathogens isolated by the CFIA, in real-time. The data is analysed on a daily basis for the purpose of detecting potential outbreaks, particularly multijurisdictional outbreaks as early as possible. It also provides the laboratory investigation during multijurisdictional outbreak response and support for single jurisdiction response to enable timely public health action. Activities link to those of both NESP and FoodNet Canada.

FoodNet Canada is a national food safety “sentinel site” surveillance system facilitated by PHAC. Its activities are intended to integrate human, food, and environmental monitoring. A sentinel site can be described as a community from which in-depth data are gathered and the resulting analysis is used to inform programs and policies affecting a larger geographic area. The system currently includes four such sites, which are made up of integrated local networks of public health units, public health and private laboratories, farms, retail food outlets and sources of drinking water. Information about pathogens that cause enteric illness (those that affect the intestines) that are found in those environments is gathered and analysed to better understand the links between these enteric pathogens and illness

Together with the CFIA, the PHAC regularly contributes to the scientific literature details of sampling and testing methodologies as well as foodborne disease incidents.

6.4.3 Canadian Health Measures Survey

Canadian Health Measures Survey (CHMS) is led by Statistics Canada, in partnership with Health Canada and PHAC, and collects information from Canadians

about their general health. Through personal interviews and the collection of physical measurements, the survey provides baseline data on indicators of environmental exposures, chronic diseases, infectious diseases, fitness, and nutritional status, as well as risk factors and protective characteristics related to these areas. The physical measurements include such factors as height and weight, blood pressure, physical fitness and lung function measures, as well as many measures based on blood and urine samples including environmental chemicals.

The survey operates on a cyclic basis, with chemicals to be measured under the biomonitoring component being selected on the basis of one or more of the following considerations:

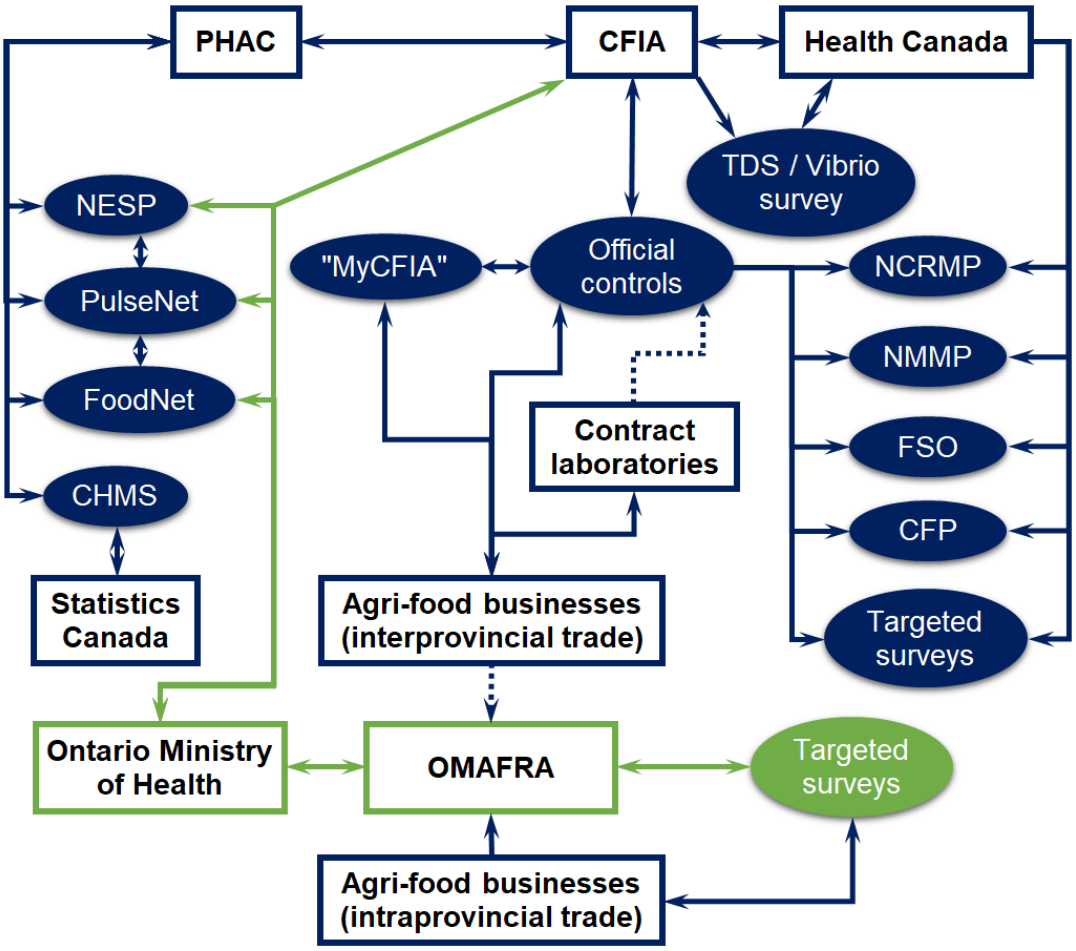
- Known or suspected health effects.
- Level of public concern.
- Evidence of exposure in the Canadian population.
- New or existing requirements for public health action.
- The ability to detect and measure the chemical or its breakdown products in humans.
- Similarity to chemicals monitored in other national and international programs to allow for meaningful comparisons.
- Costs of performing the analysis.

Chemicals can therefore be rotated in and out of the biomonitoring component. In some cases, chemicals have been measured in multiple cycles to obtain additional information or a larger number of samples. In other cases, chemicals have been removed and may be added back in later cycles. New chemicals have been included to obtain national baseline data where none may have existed before. A summary of the environmental chemicals measured or planned for measurement in blood, urine and/or pooled serum samples collected as part of the CHMS to date has been published.

6.4.4 Data exchange

An overview of data exchange processes is provided in Figure 9. The regulations are enforced by a single entity, the CFIA, which addresses all aspects of the food chain from farm to retail, which range from food and feed safety through to compliance with quality standards.

Figure 9. Analytical data and other data flows between various stakeholders in Canada



The CFIA inspectors take samples for testing as part of their official control functions as well as for national surveys managed by the CFIA or Health Canada. Outputs from control exercises and surveys are used to inform policy development.

Data obtained by the CFIA integrates with disease incidence data generated by PHAC, in particular the NESP and FoodNet Canada. The FoodNet Canada system integrates test data from diverse stakeholders including regulators, public health officials, and agri-food businesses.

Together with Statistics Canada, PHAC also operates the CHMS which provides biomonitoring data contributing to the risk assessment of chemical contaminants in food.

The Safe Food for Canadians Regulations require agri-food businesses to collect samples and test them as part of the process of verifying the efficacy of their Preventive Control Plans. Under certain circumstances, food businesses must collect

samples in a prescribed manner and submit them for testing for specific endpoints by an approved laboratory. Under these circumstances not only is the food business obliged to advise CFIA officials of the results (positive or negative) but laboratories must also report the data to the CFIA. Where reporting of test data is not mandatory, food businesses are encouraged to submit data through their account with the CFIA. Such data may then be used in the development of Establishment-based Risk Assessment models.

Agri-food businesses solely operating in a single province are subject to control and inspection by the provincial government (in Ontario, OMAFRA). In addition to analysis of samples taken for inspection and control purposes, provincial governments may also conduct their own targeted surveys, for example, the Ontario Grain Corn Ear Mould and Deoxynivalenol (DON) Mycotoxin Survey which is undertaken in collaboration with business stakeholders. Provincial governments also play a significant role in the control of foodborne diseases and have a “Foodborne illness outbreak response protocol” (in Ontario, ON-FIORP), which details the interactions between province and federal stakeholders.

7 New Zealand

New Zealand is a unitary state, where competency for food safety rests with the national government. In 2018, agriculture contributed 4.3% to GDP. Agriculture exports were worth NZD 28 billion in 2016. The significance of agriculture to New Zealand's foreign currency earnings has led to an agricultural policy which integrates regulation of both biosecurity and food safety.

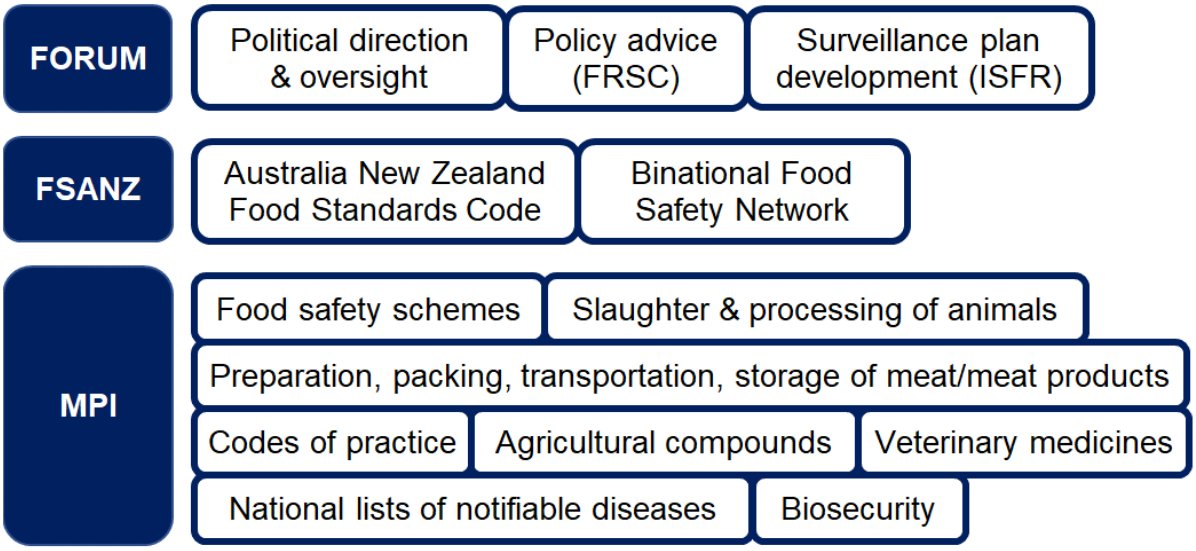
7.1 Development and implementation of food law

In 1995, Australia and New Zealand signed the Food Standards Treaty, which committed both countries to the development and implementation of a single set of food standards – Australia New Zealand Food Standards Code. The code is developed and maintained by Food Standards Australia New Zealand (FSANZ) which is a statutory authority operating under the Food Standards Australia New Zealand Act 1991. The joint food regulation system is overseen by the Australia and New Zealand Ministerial Forum on Food Regulation (Forum).

Additionally, Trans-Tasman Mutual Recognition Arrangement between the New Zealand government and the commonwealth, state, and territorial governments of Australia allows products made or imported into New Zealand that meet New Zealand's legal requirements to be also sold in Australia and vice versa.

An overview of the authorities responsible for enacting food laws and regulations in New Zealand is presented in Figure 10.

Figure 10. Overview of authorities with responsibilities for enacting food laws and regulations in New Zealand



Forum:

- Political direction and oversight
- Policy advice (FRSC)
- Surveillance plan development (ISFR)

FSANZ:

- Australia New Zealand Food Standards Code
- Binational Food Safety Network

MPI:

- Food Safety schemes
- Slaughter and processing of animals
- Preparation, packing, transportation, storage of meat/meat products
- Codes of practice
- Agricultural compounds
- Veterinary medicines
- National lists of notifiable diseases
- Biosecurity

7.1.1 Australia and New Zealand Ministerial Forum on Food Regulation

Refer to section 5.1.1.

7.1.2 Food Standards Australia New Zealand

In New Zealand, FSANZ is responsible for standards relating to labelling, composition, and contaminants. The standards developed by FSANZ are described in the Australia New Zealand Food Standards Code, which applies to both Australia and New Zealand. MPI is responsible for its implementation in New Zealand, including compliance policy. Some standards listed in Part 1 and Part 2 of the Food Standard Code are common to both jurisdictions, while Standard 2.9.6, a transitional standard for special purpose foods, applies to New Zealand only.

New Zealand has its own standards for maximum residue limits (MRLs) for agricultural compounds in food, food hygiene and food safety provisions, including those for high-risk imported foods, materials permitted to be added to or used to produce food packaging materials, export requirements relating to destination markets other than Australia, and dietary supplements.

As discussed in section 5.3, FSANZ coordinates and manages surveys instigated by ISFR and conducts *ad hoc* surveys in support of its activities to maintain the Food Standards Code, to monitor the food supply to ensure it is safe, and that the foods comply with the Food Standards Code in New Zealand.

7.1.3 Ministry of Primary Industries

The Ministry of Primary Industries (MPI) is the key regulatory authority regarding domestic food and food imported into New Zealand as it administers food safety legislation and develops the standards that food business must meet. Its remit extends across the entire food chain and includes animal feed, agricultural compounds, and veterinary medicines.

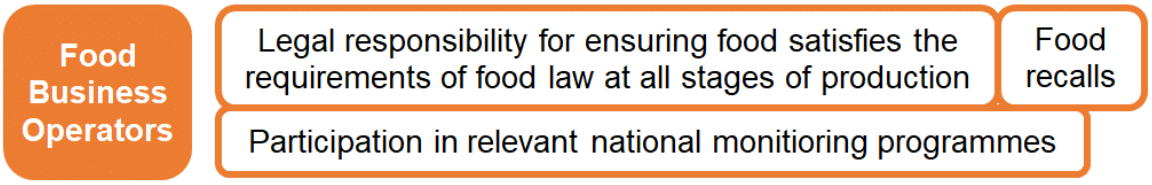
The MPI's authority is based upon four pieces of legislation – Agricultural Compounds and Veterinary Medicines Act 1997, Animal Products Act 1999, Food Act 2014 and Biosecurity Act 1993. Most of the activities considered within this document are conducted by New Zealand Food Safety, a business unit of the MPI.

7.2 Ensuring that food satisfies the requirements of food law

As summarised in Figure 11, food business operators have a legal obligation to comply with relevant food safety legislation. As part of their registration requirement, food businesses considered to be higher-risk must have food safety management systems in place. Depending on the type of business, these are either referred to as

a Risk Management Programme (RMP, Animal Products Act 1999) or a Food Control Plan (FCP, Food Act 2014). Lower and medium-risk food businesses must operate their food safety management systems within the context of a National Programme.

Figure 11. Responsibilities of food businesses in New Zealand



Food Business Operators:

- Legal responsibility for ensuring food satisfies the requirements of food law at all stages of production
- Food recalls
- Participation in relevant national monitoring programmes

As part of the verification process and depending on business size, food businesses are required to collect samples and conduct testing. Depending on its nature, a food business may also have a mandatory requirement to submit samples for testing and to share the resultant data with the MPI.

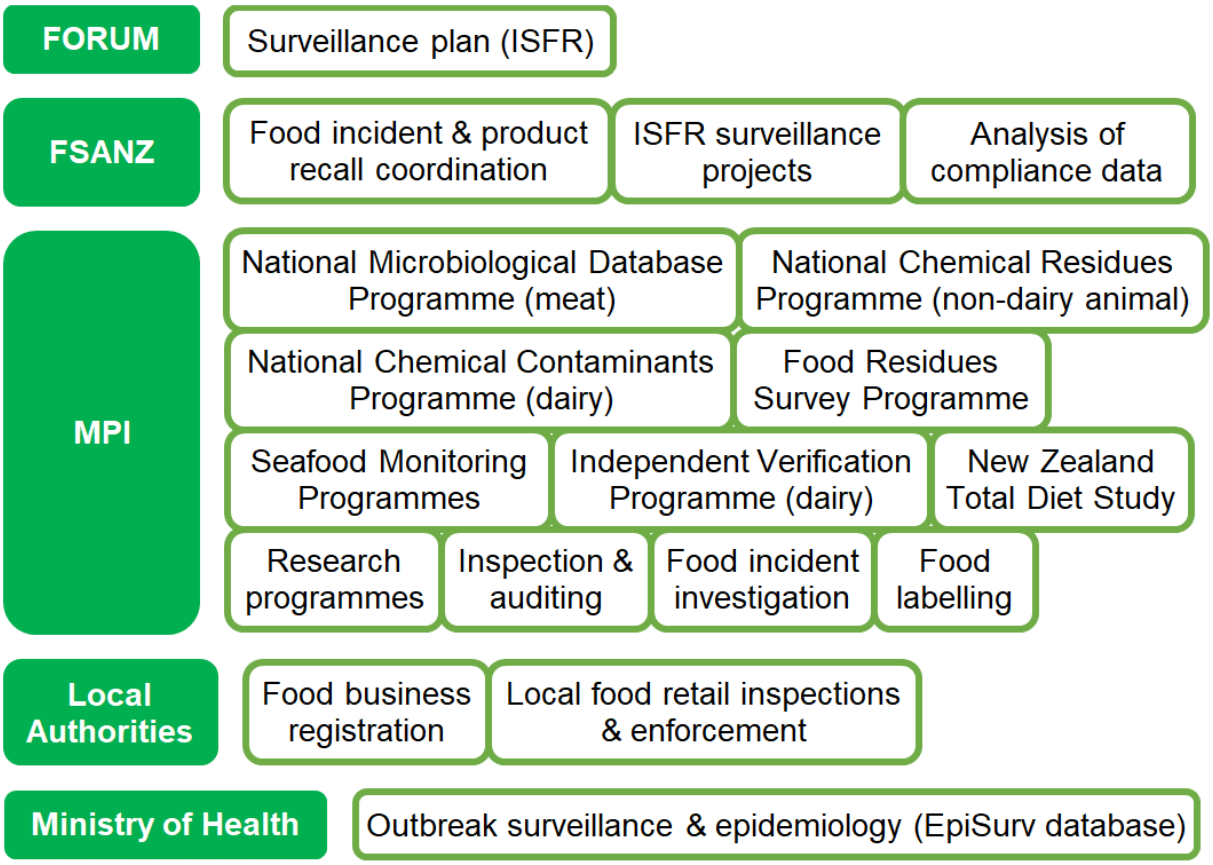
For instance, meat processing businesses must take part in the National Microbiological Database Programme (NMDP) and are responsible for the collection and testing of samples using specified approaches. Similarly, certain food businesses must collect and test samples and share the resultant data within the context of specific subsidiary programmes under the National Chemical Residues Programme. Another example is the Shellfish Biotoxin Monitoring Programme, which includes industry testing of bivalve molluscan shellfish for the presence of biotoxins.

Additional sampling, testing, and reporting requirements may be established for exporting establishments. For example, all U.S.-listed operations and packhouses exporting to the U.S. that manufacture beef and/or bobby veal which may be used in the preparation of ground beef must participate in the Top 7 Shiga Toxin-Producing *Escherichia coli* programme. The programme is operated under the USA Overseas Market Access Requirements (OMAR). These are considered to be commercially sensitive and are password protected, and no further information was available.

7.3 Sampling activities in respect of food

An overview of roles played by different competent authorities in New Zealand in relation to sampling is provided in Figure 12.

Figure 12. Sampling activities in respect of food law in New Zealand



Since the roles of the Forum and FSANZ affecting both Australia and New Zealand have already been discussed in section 5.3, this section is limited to New Zealand's national competences (i.e. sampling activities overseen by the MPI).

MPI operates a range of food monitoring and surveillance programmes. These are part of a process to verify that agri-food business production systems are managing risks to food safety and establishes safe levels for residues, contaminants, and other hazards. Additionally, MPI conducted different types of research programmes to identify and monitor food safety hazards and manage foodborne risks to human health. MPI is also responsible for coordinating food recalls, programmes registration and abattoir inspection. Key sampling surveys and programmes are summarised in Table 8.

Table 8. Key sampling surveys and programmes in New Zealand

Activities	Description
National Microbiological Database Programme (NMDP)	Under this programme administered by the MPI, meat processing businesses are required to collect samples and submit for testing to laboratories approved by the MPI. Data is used by MPI to evaluate specific microbiological hazards and establish the National Profile as well as by operators to measure their performance against national results.
National Chemical Residues Programme (NCRP)	A risk-based sampling and testing programme for chemical residues (for example agricultural compounds, veterinary medicines, and contaminants) in non-dairy animal products. Monitoring samples are taken from randomly selected animals and their products. Surveillance samples are taken from targeted animals, animal materials, and animal products at risk of containing residues greater than maximum levels.
National Chemical Contaminants Programme (NCCP)	An annual programme for dairy products and milk. Incorporates random monitoring, directed surveillance, and surveys. Designed to confirm the effectiveness of the regulatory controls in place for ensuring residues and contaminants in raw milk and manufactured dairy products do not pose a threat to human health, that GAP are being followed, and that relevant importing country requirements will be met.
Food Residues Survey Programme (FRSP)	A monitoring programme for chemical and microbiological contaminants in domestic and imported foods sold in New Zealand. The focus is on foods not covered by other monitoring programmes of the MPI. Sampling and testing arrangements depend on the scope and type of the survey. Screening tests for chemical contaminants usually include between 200 and 500 different pesticide residues in crops and plant-based foods.

Activities	Description
Shellfish Biotoxin Monitoring Programme	Monitoring programme mainly for algal toxins in bivalve molluscan shellfish (both gathered commercially and recreationally). The programme for commercial growers and harvesters is funded by industry and requires commercial growers and harvesters to take samples and test in approved laboratories. MPI also runs an additional monitoring program for recreationally gathered shellfish.
Independent Verification Programme (IVP)	A monitoring programme for dairy products by MPI which aims to verify the accuracy of industry test results. It applies to exporting dairy businesses operating under a risk management programme. Samples collected by MPI are tested to check conformance to acceptable microbiological levels for New Zealand, as well as those set by importing countries.
New Zealand Total Diet Study (NZTDS)	A monitoring programme to assess New Zealanders' exposure to certain contaminants and nutrients. It focuses on foods consumed in a typical diet and is performed approximately every 5 years. The results are used to inform food standards and verify the efficacy of food legislation.
Research programmes	Project-based research programmes by MPI concerned with the safety of domestic and imported food. Programmes are informed by surveillance data, scientific literature, expert opinions, and experimental projects.

7.4 Intelligence gathering and data integration

7.4.1 Ministry of Primary Industries

It manages diverse food monitoring programmes to assess the risk presented by microbiological, chemical, nutrient-related and physical hazards. Additional research is commissioned if issues arise and risk management strategies developed. An example of such a strategy is *Salmonella* Risk Management Strategy 2013-2014.

Data from surveys are used by MPI to effect ongoing risk assessments to inform risk management strategies.

