Assessing attitudes for moving towards preventive approaches to effective management of food safety risks in China

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Global Food Safety Partnership

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1. Executive Summary

New Challenges

1.1. The regulatory approach to Food Safety in the 21st Century has been changing across the world as the nature of the problem has also been changing. Urbanization has created new problems in supplying safe food to huge populations, making the supply chain more complex and more dangerous. Food technology has also been enabling more food products to be offered that can last longer and be produced more cheaply, which carries both benefits and risks. Globalization has intensified competition and reduced profit margins but has also increased the need for more compatible regulatory approaches to Food Safety in major trading countries.

1.2. The regulatory answer that has been gradually spreading across the major trading countries is based on risk analysis and prevention of unsafe food, with proactive involvement of the State. China is now part of that trend, with the Food Safety Law of 2015. However, the Law is only an abstract framework for action and the next challenge is to implement it effectively.

1.3. Another trend this Century has been a growing appreciation of the difficulties in implementing regulatory systems and finding ways to ensure that they deliver what is intended, leading to a new discipline of Regulatory Delivery. This trend is also international, with learning from very diverse systems in both developing and developed economies. That learning has been especially focused on Food Safety regulatory systems because they are often the most fundamental regulatory systems that a country has to get right.

1.4. There is no single answer to implementing Food Safety regulatory systems. Although the EU has a single regulatory framework, it has at least 28 different ways of implementing it across its Member States, reflecting the diversity of these countries’ institutions, cultures and priorities. China faces a similar challenge in implementing a single regulatory framework across 31 Provinces and will produce its own solution – or range of solutions. But it can learn from as well as build on experience from other countries that have faced similar challenges.

The Attitudinal Survey

1.5. In February 2014, China Food and Drug Administration (CFDA) began collaboration with the Global Food Safety Partnership in a survey of regulatory officials and some companies from specific value chains to assess the needs for capacity building in order to tackle the challenges of implementing the Food Safety Law effectively. It operated across five Provinces – Heilongjiang, Jilin, Shandong, Sichuan and Fujian – and engaged with regulatory staff in each Province from all levels of administration, from Provincial to Township, and at different ranks of inspector.

1.6. The intention was to understand the attitudes, perceptions and practices of regulatory staff in order to see how ready they would be to make the transition to the new approach to regulatory enforcement that is needed under the new Law. It was not a statistical survey but an attitudinal survey. Experience from many other countries is that the most difficult part of changing methods of enforcement is not the technical issues but the mindsets and prejudices of the people involved. If they do not understand or are opposed to new ways of working, they will adapt the new ways back to something that they are more comfortable with and therefore little will change.
1.7. Fundamental to the new approach of Proactive Prevention is ensuring that food business operators apply good practices to whatever their task is in the food chain. Safety comes from successfully managing the risks that arise in what they do with the food under their control – whether that control is growing, transporting, processing, storing or cooking. Good practices reduce the risks. The new regulatory systems are therefore focused on ensuring that the right things are done and not just on the more traditional regulatory approach of stopping the wrong things being done. Stopping a food business from producing unsafe food does not create a business delivering safe food. To feed the urban populations, the challenge is to ensure that enough food businesses do the right things. This has a major impact on enforcement policy. It turns inspectors from something like policemen into something more like advisers. The survey was designed to see how ready the inspectors in the five Provinces are for that change in role.

The Results

1.8. The results are very encouraging. There was remarkable consistency across the range of respondents in their perception of food businesses that they knew well from their everyday interactions as being basically honest and trying to do a good job. This perception averaged 94%, with a variation of 90% to 97% across the five Provinces. Contrary to much of the popular media representation of food businesses as being criminals prepared to poison their customers, the inspectors’ experience is different. This finding was also supported by various other results in the survey, such as indicating whether violations were deliberate or unintentional, with the vast majority being unintentional. But there were also voluntary comments in some of the open questions that again indicated that the inspectors see businesses as trying to get it right.