7.4.2 Ministry of Health

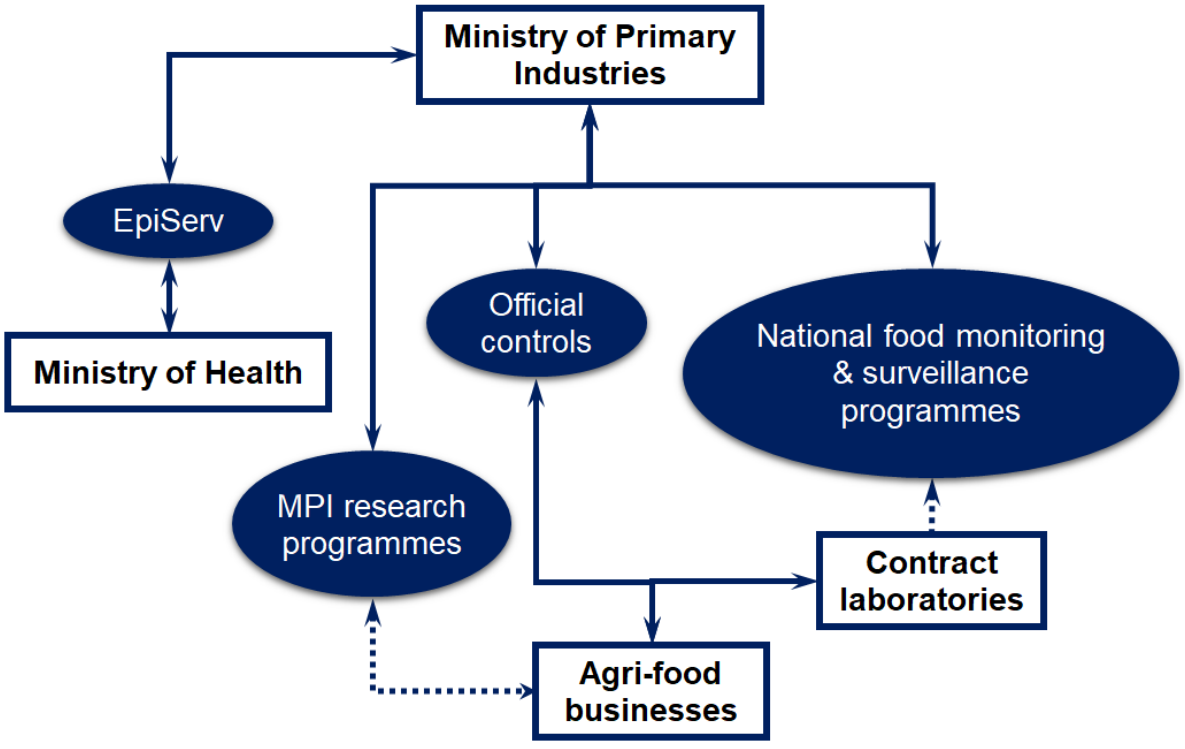
The Ministry of Health (MoH), through its contractor, the Institute of Environmental Science and Research Ltd, conducts national public health surveillance. One of the national health surveillance systems is EpiSurv, which collates notifiable disease information on a real-time basis from the Public Health Services (PHS) in New Zealand and incorporates an outbreak functionality that enables cases to be linked via a common cause.

7.4.3 Data exchange

An overview of data exchange processes is provided in Figure 13.

Since the MPI has monitoring and surveillance programmes which address not only food but also foodborne disease, these make for a highly integrated data exchange system, which permits operation and management according to statistical process control principles. Such a system therefore provides advance warning of the possibility of untoward events.

Figure 13. Analytical data and other data flows between various stakeholders in New Zealand



8 United States of America

The United States of America (USA) is a country primarily located in North America and consisting of 50 states, a federal district, five major unincorporated territories, 326 Indian reservations, and some minor possessions.

Each state has a sovereignty separate from that of the federal government and each federally recognised Native American tribe possesses limited tribal sovereignty as a "dependent sovereign nation". Unincorporated territories are not considered to be integral parts of the United States (U.S.), and the U.S. legislation applies only partially in those territories.

8.1 Development and implementation of food law

The regulation and oversight of foods and beverages in the United States is very fragmented. The U.S. Constitution divides the power of government vertically between federal and state governments – the federal government only holds the powers delegated to it by the Constitution, while all the other powers are automatically reserved to the states or to the people. As such, only the states possess the power to regulate specifically for the health, safety, welfare, and general well-being of the people. On the other hand, the Commerce Clause of the Constitution is broadly interpreted to allow the federal government to regulate an ever growing range of aspects of commerce with foreign nations, among the states, and with the Indian tribes, including those related to food safety. Foods produced without an interstate element whatsoever (for example all raw materials and packaging is sourced as well as product manufactured and sold within the boundaries of a single state) may potentially be subject to state oversight exclusively.

The federal authority to oversee foods is divided between three main agencies:

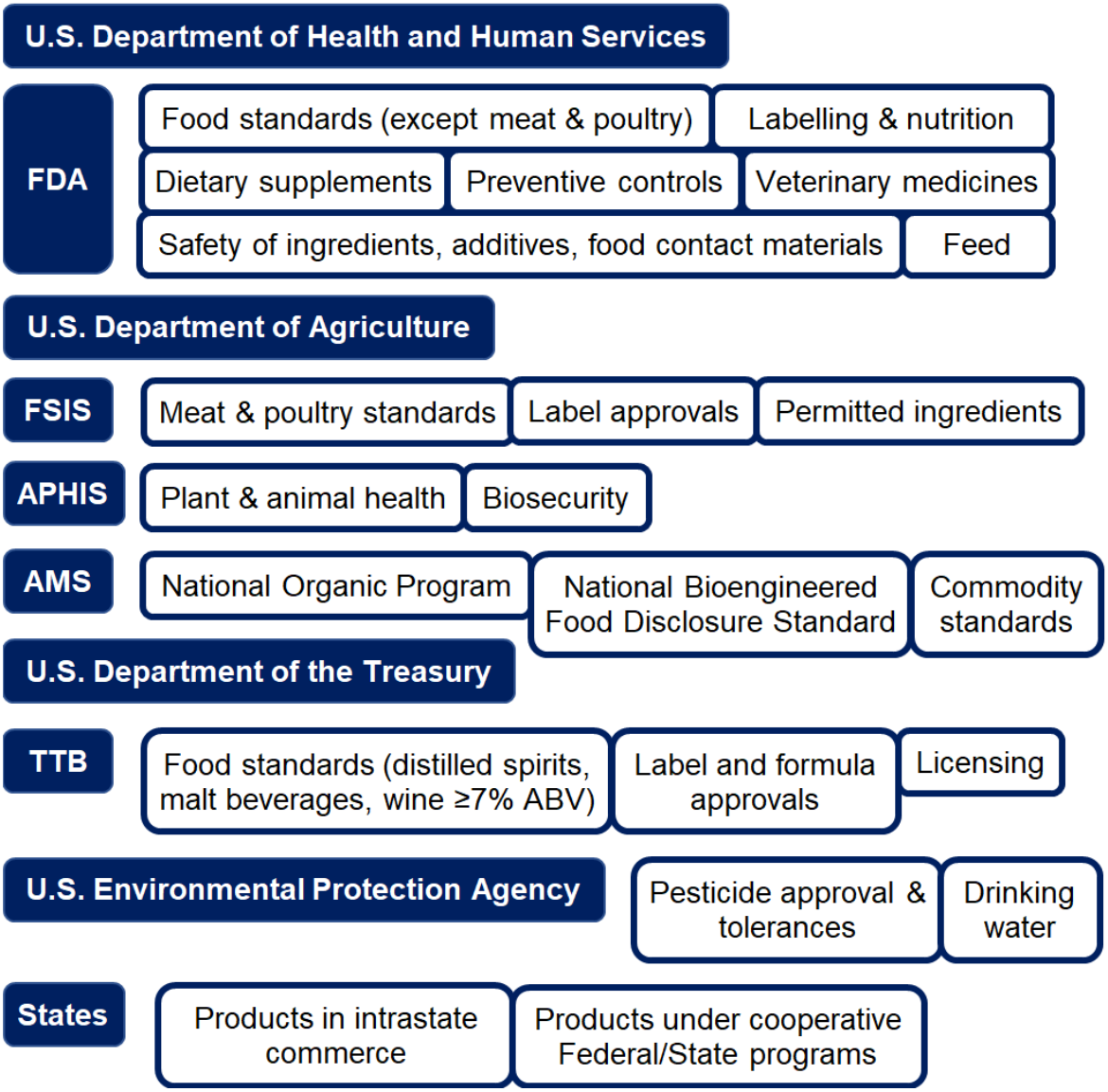
- The Food and Drug Administration (FDA), an agency within the U.S. Department of Health and Human Services (HHS);
- The Food Safety and Inspection Service (FSIS), a federal agency within the U.S. Department of Agriculture (USDA);
- The Alcohol and Tobacco Tax and Trade Bureau (TTB), a bureau under the Department of the Treasury.

Depending on the product, other agencies may also play a role. For example, National Marine Fisheries Service (NMFS) of the National Oceanic and Atmospheric Administration (NOAA) oversees certain aspects of fish and seafood products and also runs a voluntary, fee-for-service Seafood Inspection Program to ensure the seafood industry is meeting or exceeding the FDA's Seafood HACCP requirements (21 CFR Part 123).

U.S. Customs and Border Protection (CBP) oversees imported foods but does so jointly with the corresponding federal regulatory agencies (FDA, FSIS, or TTB).

An overview of the federal agencies with key responsibilities for developing and implementing food and feed law in the U.S. is presented in Figure 14.

Figure 14. Overview of authorities with responsibility for enacting food laws and regulations in the United States



8.1.1 Food and Drug Administration

Most foods in the U.S. are regulated on the federal level under the Federal Food, Drug and Cosmetic Act (FD&C Act) administered by the FDA. Exceptions include certain alcoholic beverages overseen by TTB but some alcoholic beverages such as beers not meeting the definition of “malt beverage” as well as wines and cider under 7% ABV are under FDA’s jurisdiction. Meat, poultry, egg products, and fish of the order of *Siluriformes* overseen by FSIS is another exception. Anything not regulated by TTB or FSIS automatically falls back onto the FDA. Importantly, FDA is responsible for regulating the safety aspects of all food ingredients, additives, food

contact substances, and sources of radiation regardless of the jurisdiction of the final product where it is used (i.e. TTB, FSIS, or FDA).

Notably, the definition of "food" in FD&C Act includes "articles used for food or drink for man or other animals" (21 U.S.C. §321(f)). Therefore, animal feed is regulated by FDA under FD&C Act. Certain aspects, such as labelling and ingredient permissibility, are effectively self-regulated by the Association of American Feed Control Officials (AAFCO).

8.1.2 Food Safety and Inspection Service

FSIS oversees the production, safety and labelling of meat from amenable species (i.e. cattle, sheep, swine, goats, horses, mules, and other equines) under the Federal Meat Inspection Act (FMIA), meat of domesticated birds (i.e. domestic chickens, turkeys, ducks, geese, and guineas) under the Poultry Products Inspection Act (PPIA), and egg products (dried, frozen, or liquid, but not shell eggs) subject to Egg Products Inspection Act (EPIA). Catfish and related species of fish of the order of *Siluriformes* are now covered by the FMIA and, therefore, are under FSIS jurisdiction as well.

8.1.3 Alcohol and Tobacco Tax and Trade Bureau

TTB works to ensure compliance with federal alcohol permitting, labelling, and marketing requirements to protect consumers. Distilled spirits, wines (7% ABV and above), and malt beverages are regulated under the Federal Alcohol Administration Act, administered by the TTB. Only certain beers that do not meet the definition of a "malt beverage" and wines under 7% ABV (including cider, perry, sake) are under FDA's jurisdiction.

8.1.4 Environmental Protection Agency

The manufacture, sale, and use of pesticides is regulated by U.S. Environmental Protection Agency (EPA) under both FD&C Act and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA reviews and approves pesticides under FIFRA. Under FD&C Act, the EPA must establish a tolerance or exempt the pesticide from the requirement to have a tolerance for pesticide chemical residues that could remain in or on food. Notably, responsibility for enforcing these tolerances in foods under their supervision falls onto the FDA and FSIS.

EPA is responsible for setting safe drinking water standards and also regulates toxic substances and wastes to prevent their entry into the environment and food chain.

8.1.5 Other federal authorities

Biosecurity and control of animal and plant diseases as well as the movement of animals or plants modified or developed by genetic engineering is under the responsibility of USDA's Animal and Plant Health Inspection Service (APHIS).

Organic food products are regulated under the Organic Food Production Act, administered by USDA's Agricultural Marketing Service (AMS).

AMS is also tasked with implementing the National Bioengineered Food Disclosure Standard and maintaining the List of Bioengineered Foods which are automatically deemed bioengineered unless proven otherwise.

8.1.6 State authorities

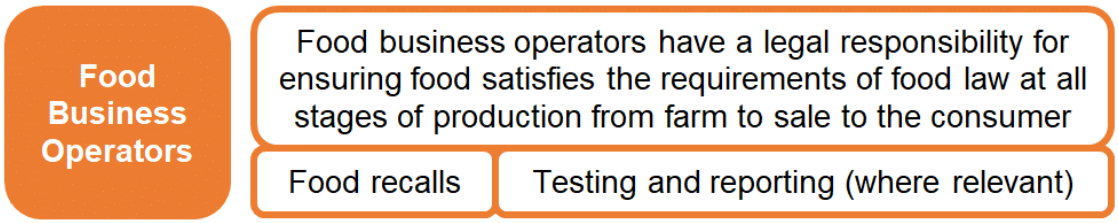
States usually operate under their own legislation which is predominantly based on the federal legislation but may have some additional provisions not pre-empted by the federal legislation. State legislation mostly applies to establishments operating within a single state.

Although FDA has jurisdiction over restaurants and retail food stores, these are primarily regulated by the state, local, and tribal agencies. There also other areas where federal authorities share responsibilities with state authorities or at least assist them. For further details on state authorities and cooperation between the state and federal authorities on the example of California refer to Annex 7.

8.2 Ensuring that food satisfies the requirements of food law

As indicated in Figure 15, food business operators have a legal responsibility for ensuring food satisfies the requirements of food law at all stages of production, processing, and distribution, from farm to fork. The extent of obligations will vary depending on product's characteristics, its intended use, and the authorities that oversee the product. The below sections provide some details based on the authority that oversees the product.

Figure 15. Responsibilities of food businesses in the United States



Food Business Operators:

- Food business operators have a legal responsibility for ensuring food satisfies the requirements of food law at all stages of production from farm to sale to the consumer
- Food recalls
- Testing and reporting (where relevant)

8.2.1 Food and Drug Administration

The FDA Food Safety Modernization Act (FSMA) that forms the basis of the current FDA's approach to food safety focuses on preventing problems before they happen, rather than solely responding to outbreaks of foodborne illness. FSMA imposes numerous food safety requirements on food companies regulated by FDA, including a mandate that companies that manufacture, pack, or hold food develop written food safety plans. Equally, importers are required to perform certain risk-based activities to verify that food imported into the U.S. has been produced in a manner that meets applicable U.S. safety standards, including whether the manufacturing facility has a written food safety plan. These food safety plans include, among other things, a hazard analysis to identify reasonably foreseeable hazards to humans or animals and controls to minimise or prevent those hazards. FSMA's Produce Safety rule requires periodic testing of agricultural water for microbial contamination.

FSMA also arms FDA with enhanced monitoring and enforcement powers, including the authority to issue a mandatory recall when there is "reasonable probability" that a food is adulterated or misbranded and will cause serious adverse health consequences or death to humans or animals.

FSMA requires FDA to inspect domestic food facilities (such as manufacturers / processors) at specified frequencies based on two broad categories of risk. High-risk domestic food facilities must be inspected at least once every 3 years, while non-

high-risk food facilities are to be inspected at least once every 5 years. FDA is also required to inspect an increasing number of foreign food facilities. Depending on the type of the inspection, it may involve sampling activities.

8.2.2 Food Safety and Inspection Service

FSIS-regulated establishments are subject to continuous inspection by FSIS inspection program personnel who are usually directly involved in everyday operation of an establishment. FSIS personnel conduct a range of sampling and compliance verification activities, including reviewing the results of testing initiated by the establishments to meet their legal obligations. Products overseen by FSIS are also subject to pre-market labelling and label approval.

Establishments under FSIS jurisdiction may be legally required to conduct some sampling, testing, and record keeping. For examples of such requirements, see Annex 7.

8.2.3 Alcohol and Tobacco Tax and Trade Bureau

Products under TTB jurisdiction are subject to pre-market label approvals. Alcohol producers must apply for Certification/Exemption of Label/Bottle Approval (COLA) before producing or importing an alcohol beverage.

Certain alcohol beverages also require formula approval with laboratory sample analysis before the products may be produced or imported and before the domestic producer or U.S. importer may apply for COLA. Any distilled spirit, wine or beer/malt beverage made with any ingredient that typically contains thujone (for example wormwood) and alcohol-free malt beverages would automatically require formula approval with laboratory sample analysis, regardless whether domestically produced or imported. Other products subject to formula approval with laboratory sample analysis would only trigger this requirement if offered for import into the U.S.

Additionally, TTB requires laboratory analysis without formula approval for certain other products and may also request samples of any alcohol beverage on a case-by-case basis.

8.2.4 State authorities

Although the safety of foods in interstate commerce falls under the federal jurisdiction, the execution of a number of functions (including sampling and testing) is

often delegated to or is shared with the state and local authorities under various memorandums of understanding. This is because the numbers of food inspectors and other officials, scientists and other specialists employed by state and local governments vastly exceed the numbers of federal regulatory personnel. So, state and local governments play a prominent role in food safety regulation in the US. Their duties are largely dictated by state and local laws. Notably, state authorities have broader authority and additional tools to protect public health and safety compared to the federal agencies.

More than 3,000 state, local and tribal agencies have primary responsibility to regulate the retail food and foodservice industries in the U.S. FDA supports these activities by providing a model Food Code, scientifically-based guidance, training, program evaluation, technical assistance, food recall information, and foodborne illness information.

Some states operate their own meat and poultry inspection programs. These must be assessed by FSIS to determine whether the state inspection programs are “at least equal to” the federal program. FSIS assumes responsibility for inspection in a state that chooses to end its inspection program or cannot maintain the equivalent standard. Other foods that are not in interstate commerce may be overseen by state or local authorities exclusively.

8.3 Sampling activities in respect of food

An overview of roles played by different competent authorities in the United States is provided in Figure 16. A summary of key sampling activities for food in the United States is provided in Table 9. Additional information on some of these is available in Annex 7.

Figure 16. Sampling activities in respect of food law in the United States

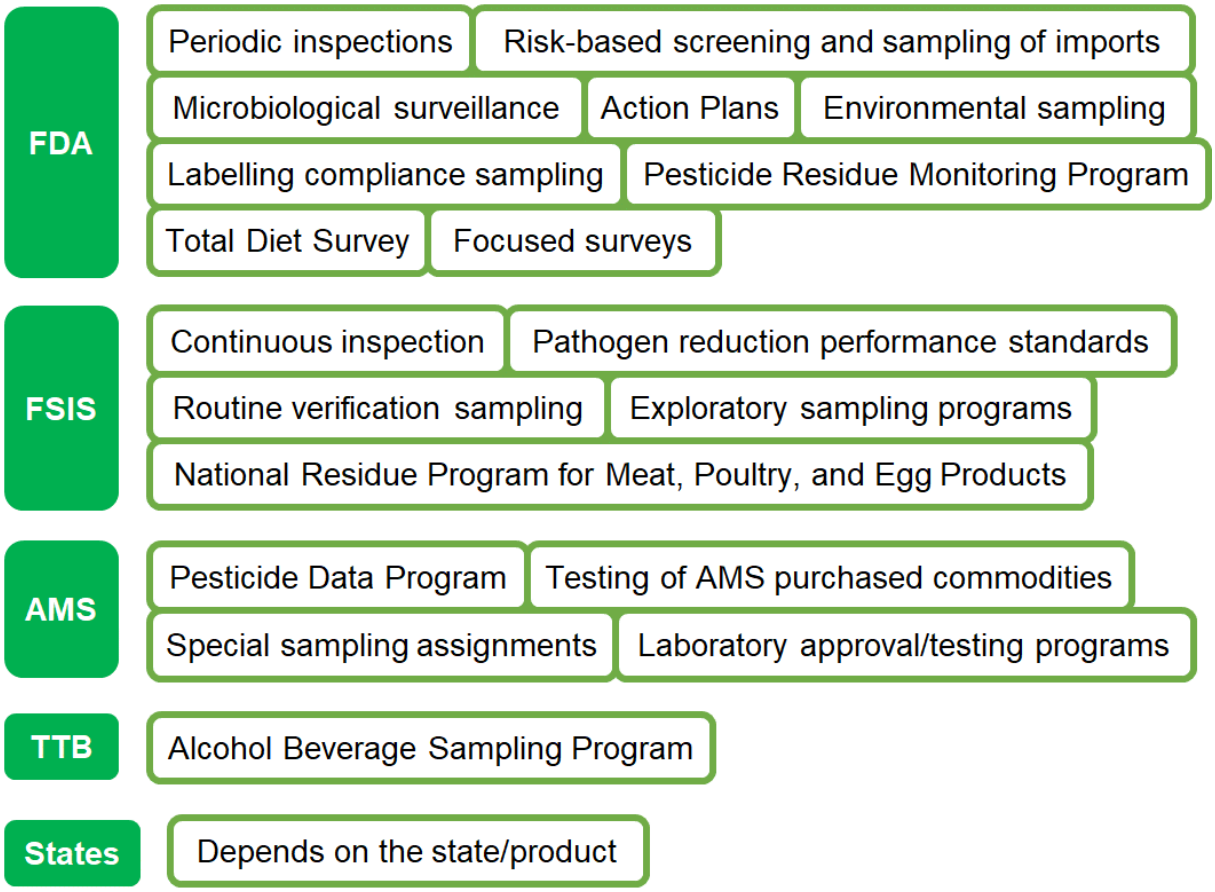


Table 9. Key sampling surveys and programmes in the United States

Activities	**Description**
Microbiological surveillance sampling (FDA)	Large numbers of samples of targeted foods are collected over relatively short period (i.e. 12 to 18 months). Sampling assignments focus on commodities most associated with outbreaks and are prioritised based on potential microbial risk and associated data gaps such as lack of data on pathogen prevalence or common factors associated with positive findings. The sampling design aims to represent what U.S. consumers are likely to find on the marketplace and also tends to reflect different stages of supply chain.
Special action plans (FDA)	In case of recurring significant issues, FDA may institute a comprehensive action plan (for example for STEC in leafy greens or *Cyclospora* in produce) which may incorporate

Activities	Description
	enhanced sampling activities for the purposes of prevention and to address existing knowledge gaps.
Environmental sampling (FDA)	Samples are collected from the environment surrounding the food to determine whether the food is produced under insanitary conditions. Environmental sampling can be conducted “for cause” or as part of commodity-based assignments to gain insight into how widespread certain harmful bacteria may be in the manufacturing environment across the specific industry.
Labelling compliance sampling (FDA)	Sampling and testing of products to assess compliance with specific labelling requirements or compositional standards is conducted either as part of once-off assignments (for example assessing compliance with gluten-free or dairy-free labelling) or as part of inspections.
Pesticide Residue Monitoring Program (PRMP) (FDA)	This regulatory programme is a backbone of the FDA’s strategy to enforce EPA’s tolerances for pesticide chemical residues in human and animal foods. A broad range of imported and domestic commodities is selectively tested for approximately 800 pesticide residues. Domestic samples are typically collected close to the point of production in the distribution system. Import samples are collected when products are offered for entry into the U.S.
Focused sampling for pesticide residues (FDA)	In addition to sampling under PRMP, FDA may conduct some focused sampling surveys for specific commodities or selected pesticide chemical residues of special interest.
Total Diet Study (FDA)	An ongoing FDA programme that monitors levels of about 800 contaminants and nutrients in the average U.S. diet. It

Activities	Description
	complements FDA's other food safety and nutrition programmes such as PRMP.
Specialised sampling for chemical contaminants (FDA)	Monitoring programmes or sampling assignments for industrial chemicals to assess the potential exposure and risk posed by chemicals of concern. Conducted either as part of TDS, under FDA's compliance program for Toxic Elements in Food and Foodware, and Radionuclides in Food, or as a separate sampling assignment.
Microbiological sampling (FSIS)	This includes planned direct sampling such as routine verification sampling and testing for indicator organisms and specific pathogens as well as planned sampling for pathogen reduction performance standards purposes. Additional unscheduled sampling can be initiated by inspection program personnel (for example in response to foodborne illness investigation, animal pathology sampling, or positive in-plant test).
National Residue Program (NRP) for Meat, Poultry, and Egg Products (FSIS)	An interagency programme designed to identify, prioritise, and analyse chemical residues and contaminants in FSIS-regulated meat (including *Siluriformes* fish products), poultry, and egg products. Includes scheduled surveillance sampling plan as well as inspector-generated sampling. Imported products are sampled through the point-of-entry Import Reinspection Sampling Plan.
Exploratory sampling programs (FSIS)	Targeted sampling conducted to verify product compliance, to eliminate a specific knowledge gap, or to help plan other sampling and/or verification activities.
Pesticide Data Program (AMS)	National pesticide residue monitoring programme for pesticide residues (more than 700 compounds) on agricultural commodities in the U.S. food supply administered

Activities	Description
	by the AMS and implemented through cooperation with state agriculture departments and other federal agencies. The emphasis is on those commodities highly consumed by infants and children. May include special projects.
Microbiological testing (AMS)	Testing of meat, poultry, and egg commodities purchased by the AMS for various federal and nutrition assistance programmes. Samples from potential suppliers are selected and tested by the AMS designated laboratory.
Special sampling assignments (AMS)	Targeted short- or long-term sampling tasks conducted on request from the industry or from foreign or domestic agencies. Arrangements differ from task to task.
Laboratory Approval Programs (AMS)	Under these programs, AMS approves laboratories to perform specific type of testing. To meet specific regulatory or industry's self-regulatory requirement, the testing must be done by either AMS laboratory or by one of the AMS-approved laboratories.
Alcohol Beverage Sampling Program (TTB)	Random and risk-based sampling of products in the marketplace aimed at evaluating whether TTB is successful in meeting its mission in ensuring that alcohol beverages are properly labelled, formulations are compliant, and to determine where compliance issues exist.
State sampling activities	The range and extent of sampling activities may differ greatly from state to state depending on numerous factors such as industries present in the state, resources available etc.