1.9. In terms of practices, the survey showed that Chinese food inspectors are used to operating a disciplined enforcement system. It is not the enforcement system that they will develop under the new Law but the basic skills and discipline are there and should be fairly easy to adapt. Workflow skills are important and are independent of the actual work activities being managed.

1.10. The survey looked at current training and at what the inspectors are looking for in future training. They understand the importance of good food management systems and that came out as one of the main priorities, along with a better understanding of the application of risk.

1.11. The results showed not only a readiness to make the transition to the new ways of working but in many instances showed that they are already in transition.

Capacity-Building

1.12. The survey showed that there is a large group of food businesses that are willing to comply with the Law but are not yet compliant. Supporting them to move into compliance is the primary challenge of implementing the new Law and is a challenge for the regulatory bodies involved at the different levels. Although the businesses need capacity-building in being more compliant, the inspectors need to develop the capacity to assist and those running the regulatory bodies need to work this into their approach to enforcement.

1.13. The survey also addressed various companies in specific value chains in the five Provinces and the results from that supplement where some of their capacity-building needs are, in terms of improving compliance. More will need to be done to identify and assess all the barriers to better compliance but that is the task of the regulatory bodies, in collaboration with the private sector, and a role that has been adopted by their counterparts in other countries that have already started down this road.

1.14. A full set of Recommendations can be found at the end of the report.
2. Historical and International Context

New Problems and New Solutions

2.1. Unsafe food is increasingly an urban illness—or at least an illness significantly affected by urbanization. When food was grown and consumed locally, there were still dangers but these were confined to a fairly limited range. But providing food for millions of people in a city has transformed the range of dangers. Time and distance are the first challenges because it takes time to deliver the food. So that introduces dangers in transportation and possibly storage, plus additives to preserve the food for longer. The development of food science has certainly increased the safety of many foods but it has also allowed the production of new foods and food products, which also means new risks and more complexity. A modern supermarket like Tesco offers 60,000 different products\(^1\), the majority of them food products. They can include ingredients from anywhere in the world. The complexity of modern food creation and distribution both solves and creates problems\(^2\).

2.2. There can be problems with the basic raw materials but the nature of the modern food chain adds risk to the food at every stage in that chain, with every operation that the food is subject to — growing, harvest, slaughter, cutting, storage, transport, processing, distribution, display and cooking. But it is risk that is added, not damage. All these operations add the risk of damage but these risks can be managed safely to ensure that the food remains safe—or even that unsafe food is made safe. Ensuring the safety of food depends on those responsible for managing food at their stage in the chain knowing how to manage it safely. Depending on the operation, this can be done with some basic but good practices or it can be an extremely technical exercise, requiring specialist expertise. The people who endanger our food are also those that can ensure its safety.

2.3. Ensuring that all those involved in the food chain carry out their part properly is the role of food safety regulatory systems. A full regulatory system is not just a set of regulations but is the combination of day-to-day actions carried out by all those involved, including the food businesses, the enforcement agencies and the consumers. Having a Food Safety Law and numerous regulations and standards is a

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\(^1\) [http://www.theguardian.com/business/2015/jan/30/tesco-cuts-range-products](http://www.theguardian.com/business/2015/jan/30/tesco-cuts-range-products)

completely abstract exercise until it is put into practice. It provides a framework for that practice, both abstract and institutional, but what provides safety is the way that the system operates.

2.4. Just as food science has evolved to make food safer, more attractive, more nutritional and cheaper (although not all at once), the last ten to fifteen years has seen the evolution of expertise in how to make regulatory systems work — referred to as “regulatory delivery”³. This is not confined to food safety regulatory systems but these have often been at the forefront of the learning because food safety is one of the most fundamental regulatory systems in any country. In a wide range of countries across the world, there are people working on regulatory delivery in order to improve how regulatory systems deliver public benefits. As an illustration of the spread of interest, a conference on Regulatory Delivery in London in September 2014 attracted delegates from 57 countries, from both developed and developing economies⁴.

2.5. This Report examines how China is developing its food safety regulatory system in the context of an international understanding of both food safety risks and regulatory delivery practices. In 2015, China adopted the Food Safety Law which takes its food safety regulatory system in a new direction. It provides a good framework but that framework has to be brought to life through the actions of all those involved. The Report will look at different approaches to regulatory delivery in the context of food safety and assess how ready China is to take on new challenges and, indeed, the significant progress it has already made. Evidence of that progress will be identified, including the results of a survey carried out across five Provinces in 2015 to assess the need for capacity-building for further change.

2.6. Annex A sets out ten of the top trends in Regulatory Delivery, with examples including international best practice, and a brief assessment of China’s progress within these trends.

**Different approaches to Food Safety Regulation**

**The Product Testing Approach**

2.7. The oldest approach to food safety is to have a system for testing food to see if it is safe. It gives the greatest re assurance to the consumer to know that the product about to be eaten has been tested and found to be safe. However, it is not as reliable a technique as the public traditionally believe. There are some significant problems with it:

- Fundamentally, testing provides information about the past, not the future.
- It is only as good as the quality of the testing process and the state of knowledge when designing that test. New dangers keep appearing and some dangers take many years to take effect⁵. There are so many potential dangers in different foods that the actual test may only have covered a few of them, therefore the claim that the food is “safe” because it has been “tested” is a bit too simple.
- The actual food product that is about to be consumed will not itself have been tested. Food products of the same type will have been tested but, unlike production of physical


[⁵ In particular, there is a danger of a lack of micronutrients leading to malnutrition over a period of years, even although the food does not cause sickness within days. The connection between “safety” and nutrition is a complex one.](https://www.gov.uk/government/organisations/regulatory-delivery)
objects such as bicycles, the production of food is subject to fresh risk each time the production line is run. There may be a difference in the raw materials or there may be changes in temperature or contamination in the environment, or even a problem with the machinery. A negative test of one food product does not guarantee a negative test of the next one.

2.8. Testing is still essential in a food safety system. It has a vital role but that role has to be understood. Although a negative test will not say anything about the safety of the next product to be tested, a positive test may do. Testing of raw materials at the stage of primary production is essential as a check on the production conditions. There may be over-use of pesticides or growth hormones or there may be contamination in the land. A positive test on one batch will indicate that any other batches from the same source may also be positive. If the same production conditions apply, then there is a problem with that production system which will have to be rectified before it can produce safe raw materials.

2.9. However, the further along the food chain that testing is carried out, the less effective it is. It is effective as a check on a stage in the production process only insofar as its results can be used to improve that process. It is actually checking the process rather than the product. The state of the product is result of the process. There is no point in checking for the presence of heavy metals in a food product at the end of a production line. That check needed to be done on the raw materials going into the production line since the production line could not have added heavy metals. The least effective use of testing (as a form of control) is in the case of final products at the retail stage, especially if processed and packaged. Testing at that stage is an essential technique as a form of market surveillance, monitoring the safety (and integrity) of the overall food safety system. But it is not a technique for providing safe food. The product will have gone through so many stages it may be impossible to tell where the problem occurred and whether any other batches will have been similarly affected.

2.10. But there will be other cases where end-product testing will indeed be possible to identify a problem and take remedial action. The point is to understand the limitations and strengths of product testing. As part of an overall regulatory system for food safety, product testing is vital – but only as a part of the system, at the right stage, in the right way, for the right reasons and at a stage where the results can be used. At a conference in Qingdao in February 2015, CFDA Vice Minister Teng expressed the concern that a large percentage of the budget spent in China on testing food products could be put to better use. That is one of the challenges facing CFDA in improving the food safety regulatory system but it is one where there could be “quick wins” by some relatively simple analysis of the current approach to testing.