8.3.1 Food and Drug Administration

In general, FDA may collect samples in accordance with one of the applicable food compliance programs, under routine surveillance sampling programs such as CFSAN's Sample Collection Operation Planning Effort (SCOPE), under workplans for active assignments by Center for Food Safety and Applied Nutrition (CFSAN), Center

for Veterinary Medicine (CVM), Office of Regulatory Affairs (ORA), or other branches of the FDA, or as directed for compliance purposes. Unfortunately, FDA's sampling planning documents were not available for review.

Overall, due to resource constraints and extensive range of products it oversees, FDA tends to apply a risk-based prioritisation approach when planning sampling and other activities. Adverse results from most sampling activities can potentially lead to enforcement actions.

For the purposes of protecting the food supply, FDA distinguishes three types of sampling – product sampling, environmental sampling, and emergency response/emerging issues sampling.

Product sampling involves collecting samples of food products ready to go to market, as well as in-process and raw ingredient samples, to ensure they don't reach consumers with harmful contaminants (for example microbiological surveillance sampling), or to verify that they contain ingredients at levels as declared on product labelling.

The FDA also conducts environmental sampling, which means collecting samples from the environment surrounding the food, typically in a production facility during inspection.

The third type of sampling can take the form of either environmental sampling or product sampling, and often involves both. Emergency response sampling is routinely conducted in response to outbreaks of foodborne illness to help identify the source of the disease-causing pathogen. Emerging issues sampling helps the FDA to gather information about potential food safety issues based on trends or intelligence the FDA might have.

To enforce EPA's tolerances for pesticide chemical residues in human and animal foods it oversees, FDA employs a three-fold strategy:

- Pesticide Residue Monitoring Program (primarily raw commodities);
- Monitoring of the levels of pesticide chemical residues in foods prepared for consumption in FDA's Total Diet Study (table-ready);

- Focused sampling surveys for specific commodities or selected pesticide chemical residues of special interest.

Details of specific sampling activities can be found in FDA's Food Compliance Programs where instructions are provided to FDA personnel for conducting activities to evaluate industry's compliance with FD&C Act and other laws administered by FDA. Chapter 4 of Investigations Operations Manual provides details on types of samples and overall sampling organisation. Additional details on some of the activities are provided in Annex 7.

8.3.2 Food Safety and Inspection Service

FSIS releases an Annual Catalogue of Sampling Projects. The most recent Annual Sampling Program Plan FY 2021 covering all FSIS sampling programs includes sampling for microbiological parameters, chemical residues, antimicrobial resistance, label verification, foodborne illness and outbreak sampling, species identification, import species identification, food chemistry, pathology, and abnormal containers. Annual Sampling Summary Report FY 2020 is available as well.

The FSIS recently undertook a Strategic Assessment of Sampling Resources to fully account for and prioritise resources (see Annex 7). The overall goal was to maximise the efficiency, effectiveness, and value of sampling projects aimed at verifying the safety of products regulated by FSIS. The results of the assessment are taken into account when drafting the Annual Sampling Plan through the use of tools developed as part of the assessment to optimise the benefits of each sampling project. Implementation of provided recommendations also helps with improving internal procedures around sampling planning.

FSIS collects samples at domestic, federally-inspected establishments, in commerce, and at FSIS-regulated import houses. FSIS also collects samples as part of outbreak investigations and in response to consumer complaints. Samples collected by FSIS personnel are sent to one of FSIS' laboratories to conduct microbiological analysis, chemical residue analysis, or other analyses, such as pathology or speciation. In addition, FSIS inspection program personnel conduct many chemical residue screening tests in the establishment, such as Kidney Inhibition Swab (KIS) tests. Details of such activities can be found in the corresponding FSIS directives.

To assess food safety performance of regulated establishments that slaughter and process meat and poultry products, FSIS employs pathogen reduction performance standards which involves sampling by FSIS personnel on an unannounced basis and consequently categorising establishments based on the results (see Annex 7).

FSIS also conducts a range of compliance verification activities, such as routine verification testing of indicator organisms, *Escherichia coli* O157:H7 and non-O157 STEC, *Listeria monocytogenes*, *Salmonella*, *Campylobacter* for various products including raw beef, poultry, pork, and *Siluriformes*, as well as ready-to-eat (RTE) products.

Sampling and testing for chemical residues and contaminants in FSIS-regulated meat (including *Siluriformes* fish products), poultry, and egg products is conducted under the National Residue Program (NRP) for Meat, Poultry, and Egg Products, an interagency programme administered by FSIS (see Annex 7).

FSIS also conducts a number of exploratory sampling programs. Examples of current exploratory sampling programs include:

- Imported Raw Poultry Products Sampled for *Salmonella* and *Campylobacter* Analysis (FSIS Notice 56-20);
- Raw Pork Products Sampling Program (FSIS Notice 65-20);
- In-Field Study to Test a New Sample Collection Method for Beef Manufacturing Trimmings (FSIS Notice 69-20);
- Sampling for labelling claims verification (FSIS Notice 15-21).

8.3.3 Agricultural Marketing Service

AMS administers some surveillance programmes and surveys that involve sampling. This includes Pesticide Data Program (PDP) implemented through cooperation with state agriculture departments and other federal agencies, microbiological testing of meat, poultry, and egg commodities purchases by AMS for various federal food and nutrition assistance programs, and targeted sampling tasks on request by foreign or domestic agencies or the industry. Equally, AMS runs a number of Laboratory Approval Programs that may require sampling and testing by the AMS or by one of the AMS-approved laboratories. For further details on the above, see Annex 7.

8.3.4 Alcohol and Tobacco Tax and Trade Bureau

As stated in TTB Strategic Plan for Fiscal Years 2018-2022, TTB aims to focus on both random and risk-based market sampling through its Alcohol Beverage Sampling Program (ABSP) to detect where issues may exist in the marketplace as well as evaluate products that may have a higher likelihood of non-compliance based on certain risk factors. The purpose is to inform decisions on enforcement actions and priorities to effectively direct investigative and regulatory resources (see Annex 7 for more details).

While the FDA is responsible for determining which ingredients are prohibited from use in food and/or beverage products, TTB's Beverage Alcohol Laboratory (BAL), under a Memorandum of Agreement (MOA) with the FDA, analyses alcohol beverage products for limited and prohibited compounds (for example harmful ingredients, adulterants, unauthorised additives). The laboratory enforces these restrictions for alcohol beverages as per FDA guidance.

TTB also plays a role of the primary investigator of consumer complaints related to alcohol beverages. A TTB investigator would collect the sample and the reference and submit to the BAL.

8.3.5 State authorities (California)

States may conduct own sampling. This can be done for surveillance purposes or targeted surveys to address a specific knowledge gap. The extent of such activities primarily depends on what industries are important in the state.

For example, California Department of Pesticide Regulation (CDPR) runs California Pesticide Residue Monitoring Program. The samples are collected by CDPR Enforcement Branch personnel and sent to CDFA's Food Safety Laboratory to be screened for more than 400 pesticides and breakdown products. The latest report indicates that 3,274 produce samples from wholesale and retail outlets, distribution centres, and roadside and farmers markets were collected in 2019.

8.4 Intelligence gathering and data integration

8.4.1 Food and Drug Administration

FDA's CFSAN applies risk analysis to prioritise risks and calculate optimal interventions. Both conventional methods and far-reaching tools that use advanced technology are used.

CFSAN currently lists the following risk assessment projects as ongoing:

- *Listeria* in soft-ripened cheese (with Canada);
- *Listeria* in hot- and cold-smoked finfish;
- Drug residues in milk (with CVM);
- On-Farm Produce Risk Model, QPRAM;
- Updated *Listeria* in RTE foods (with FSIS);
- Norovirus in shellfish (with Canada).

CFSAN is also working on risk profiles which are comprehensive descriptions of a hazard, the supply and consumption chains of the foods it affects, and potential interventions. Examples of risk profiles could be for hepatitis A in produce, pathogens in raw milk cheese, *Listeria* in fresh produce etc.

CFSAN is involved in research and data collection activities such as Market Basket Survey (with USDA Agricultural Research Service) regarding prevalence and levels of *Listeria monocytogenes* in ready-to-eat foods to inform planned or ongoing risk profiles and assessments.

The data from risk assessment, risk profile projects, and related data collection activities is used by FDA (and other agencies) in the development of risk analysis tools.

In terms of imports, since all shipments are subject to prior notice requirement, these are screened by two of FDA's electronic systems, Import Entry Review System and Operational and Administrative System for Import Support (OASIS), in combination with a screening tool called Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT). These are used by the FDA to enforce Import Alerts and also to prioritise the sampling of imports. In 2020, out of 13,653,606 lines of human foods and 405,841 lines of animal feed imported, only 8,597 and 199 lines, respectively, were sampled.

FDA is engaged in a number of efforts to gather information about the foods consumed in the United States. Some of these on-going monitoring programs such as the Total Diet Study and the Pesticide Residue Monitoring Program were covered previously. Retail Food Risk Factor Study is another such long term study that looks at food safety practices in the food service environment. In 2013, the FDA initiated a

second 10-year study to measure the occurrence of practices and behaviours commonly identified by the CDC as contributing factors in foodborne illness outbreaks.

Under its Whole Genome Sequencing (WGS) Program, FDA gathers sequences of pathogens collected from foodborne outbreaks, contaminated foods, and environmental sources. The genome sequences are archived in an open-access genomic reference database called GenomeTrakr.

The National Milk Drug Residue Database (NMDRD) is a voluntary industry reporting program authorised by the NCIMS to compile the results of milk drug residue testing by industry and state regulatory agencies. Data are reported on the extent of the national testing activities, the analytical methods used, the kind and extent of the animal drug residues identified, and the amount of contaminated milk that was removed from the human food supply. Program's Annual Report FY 2020 published by FDA indicates that 3,870,695 samples were taken in total. This includes 177,299 samples taken by state regulatory agencies. Remaining samples were taken and reported by the industry.

8.4.2 Food Safety and Inspection Service

FSIS Annual Plan for Fiscal Year 2021 provides a summary of FSIS collaborations with federal, state, tribal, territorial, and local agencies and stakeholders to improve efficiency and effectiveness of food safety outcomes. It includes Food Emergency Response Network (FERN) which is a network of more than 160 federal, state, local, and tribal food testing laboratories jointly administered by FSIS and FDA. The network has worked to protect the food system through targeted food defence surveillance activities associated with imported foods, the school lunch program, retail samples, and national special security events. In FY 2021, FSIS intends to work with state partners to support targeted food defence analysis of FSIS regulated commodities sampled at retail in 11 states (4,500-5,000 samples annually).

FSIS works with other federal partners on the application of whole genome sequencing (WGS) data for regulatory purposes. FSIS laboratories perform WGS on all positive sample isolates for all pathogens from FSIS-regulated products. In FY 2020, FSIS uploaded ~14,000 bacterial isolate sequences to National Center for Biotechnology Information (NCBI). FSIS uses WGS data to routinely determine

Salmonella serotype. In FY 2020, FSIS laboratories additionally began inputting antimicrobial resistance genes, adaptability genes and *E. coli* virulence genes into the Data Warehouse. The WGS data is then used by FSIS analysts for risk assessment purposes.

In cases, where FSIS laboratory detects a chemical compound at a level exceeding an established tolerance or action level, or if the presence of chemical compound detected renders the product adulterated in the absence of an established tolerance, FSIS enters information about residue violations into the Residue Violator Tracking (RVT) system, an FSIS-FDA interagency database. FSIS also notifies establishment and the designated FSIS inspection program personnel with the analysis results. The establishment then usually notifies the producer of an animal.

FSIS shares the violation data with FDA as it has on-farm jurisdiction as well as with EPA. FDA and cooperating state agencies investigate producers linked to residue violations and, if conditions leading to residue violations are not corrected, can enforce legal action.

To inform the public and the industry, FSIS publishes a weekly Residue Repeat Violators List on its website. The list is used by processors and producers supplying under AMS School Lunch Program to avoid illegal levels of residues.

Even in the absence of violation, testing data is routinely reviewed and analysed by FSIS for trends and even individual results may trigger specific agency responses, including consultation between FSIS, FDA, and EPA, as well as follow-up actions if appropriate.

8.4.3 Centers for Disease Control and Prevention

One of the primary functions of the Centers for Disease Control and Prevention (CDC) in terms of food safety is to investigate the sources of foodborne disease outbreaks together with local, state, and other federal agencies. CDC maintains a nationwide system of foodborne disease surveillance. The Foodborne Disease Outbreak Surveillance System (FDOSS) collects information from state and local health departments about foodborne disease outbreaks.

CDC also administers a number of databases used by other agencies in their everyday activities such as PulseNet USA database which is the national repository

of PFGE test results. It includes public health laboratories in all 50 states and Puerto Rico and food regulatory laboratories within the FDA and USDA. Notably, PulseNet is transitioning toward using whole genome sequencing. For a few organisms, PulseNet also uses multi-locus variable tandem repeat analysis (MLVA) to aid outbreak investigations.

It is worth mentioning three other collaborations co-led by CDC. Interagency Food Safety Analytics Collaboration (IFSAC) is a collaboration between CDC, FDA, and FSIS aimed to coordinate analysis from these three federal agencies on foodborne illness source attribution, to inform strategic planning and risk-based decision making, estimate benefits of interventions, and evaluate the impact of interventions. All three work collectively to analyse and interpret human surveillance and food contamination data, share data and methods, and monitor progress toward the goal of preventing foodborne illness.

The Foodborne Diseases Active Surveillance Network (FoodNet) is a collaborative program among CDC, 10 state health departments, FSIS, and FDA. FoodNet personnel located at state health departments conduct surveillance for *Campylobacter*, *Cyclospora*, *Listeria*, *Salmonella*, Shiga toxin-producing *Escherichia coli* (STEC) O157 and non-O157, *Shigella*, *Vibrio*, and *Yersinia* infections diagnosed by laboratory testing of samples from patients. The surveillance area includes 15% of the U.S. population (48 million persons).

National Antimicrobial Resistance Monitoring System for Enteric Bacteria (NARMS) is a collaboration among state and local public health departments, CDC, FDA, and USDA. This national public health surveillance system tracks changes in the antimicrobial susceptibility of certain enteric bacteria found in ill people, retail meats, and food animals in the United States. USDA tests bacterial samples taken from food-producing animals. FDA, health departments, and universities contribute data on antimicrobial susceptibility in retail chicken, ground turkey, ground beef, and pork from grocery stores. CDC as well as health departments in all 50 states provide antimicrobial susceptibility data in isolates from ill persons. During outbreaks, CDC also tests leftover foods found in outbreak patient homes. CDC, through NARMS, tracks antibiotic resistance and studies patterns of emerging resistance in select bacteria transmitted commonly through food.

Glossary

Acronym	Definition
AAFCO	Association of American Feed Control Officials
ABSP	Alcohol Beverage Sampling Program
AEMIS	Australian Export Meat Inspection System
AHFSS	Animal Health and Food Safety Services
APC	Aerobic Plate Count
APHIS	Animal and Plant Health Inspection Service
AMS	Agricultural Marketing Service
ARS	Agricultural Research Service
APVMA	Australian Pesticides and Veterinary Medicines Authority
ATDS	Australian Total Diet Study
BAL	Beverage Alcohol Laboratory
CBP	U.S. Customs and Border Protection
CDC	Centers for Disease Control and Prevention
CDFA	California Department of Food and Agriculture
CDPH	California Department of Public Health
CDPR	California Department of Pesticide Regulation
CFIA	Canadian Food Inspection Agency
CFR	Code of Federal Regulations
CFSAN	Center for Food Safety and Applied Nutrition
CFSIN	Canadian Food Safety Information Network
COLA	Certification/Exemption of Label/Bottle Approval
CPHD	Consumer and Public Health Dialogue
CVM	Center for Veterinary Medicine
DAWE	Department of Agriculture, Water and the Environment
DEDJTR	Department of Economic Development, Jobs, Transport and Resources
DHHS	Department of Health and Human Services
EPA	U.S. Environmental Protection Agency
EPIA	Egg Products Inspection Act
FCP	Food control plan
FD&C Act	Federal Food, Drug and Cosmetic Act
FDA	Food and Drug Administration
FDOSS	Foodborne Disease Outbreak Surveillance System

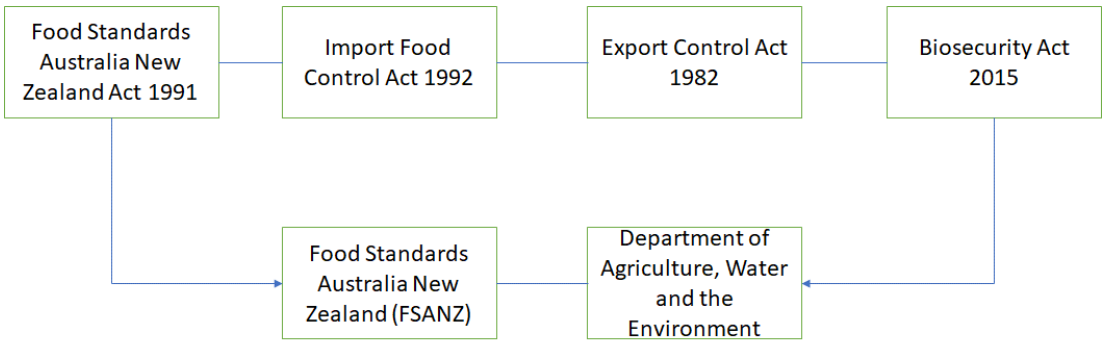
Acronym	Definition
FERN	Food Emergency Response Network
FGIS	Federal Grain Inspection Service
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FMIA	Federal Meat Inspection Act
Forum	Australia and New Zealand Ministerial Forum on Food Regulation
FR	Federal Register
FSANZ	Food Standards Australia New Zealand
FSIS	Food Safety and Inspection Service
FSMA	FDA Food Safety Modernization Act
FSO	Food Safety Oversight Program
HHS	U.S. Department of Health and Human Services
ICSSL	Interstate Certified Shellfish Shippers List
IFSAC	Interagency Food Safety Analytics Collaboration
ISFR	Implementation Subcommittee for Food Regulation
ISSC	Interstate Shellfish Sanitation Conference
IVP	Independent Verification Programme
KIS	Kidney Inhibition Swab
MDFS	Milk and Dairy Food Safety Branch
MEDC	Meat Export Data Collection
MLVA	Multi-locus variable tandem repeat analysis
MOU	Memorandum of Understanding
MPD	Monitoring Programs Division
MPI	New Zealand Ministry of Primary Industries
NARM	National Antibacterial Residue Minimisation Program
NARMS	National Antimicrobial Resistance Monitoring System for Enteric Bacteria
NASS	National Agricultural Statistics Service
NCBI	National Center for Biotechnology Information
NCIMS	National Conference on Interstate Milk Shipments
NCRMP	National Chemical Residue Monitoring Program
NCRP	National Chemical Residues Programme
NMFS	National Marine Fisheries Service
NMMP	National Microbiological Monitoring Program

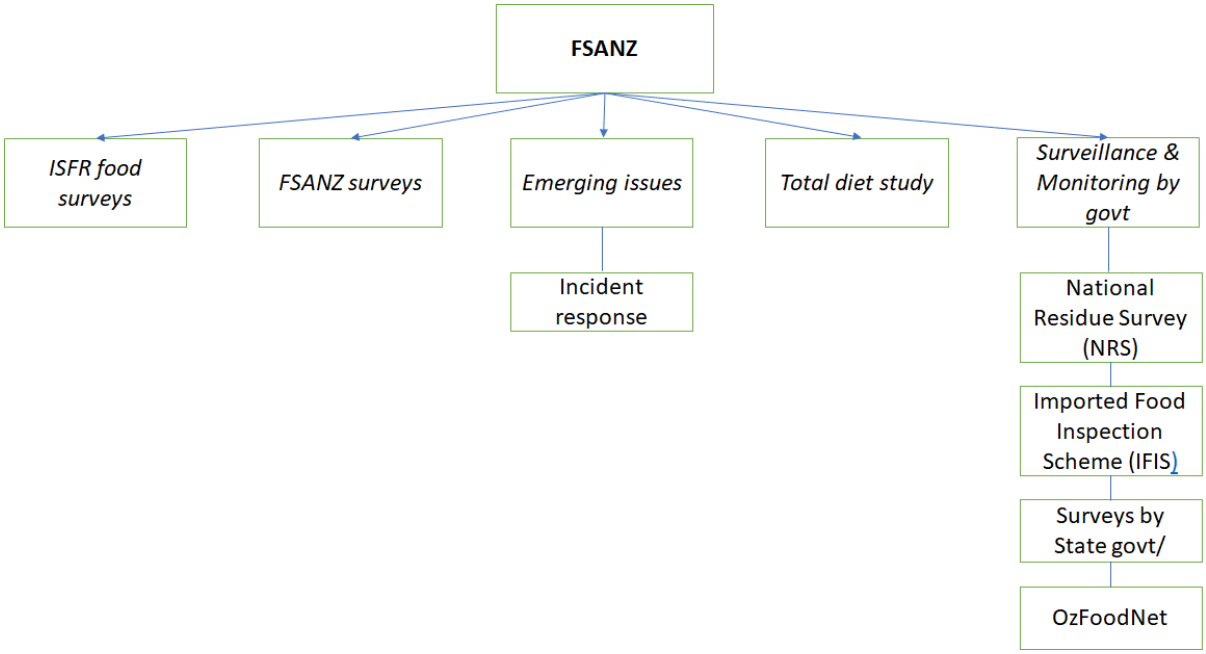
Acronym	Definition
NMDRD	National Milk Drug Residue Database
NOAA	National Oceanic and Atmospheric Administration
NORM	National Organochlorine Residue Management Program
NRP	National Residue Program
NRS	National Residue Survey
NSSP	National Shellfish Sanitation Program
NSW	New South Wales
NZTDS	New Zealand Total Diet Study
OASIS	Operational and Administrative System for Import Support
OC	Organochlorine
OMAFRA	Ontario Ministry of Agriculture Food and Rural Affairs
ON-FIORP	Ontario foodborne illness outbreak response protocol
ORA	Office of Regulatory Affairs
PCP	Preventative Control Plan
PDP	Pesticide Data Program
PFGE	Pulsed-field gel electrophoresis
PHAC	Public Health Agency Canada
PPIA	Poultry Products Inspection Act
PREDICT	Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting
PRMP	Pesticide Residue Monitoring Program
QPRAM	Quantitative Produce Risk Assessment Model
RMLC	Retailers and Manufacturers Liaison Committee
RMP	Risk management programme
RTE	Ready-to-Eat
RVT	Residue Violator Tracking system
SAT	Surveillance Advisory Team
SCOPE	Sample Collection Operation Planning Effort
STEC	Shiga toxin-producing *E. coli*
TDS	Total Diet Study
TTB	Alcohol and Tobacco Tax and Trade Bureau
U.S.C.	United States Code
USDA	U.S. Department of Agriculture
WGS	Whole genome sequencing