2.11. At present, the main testing resources are spent at the wrong end of the supply chain. Testing end-products at the retail stage is needed as part of a surveillance programme, as a check on levels of safety, but it is of very little use as a method of control. Where it is most effective is where action can be taken on the basis of the results, to prevent damage. That is particularly the case at the primary production stage. Figure 1 below shows how the incremental risks reduce as the product goes through the supply chain but it also shows that the testing volumes increase.

2.12. There is also an issue about who does the testing. Testing is most important at the stage of raw materials and at the stage of the end of a particular process. An honest food business that cares about the safety of its products will do this anyway and there is no need for the State to duplicate it as a matter of routine. For the State, it should be used as a check on particular cases where there is reason to be concerned. That can justify extensive checks on primary production, such as with the current categories of pollution-free, green and organic, in parts of the country where there is reason to be concerned about

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6 What it could have added is tiny bits of actual metal if part of the machinery was old and many food processing plants will have metal detectors as part of their production line but that is a very different test.
production conditions. But even there, there is scope for being more specific. A food safety project run by the World Bank Group in Jilin Province experimented with using mapping of environmental conditions as a way of identifying where in the Province it was better to grow particular products and, conversely, where it would be more important to carry out testing.

Figure 1. Reversing the Priorities in Product Testing

![Diagram showing the current situation where food production focuses on product testing, processing, and market, with incremental risks from overuse of growth enhancers, pesticides, veterinary drugs, soil and water pollution, and heavy testing for quality control.]

Source - Authors

2.13. But there is a more fundamental issue to the use of product testing as a primary element in a food safety regulatory system. It is focusing attention in the wrong place. The focus of attention should be the food business and not the food product. It is the business and its operational systems that need to be tested, more than the products. This is true even at the stage of the raw materials because the issue there is still with the primary production systems that produce the raw materials. It is the business that adds risk, through its operations, and it is also the business that can control the risks. The food product is passive and is not going to do anything itself (except decay, if left long enough). It is what businesses do with it that matters and it is businesses that should be the true focus of a food safety system.

2.14. Even if all raw materials were safe, the modern food chain that feeds the massive urban populations is the major source of risk, through the way that the raw materials are managed at each stage. The food chain can add risk to safe raw materials but it can also ensure safety and may even make use of raw materials that are in some ways unsafe at the start. The operation of the food chain is the key to food safety. If it operates badly, food is unsafe. If it operates well, food is safe. Product testing is only a commentary on the operation of the food chain.
The Standards Approach to Food Safety

2.15. Another widespread approach to providing safe food has been through the use of standards for production and for food products. The most extreme examples were in centrally planned economies where production was the responsibility of the State and not private sector businesses. There was no distinction between a standard as an end result that a product has to meet and a full set of instructions on how to achieve that result. The standards covered the production process in detail and, if that entire process was correctly followed, then the end result was expected to be safe. Again, as with product testing, this has a strong appeal to the public as a way of explaining how safety is achieved.

2.16. There are limitations to the effectiveness of this approach:

- It is a static representation of food production. Even if it is well designed and based on the best scientific knowledge of the risks from the type of raw materials and the processes, it only describes what was best at that time. New risks emerge, scientific knowledge develops and processes improve.
- Food production is subject to more risks than production of most non-food products, mainly because the raw materials are more vulnerable than steel, wood or plastics. Safety control of the raw materials is vital, as is ongoing control of the production environment, especially temperature. Food production needs hazard analysis and specific controls to manage these hazards. It is difficult to build this into a technical specification for a production process in a standards document because the hazards can change during the production process.
- Because it is a static description of a dynamic system, it needs to be capable of easy updating but this has proved to be a major obstacle to the success of this approach. Once there are thousands of these standards, updating them in the light of emerging risks and improved production processes becomes almost impossible. That then holds back improvements in production processes and can also leave the food vulnerable to new risks.
- This system is then very difficult to apply if the economy moves from central planning to free markets. The rigidity of the approach keeps the products and processes stuck in the past and therefore vulnerable to competition from more flexible production and innovation in other parts of the market.