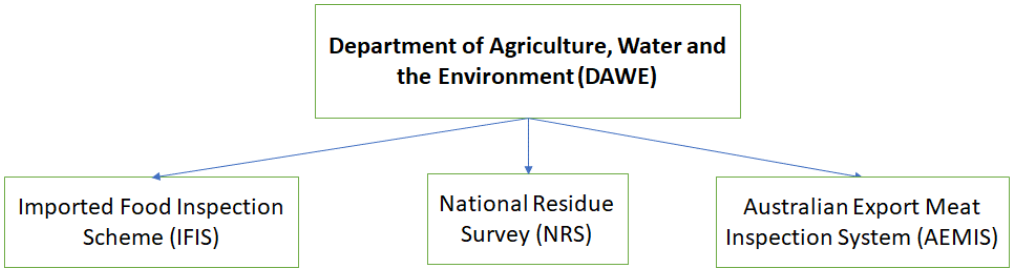
Annex 1 Overview of official website interrogation strategies

A1.1 Australia

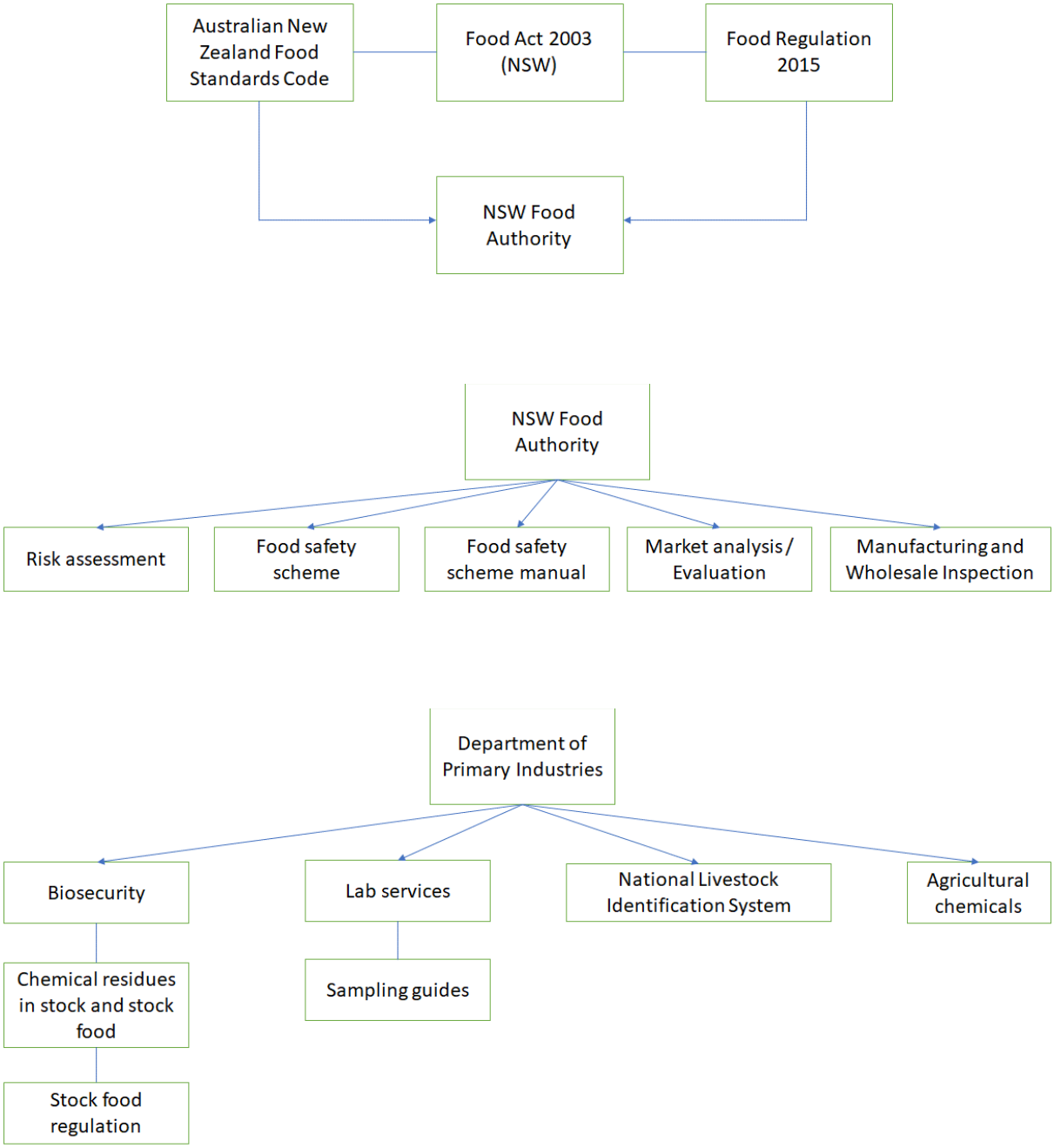
National regulatory framework







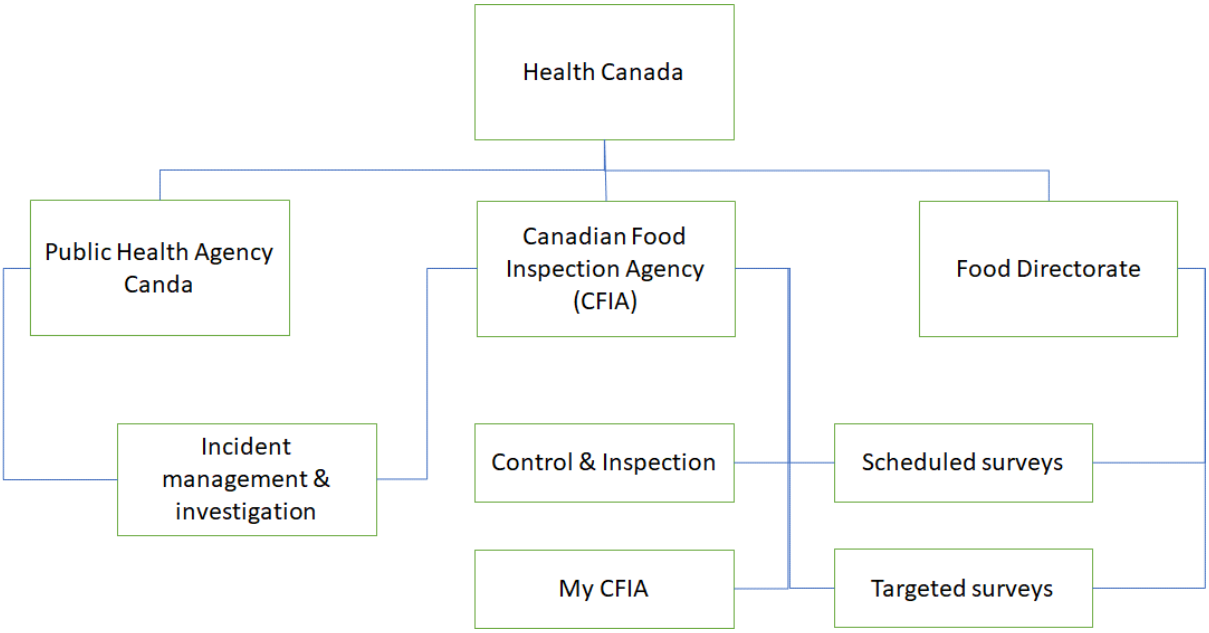
State regulatory framework (New South Wales)



A1.2 Canada

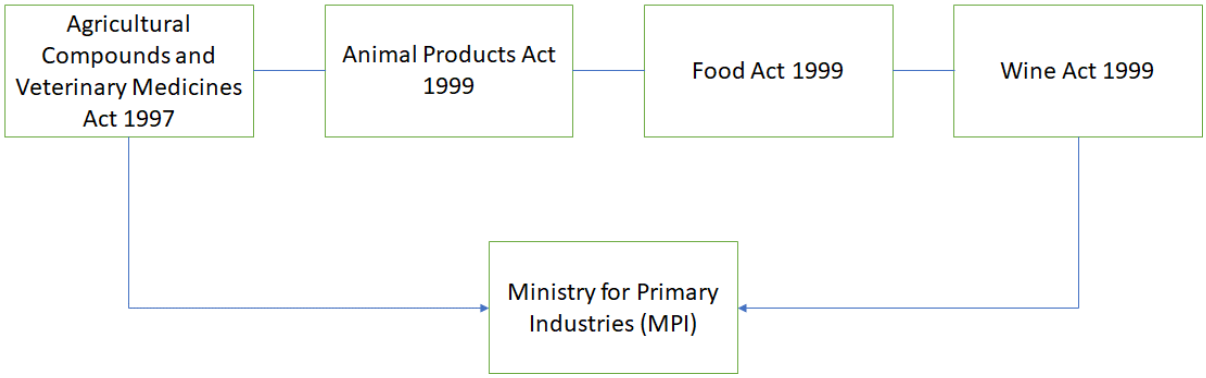
National regulatory framework

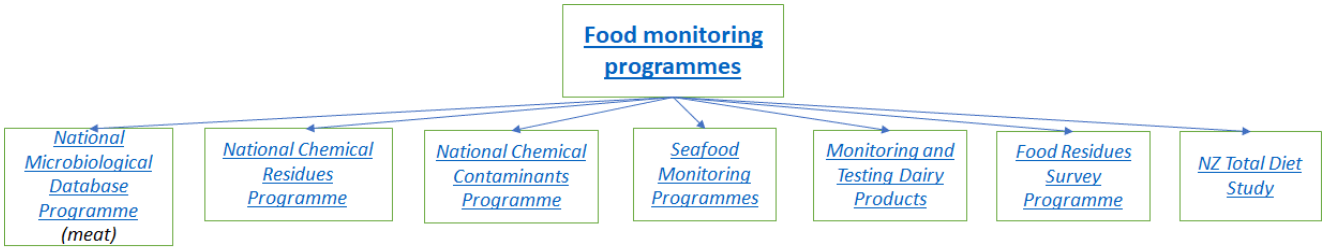
Role of CFIA and other Health Canada partners

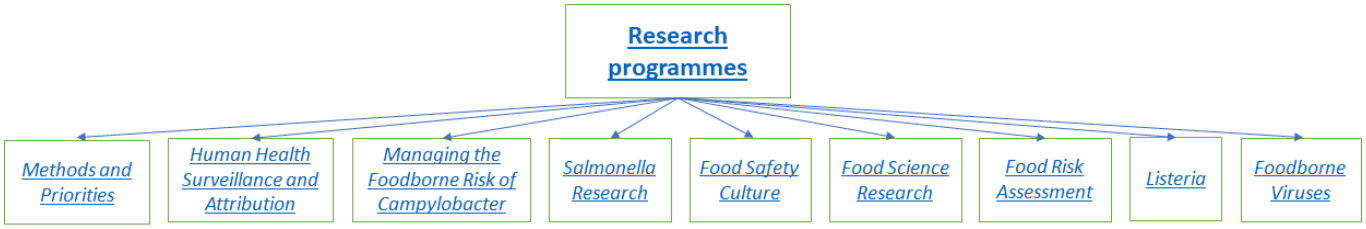


A1.3 New Zealand

National regulatory framework

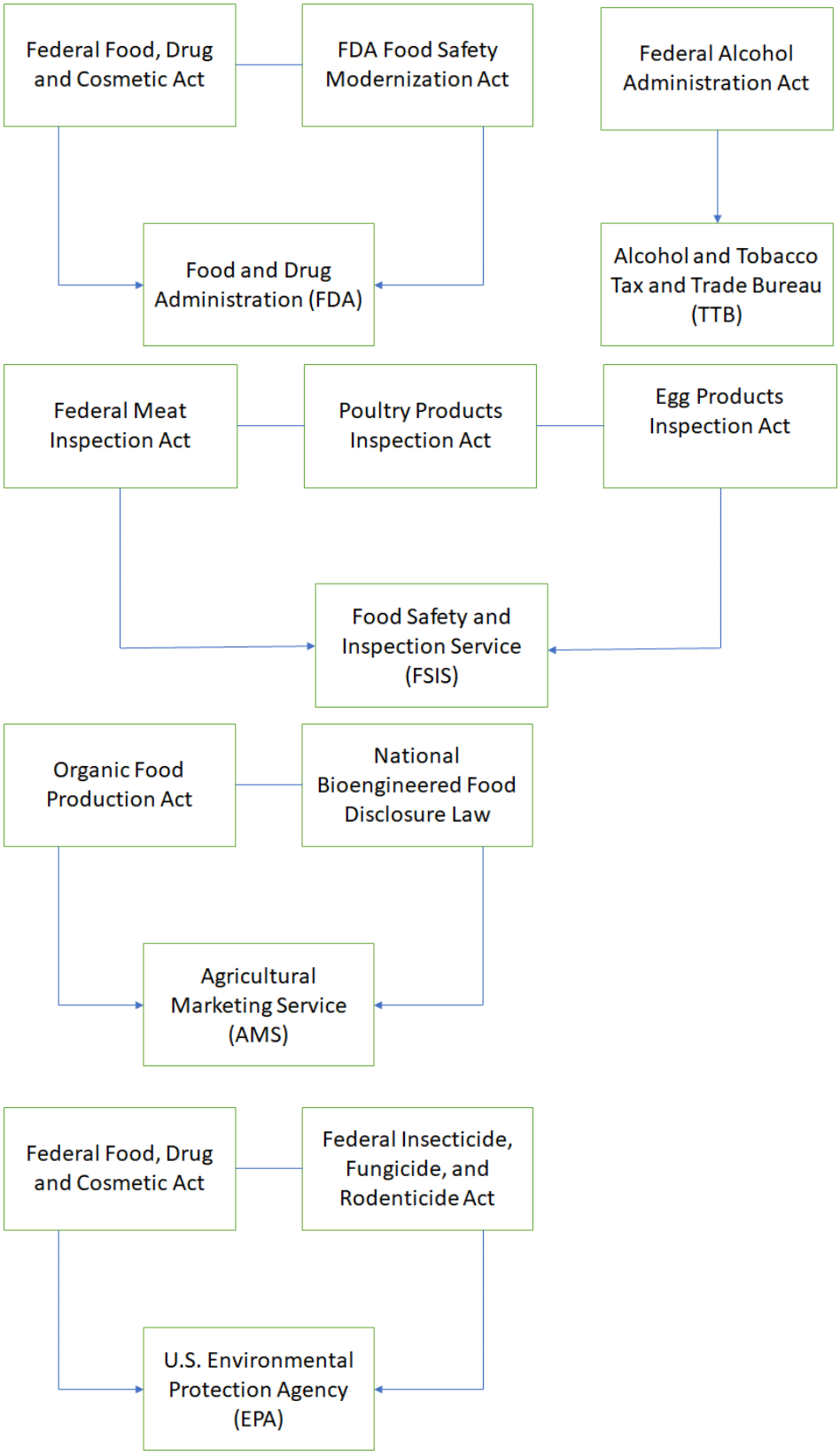






A1.4 United States of America

National regulatory framework



Annex 2 Structured interview questionnaire / aide memoire

Number	Topic / background	Key question	Comments / subsidiary questions
1	**Multi-Annual National Control Plan** The United Kingdom Food Standards Agency produces a Multi-Annual National Control Plan , which provides general information on the structure and organisation of the official control systems in place for monitoring and enforcing feed and food law	Is there a similar type of overarching planning document generated in your jurisdiction; or at least for products overseen by your organisation?	1. If yes, how is the document prepared? 2. Is sampling for control programmes exclusively co-ordinated at a national level or are there regional programmes as well? 3. If regional programmes are undertaken, are the outputs integrated into the national control plan/strategy?
2	**Official control plans** In this context, official control plans relate to sampling and testing of food and feed as mandated by regulation (for example import controls)	What is the strategy underpinning official control plans?	1. How are strategies for official control plans (numbers of samples, frequency of sampling etc.) developed? 2. Who collects samples and commissions testing (for example enforcement officers, industry, both)? 3. How is situational awareness maintained to ensure that emerging issues either

Number	Topic / background	Key question	Comments / subsidiary questions
			from official control results or external events can be addressed in a timely manner?

Number	Topic / background	Key question	Comments / subsidiary questions
3	**Surveys** Surveys involve the collection of particular types of food or feed which are tested for one or more analytes. These can be undertaken to meet legislative requirements or to provide an additional source of intelligence on the safety of the countries food and feed system.	Why and how are surveys commissioned?	1. Are any surveys required by regulation and, if so, can examples be provided? 2. Where surveys are not required by regulation, what are the mechanisms to determine: a. What issues should be addressed b. The structure of the survey 3. Following on from question 2a what types of intelligence are used to assist in identifying issues, for example outputs of other sampling, information from industry, notifications from other countries. 4. How extensive are surveys regarding feed (for example limited to *Salmonella* spp and mycotoxins or includes additional analytes)?

Number	Topic / background	Key question	Comments / subsidiary questions
4	**Interaction with industry** This section concerns leverage mechanisms to enable the food and feed industries to share their own data with regulators	How do regulators interact with the industry in terms of sampling?	1. Do fora exist for regulators and industry to discuss trends in test data etc. 2. Is there a regulatory requirement for: a. Industry to perform tests for particular food analyte combinations and submit the results to the regulator? b. Testing laboratories to directly report positive test results for particular analytes (for example *Salmonella* spp.) in food or feed to the regulator?
5	**Sampling guidance** This section concerns internal guidelines on the collection of samples for either official control purposes or for the conduct of surveys.	Is it possible for the Food Standards Agency to have sight of these guidelines?	3. Scope should be extensive as possible to consider microbiological, chemical and physical (for example radiological) endpoints.

Annex 3 Supplementary literature search of relevant publications in the scientific literature

A3.1 Australia

Search ontology: (fsanz OR “food standards australia new zealand”) AND (sampl* OR survey OR control OR monitor* OR intelligence)

Meta-statistics PubMed, 64 records recovered; 19 considered relevant

FSTA, 24 records recovered; 9 considered relevant

Pubmed results:

1. Airey D. Total mercury concentrations in human hair from 13 countries in relation to fish consumption and location. Sci Total Environ. 1983 31(2): 157-80 PMID: 6658448

2. Ashmore E, Molyneux S, Watson S, Miles G, Pearson A. Inorganic arsenic in rice and rice products in New Zealand and Australia. Food Addit Contam Part B Surveill. 2019 Dec; 12(4): 275-279. PMID: 31409256

3. Dugbaza J, Cunningham J. Estimates of total dietary folic Acid intake in the Australian population following mandatory folic Acid fortification of bread. J Nutr Metab. 2012; 2012:492353. PMID: 22957218; PMCID: PMC3432557

4. El-Din Bekhit A, Al-Amer S, Gooneratne R, Mason SL, Osman KA, Clucas L. Concentrations of trace elements [corrected] and organochlorines in Mutton bird (Puffinus griseus). Ecotoxicol Environ Saf. 2011 Sep; 74(6):1742-6. PMID: 21676460

5. Fransisca Y, Small DM, Morrison PD, Spencer MJ, Ball AS, Jones OA. Assessment of arsenic in Australian grown and imported rice varieties on sale in Australia and potential links with irrigation practises and soil geochemistry. Chemosphere. 2015 Nov; 138: 1008-13. PMID: 25577696

6. Griffin CT, Mitrovic SM, Danaher M, Furey A. Development of a fast isocratic LC-MS/MS method for the high-throughput analysis of pyrrolizidine alkaloids in Australian honey. Food Addit Contam Part A Chem Anal Control Expo Risk Assess. 2015;32(2):214-28. PMID: 25491228

7. Miles D, Jansson E, Mai MC, Azer M, Day P, Shadbolt C, Stitt V, Kiermeier A, Szabo E. A survey of total hydrocyanic acid content in ready-to-eat cassava-based chips obtained in the Australian market in 2008. J Food Prot. 2011 Jun;74(6):980-5. PMID: 21669076

8. Munnoch SA, Ashbolt RH, Coleman DJ, Walton N, Beers-Deeble MY, Taylor R. A multi-jurisdictional outbreak of hepatitis A related to a youth camp–implications for catering operations and mass gatherings. Commun Dis Intell Q Rep. 2004;28(4):521-7. PMID: 15745403

9. Nolan-Clark DJ, Neale EP, Charlton KE. Processed pork is the most frequently consumed type of pork in a survey of Australian children. Nutr Res. 2013. PMID: 24176231

10. Padovan A, Kennedy K, Rose D, Gibb K. Microbial quality of wild shellfish in a tropical estuary subject to treated effluent discharge. Environ Res. 2020 Feb;181:108921 PMID: 31757407

11. Probst Y, Guan V, Neale E. Development of a Choline Database to Estimate Australian Population Intakes. Nutrients. 2019 Apr 23;11(4):913. PMID: 31018620; PMCID: PMC6521034

12. Russell S, Sullivan CA, Reichelt-Brushett AJ. Aboriginal Consumption of Estuarine Food Resources and Potential Implications for Health through Trace Metal Exposure; A Study in Gumbaynggirr Country, Australia. PloS One. 2015 Jun 22;10(6):e0130689. PMID: 26098897; PMCID: PMC4476661

13. Tapsell LC. Evidence for health claims: a perspective from the Australia-New Zealand region. J Nutr. 2008 Jun;138(6):1206S-9S. doi: 10.1093/jn/138.6.1206S. PMID: 18492858

14. Tonkin E, Webb T, Coveney J, Meyer SB, Wilson AM. Consumer trust in the Australian food system – The everyday erosive impact of food labelling. Appetite. 2016 Aug 1;103:118-127. PMID: 27063669

15. Unicomb LE, Simmons G, Merritt T, Gregory J, Nicol C, Jelfs P, Kirk M, Tan A, Thomson R, Adamopoulos J, Little CL, Currie A, Dalton CB. Sesame seed products contaminated with Salmonella: three outbreaks associated with tahini.