2.17. But there is another version of what could still be described as a Standards Approach. That is where the State prescribes standards to be achieved but leaves it to the market to meet these standards. This is the approach taken by many countries until the end of the last century. At the top of this approach to food safety sits Codex Alimentarius, an international agreement that applies the best scientific knowledge about food to set standards of what is safe and unsafe. For example, it sets standards for the maximum amount of chemical contamination left over from pesticides that will still leave the food safe for human consumption – Maximum Residue Levels (MRLs) – and other similar detailed standards for levels of chemical or microbiological contamination in food.

2.18. Under this more flexible Standards Approach, the regulatory system imposes duties on food businesses to observe the standards but, to varying degrees, leaves it up to them to find their own ways to meet the standards. Some countries intervened more than others in how businesses operated but the role of the State was essentially passive and reactive. If things went wrong, the State had powers to manage the outbreak.

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Proactive Prevention – the Risk-Based Approach, from Farm to Fork

2.19. The approach that is increasingly being followed across the world this century is based on preventing unsafe food and being increasingly proactive in the role of the State in doing so. Prevention is based on applying risk analysis to the problem at every stage.

2.20. The pioneer of this was the EU in its General Food Law of 2002\(^9\). It expressly stated that food law should be based on risk analysis. That involved three stages of Risk Assessment, Risk Management and Risk Communication. It was also clear that the regulatory system had to apply to the entire food chain “from farm to fork.” The focus was not on products but on the entire food chain and therefore on the series of operations along the chain that added risk. The major source of risk was the food business and it was the legal responsibility of the food business to manage these risks and ensure safety. It mandated each food business to implement systems of food safety management based on the Hazard Analysis Critical Control Point (HACCP)\(^{10}\) system.

2.21. The EU law was unusual in how far it went into the implementation and enforcement of the regulatory system it was setting up. It provides for “Official Controls” to be carried out in each Member State, under the supervision of Competent Authorities, each of whom is responsible to a Central Competent Authority for that Member State. It also established the European Food Safety Authority, not as an enforcement agency but as a center for good science and advice on risk assessment. Implementation of the regulatory system is still a matter for each Member State and there are significant differences of approach from one to another, despite the level of detail in the regulatory framework. It is a single legislative system but a very diverse regulatory system in practice.

2.22. The USA adopted the Food Safety Modernization Act\(^{11}\) in 2011 with a strong focus on prevention of contamination rather than reacting to it after it occurred. Preventive systems use risk to identify the hazards that are to be prevented and use risk management to prevent the risks from materialising. So the Preventive Approach is also essentially the Risk-Based Approach.

2.23. But the shift towards prevention has also involved a shift towards a more proactive role for the State. Prevention is also about doing the right things rather than just stopping doing the wrong things. It places an emphasis on positive action by food businesses to anticipate and manage risks. This is more proactive than simply setting standards to be achieved and taking action if the business failed. There is inevitably an element of prevention in stopping doing the wrong things since that itself will prevent something going wrong but it may not deliver safe food, or any food. Avoiding delivering unsafe food is not the same as delivering safe food. The urban populations need a massive amount of safe food to be delivered so preventing unsafe food alone does not meet the scale of the challenge. These modern food safety regulatory systems recognise that they must have as a goal not just the avoidance of harm but the delivery of benefit.

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\(^9\) http://ec.europa.eu/food/safety/general_food_law/index_en.htm
\(^{10}\) http://www.fao.org/docrep/005/y1579e/y1579e03.htm
\(^{11}\) http://www.fda.gov/Food/GuidanceRegulation/FSMA/
The New Chinese Approach

2.24. How does this thinking apply to the current situation in China? Article 1 of the Food Safety Law of 2015 sets out the overall objective of the legislation:

“This Law is formulated to assure food safety and safeguard people’s health and life”.