Epidemiol Infect. 2005 Dec;133(6):1065-72. PMID:16274503; PMCID: PMC2870340

16. Willems DJ, Reeves JM, Morrison PD, Trestrail C, Nugegoda D. Trace metal biomonitoring in the east Gippsland Lakes estuary using the barnacle Amphibalanus variegatus and mussel Mytilus edulis. Environ Sci Pollut Res Int. 2020 Jan;27(3):3361-3383. PMID: 31845271

17. Gilbert JM, Reichelt-Brushett AJ, Butcher PA, McGrath SP, Peddemors VM, Bowling AC, Christidis L. Metal and metalloid concentrations in the tissues of dusky Carcharhinus obscurus, sandbar C. plumbeus and white Carcharodon carcharias sharks from south-eastern Australian waters, and the implications for human consumption. Mar Pollut Bull. 2015 Mar 15;92(1-2):186-194. PMID: 25656241

18. Dunlop E, Cunningham J, Sherriff JL, Lucas RM, Greenfield H, Arcot J, Strobel N, Black LJ. Vitamin D_3 and 25-Hydroxyvitamin D_3 Content of Retail White Fish and Eggs in Australia. Nutrients. 2017 Jun 22;9(7):647. PMID: 28640196; PMCID: PMC5537767

19. Petersen KS, Torpy DJ, Chapman IM, Guha S, Clifton PM, Turner K, Keogh JB. Food label education does not reduce sodium intake in people with type 2 diabetes mellitus. A randomised controlled trial. Appetite. 2013 Sep;68:147-51. PMID: 23665299

FSTA Results:

1. Williams, P; Yeatman, H; Zakrzewski, S; Aboozaid, B; Henshaw, S; Ingram, K; Rankine, A; Walcott, S; Ghani, F. Nutrition and related claims used on packaged Australian foods – implications for regulation. Asia Pacific Journal of Clinical Nutrition. 2003; 12: 138- 150

2. Williams, P; Yeatman, H; Ridges, L; Houston, A; Rafferty, J; Roesler, A; Sobierajski, M; Spratt, B. Nutrition function, health and related claims on packaged Australian food products – prevalence and compliance with regulations. Asia Pacific Journal of Clinical Nutrition. 2006; 15; 10-20

3. McCarthy, J; Barr, D; Sinclair, A. Determination of trans fatty acid levels by FTIR in processed foods in Australia. Asia Pacific Journal of Clinical Nutrition. 2008; 17: 391-396

4. Duffy, G; Sobolewski, R. Getting to grips with working in government – Key Foods and the Children's Dietary Survey nutrition database. Food Australia, 2008; 60: 34-36

5. Cressey, PJ. Mycotoxin risk management in New Zealand and Australian food. World Mycotoxin Journal, 2009; 2: 113-118

6. Hsu, J; Arcot, J; Lee, NA. Nitrate and nitrite quantification from cured meat and vegetables and their estimated dietary intake in Australians. Food Chemistry, 2009; 115: 334-339

7. [Anonymous]. FSANZ survey of raw chicken meat. Food Australia, 2010; 62: 244-244

8. Petersen, KS; Torpy, DJ; Chapman, IM; Guha, S; Clifton, PM; Turner, K; Keogh, JB. Food label education does not reduce sodium intake in people with type 2 diabetes mellitus. A randomised controlled trial. Appetite, 2013; 68: 147-151

9. Yee, NS; Shao, QQ; Uraipong, C; Shoji, M; Lee, NA. A comprehensive survey of allergen labeling on pre-packaged food products imported from Mainland China. Food Control, 2021; 123: 107749

A3.2 Canada

Search ontology: (cfia OR “canadian food inspection agency”) NOT (fragilis OR “gene cfia” OR “cfia gene OR cfia-gene”) AND (sampl* OR survey OR control OR monitor* OR intelligence)

Meta-statistics PubMed, 697 records recovered; 52 considered relevant

FSTA, 85 records recovered; 28 considered relevant

PUBMED Results:

1. Agunos A, Arsenault RK, Avery BP, Deckert AE, Gow SP, Janecko N, Léger DF, Parmley EJ, Reid-Smith RJ, McEwen SA. Changes in antimicrobial resistance levels among Escherichia coli, Salmonella, and Campylobacter in Ontario broiler chickens between 2003 and 2015. Can J Vet Res. 2018 82(3):163-177. PMID: 30026640; PMCID: PMC6038833

2. Andrievskaia O, Tangorra E. Detection of bovine central nervous system tissues in rendered animal by-products by one-step real-time reverse transcription PCR assay. J Food Prot. 2014 77(12):2088-97. PMID: 25474055

3. Bietlot HP, Kolakowski B. Risk assessment and risk management at the Canadian Food Inspection Agency (CFIA): a perspective on the monitoring of foods for chemical residues. Drug Test Anal. 2012 4 Suppl 1:50-8. PMID: 22851361

4. Bisaillon JR, Feltmate TE, Sheffield S, Julian R, Todd E, Poppe C, Quessy S. Classification of grossly detectable abnormalities and conditions seen at postmortem in Canadian poultry abattoirs according to a hazard identification decision tree. J Food Prot. 2001 64(12):1973-80. PMID: 11770626

5. Campbell HM, Armstrong JF. Determination of zearalenone in cereal grains, animal feed, and feed ingredients using immunoaffinity column chromatography and liquid chromatography: interlaboratory study. J AOAC Int. 2007 90(6):1610-22. PMID: 18193738

6. Carrillo CD, Plante D, Iugovaz I, Kenwell R, Bélanger G, Boucher F, Poulin N, Trottier YL. Method-dependent variability in determination of prevalence of

Campylobacter jejuni and Campylobacter coli in Canadian retail poultry. J Food Prot. 2014 77(10):1682-8. PMID: 25285484

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8. Currie A, Galanis E, Chacon PA, Murray R, Wilcott L, Kirkby P, Honish L, Franklin K, Farber J, Parker R, Shyng S, Sharma D, Tschetter L, Hoang L, Chui L, Pacagnella A, Wong J, Pritchard J, Kerr A, Taylor M, Mah V, Flint J; Investigative Team. Outbreak of Escherichia coli O157:H7 Infections Linked to Aged Raw Milk Gouda Cheese, Canada, 2013. J Food Prot. 2018 81(2):325-331. PMID: 29369688

9. Currie A, Honish L, Cutler J, Locas A, Lavoie MC, Gaulin C, Galanis E, Tschetter L, Chui L, Taylor M, Jamieson F, Gilmour M, Ng C, Mutti S, Mah V, Hamel M, Martinez A, Buenaventura E, Hoang L, Pacagnella A, Ramsay D, Bekal S, Coetzee K, Berry C, Farber J, Team OBOTNI. Outbreak of Escherichia coli O157:H7 Infections Linked to Mechanically Tenderized Beef and the Largest Beef Recall in Canada, 2012. J Food Prot. 2019 82(9):1532-1538. PMID: 31414901

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Doualla-Bell F, Fliss I, Fong K, Fournier E, Franz E, Garduno R, Gill A, Gruenheid S, Harris L, Huang CB, Huang H, Johnson R, Joly Y, Kerhoas M, Kong N, Lapointe G, Larivière L, Loignon S, Malo D, Moineau S, Mottawea W, Mukhopadhyay K, Nadon C, Nash J, Ngueng Feze I, Ogunremi D, Perets A, Pilar AV, Reimer AR, Robertson J, Rohde J, Sanderson KE, Song L, Stephan R, Tamber S, Thomassin P, Tremblay D, Usongo V, Vincent C, Wang S, Weadge JT, Wiedmann M, Wijnands L, Wilson ED, Wittum T, Yoshida C, Youfsi K, Zhu L, Weimer BC, Goodridge L, Levesque RC. A Syst-OMICS Approach to Ensuring Food Safety and Reducing the Economic Burden of Salmonellosis. Front Microbiol. 2017 8:996. PMID: 28626454; PMCID: PMC5454079

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FTSA RESULTS

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A3.3 New Zealand

Search ontology: (fsanz OR “food standards australia new zealand”) AND (sampl* OR survey OR control OR monitor* OR intelligence)

(mpi OR “ministry of primary industries”) AND “new zealand” AND (sampl* OR survey OR control OR monitor* OR intelligence)

Meta-statistics PubMed, 123 records recovered; 16 considered relevant
FSTA, 20 records recovered; 2 considered relevant

PUBMED RESULTS

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11. Pearson AJ, Gaw S, Hermanspahn N, Glover CN. Activity concentrations of (137)Caesium and (210)Polonium in seafood from fishing regions of New Zealand and the dose assessment for seafood consumers. J Environ Radioact. 2016 151 Pt 3:542-50. PMID: 26272653

12. Phillips NR, Stewart M, Olsen G, Hickey CW. Human health risks of geothermally derived metals and other contaminants in wild-caught food. J Toxicol Environ Health A. 77(6):346-65. PMID: 24593147

13. Sadhu AK, Kim JP, Furrell H, Bostock B. Methyl mercury concentrations in edible fish and shellfish from Dunedin, and other regions around the South Island, New Zealand. Mar Pollut Bull. 2015 101(1):386-390. PMID: 26478458

14. Tapsell LC. Evidence for health claims: a perspective from the Australia-New Zealand region. J Nutr. 2008 Jun;138(6):1206S-9S. PMID: 18492858

15. Unicomb LE, Simmons G, Merritt T, Gregory J, Nicol C, Jelfs P, Kirk M, Tan A, Thomson R, Adamopoulos J, Little CL, Currie A, Dalton CB. Sesame seed

products contaminated with Salmonella: three outbreaks associated with tahini. Epidemiol Infect. 2005 133(6):1065-72. PMID: 16274503; PMCID: PMC2870340

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FSTA RESULTS

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A3.4 United States of America

Search ontology: ("food safety inspection service" OR fsis) AND (sampl* OR survey OR control OR monitor* OR intelligence)

("center for food safety and applied nutrition") AND (sampl* OR survey OR control OR monitor* OR intelligence)

Meta-statistics PubMed, 1,394 records recovered; 135 considered relevant
FSTA, 47 records recovered; 10 considered relevant

PUBMED Results:

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12. Gurtler JB, Hinton A Jr, Bailey RB, Cray WC Jr, Meinersmann RJ, Ball TA, Jin TZ. Salmonella isolated from ready-to-eat pasteurized liquid egg products: Thermal resistance, biochemical profile, and fatty acid analysis. Int J Food Microbiol. 2015 Aug 3;206:109-17. PMID: 26001379

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Annex 4 Further details for Australia

A4.1 ISFR Coordinated Food Survey Plan

A Coordinated Food Survey Plan, developed by the ISFR to help monitor and enforce standards implementation across jurisdictions, identifies and prioritises the national and binational coordinated surveillance and monitoring activities. Activities planned under this plan are usually coordinated by FSANZ but other government bodies (for example state/territory agencies) can take a lead depending on the task. Participants usually include DAWE, FSANZ, MPI NZ, and state/territory agencies.

An overview of recently published reports is provided in Table 10. The rationale underpinning each survey was different, and, if laboratory analyses were commissioned, results were crosslinked to other data collected at the same time. Thus, the survey published in 2019 looking at the alcohol content of fermented low alcohol beverages used the analytical data to determine compliance with alcohol labelling regulations, while the 2018 survey concerned with plasticisers in foods was used to inform risk assessments concerning dietary exposure to them. Two surveys (2018, folic acid in bread making flour, and 2016, on-farm food safety practices survey of strawberry growing) used analytical data to verify information concerning quality and/or food safety management systems. One survey (2017, assessment of *trans* fatty acids in imported oils) was a follow-up to previous surveys based on laboratory analyses but in this case relied on data from customs authorities and importers.

Given that some of the studies are specifically addressed at verifying the efficiency of specific food safety management practices (for example On-farm food safety practices survey of strawberry growing in Victoria), the term “data” is taken to include not only the results of analytical testing of samples but also other relevant information collected during a specific study.

Table 10. Recently published reports from ISFR Coordinated Food Survey Plan

Year	Title & link	Lead authority	Food	Where collected	Parameters considered	No. of samples
2019	Coordinated survey of alcohol content and labelling of fermented soft drinks	Victoria DHHS	Kombucha, water and dairy kefir, and other fermented soft drinks	Market place	Ethanol	239
2018	Survey of Plasticisers in Australian Foods	FSANZ	Packaged foods and beverages	Market place	Various phthalate, adipate and citrate plasticisers	65
2018	Mandatory folic acid fortification of wheat flour for bread making	Queensland Health	Bread making flour	Flour mills	Folic acid & flour mill quality systems	12
2017	Assessment of Trans Fatty Acids in Imported Oils	FSANZ & New Zealand MPI	Imported fats and oils	Not applicable	Desk-based study using data from customs authorities and importers. No laboratory analyses commissioned	N/A

Year	Title & link	Lead authority	Food	Where collected	Parameters considered	No. of samples
2016	On-farm food safety practices survey of strawberry growing in Victoria	FSANZ & Victoria DEDJTR	Strawberries	Farms	*Escherichia coli* & farm food safety management systems	330

A4.2 Australian Total Diet Study

The Australian Total Diet Study (ATDS) forms part of FSANZ's monitoring programme and is conducted approximately every two years. FSANZ coordinates the study, while the state and territory food regulatory agencies collect the samples. Analytical data from the study are used to perform risk assessments to determine the efficacy of food safety legislation and identify future areas of intervention. It is considered to be Australia's most comprehensive assessment of consumers' dietary exposure (intake) to pesticide residues, contaminants and other substances in food. In order to achieve the most accurate dietary exposure estimates, the foods examined are representative of a typical Australian diet and are prepared as they are typically consumed prior to analysis. Consequently, both raw and cooked foods are examined, for example, potatoes are cooked.

The latest published report concerns the 25th study, with samples collected over two sampling periods (May 2013 and February 2014). A total of 88-different food types (including drinking water) were sampled from all Australian states and territories and tested for a range of agricultural and veterinary chemicals as well as metal contaminants. For each of the 88 foods, 3 primary (individual) sample purchases were collected from between 4-8 different Australian states or territories. A total of 1524 individual food samples were purchased and combined into a total of 508 composite samples for analyses. Each analysed composite sample was made up of three individual samples from a single state or territory. Foods were selected if they were: suspected or known to contribute significantly to dietary exposure for the chemical analysed, and/or represented current patterns of food and beverage consumption in Australia. Foods in the sample list were classified as either regional or national foods. Higher numbers of regional food samples were collected to account for the increased potential for regional variation in composition. Regional foods were defined as those that might be expected to be sourced regionally and show geographical variation in chemical concentrations. These foods included milk, tap water, fish, fruit, vegetables, red meat and red meat products, chicken, bread and bakery items, wine and selected takeaway foods. For each regional food, eight composite samples were analysed, each consisting of three primary purchases collected from each Australian state and territory. National foods were defined as foods distributed nationwide and therefore expected to show little regional variation in

chemical concentrations. These included breakfast cereals, processed meats, infant foods, tea, coffee, sugar and a variety of canned and other shelf-stable packaged foods. For each national food, four composite samples were analysed, each consisting of three primary purchases collected from four Australian states and territories.

A4.3 Surveys to support development and implementation of the Food Standards Code

One of the roles of FSANZ is the development of food standards which become part of the Australia New Zealand Food Standards Code. FSANZ may undertake surveys as part of its work in maintaining, improving, and implementing the Food Standards Code, for example, when developing food additive standards or in response to emerging issues and national food incidents. These might be food or consumer behaviour surveys and are undertaken as required and as resources permit. Occasionally, such studies are instigated by the ISFR under its Coordinated Food Survey Plan rather than FSANZ (for example Survey of Plasticisers in Australian Foods) but are still used for this purpose. An overview of studies published during the period 2015-2021 is provided in Table 11. Further details can found here.

All of the recently published surveys conducted by FSANZ for the purposes of developing and implementing the Food Standards Code related to the presence of specified chemical contaminants in foods currently on sale in Australia. Samples were collected and analysed by an accredited contract laboratory and data subsequently evaluated by FSANZ.

A4.4 National Residue Survey

The National Residue Survey (NRS) operates a series of monitoring programmes designed in consultation with industry and the Exports Division of the DAWE, aimed at monitoring Australian animal and plant products for chemical residues and environmental contaminants, and is a vital part of the DAWE strategy to minimise chemical residues and environmental chemicals in agricultural produce. The NRS supports Australia's primary producers and agricultural industries by confirming Australia's status as a producer of clean food and facilitating access to domestic and export markets.

At its core, the NRS facilitates testing of animal and plant products for pesticide and veterinary medicine residues, as well as environmental contaminants. National residue monitoring programmes operated by the NRS are used by Australian primary producers to verify good agricultural practice around the use of pesticides and veterinary medicines. For instance, exporters of animal products are required under Australian law to participate in a national residue management programme and use the NRS to satisfy these obligations. Other industries such as the grain, horticulture or non-exporting animal product industries also use the NRS albeit on a voluntary basis in order to demonstrate compliance with state food safety obligations and/or importing country requirements. Participating industries also use relevant NRS residue monitoring data in industry reports as a way of further demonstrating the integrity of their produce to customers. NRS residue monitoring programmes and associated activities are funded by participating industries either through levies or direct payments. Levy rates are established in consultation with participating industries in accordance with relevant Australian government policy.

Product sampling is done through either random or specifically designed sampling protocols. Testing is conducted by contracted accredited third-party laboratories. DAWE publishes the results of all animal and plant products tested under the NRS. Information is made available through residue testing datasets, which are published each financial year together with commodity and summary brochures for the most recent year. Consideration of data for the year 2019/2020 revealed that 10,476 samples of animal origin and 4,842 of plant origin were tested, with compliance rates of 99.72% and 99.26% respectively.

If a laboratory finds a sample that contains a residue above the Australian Standard, a traceback investigation is undertaken to establish the cause. The responsible state or territory agency then provides advice to the producer to prevent recurrence. In more serious circumstances, regulatory action may also be taken. All traceback activities and findings are reported to the NRS.

Table 11. Recently published reports in connection with development of the Food Standards Code

Year	Title & link	Food	Where collected	Parameters considered	No. of samples
2018	Analytical survey of mineral oil hydrocarbons in food and food packaging	• Phase I: Packaging samples • Phase II Food samples from a range of common foods (pasta, cereals, sugar, packet powders and cake mixes, and frozen items such as fish and chicken)	Market place	Mineral oil saturated hydrocarbons, mineral oil aromatic hydrocarbons	Phase I: 61 Phase II: 121
2018	Survey of Plasticisers in Australian Foods	Packaged foods and beverages	Market place	Various phthalate, adipate and citrate plasticisers	65
2016	Survey of scheduled pharmaceuticals in foods intended to promote weight loss	Weight-loss products	Market place	"Drug screen which analyses the levels of approximately 500 pharmaceutical compounds and their analogues"	36

Year	Title & link	Food	Where collected	Parameters considered	No. of samples
2015	Survey of tinned fruits for tin, lead and arsenic	Tinned fruit	Market place	Arsenic (total), lead and tin	45

The NRS also includes targeted residue testing programs to assess meat and meat products for the presence of chemical residues as a result of feeding regimes:

- National Organochlorine Residue Management (NORM) Program. It focusses on minimising the risks of organochlorine (OC) residues in beef and is jointly funded by the beef industry and state/territory governments. Besides testing cattle from at-risk properties at abattoirs, the NORM program results assist owners of properties with identified OC contamination hazards to develop and apply on-farm property management plans to minimise the risk of OC residues in meat products.
- National Antibacterial Residue Minimisation (NARM) Program. It aims to minimise the occurrence of antibacterial residues in bobby calves from dairy farms and is funded by the beef industry. State/territory governments support the program through activities related to traceback investigation, and the management of dairy farms found to have consigned bobby calves for slaughter with antibacterial residues above relevant Australian standards.
- Targeted Antibacterial Residue Testing Programs. There are several programs, each targeted to a different animal species (cattle, pigs, sheep/lambs, goats, and horses), which focus on animals at exporting establishments suspected by veterinary inspectors of having received antibacterial treatment inside the required withholding period.

Sample collection for targeted monitoring programs is organised by the DAWE on-plant veterinary officers. Some samples may be collected by establishment personnel with the control and accountability for sampling protocols and program compliance still held with the on-plant veterinarian.

A4.5 Imported Food Inspection Scheme

All food imported into Australia must comply with the requirements of the Imported Food Control Act 1992, the applicable standards of which are those in the Australia New Zealand Food Standards Code. The Imported Food Inspection Scheme (IFIS) monitors food imported into Australia to ensure it meets legal requirements for public health and safety. Inspections undertaken to determine compliance with the Food Standards Code are additional to any concerned with biosecurity. Under the IFIS, food is classified as either a “risk food” or “surveillance food”. A “risk food” is one that

has been assessed by FSANZ as posing a medium to high risk to public health, thereby requiring stricter border controls. “Surveillance food” is considered to pose a low risk to human health and safety. FSANZ publishes a list of foods which fall into either category and which is regularly updated. The DAWE publishes the lists of tests and/or assessments that apply to a specific type of “risk food” or “surveillance food” and the standard against which the test results are assessed.

During an inspection, a DAWE authorised officer conducts both a visual and label inspection and takes samples of food for testing, if required. Sampling and testing regimes are set out in the Imported Food Control Regulations 2019. Costs incurred from the inspections are borne by the importer. The DAWE publishes an annual report summarising the outcomes over the previous calendar year. During calendar year 2019, the last year for which data are available, it was reported that 42,889 lines of imported food had been inspected. Of these, 22% were “risk food”, 72.7% were “surveillance food”, and 5.3% were “surveillance food” subject to a holding order. In all, 132,002 tests (including label and visual checks) were conducted, comprising 54,486 label and composition assessments, 25,084 analytical tests, and 52,432 other tests. The compliance rate for all food inspected was 98.4%.

A4.6 Australian Export Meat Inspection System

Food businesses that export from Australia can only do so if licensed by the DAWE. In the case of the meat industry, abattoirs and meat processing plants who wish to export must take part in the Australian Export Meat Inspection System (AEMIS), which is an integrated set of controls specified and verified by the government that ensure the safety, suitability, and integrity of Australian meat and meat products. The system managed by the DAWE requires meat processors to collect and submit samples for testing in approved laboratories for a number of end-points. These include microbiological testing of meat and meat products, participation in the NRS, and testing for product hygiene indicators (PHI). The exporters’ responsibilities under the NRS were described previously and only microbiological testing aspects will be discussed here.

Exporting meat establishments must participate in the microbiological testing programs for determining establishment’s hygienic performance. As such, all export registered slaughtering establishments must participate in the National Carcase

Microbiology Monitoring Program which requires aerobic plate count (APC) and *Escherichia coli* testing for process control verification as well *Salmonella* spp. testing for the purposes of pathogen reduction performance standards to verify slaughtering and chilling operations. Similarly, all establishments producing carton or bulk packed meat for export are required to participate in the National Carton Meat Microbiology Testing Program, which requires sampling and testing final products for APC. Both monitoring programs are primarily for surveillance purposes. However, consecutive failure to meet *Salmonella* Performance Standards may potentially result in sanctions.

All meat exporting businesses are also obliged to take part in the Product Hygiene Indicators Program, which uses a number of key performance indicators (KPIs), such as APC, *E. coli* (including STEC and O157), and coliform counts, to produce the Product Hygiene Index, which is a measure of hygienic meat production at individual export establishment. The KPIs can be used within an establishment to monitor and assess performance of process control and can be used across establishments to compare performance against other similar slaughter and boning operations.

Sampling and testing is underpinned by a laboratory manual issued by the DAWE, which provides details of sampling and test methods both for participation in the programs referred to above as well as to meet the requirements of importing countries. Analyses are performed by appropriately accredited laboratories that can be either third-party or located within the food business. In addition to informing relevant stakeholders, laboratory results must be entered into the national database MEDC (Meat Export Data Collection). Data entered into MEDC is processed to enable a form of statistical process control using a series of dashboards. These describe trends at both plant and industry levels. Individual plants can therefore monitor performance on both a trend basis and also in comparison with others and, where necessary, after consultation with the DAWE on-plant veterinarian, effect corrective actions. Regulators also have access to the data and can perform own trend analyses as well identifying outliers which may require direct intervention.

A4.7 NSW Food Safety Schemes Manual

Food Safety Schemes Manual is concerned with the microbiological safety of food and specifies mandatory minimum testing regimes (material, test endpoint, laboratory

method, sample number, and frequency) for food businesses licenced under particular food safety schemes (i.e. Dairy food safety scheme, Egg food safety scheme, Meat food safety scheme, Plant products food safety scheme, Seafood safety scheme, Vulnerable persons food safety scheme). It also establishes the role of sampling and testing within the context of a food business' food safety management system.

As stated in the manual, the testing of finished products can be used in investigation, verifying corrective action, assisting in establishing benchmarks and identifying trends. Product testing alone is not sufficient to demonstrate the safety of food because it has a high probability of not identifying contaminated product even when large sample numbers are tested. However, it can be used to verify the effectiveness of the control measures outlined in the business' food safety program and associated documentation.

The manual is supported by five appendices which address:

- Techniques required to collect samples for testing and the testing regimes to put in place if a failure is reported;
- Criteria necessary for demonstrating *L. monocytogenes* growth will not occur in a particular ready-to-eat meat product;
- Environmental control of *L. monocytogenes;*
- Procedures for *Listeria* spp. environmental sampling;
- The use of in-pack pasteurisation as a possible *Listeria* spp. control process.

Food businesses may apply for variations of the testing requirements. These are assessed on a case-by-case basis by the NSW Food Authority.

It is a legal requirement that microbiological analysis of finished products and water specified in the manual must be carried out in a laboratory accredited by the National Association of Testing Authorities, Australia (NATA) for the particular type of analysis to be undertaken. Some tests can be done in-house using a validated method, however, the only permitted tests that can be conducted in-house without holding NATA accreditation relate to detection of antimicrobial drug residues, measurement of pH, and environmental swabbing for *Listeria* spp.

In the event of a laboratory result indicating that a sample fails to meet the standards set out in the manual, a food business must verbally notify the NSW Food Authority within 24 hours of receiving the laboratory result and in writing within 7 days. Written notification is effected using the notification of pathogen detection form which requires details not only of the test result but also of traceability and product recall activities (if appropriate), root cause analyses, and corrective actions. Notification requirement also applies in case of detecting antibiotics in raw milk. Food businesses must also notify FSANZ who have responsibility for the coordination and monitoring of recalls using a Food Recall Report.

A4.8 NSW Food Authority verification programs, research and targeted projects, and food safety compliance testing

In its annual report for the financial year 2019/2020, the NSW Food Authority stated that a total of 4,540 samples were submitted for testing by the NSW Food Authority, on which 13,054 individual tests had been performed. Of these, 663 samples related to verification programmes, 255 to research and targeted surveillance projects, and 3,622 to food safety compliance sampling. The numbers of samples were lower than in previous years as sampling was suspended due to COVID-19 movement restrictions. Sample types analysed included meat, seafood, dairy, plant products, packaged food, eggs, food from retail outlets, and environmental samples (for example swabs). Many samples were submitted for multiple tests which may have included both chemical profiling and microbiological assessment. Over 70 different types of tests were performed including microbiological assessment, chemical assessment, pH, water activity, and for the presence of allergens. Testing is conducted by contracted laboratories.

The NSW Food Authority conducts surveillance of food products to ensure compliance with regulatory requirements under its three verification programs. The first is concerned with compliance of ready-to-eat foods with the requirements set out in the Food Safety Schemes Manual. In 2019/2020, samples collected as part of this program included dairy, meat, eggs, plant products, and seafood (*n* = 87). The prevalence and levels of *Campylobacter* and *Salmonella* in raw poultry is verified under the raw poultry verification program (*n* = 388). In turn, kilojoule menu labelling verification program aims to compare the declared value

to the actual energy value from testing (*n* = 147). Foods were purchased or sourced directly from the manufacturer/processor or from retail outlets.

The NSW Food Authority also undertakes a number of research and targeted surveillance projects each year to identify and better understand key food safety issues and to inform its future risk assessment work. Surveys are undertaken in accordance with the NSW Food Authority's strategy, which is documented in its Survey program overview. During the financial year 2019/2020, four projects were completed (summarised in Table 12). Two of these related to the occurrence of *Campylobacter* spp. in food, one was concerned with the microbiological safety of plant-based meat substitutes, and one focused on the occurrence of algal biotoxins in wild harvest shellfish.

However, the largest number (3,622) of samples were collected in respect of compliance investigations. These could be assigned to one of three categories:

- Samples taken during audits and inspections (*n* = 33);
- Foodborne illness investigations (*n* = 1,178);
- Complaints and compliance projects (*n* = 2,411).

Table 12. Recent research and targeted projects by NSW Food Safety Authority

Topic	**Survey target**	**Where collected**	**Parameters considered**	**No. of samples**
Plant-based alternative products survey	Plant-based meat substitutes	Marketplace	A range of microorganisms, pH, and water activity	85
Campylobacter attribution study	*Campylobacter* isolates collected from humans, animals, and food sources in four states across Australia	Clinical, processing and marketplace	Whole genome sequencing to improve understanding of the source of the *Campylobacter* and the relationship between food, human and animal isolates	611 food samples (NSW)
Campylobacter 2018-2019 retail survey	'An attempt to explore if and how *Campylobacter* is transferred from raw chicken and liver to ready-to-eat products.'	Marketplace	*Campylobacter* spp.	593 swabs 281 food samples

Topic	Survey target	Where collected	Parameters considered	No. of samples
Algal biotoxins in wild harvest shellfish	Pipi's, cockles & clams	Marketplace	Amnesic shellfish toxin, diarrheic shellfish toxins and paralytic shellfish toxins	76 (2018/19) 37 (2019/20)

Source: NSW Food Authority, Annual Food Testing Report 2019-2020

With regards to samples collected during audits and inspections, most of these related to the suspected presence of sulphites above the maximum residue limit in meat products as well as speciation. In terms of foodborne infections, a significant number of samples collected were as part of an investigation into a nation-wide outbreak of *Salmonella* Typhimurium*,* which affected over 1,000 people, including over 200 in New South Wales. As part of the national effort to find the source of the outbreak, over 590 food and environmental samples were obtained by the NSW Food Authority.

By number of samples the largest category was concerned with complaints and compliance projects (*n* = 2,411). Complaint samples usually result from either a member of the public contacting the NSW Food Authority's helpline or from local council. In the year 2019/2020, 67 samples were submitted for testing due to a complaint. Of these, 43 were submitted for testing due to complaints regarding allergens in food. Compliance projects included surveillance for *Salmonella* Enteritidis at egg farms (*n* = 2,022), a survey for *Salmonella* and *Listeria monocytogenes* on rock melons (*n* = 120) to verify the effectiveness of food safety systems, and a preliminary microbiological survey of high risk horticultural products such as berries and leafy green vegetables.

Annex 5 Further details for Canada

A5.1 Legally prescribed sampling/testing for establishments

Sampling and testing methods may be prescribed in law. An example of this would be control measures for *Escherichia coli* O157:H7/NM in raw beef products, which are incorporated by reference into the Safe Food for Canadians Regulations (SFCR), meaning that it has the same effect as if it appeared in the regulations. As a result, food businesses producing "beef product processed for raw consumption" or "finished raw ground beef products" must operate sampling and testing programmes to monitor for the presence of *Escherichia coli* O157:H7/NM in product. In this particular case, not only sampling and testing requirements are specified but also requirements in terms of data processing, their use for statistical control purposes, and application to a corrective action plan.

A5.2 National Chemical Residue Monitoring Program

The National Chemical Residue Monitoring Program (NCRMP) is an annual CFIA regulatory surveillance program which verifies compliance of foods to Canadian standards and guidelines for chemical residues and contaminants. Other strategic aims of the NCRMP are to:

- Identify trends and develop strategic plans to minimise potential health risks to the public;
- Collect baseline data on the presence and levels of chemical hazards in food products available in the Canadian market;
- Support international trade and demonstrate equivalency with Canada's trading partners.

In the 2014/2015 financial year, an initiative known as the Food Safety Oversight (FSO) Program was introduced to complement the NCRMP and to increase CFIA's oversight in the non-meat food sectors. In the following years, the CFIA increased the sampling and testing of fresh fruit and vegetables as well as fish and seafood products. Some of these additional FSO program samples were collected at federally registered establishments/importers by inspectors in the same manner as the NCRMP samples. The majority of the FSO samples, however, were collected at retail by contracted third party samplers. Consideration of the report published for the financial year 2016/2017 indicated that over 120,000 tests for residues of veterinary

drugs, pesticides, metals, and contaminants were performed on more than 15,000 NCRMP and FSO monitoring samples.

Notably, all sample results from the CFIA and contracted third party laboratories are reviewed and assessed by the CFIA's Food Safety Science Services Division (FSSSD) Chemistry to determine whether a follow up action is necessary. Follow up actions in case of non-compliance vary according to the magnitude of the health risk, with the objective of preventing any repeat occurrence or further distribution of items remaining in the marketplace, and may include notification of the producer or importer, notification of the foreign competent authority, follow up inspections, further directed sampling, or recall of products if Health Canada determined that the product posed an unacceptable health risk to consumers or a certain segment of the population.

A5.3 National Microbiological Monitoring Program

The National Microbiological Monitoring Program (NMMP) is a food surveillance program managed by the CFIA to verify industry compliance with food microbiological safety and quality standards. Its strategic aims are similar to those outlined for NCRMP, namely:

- Assess and promote compliance with Canadian regulations and food safety standards;
- Monitor the effectiveness of the various food safety controls, policies and programs in place;
- Identify and characterise new and emerging hazards;
- Inform trend analyses, thereby prompting and refining health risk assessments.

Under the NMMP, a broad range of imported and domestic food products are sampled by CFIA inspectors and tested at CFIA laboratories. Similar to the NCRMP, food products are frequently sampled at federally registered establishments (i.e. those that produce food products that are exported or traded interprovincially), which are inspected by CFIA inspectors, but samples may also be collected at other establishment types, such as warehouses, distribution centres, and wholesalers.

The NMMP is also complimented by the Food Safety Oversight (FSO) Program which increases CFIA's oversight over fresh fruit and vegetables, fish and seafood and manufactured products. Some FSO samples are collected by CFIA inspectors but the majority are collected at retail by contracted third party samplers.

The report for the financial year 2018/2019 indicates that 12,899 tests were performed on 5,308 domestic and imported food products collected under the NMMP together with 2,039 tests performed on 1,666 environmental samples. In addition, under the FSO, 9,228 tests were performed on 2,742 food products together with 22 tests performed on 22 environmental samples. Anonymised individual data sets supporting the surveys can be obtained through the Open Government Portal.

All samples are subject to follow up actions by both industry and the CFIA. Such follow up actions may include follow up inspections, additional investigative sampling, product disposal, corrective action requests, food safety investigations, product recalls, etc.

A5.4 Children's Food Project

The Children's Food Project (CFP) began in 2003 to look at levels of pesticide residues and metals, in foods for infants and children. Its existence is based on the observation that due to their smaller body weight, development and growth, and consumption patterns, this consumer group may be at higher risk from exposure to these chemicals. Outputs from the CFP complement other activities undertaken by the CFIA (for example National Chemical Residue Monitoring Program) by specifically collecting information on domestically produced and imported manufactured foods frequently consumed by and targeting children (for example, infant formula, cereal-based products, fruit juices and beverages). Together, the data from these programs help health authorities assess potential exposure to chemical residues and contaminants in a number of foods consumed by Canadian children.

During the survey period 2018/2019, the main objectives of the CFP were to collect:

- Data and assess the compliance of infant foods to Canadian standards for residues of veterinary drugs, pesticides and metals;
- Baseline data on the levels of aflatoxin M1 in infant foods and formula containing milk.

A total of 143 samples of infant and toddler foods were purchased in the National Capital Region (Ottawa, Ontario and Gatineau, Quebec). These samples included dairy and soy infant formula, pasta, baby/toddler meals containing meat, baby/toddler meals containing dairy and pureed infant food containing meat.

All data from surveillance programs like the CFP is reviewed by Health Canada and follow up actions may be recommended. For example, products posing an unacceptable health risk to consumers or a certain segment of the population may be subject to a recall.

A5.5 Other CFIA annual surveillance programmes

CFIA's operational procedures for food sample collection for national sample collection plans include instructions for sampling under Additives, Adulteration, Allergens, Composition, Irradiation and Nutrition (AAACIN) and Fish Plans. Information on these two annual surveillance programs is very limited.

It appears that sampling under both AAACIN and Fish Plans is conducted annually to assess for potential health risks, perform risk assessments, monitor trends, and verify industry compliance with the Canadian standards by randomly collecting samples from the regulated parties. Fish Plan samples are collected by both CFIA inspection personnel and contracted third-party samplers while AAACIN samples are collected by CFIA inspection personnel only.

AAACIN and Fish Plan sample results must be reviewed by CFIA inspector to determine compliance. Non-compliant results may trigger follow-up actions by the authorities.

A5.6 Canadian Shellfish Sanitation Program

The Canadian Shellfish Sanitation Program (CSSP) is a federal food safety program jointly administered by the CFIA, ECCC, and DFO. Under the CSSP, the CFIA maintains a marine biotoxin surveillance program. Under this program, molluscan shellfish harvest area samples are collected by both CFIA inspection personnel and contracted third party samplers and tested for various microbiological and chemical contaminants. The results are used to recommend to DFO closing or opening specific shellfish harvest areas.

Shellfish samples are collected from predetermined areas and at specified frequencies based on factors such as season, historical biotoxin levels, and harvesting activity. If increasing biotoxin levels are observed, sampling frequency may increase to ensure that any required closures are implemented in a timely fashion. Where additional samples cannot be obtained, the CFIA may recommend a closure of a shellfish harvesting area simply based on previous knowledge of the risk posed by biotoxins in a particular area. The CFIA may also recommend a closure of a shellfish harvesting area when biotoxin levels are increasing rapidly but have not exceeded standards.

A5.7 Targeted surveys

Targeted surveys are used by the CFIA to focus its surveillance activities on areas of highest health risk. The information gained from these surveys provides support for the allocation and prioritisation of the CFIA's activities to areas of greater concern. The CFIA considers them to be a valuable tool for generating information on certain hazards in foods, identifying and characterising new and emerging hazards, informing trend analysis, prompting and refining health risk assessments, highlighting potential contamination issues, as well as assessing and promoting compliance with Canadian regulations. The duration of sampling and testing depends on the issue the survey was designed to address. Where samples are collected over a number of financial years, interim reports may be issued. Interim and final reports can be accessed through a dedicated web page. A summary of reports published in January-July 2021 is presented in Table 13.

Samples for targeted surveys are collected by contracted third party samplers. Sampling quantities collected depend partly on the endpoints tested. In the case of microbiological surveys, samples usually consisted of a single or multiple unit(s) (individual consumer-size packages) from a single lot with a total weight of at least 250 g. For chemical analyses, standard consumer units are usually used. In all surveys, samples of products were collected from local/regional retail locations located in major cities across Canada which encompassed the four Canadian geographical areas. The number of samples collected from these cities was in proportion to the relative population of the respective areas.

The CFIA's Food Safety Science Services Division (FSSSD) Chemistry is responsible for reviewing and assessing all laboratory test results from targeted surveys for chemical hazards and allergens while the CFIA's Laboratory Coordination Division (LCD) is reviews and assesses all microbiological testing results. In case of non-compliant results, follow up actions may be considered.

A5.8 Canadian Total Diet Study

The Canadian Total Diet Study (TDS) is a food surveillance program that monitors the concentrations of chemical contaminants in foods that are typically consumed by Canadians. Under the Canadian TDS, levels of priority chemicals are measured in food samples either annually, on a pre-determined cycle, or in response to a specific food safety issue. Examples of chemicals included in the Canadian TDS are trace elements, pesticides, radionuclides, and a variety of other industrial chemicals.

Health Canada's Bureau of Chemical Safety within Food Directorate leads the Canadian TDS with support from other federal food safety partners, including the Radiation Protection Bureau of Health Canada and the CFIA.

Over a 5-week period each year, approximately 2,100 food samples from different food retail outlets or restaurants in one of the nine Canadian cities are collected by the CFIA and sent to Health Canada for laboratory analysis. Health Canada prepares the foods for consumption as they would be at home, which provides realistic information about contaminant exposure from the diet. Preparation steps include washing, peeling, and cooking. Similar types of foods are combined into approximately 160 composite samples that are frozen at -35°C until analysis. Summary data broken down by where samples were collected and analyte tested for have been made available; as too a list of related publications in the scientific press.

Table 13. Recently published (January-July 2021) reports from CFIA targeted food survey program

Publication date	Title & link	Food	Parameters considered	No. of samples
2021-07-07	Analysis of Microbiological and Chemical Hazards in Edible Insects Available to Canadian Consumers 2017-2018	Dried whole insects and insect powder Crickets (protein bars, powders, flour, and whole insects), whole silkworm	Generic *Escherichia coli, Salmonella* spp. Pesticides Arsenic, cadmium, mercury, lead	51 43 19
2021-06-16	Bacterial Pathogens and Indicators in Oats – April 1, 2018 to March 31, 2020	Domestic (61.3%) and imported (32.7%) oats (steel cut, quick, rolled, and instant, both organic and conventional)	*Salmonella* spp., *E. coli* O157, generic *E. coli*, total coliforms, APC, *B. cereus*, *C. perfringens*, and *S. aureus*	318

Publication date	Title & link	Food	Parameters considered	No. of samples
2021-05-05	Bacterial Pathogens and Indicators, Viruses and Parasites in Various Food Commodities – April 1, 2016 to March 31, 2020	Pasteurised cheese, milk, raw ground meat, ready-to-eat (RTE) meat, RTE fish and seafood, fresh fruits and vegetables, processed fruits, plant-based milk, cheese and ice cream, powdered spices	Food product dependent: aerobic colony count, total coliforms, generic *Escherichia coli, Bacillus cereus, Clostridium perfringens, E. coli* O157, Non-O157 verotoxigenic *E. coli, Listeria monocytogenes, Salmonella* spp., *Staphylococcus aureus, Cryptosporidium, Cyclospora, Toxoplasma,* Hepatitis A Virus Norovirus Genotype (I and II)	21,626

Publication date	Title & link	Food	Parameters considered	No. of samples
2021-04-07	Food Colours in Essences/Flavourings, Oils, Sweets and Processed Vegetables – April 1, 2018 to March 31, 2019	Domestic and imported essences / flavourings, oils, sweets (baked goods, candy, fruit snacks, preserves and pudding), and processed vegetables (pickled asparagus, beans, beets, cucumbers, onions, peppers and turnips)	Artificial colours	399
2021-04-07	Multi-Mycotoxins in Corn Products, Crackers, Other Grain Products, Pasta and Gluten-Free Products 2018 to 2019	Corn and pasta products, crackers, gluten-free and other grain products	Aflatoxins, cyclopiazonic acid, ergot alkaloids, fumonisins, ochratoxin A, sterigmatocystin, T-2 and HT-2 toxins, zearalenone	750
2021-03-10	Undeclared Gluten in Gluten-Free Bakery Mixes 2017 to 2018	All-purpose mixes, bread mixes, dessert mixes	Gluten	300

Publication date	Title & link	Food	Parameters considered	No. of samples
2021-03-10	Bacterial Pathogens and Indicators in Frozen Berries and Frozen-Cut Fruits and Vegetables for Smoothies 2017 to 2020	RTE frozen fruits and vegetables	Aerobic colony count, *Escherichia coli, E. coli* O157, *Listeria monocytogenes Salmonella* spp.	2,595
2021-03-10	Viruses in Ready-to-Eat Fresh-Cut Fruits 2017 to 2020	RTE, pre-packaged single types of fresh-cut fruits (excluding berries)	Hepatitis A, norovirus (GI, GII)	1,149
2021-02-10	Undeclared Allergens and Gluten in Prepackaged Salads 2018 to 2019	Prepackaged salad products	Egg, sesame, soy, peanut, almond, hazelnut, gluten, casein and beta-lactoglobulin	260
2021-02-10	Undeclared Allergens and Gluten in Maple Products 2018 to 2019	Maple butter/spread; maple candy, maple sugar, maple syrup, maple product (other)	Egg, sesame, soy, peanut, almond, hazelnut, gluten, casein and beta-lactoglobulin	319

Publication date	Title & link	Food	Parameters considered	No. of samples
2021-01-13	Undeclared Allergens and Gluten in Valentine's Day-Themed Candy and Chocolate Products 2018 to 2019	Sugar and chocolate confectionery	Egg, sesame, soy, peanut, almond, hazelnut, gluten, casein and beta-lactoglobulin	359
2021-01-13	Undeclared Allergens in Multi-Ingredient Meat Products 2017 to 2018	Meat-balls, patties, sausages & hot dogs	Egg, sesame, soy, peanut, almond, hazelnut, gluten, casein and beta-lactoglobulin	359
2021-01-13	Undeclared Gluten in Gluten-Free Prepackaged Ready-to-Eat Bakery Products 2017 to 2018	Gluten-free pre-packaged ready-to-eat (RTE) bakery products	Gluten	300

Annex 6 Further details for New Zealand

A6.1 National Microbiological Database Programme

The MPI is the custodian of the National Microbiological Database Programme (NMDP), based on data which the industry is obliged to provide. The monitoring programme measures microorganisms that are a risk to food safety and acts as part of the food safety management system verification process, telling the operator if their current processes are producing food that is safe to eat. Testing requirements are different for different types of meat and numbers of carcasses processed.

Samples are analysed using defined methods in laboratories approved for the programme. Sampling and testing are standardised so results can be compared between processors. Once results are authorised by a laboratory, they are entered into the database.

The programme database is maintained by the MPI and all data is collected by the sampler at the time of sampling, the laboratory when they receive the sample and after samples have been analysed. The operator checks data from samples every week to make sure that hygiene standards are being met. The database automatically highlights any results that exceed safe limits. Every 3 months operators are sent a ranked list that shows their premises' performance against the national benchmark. A statistical summary of all data is published on the MPI website. This is known as the National Profile. This data doesn't identify any of the participants. Operators can measure their performance against national results through this reporting. This encourages everyone to achieve the best possible food safety outcomes.

MPI has used the infrastructure underpinning the programme to evaluate specific microbiological hazards. Two examples are discussed further.

A baseline survey of antimicrobial resistance among bacteria associated with livestock which was undertaken in 2009-2010. *Campylobacter* and *Salmonella*, representative of pathogenic bacteria, and *Escherichia coli* and *Enterococci* (*Enterococcus faecalis* and *E. faecium*), representative of commensal bacteria, were included in the survey. The isolates were sourced, in various ways, from specimens routinely collected from freshly dressed carcasses of very young calves, pigs and broiler poultry as part of the NMDP programme. Isolates from NMDP programme

specimens taken between 5 October 2009 and 3 October 2010 were included in the survey. In addition, *Salmonella* (*n* = 2) and *E. coli* (*n* = 90) isolated during a Fresh Produce Survey conducted in 2008-2009 were included.

MPI has also reviewed porcine carcass *Salmonella* testing to measure the strategic intervention for *Salmonella* spp. under the *Salmonella* Risk Management Strategy. The porcine programme involved sampling of five carcasses per week for standard throughput operators or one carcass per week for very low throughput (VLT) operators (those processing less than 10,000 carcasses per annum).

A6.2 National Chemical Residues Programme

The National Chemical Residues Programme (NCRP) is authorised under Animal Products (Regulated Control Scheme – Contaminant Monitoring and Surveillance) Regulation 2004. It is a risk-based sampling and testing programme for chemical residues (for example agricultural compounds, veterinary medicines, and contaminants) in non-dairy animal products.

The programme is divided into two parts, monitoring and surveillance. For monitoring, samples are taken from randomly selected live and slaughtered wild and farmed animals and their products. The animal types, numbers of animals, animal products or animal material to be sampled and substances to be analysed in the monitoring programme depend on the risk profile of the residue or contaminant. For surveillance, samples are taken from targeted animals, animal material, and animal products at risk of containing residues greater than maximum levels. The risk could be to human or animal health or risk to trade. MPI authorises persons to collect samples and has procedures in place to ensure that traceability, security, and quality management are maintained from collection through to analysis and storage. All samples are tested in laboratories contracted by New Zealand Food Safety. These laboratories with ISO/IEC 17025 accreditation are registered under the Recognised Laboratory Programme (RLP).

In the latest report for July 2018 – June 2019, over 1,900 samples were collected and tested. Over 230,000 test results were obtained, with eight results higher than maximum permissible levels. This represents a conformance rate in New Zealand of 99.997%. No human health food safety issues were identified. The result confirmed that regulatory compliance is being met and good agricultural practice is being

followed in the use of agricultural compounds and veterinary medicines. The results of the species verification programme verified there was no species substitution.

A6.3 National Chemical Contaminants Programme

The National Chemical Contaminants Programme (NCCP) for dairy products and milk authorised under Dairy Industry (National Residue Monitoring Programme) Regulations 2002 is an annual programme which monitors New Zealand's dairy industry but also incorporates surveillance and survey activities where necessary. It is designed to confirm the effectiveness of the regulatory controls in place for ensuring residues and contaminants in raw milk and manufactured dairy products do not pose a threat to human health, that Good Agricultural Practices (GAP) are being followed, and that relevant importing country requirements will be met.

Under this program, raw milk, colostrum, and dairy products are sampled and tested at recognised accredited laboratories for more than 500 individual compounds or elements, including veterinary drugs, contaminants, agricultural compounds, and other not permitted compounds. Sampling plans and reports for previous years are accessible through a common webpage.

The programme consists of three components – random monitoring, directed surveillance, and surveys. The raw milk monitoring component is a non-biased sampling programme designed to provide profile information on the occurrence of residues and contaminants in raw milk on a national basis. All random raw milk sampling mostly occurs at the farm bulk milk tank prior to any mixing with raw milk from other farms and as such monitors the conformance of individual milk producers. Dairy farms are randomly chosen throughout the dairy season to be part of the sampling regime. Milk producers are not given advance notice of being sampled. A minimum of 50 raw milk samples is taken from each farm's bulk-milk tank on 6 occasions each dairy season. Additional samples are collected over the winter and early spring periods when most farms are dry. Sampling plan for the 2020/2021 dairy season provided for a minimum of 306 random monitoring samples to be taken (or 1 sample per 37 herds).

Each season, a selection of finished dairy products is also randomly sampled. For instance, 190 product samples were collected and tested under NCCP in 2019/2020. Samples are collected by trained, independent samplers operating under contract

and in accordance with formal competency criteria set by MPI during a performance-based verification audits conducted at the manufacturer's premises. Only dairy products deemed eligible for export are sampled.

The directed surveillance component of NCCP is designed to investigate and, if necessary, control the movement of dairy material, which might pose a higher risk based on the risk profile of either the producer, the process or the material which is considered in relation to particular chemical hazards. Directed sampling is performed on the basis of the risk associated with the compound and its use, the existing level of management control, and the likelihood of non-conformance based on information available to MPI, such as reports, instances of non-conformance, audits, and investigations. It is a biased sampling since the sampling is undertaken in response to the risk profile associated with a particular hazard. A plan for 2020/2021 provides for a minimum of 5 colostrum supplies to be taken at the farm.

Surveys are used to fill knowledge gaps and are typically a one-off exercise to look at a specific combination of compound and the target material. They also help to identify new or emerging risk factors or enhance the understanding of potential issues and natural background levels for minor components that naturally occur in milk.

A6.4 Food Residues Survey Programme

The Food Residues Survey Programme (FRSP) is used to investigate chemical and microbiological contaminants in foods intended for sale in New Zealand. FRSP samples are typically collected from foods that are not part of other MPI monitoring programmes. Both domestic and imported foods are included in the surveys. FRSP targets crops and foods that may present potential food safety risks and checks samples for residues (and contaminants when an issue arises). It targets a broad range of agricultural chemicals registered in New Zealand for use on agricultural / horticultural produce. However, the programme does not target the individual food producers nor does it function as a "test and release" tool for imported foods. Typically, screening tests used in surveys include between 200 and 500 different pesticide residues.

The latest report covered two financial years (July 2017 to June 2018 and July 2018 to June 2019). The survey was planned on the basis of acquiring 60 samples from

each of ten Codex classified groups of plant foods which were collected from retailers, importers or wholesalers based on market availability. In the end, 591 samples were tested. The overall rate of compliance was 99.9%.

A6.5 Shellfish Biotoxin Monitoring Programme

MPI monitors both commercial growers/harvesters as well as recreational gatherers of bivalve molluscan shellfish under its Shellfish Biotoxin Monitoring Programme. This involves sampling shellfish and seawater around New Zealand to check if they are contaminated with biotoxins from toxic algal blooms.

Monitoring of commercial growers and harvesters is carried under the Regulated Controls Scheme for bivalve molluscan shellfish and is funded by industry. If commercial shellfish growing areas are affected by shellfish toxins, the areas are closed for harvesting. In turn, if biotoxins are found in samples of shellfish and seawater under the programme for recreational gathering, MPI issues warnings and notifies the local district health board.

A6.6 Independent Verification Programme

The Independent Verification Programme (IVP) is part of the national monitoring and testing programme and applies to dairy businesses operating under a risk management programme (RMP) and exporting dairy products or materials. Under the IVP, MPI collects samples of dairy products from across the country. These are tested by independent laboratories to check that they conform to acceptable microbiological levels for New Zealand, as well as those set by importing countries.

This programme enables MPI to assess whether dairy manufacturers' quality programmes are sound and whether the self-monitoring programmes for sampling and testing dairy material and products are reliable and sufficiently robust. From this assessment, MPI can establish whether the regulatory framework is effective and continues to ensure that dairy products manufactured in New Zealand meet food safety outcomes.

A6.7 New Zealand Total Diet Study

The New Zealand Total Diet Study (NZTDS) assesses New Zealanders' exposure to certain contaminants and nutrients. It is part of the MPI monitoring and testing programme and looks at a range of foods consumed in a typical diet. The study is

performed approximately every 5 years. The results are used to inform food standards and verify the efficacy of food legislation.

The study considers the most common foods in the New Zealand diet and includes around 130 foods that make up 90% of the population's intake. Foods are selected based on information from the New Zealand National Nutrition Surveys operated by the Ministry of Health. Selection is made on the bases of the foods being nationally or regionally consumed and in a small number of cases as being foods known to be high-risk sources of contaminants. Food samples are sampled twice in a calendar year to allow for seasonal variations and taken from a number of regions. All foods are prepared as they would be consumed prior to testing. Sampling and analysis are managed over 4 testing periods, each lasting about 6 weeks. MPI often does follow-up studies to look at any unusual findings from the NZTDS. These look more closely at targeted foods to check if the results are outliers or part of a broader trend.

The most recent report describes the 2016 Total Diet Study, which involved the analysis of 1,056 composite food samples with eight samples taken of 132 different foods type. Samples were collected quarterly: 62 different regional food types were sampled in January/February and July/August 2016 and 70 different national foods were collected in April/May and October/November 2016. Regional foods were expected to show regional variation due to local production, were sampled from food retail outlets in Auckland, Christchurch, Napier and Dunedin. National foods were expected to be consistent across the country due to centralised distribution, or resulting from an imported source, were all sampled in Christchurch. All samples were prepared using common food preparation and cooking methods to reflect the way these foods are usually consumed. All 1,056 of the collected samples were analysed for 301 agricultural chemical analytes.

The survey indicated that none of the estimated dietary exposures to agricultural chemicals represented a risk to health. The majority of the agricultural chemicals analysed were not detected and therefore calculated to have a zero exposure. Dietary exposure estimates for the other contaminant elements analysed (cadmium, inorganic mercury, methyl mercury and tin) were below levels that would represent a health concern. Dietary intake estimates for the nutrient element iodine show large increases for all the population cohorts, compared with previous Total Diet Studies.

The increase reflects the mandatory fortification of bread with iodine, through the replacement of non-iodised salt with iodised salt. Most age groups are being exposed to 30-40% less lead in foods than in 2009.

The survey found the herbicide clopyralid in potatoes, kumara, and mushrooms. MPI therefore carried out a follow-up survey of clopyralid residues in potatoes, kumara and mushrooms to see if this was an isolated event. The result provided that the clopyralid residues reported in the 2016 study may have been an incidental occurrence, potentially limited contamination of a composting operation that has since been rectified. Another observation was that aluminium concentrations were found to be higher than expected in certain bakery goods, which was considered to be a potential health concern. Engagement with the industry led to the phasing out an aluminium-containing food additive (sodium aluminium phosphate).

A6.8 Research programmes

MPI also conducts project-based research programmes concerned with the safety of both New Zealand produced and imported food. Programmes are informed by surveillance data, scientific literature, expert opinions and experimental projects. Some research programmes are discussed below.

Under the human health surveillance programme, MPI gathers foodborne illness and attribution data and publishes scientific reports to reduce the incidence of foodborne illness. The programme encompasses projects that aim to improve the surveillance of foodborne illnesses and to attribute the incidence to reservoirs and food sources. A central component of the programme has been research into campylobacteriosis. Historically, New Zealand has had some of the highest notified rates of foodborne campylobacteriosis in the world and MPI established a *Campylobacter* Risk Management Strategy 2017-2020. This strategy is underpinned by research projects on poultry, meat, and milk food chain to understand the different sources and pathways of human infection. In addition it has established the *Campylobacter* performance target – which measures *Campylobacter* levels in processed chicken to check how effective the control measures were at reducing levels and continue to use *Campylobacter* sampling to make sure processors are producing food within safe limits. MPI has also conducted research and surveys concerning the bacterial pathogen *Salmonella*. And also operates a foodborne virus science programme to

improve methods of identifying reservoirs and sources of viruses and to identify and implement effective control measures.

In addition, MPI consolidates data concerning out-breaks of food poisoning, the outputs being published in an annual foodborne disease report.

The ministry also conducts research into other types of foodborne hazard. These include Food Composition Research, Labelling Research, Biological Hazard Research, Chemical Hazard and Mycotoxin Research and Research on Production, Processing and Handling of Food.

Annex 7 Further details for the United States

A7.1 State authorities and cooperation with federal authorities (California)

States usually operate under their own legislation which is predominantly based on the federal legislation but may have some additional provisions not pre-empted by the federal legislation. Most states have primary food laws that are largely the same as the federal law. As an example, California's Sherman Food, Drug, and Cosmetic Law incorporates many elements of the federal FD&C Act. Although, it establishes some additional or stricter requirements as well.

Restaurants and retail food stores are primarily regulated by the state, local, and tribal agencies. FDA has jurisdiction but nonetheless relies on state and local governments to oversee these due to large numbers of establishments and limited resources. Each state or territorial agency chooses whether to adopt a model Food Code provided by the FDA and, if adopted, whether to update to a newer version.

Responsible agencies differ in each jurisdiction. In California, restaurants and retail food stores are overseen by Food and Drug Branch of California Department of Public Health (CDPH) under its Retail Food Program. Remarkably, this Californian agency is the only state agency that has not adopted the FDA Food Code and operates under its own California Retail Food Code.

Federally-assisted State Meat and Poultry Inspection programs provide for the licensing and inspection of meat and poultry establishments that are exempt from federal inspection. These state programs must be "at least equal to" the federal inspection requirements and are reviewed by FSIS annually. As part of the review, FSIS checks that the state program meets necessary laboratory quality assurance standards and testing frequencies; and has the capability to perform microbiology and food chemistry methods that are "at least equal to" methods performed in the FSIS laboratories.

In California, State Meat and Poultry Inspection Programs are operated by Meat, Poultry & Egg Safety Branch of the Animal Health and Food Safety Services (AHFSS) of California Department of Food and Agriculture (CDFA). Animal Health

Branch of AHFSS is tasked with detecting and controlling animal illness and zoonotic diseases through surveillance and monitoring programs.

State-inspected meat and poultry processors may be able to ship their products across state lines if the state operates a Cooperative Interstate Shipment (CIS) Program and has signed an agreement with FSIS in this regard.

Some states also have dedicated programs to license and inspect milk and dairy food producers and processors. An example of this could be Milk and Dairy Food Safety Programs run by Milk and Dairy Food Safety Branch (MDFS) of AHFSS charged with regulating California's milk quality and safety by addressing physical, chemical, and biological hazards in milk, dairy foods, and dairy-like foods via inspections and sampling. MDFS also evaluates dairy farms, milk plants, and laboratories based in California for the FDA for dairy products in interstate commerce for purpose of compiling the Interstate Milk Shippers List.

This is directly related to the National Conference on Interstate Milk Shipments (NCIMS) which is a voluntary organisation directed and controlled by member states to promote the availability of a safe, high quality milk supply. The FDA and the NCIMS have collaboratively developed a cooperative federal-state program (the Grade "A" Interstate Milk Shippers Program) to ensure the sanitary quality of Grade "A" milk and milk products shipped in interstate commerce.

National Shellfish Sanitation Program (NSSP) is another federal-state cooperative program. The purpose of this program recognised by both the FDA and the Interstate Shellfish Sanitation Conference (ISSC) is to promote and improve the sanitation of shellfish (oysters, clams, mussels, and scallops) moving in interstate commerce through federal/state cooperation and uniformity of state shellfish programs. Shellfish dealers shipping products into interstate commerce are required to meet the requirements of the NSSP and must be certified for listing on the Interstate Certified Shellfish Shippers List (ICSSL). In California, activities under this program are conducted by Food and Drug Branch of CDPH within the scope of Food Safety Program.

A7.2 Sampling/testing requirements for establishments (FSIS)

Establishments under FSIS jurisdiction may be legally required to conduct some sampling, testing, and record keeping. For example, sampling and testing is legally required for egg products under 9 CFR §590.580.

Also, each official establishment that slaughters livestock must test for generic *E. coli* to verify the effectiveness of sanitation and process control in slaughter facilities. Sampling requirements and criteria for evaluation of test results are established in 9 CFR §310.25. As such, slaughter establishments must take at least 1 sample per 300 carcasses of cattle, sheep, goats, horses, mules, and other equines. Failure to meet criteria (i.e. more than 3 samples out of 13 exceed the upper limit) would be an indication that the establishment may not be maintaining process controls sufficient to prevent fecal contamination and FSIS will take appropriate action.

Similar requirement to test for generic *Escherichia coli* for official establishments that slaughter ratites is established in 9 CFR §381.94. At least 1 sample must be taken per 3,000 carcasses but at least once a week. In both cases, an establishment operating under a validated HACCP plan may use a different sampling frequency provided FSIS does not object. In any case, sampling is mandatory and failure to test and record would mean that FSIS inspection of an establishment will be suspended which would effectively stop the production.

Official poultry slaughter establishments must develop, implement, and maintain written procedures to prevent contamination of carcasses and parts by enteric pathogens and fecal contamination throughout the entire slaughter and dressing operation. These procedures must be incorporated into HACCP plans, or sanitation SOPs, or other prerequisite programs and must, at a minimum, include sampling and analysis for microbial organisms in accordance with the sampling location and frequency requirements in 9 CFR §381.65 to monitor their ability to maintain process control. As a result, chickens should be sampled at least once per 22,000 carcasses but at a minimum once each week of operation. Turkeys, ducks, geese, guineas, and squabs should be sampled at least once per 3,000 carcasses (at least once a week).

Swine slaughter establishments are required to prevent contamination of swine carcasses and parts throughout the slaughter and dressing operation. The sampling plan is prescribed in 9 CFR §310.18.

In addition to what is legally required, establishments may implement additional sampling programs, for example, to monitor or assess the effectiveness of their sanitation SOPs etc.

A7.3 Microbiological sampling (FDA)

To support prevention under the FDA Food Safety Modernization Act, FDA started using a new sampling model where it collects a large number of samples of targeted foods over a relatively short period, 12 to 18 months, to ensure a statistically valid amount of data is available for decision making. The purpose of this new sampling approach is to help the FDA determine if there are common factors among positive findings, such as origin, variety or season. The FDA's past approach to microbiological surveillance sampling has been to collect a relatively small number of samples of many different commodities over many years. See Table 14 for details of FDA's microbiological surveillance assignments conducted using the new sampling model.

The choice of commodities sampled as part of microbiological surveillance sampling reflects the ones most associated with outbreaks. Sampling assignments are also prioritised based on potential microbial risk and associated data gaps such as lack of data on pathogen prevalence or common factors associated with positive findings.

The sampling design for each food represents what U.S. consumers are likely to find in the marketplace. Accordingly, the FDA takes into account the volume of the target food that is imported and produced domestically and the number of states/countries that produce the target food. Depending on the assignment, samples may be collected from growers, packinghouses, distributors, and/or retailers. The testing is usually conducted by FDA laboratories, but some assignments also make use of contracted local laboratories so that analysis results are provided more promptly in order to minimise the possibility that potentially contaminated produce would be distributed. Microbiological testing is usually followed by pulsed-field gel

electrophoresis (PFGE) and/or whole genome sequencing (WGS). This can be conducted by the FDA or state laboratories on contract.

Recurring food safety issues may sometimes require a comprehensive multifaceted action plan to address a specific issue. For instance, considering that leafy greens have been repeatedly implicated in outbreaks of foodborne illness caused by STEC, FDA has published Leafy Greens STEC Action Plan, which includes planned sampling activities for the purposes of prevention and to address existing knowledge gaps.

Another example of a focused long term action plan is *Cyclospora* Prevention, Response and Research Action Plan, which provides for the surveillance sampling of *Cyclospora cayetanensis* in produce.

Table 14. Overview of published FDA's microbiological surveillance sampling results

Years	Parameters considered	What was sampled?	No. of samples
2021	*Salmonella*, *E. coli* O157:H7, other STEC	Romaine lettuce from commercial coolers in Yuma County, Arizona	500 (planned)
2019-2020	*Salmonella*, STEC	Romaine lettuce as raw agricultural commodity	279
2018-2019	*Salmonella*, STEC	Romaine lettuce from commercial cooler and cold storage facilities in Yuma, Arizona	118
2018-ongoing	Hepatitis A virus, norovirus	Frozen berries (strawberries, raspberries, blackberries) (50% imported)	2,000 (planned)
2017-2021	*Salmonella*, STEC, *Cyclospora cayetanensis*	Fresh herbs (cilantro, basil, parsley) (52% imported)	1,600 (planned)
2017-2019	*Salmonella*, *L. monocytogenes*	Processed avocado and guacamole (12.4% imported)	887
2015-2017	*Salmonella*, *E. coli* O157:H7	Cucumbers (76% imported)	1,601
2015-2017	*Salmonella*, *E. coli* O157:H7, other STEC	Hot peppers of the genus *Capsicum* (for example habanero, jalapeño, and serrano peppers) (80% imported)	1,615

Years	Parameters considered	What was sampled?	No. of samples
2014-2016	*Salmonella*, *L. monocytogenes*, *E. coli* O157:H7	Domestic sprouts (seeds, finished product, and spent irrigation water)	1,600 (planned) 825 (actual)
2014-2015	*Salmonella*, *L. monocytogenes*	Whole fresh avocados (70% imported)	1,615
2014-2015	*Salmonella*, *L. monocytogenes*, *E. coli* O157:H7, other STEC, generic *E. coli*	Raw milk cheese aged for at least 60 days (71% imported)	1,606

A7.4 Environmental sampling (FDA)

Under FD&C Act, a food produced under insanitary conditions may be deemed adulterated even if the food itself is not contaminated. Therefore, FDA may collect samples from the environment surrounding the food to determine whether that environment contains harmful bacteria, such as *Salmonella* spp. or *Listeria monocytogenes*.

Environmental sampling of an establishment can be conducted "for cause":

- As a result of previous history of concern, to further investigate an establishment;
- Inspectional observations that warrant the collection of samples for microbiological analyses, such as insanitary conditions (evidence of birds, rodents, dirt etc.) or an establishment's failure to implement an effective environmental monitoring plan, as required;
- As follow-up to the detection of a pathogen in a product sample (through testing by the FDA, or a state or private laboratory, or as reported to the Reportable Food Registry).

Establishments can also be sampled as part of commodity-based assignments to gain insight into how widespread certain harmful bacteria may be in the manufacturing environment across the industry, to assess conditions and practices, and to gauge compliance with food safety regulations. An example of this would be an assignment to inspect ice cream production facilities across the United States in 2016 and 2017 to determine the prevalence of *Listeria monocytogenes* and *Salmonella* spp. contamination in these establishments. This was triggered by 16 recalls of ice cream products due to the presence of pathogens in the prior three years, and an outbreak of listeriosis linked to an ice cream maker in 2015 that involved three deaths.

Lastly, environmental sampling may also be conducted as a result of FDA's risk-based prioritisation system employing criteria related to food-hazard pairs (for example frequency of outbreaks associated with a food, likelihood of contamination, bacterial growth potential, and food consumption pattern) and establishment-specific compliance history.

A7.5 Labelling compliance sampling (FDA)

FDA may conduct sampling and testing of products to assess compliance with specific labelling requirements or compositional standards. This is usually conducted as part of once-off assignments.

For example, to assess compliance with the requirements for gluten-free labelling, FDA collected 702 individual samples from more than 250 types of products in 2015-2016, as a once-off sampling assignment.

Similarly, in 2018-2019, FDA has conducted a once-off assignment to collect and test domestically manufactured dark chocolate products labelled as “dairy-free” (or with similar free-from-milk claims). This was to gain insight into the extent to which domestically manufactured dark chocolate bars and chips that bear the claim containing potentially hazardous levels of undeclared milk may appear on the U.S. market. 119 samples were taken from 52 distinct products. This was a follow up assignment after a limited survey conducted in 2013-2014 highlighted the issue of the presence of undeclared milk in dark chocolate products and often claiming dairy-free, lactose-free, milk-free, vegan etc.

Labels and labelling as well as production records may also be sampled and reviewed during inspection of domestic and foreign food facilities by the FDA. This will largely depend on the scope and extent of inspection.

A7.6 Pesticide residue monitoring and surveys (FDA)

Under its regulatory Pesticide Residue Monitoring Program (PRMP), FDA selectively tests a broad range of imported and domestic commodities using a multi-residue method that analyses approximately 800 different pesticide chemical residues in a single analysis and selective residue methods that detect pesticide chemical residues not covered by the multi-residue method. In addition to sampling under its monitoring programme, FDA may also carry out focused sampling surveys for specific commodities or selected pesticide chemical residues of special interest.

In FY 2018, the above amounted to 4,404 human food samples. 2/3 of these were import samples from 91 countries. Domestic samples were from 47 states and Puerto Rico. 215 samples were analysed as part of “focused sampling” of domestically

produced animal-derived foods assignment. In FY 2016 and FY 2017, glyphosate was the focus of a special two-year focused assignment.

Other federal agencies and several states have their own monitoring programmes for pesticides. Through collaboration and agreements, they provide FDA information and data on violative samples found in domestic commerce. FDA collaborates with local, state, other federal and international authorities, leveraging their programmes and capacities to maximise the effectiveness of its own pesticide sampling.

For example, FDA and USDA have a Memorandum of Understanding (MOU) in which USDA alerts FDA monthly of presumptive tolerance violations they find in the Pesticide Data Program administered by AMS or in the National Residue Program run by FSIS. FDA uses this information when designing the annual pesticide residue monitoring program, and for directing immediate sample collection efforts, as appropriate.

FDA field offices interact with their counterparts in many states to enhance the effectiveness of its Pesticide Residue Monitoring Program. Partnership agreements and MOUs have been established between FDA and many state agencies. These agreements are specific to each state, take into account available resources, and provide for more efficient residue monitoring by coordinating efforts, broadening coverage, and eliminating duplication of effort. The agreements stipulate how FDA and the state will jointly plan work for collecting and analysing samples, sharing data, and enforcing compliance follow-up responsibilities for individual commodities of domestic and import products.

A7.7 Total Diet Study (FDA)

Total Diet Study (TDS) is an ongoing FDA program that monitors levels of about 800 contaminants and nutrients in the average U.S. diet. It started as a program to monitor for radioactive contamination of foods but now also includes pesticide residues, industrial and other toxic chemicals as well as nutrient elements. The data from TDS is used to estimate how much of the contaminants and nutrients the entire U.S. population, some subpopulations, and each person consumes annually, on average.

Under the previous study design, about 280 kinds of foods and beverages from representative areas of the country were purchased, prepared and analysed four times a year. For each kind of food, the samples from each of the three separate cities of the region were combined to form one composite sample of that particular food, so called “market basket”. Four regions each consisted of three cities that differed every year.

In 2018, the updated sampling plan was implemented aiming to increase the quality and utility of TDS data and to allow the FDA to determine whether nutrients and contaminants in foods vary depending on where or when the food is purchased.

The new sampling plan is based on population distributions in all 50 states – all areas are included in the sampling plan, but densely populated areas are more likely to be included as sampling sites. This was not the case under the old sampling plan.

The new sampling plan includes two types of sample collections, one for foods that are distributed nationally, and one for foods with analyte concentrations that may vary regionally and seasonally, such as fresh produce, meats, and dairy products. Foods with nutrient or contaminant concentrations that are less likely to vary by location or by time of year are categorised as “national” foods. Foods with nutrient or contaminant concentrations that may vary by location or by time of year are categorised as “regional” foods.

Under the new design, regional samples are collected in each of the six regions twice a year. The national foods are collected only once a year from a single location near the FDA’s testing laboratory in Kansas City. A complete cycle now lasts 2 years and includes 2 national and 24 regional collections.

As the eating patterns change over time, the list of foods to be analysed is periodically updated. As part of the recent study redesign, the food list was updated based on an extensive analysis of the latest data. Foods with the highest per capita consumption were identified and highly consumed foods from each major food group (for example fruits, vegetables, meat/poultry/fish, dairy) were selected.

Foods for TDS are collected from supermarkets, grocery stores, and fast-food restaurants. Analytes currently include pesticides, acid herbicides, lead, iodine, mercury, all other elements, and radionuclides. Testing is conducted at FDA's laboratories.

The results from the Total Diet Study are used in many ways. For example, along with other sources of information, they suggest potential areas of focus for FDA's food safety and nutrition programs.

A7.8 Other monitoring efforts for chemical contaminants (FDA)

FDA has or had a number of specialised monitoring programs or sampling assignments for industrial chemicals, such as dioxins, cooking or heating related chemicals, such as acrylamide, and other chemical contaminants in food such as benzene, dioxins and PCBs, ethyl carbamate, furan, perchlorate, and radionuclides, and the assessment of potential exposure and risk posed by these chemicals. These are conducted either as part of Total Diet Study, under FDA's compliance program for Toxic Elements in Food and Foodware, and Radionuclides in Food, or as a separate sampling assignment.

Sampling assignments may be conducted in response to reports of elevated levels of toxic metals or other elements in certain foods or to focus on a specific food, food additive, or specific food group (such as foods commonly eaten by infants and toddlers). See Table 15 for details of some sampling activities with published results.

FDA uses the information gathered from stakeholders, up-to-date scientific research, and data from routine monitoring to establish or adjust action levels. FDA considers action levels, in addition to other factors and scientific evidence, when considering whether to bring enforcement action in a particular case.

A7.9 Strategic Assessment of Sampling Resources (FSIS)

To maximise the efficiency, effectiveness, and value of sampling projects aimed at verifying the safety of products regulated by FSIS, the agency recently undertook a Strategic Assessment of Sampling Resources to fully account for and prioritise resources. The assessment was conducted from September 2017 to May 2019 with an underlying premise that FSIS sampling only fulfils its purpose if the data it generates is used by the agency.

The working group developed a multiphase approach where it first took inventory of all current sampling projects and the reasons behind each (Phase 1) and then developed weighted categories and criteria for scoring and ranking the potential benefits of each project (Phase 2). It was then assessed whether each sampling project, as implemented, could satisfy the stated policy objective or its intended purpose (Phase 3) and whether data from ongoing sampling projects is being used by the FSIS as originally intended (Phase 4). Lastly, a cost assessment was conducted across all sampling projects (Phase 5). A semi-quantitative evaluation to provide rankings for current and future sampling projects is earmarked for future development (Phase 6).

Table 15. Recent FDA research on chemical contaminants in foods

Years	Parameters considered	Food	Where collected	No. of samples
2005-ongoing	Inorganic arsenic	Infant rice cereals, non-rice infant cereals or other foods commonly eaten by infants and toddlers, juices; market basket samples as part of TDS; samples under FDA's Toxic Elements in Food and Foodware, and Radionuclides in Food compliance program	Retail, restaurants	2,344

Years	Parameters considered	Food	Where collected	No. of samples
2012-ongoing	Per- and polyfluoroalkyl substances (PFAS)	Produce, meat, dairy, grain products, carbonated water, non-carbonated bottled water, seafood, milk. Also, foods grown or processed in areas with known environmental contamination	Farms, retail	421
2013-2019	3-Monochloro-propane-1,2-diol (MCPD) esters and glycidyl esters	Refined vegetable oils and infant formula	Retail	320
2011, 2015	Acrylamide	Foods prone to acrylamide formation	Retail, restaurants	~2,500
2008-2012	Perchlorate	Market basket samples as part of TDS	Retail, restaurants	5,464
2004-2008	Furan	Baby food, infant formula, coffee, soups, sauces, broths, chili, fish, canned products etc.	Retail	771
2005-2007	Benzene	Soft drinks and other beverages	Retail	Almost 200

Years	Parameters considered	Food	Where collected	No. of samples
2000-2004	Dioxins and polychlorinated biphenyls (PCBs)	Dairy, eggs, fats/oils, fruits/vegetables, grains/cereals, seafood, tree nuts/peanuts, and dietary supplements in addition to market basket samples as part of TDS	Retail, restaurants	1,483 (non-TDS)

Based on the results from Phases 1-5, the workgroup identified nine major findings and made recommendations to address them. Key process-oriented findings and associated recommendations relate to:

- Overall organisation of sampling project development and maintenance (for example what information is collected, project design optimisation, centralised cost projection tracking system);
- Establishing a consistent formal process to assess when a project or portions of a project should "sunset";
- Updating a complete inventory of sampling projects each year;
- Implementing of weighted criteria to evaluate the benefits of each sampling program (any sampling project that ranked below 0.3 on the benefit score should be subjected to rigorous evaluation; ranking should also be used for proposed new or revised sampling projects).

Statistical-oriented findings highlighted the following:

- Some sampling projects could be optimised by altering the number of samples collected and analysed;
- For domestic sampling projects with very low positive rates it is not feasible to collect enough samples to product reliable estimates;
- No clear and consistent standards for when sampling data can be used to estimate national prevalence;
- Sampling of imports at reinspection serves different purposes and has different statistical design challenges than domestic sampling.

The results of the assessment are taken into account when drafting the Annual Sampling Plan via the use of tools developed as part of the assessment to optimise the benefits of each sampling project. Implementation of provided recommendations helps with improving internal procedures around sampling planning.

A7.10 Microbiological sampling (FSIS)

FSIS currently performs routine microbiological sampling and testing for *Salmonella*, *Campylobacter*, *Listeria monocytogenes*, indicator organisms, *E. coli* O157:H7 and non-O157 Shiga toxin-producing *Escherichia coli* (STEC) for various products including raw beef, poultry, pork, and *Siluriformes*, as well as ready-to-eat (RTE) products.

Two basic types of laboratory sampling tasks are distinguished – planned direct sampling (for example, *Salmonella* performance standard set for broilers) and unscheduled sampling generated by inspection program personnel (for example in response to a foodborne illness investigation, animal pathology sampling, or positive in-plant test).

To assess food safety performance of regulated establishments that slaughter and process meat and poultry products, FSIS employs pathogen reduction performance standards. Performance standards are FSIS's calculation of the national prevalence of a pathogen on the indicated raw product based on data developed by FSIS in its nationwide microbiological data collection programs and surveys. Sampling for pathogen reduction performance standards purposes is conducted by FSIS personnel on an unannounced basis.

Pathogen reduction performance standard for *Salmonella* in raw beef (9 CFR §310.25) is currently the only one remaining in the regulations.

Recently, through Federal Register notices, FSIS started issuing new pathogen reduction performance standards where assessment on whether establishments are effectively addressing pathogens is conducted using a 52-week moving window of FSIS sampling results and other related verification activities. An example of this would be pathogen reduction performance standards for *Salmonella* and *Campylobacter* in young chicken and turkey carcasses, raw chicken parts, and not-ready-to-eat comminuted chicken and turkey products (81 FR 7285, as amended by

83 FR 56046). The sampling frequency is determined on the basis of production volume and history of sampling results. Based on the sampling results (excluding those from follow-up samples), establishments are categorised into 3 categories:

- Category 1. Establishments that have achieved 50% or less of the maximum allowable percent positive during the most recent completed 52-week moving window;
- Category 2. Establishments that meet the maximum allowable percent positive but have results greater than 50% of the maximum allowable percent positive during the most recent completed 52-week moving window;
- Category 3. Establishments that have exceeded the maximum allowable percent positive during the most recent completed 52-week moving window.

An establishment assigned to Category 3 must take corrective actions and reassess their HACCP system, if necessary. In response to an establishment not meeting the standard, FSIS collects follow-up samples to verify whether the establishment has made effective corrective action in response to the initial positive detected through routine FSIS verification testing. Follow-up samples may also be collected at retail in response to a positive result.

FSIS Scheduling Algorithm for *Salmonella* and *Campylobacter* Verification Sampling Programs for Raw Poultry (FSIS-GC-2018-011) indicates that, once the list of eligible establishments that produce sufficient volumes of eligible products is prepared, it is weighted by production volume and past rates of positive product across all establishments in that product's production volume category. The total number of samples allotted to each project is then assigned across establishments, with replacement, using these weights.

In 2018, FSIS announced that it began testing all raw poultry samples using the enrichment method to detect *Campylobacter* and therefore discontinued assessing whether establishments meet the current *Campylobacter* performance standards.

As indicated in Annual Plan FY 2021, FSIS intends to expand the use of performance standards by implementing proposed new pathogen reduction performance standards for *Salmonella* in ground beef and beef manufacturing trimmings (84 FR 57688) and for *Campylobacter* in not-ready-to-eat comminuted chicken and turkey

(84 FR 38203) and by proposing new pathogen reduction performance standards for *Salmonella* in pork and *Campylobacter* in poultry.

FSIS intends to monitor the sampling results under these performance standards as well as the CDC illness data to evaluate the industry's progress in reducing product contamination and reducing illnesses.

Besides testing for pathogen reduction performance standards purposes, FSIS conducts a range of compliance verification activities, such as routine verification testing of indicator organisms, *Escherichia coli* O157:H7 and non-O157 STEC, *Listeria monocytogenes* etc. Details can be found in the corresponding FSIS directives.

A7.11 National Residue Program (FSIS)

FSIS conducts chemical residue sampling under the National Residue Program (NRP) for Meat, Poultry, and Egg Products, which is an interagency programme administered by FSIS designed to identify, prioritise, and analyse chemical residues and contaminants in FSIS-regulated meat (including *Siluriformes* fish products), poultry, and egg products.

The primary responsibility of FSIS in the NRP is to verify that establishments control animal drug residues, pesticides, environmental contaminants, and any other chemical hazards in and on meat and poultry products through sampling programs within the NRP.

As indicated in FSIS Directive 10800.1, establishments that have a supplier that has had more than one FSIS laboratory-confirmed chemical residue violation in the previous 12 months, receive livestock from a supplier that is on the Residue Repeat Violator List, do not have an effective residue control program in place, or cannot prove that the supplier of dairy cows or bob veal calves is not on the Residue Repeat Violator List are targeted for in-plant testing for chemical residues at an increased rate.

Testing includes approved and unapproved veterinary drugs, pesticides, and environmental contaminants known or suspected to be present in food animals in the U.S. or in countries exporting products to the U.S.

FSIS publishes the NRP Residue Sampling Plan (so called “Blue Book”) each year to provide information on the process of sampling meat, poultry, egg products, and fish of the order *Siluriformes* and testing them for chemical compounds of public health concern.

NRP Residue Sampling Plan is a result of cooperation and collaboration between FSIS, FDA, EPA, ARS (Agricultural Research Service, USDA), AMS, and CDC. Each year, representatives of these federal agencies convene a meeting of the Surveillance Advisory Team (SAT) consisting of experts in veterinary medicine, toxicology, chemistry, and public health to determine which chemical compounds representing a public health concern warrant inclusion in the NRP for the following fiscal year, either on a permanent or exploratory basis.

FSIS published its Pesticide Prioritisation Framework for the NRP which takes into account pesticide usage, bioavailability, health-based guideline value, and carcinogenic potential when deciding which chemicals should be tested under NRP.

As indicated in Fiscal Year 2020 Blue Book, the domestic sampling plan includes 3 types of sampling in both federal and state-inspected slaughter facilities:

- Surveillance sampling;
- Inspector-generated sampling;
- Special project sampling.

Surveillance sampling is the scheduled (directed) sampling of specified slaughter subclasses at the time of slaughter, after a carcass has passed antemortem inspection. Carcasses are randomly selected within a given production class for sampling, with the goal of providing a nationally representative sample that can be used to determine baseline levels of chemical residues. In FY 2020, 7,726 samples (7,304 from federally-inspected plants and 422 from state-inspected plants) were analysed by FSIS to detect approximately 250 different veterinary drugs, pesticides, and environmental contaminants.

Inspector-generated sampling is conducted when FSIS inspectors suspect that animals may have violative levels of chemical residues. Currently, inspector-generated sampling targets individual suspect animals, suspect animal populations, and animals retained or condemned for specific pathologies. Sampling is conducted

by FSIS inspection program personnel in federally-inspected establishments. In FY 2020, 166,306 KIS tests were conducted on animals selected by FSIS. In total, 2,783 samples were submitted to FSIS field laboratories for further analysis. Samples from animals suspected of having violative residues from state-inspected establishments that are “at least equal to” the federal requirements are collected by state inspectors.

Special project (exploratory) sampling by FSIS is conducted when a necessary analytical project cannot be performed on samples that are already being collected as part of surveillance or inspector-generated sampling.

Imported FSIS-regulated products are sampled through the point-of-entry Import Reinspection Sampling Plan which is a monitoring program conducted to verify the equivalence of inspection systems in exporting countries to U.S. standards. All imported products are subject to reinspection, and one or more types of inspection are conducted on every lot of product before it enters the United States. The reinspection of imported products includes chemical residue testing and can be done through normal sampling (random sampling from a lot), increased sampling (above-normal sampling resulting from FSIS management decision), or intensified sampling (additional samples are taken when a previous sample failed to meet U.S. requirements). A total of 6,661 samples of imported FSIS-regulated products were analysed in FY 2020 for chemical residues.

The structure of the import reinspection sampling program is based on criteria used to develop the domestic plan. The estimated annual amount of product imported into the United States is used to assign the number of samples. The compounds selected for analysis in the import plan may not necessarily be the same as those in the domestic plan.

FSIS Directive 10800.1 also provides for the possibility of national security and other special sampling in the event of emergency or in case of other special sampling situations on an as-needed basis.

Results from NRP inform the agencies about veterinary drug and pesticide use in the food animal industry, compliance with regulations governing the use of these, and information on the presence of environmental contaminants that may affect the food supply. Regulated establishments use residue testing data to assess their food safety

programs, including reviewing their suppliers of live animals. FSIS and its partners use the testing data for monitoring, enforcement, and strategic planning purposes.

A7.12 Pesticide Data Program (AMS)

The Pesticide Data Program (PDP) is a national pesticide residue monitoring programme that produces the most comprehensive pesticide residue database in the U.S. Activities within this programme, including the sampling, testing, and reporting of pesticide residues on agricultural commodities in the U.S. food supply, are administered by the Monitoring Programs Division (MPD) of the AMS. The emphasis is on those commodities highly consumed by infants and children.

The PDP is implemented through cooperation with state agriculture departments and other federal agencies. Data from the PDP enables the EPA to assess dietary exposure and provides guidance for the FDA and other governmental agencies to make informed decisions. Therefore, Program Plans are updated annually in coordination with EPA and FDA.

Results are published in the PDP Database. The database contains results for 285,844 samples tested by PDP from 1994 through 2019 for over 700 compounds (pesticides, metabolites, and isomers). Information on the number of samples analysed for each commodity and the number of commodities analysed for each pesticide each year is also available.

As indicated in the Sampling Procedures for PDP, each participating state is assigned a number of samples to collect per commodity each month. The exact number is determined by the MPD Program Administrative Director, in consultation with the USDA National Agricultural Statistics Service (NASS) statistician. The assigned number of samples per month is based on state population. Collection sites must be as close to the point of consumption as possible. Analysis is conducted by state and/or federal laboratories.

A number of special projects were conducted as part of the PDP in response to requests from stakeholders. For example, for 2,4-D in multiple commodities, pesticide residues on eggs, catfish, salmon, milk, drinking water etc.

A7.13 Microbiological testing of AMS purchased commodities

AMS oversees microbiological testing of meat, poultry, and egg commodities it purchases for various federal food and nutrition assistance programs. AMS sampling procedures and frequencies are described in the specification documents of each commodity (for example for boneless beef, ground beef, cooked diced chicken, and egg products).

For example, to be eligible, potential suppliers of fresh chilled boneless beef products for further processing into fully cooked items must send samples from each lot to the AMS designated laboratory to be tested for indicator microorganisms (standard plate count, total coliforms, and *Escherichia coli*).

Specification for frozen ground beef products would require one sample from every 10 lots of fresh chilled boneless beef, selected at random by the AMS designated laboratory, to be tested for non-O157 STECs in addition to samples of each lots tested for *E. coli* O157:H7, *Salmonella*, and indicator organisms.

A7.14 Special sampling assignments (AMS)

AMS may conduct special sampling tasks on request from foreign or domestic agencies or the industry. For example, on request from the Japan Ministry of Agriculture, Forestry and Fisheries, AMS Federal Grain Inspection Service (FGIS) tests wheat and barley exported to Japan as part of a joint study for comparison of origin and destination test results for ochratoxin A. The program covers all ship lots being exported to Japan for 4 years starting from 15 September 2018.

Under the National Export Soybean Sample Collection Plan, FGIS and official inspection agencies were tasked with collecting samples of soybean to evaluate concerns related to pesticide residues (120 export soybean samples in total).

Similarly, FGIS is collecting composite samples from all ship lots and container lots of soybean to be exported to China for weed seed survey. This sample collection program is a collaboration between FGIS and APHIS. All shipments with a certificate date starting from 2018 are included in the survey until further notice.

AMS also offers some paid services with sampling. While these are mostly for grading/quality assurance purposes, some are for legal compliance purposes as well.

For example, pesticide residue testing for grain conducted on request under the U.S. Grain Standards Act provides for official samples obtained by official personnel or by a licensed warehouseman sampler as well as samples submitted by the applicant for service to be analysed by the official personnel for routine and special pesticide residue compounds.

A7.15 Laboratory approval programs (AMS)

AMS administers a number of laboratory approval programs, including a program for aflatoxin testing of:

- Almonds destined for export to the European Union through the Pre-Export Certification program of the Almond Board of California;
- Pistachios for domestic and export markets, and import markets in accordance with 7 CFR Part 983 and 7 CFR §999.600, respectively;
- Peanuts marketed domestically for human consumption, including imports, in accordance with 7 CFR Part 996.

Under the above, almonds, peanuts, and pistachios must be analysed for aflatoxin either by AMS laboratory (National Science Laboratories) or by one of the AMS-approved laboratories.

Similarly, under its Microbiological Testing Program, AMS approves laboratories to perform microbiological testing of frozen cooked diced chicken procured for the Federal Purchase Program. Specifications for diced chicken require testing by AMS or AMS-approved laboratory.

AMS also plays a role in export verification by approving laboratories to perform testing of meat and poultry products destined for export. Foreign governments often require products destined for their country to be tested for pesticide residues, environmental contaminants, veterinary drug residues, antibiotic residues, microorganisms, and/or parasites, and they require the U.S. government to oversee the testing and verify compliance. The AMS Export Laboratory Approval Program ensures the testing of products offered for export certification by the FSIS is conducted by qualified and approved laboratories.

A7.16 Alcohol Beverage Sampling Program (TTB)

To evaluate whether TTB is successful in meeting its mission in ensuring that alcohol beverages are properly labelled and formulations are compliant and to determine where compliance issues exist, TTB conducts a random survey of products in the marketplace under its Alcohol Beverage Sampling Program (ABSP). Notably, starting with the 2017 sampling program, ABSP is being revised to include both a random and risk-based sampling. At the same time, TTB stopped publishing the results on annual basis.

TTB FY Annual Report 2020 (published in February 2021) reiterates the TTB's focus on incorporating random and risk-based product sampling to detect where issues may exist in the marketplace as well as evaluate products that may have a higher likelihood of non-compliance based on certain risk factors. Strategic risk-based approach involves a combination of data analytics and sound intelligence to support the identification of the highest risk activity. No further details on the risk factors provided.

The last published report indicates that, in 2016, 450 products in total were randomly sampled by TTB (175 distilled spirits, 157 malt beverages, and 118 wines). No further details on the sampling were provided. The sampled products were first reviewed for compliance with labelling regulations and then sent to TTB laboratories for chemical analysis to assess whether the products match the information displayed on the product labels.