2.25. Article 3 says:

Food safety work shall follow the principles of “putting prevention first, risk management, whole-process control, and making efforts by the whole of society”, aiming to establish a science based and strict oversight system.

It clearly sets out to deliver positive benefits and even refers to “making efforts by the whole of society”. It also expressly supports Prevention, which aligns this Law with the Food Safety Modernization Act of 2011 in the USA as regards a focus on prevention. It is also based on Risk Management, which aligns with the EU’s General Food Law. “Whole process control” moves the focus away from products to processes. This one Article contains all the key factors needed for a Law on food safety that aligns with international good practice.

2.26. Indeed, the addition of “making efforts by the whole of society” may take it beyond current international practice, although it is not clear exactly how this element will develop. This element has been referred to as “social co-governance” which has at its heart a move away from responsibility resting with the State, towards sharing responsibility more widely – across the State, consumers and businesses. There are different ways that this responsibility can be shared, with cases in other countries where something like this is already being tried:

- If it is a matter of strengthening consumer voice then it fits well with the EU system and particularly with the emphasis on consumers in the UK’s Food Standards Agency’s strategy - “our pledge to put consumers first in everything we do”.

- If it is a matter of working in partnership with businesses, sharing the risks of managing food safely, it shares the thinking in the UK’s transformational approach to regulatory delivery through “Primary Authority”. This allows partnerships between specialized regulators at local government level and individual large businesses, which in some cases almost amounts to a consultancy service by the regulator.

- If it is a matter of better engagement with the public, this could be seen as Risk Communication, which is one of the key principles on which the EU system is based. The new provisions on “whistle-blowers” – Article 12 and 13 – encourage and reward feedback from the public, although that also strengthens a negative perception of food businesses. The Dutch have recently completed a four year programme – “Risk and Responsibility” – on managing Risk Communication on regulatory issues, particularly what it called the “risk regulation reflex” of governments.

2.27. Article 6 covers the key delivery responsibility for the new system:

County and above level governments shall be responsible for the food safety supervision and management in the region; they shall lead, organize and coordinate food safety oversight, as

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12 https://www.food.gov.uk/about-us/about-the-fsa
13 https://www.gov.uk/government/publications/primary-authority-overview
well as respond to food safety incidents, establish/improve the whole process of food safety management mechanisms and the information sharing mechanism.

It starts by assigning responsibility for oversight, which is passive, but then becomes more proactive, with phrases like “lead, organize and coordinate” and “establish / improve the whole process of food safety management mechanisms”. The responsibilities assigned in Article 5 to the higher level authorities – the Food Safety Committee, the CFDA and the NHFPC – are passive ones of oversight. The delivery level for this system is at County and above government level. But the duty is a proactive one to deliver.

2.28. Article 36 also imposes a duty to be proactive in the case of small food businesses:

County and above level government shall be responsible for the comprehensive oversight of the small food workshops and food vendors by means of strengthening service and planning, improving their production/trading environment, encouraging and supporting them to improve production/trading conditions, and entering into the consolidated trading markets/shops, or trading in a designated temporary area or at a specified period of time.

This fits very well with thinking on providing support to rather than rigid enforcement of small businesses. Because of the issue of affordability of compliance costs, it is particularly good that Article 36 is taking into account economic conditions and looking to encouraging economic solutions.

Conclusions on Approaches to Food Safety Regulation

2.29. With the new Food Safety Law, the Chinese Food Safety regulatory system is aligned with the best developments in this field in other countries and may be introducing new ways forward through the element of social co-governance. Although this brief review has focused only on general principles, the new Law also has the basic elements of modern Food Safety laws, such as producer responsibility, traceability, safety management systems, etc.. At this stage, it is still at the level of an adopted law but not yet at the stage of a fully implemented, fully operational system. That is the next challenge, and a major one. How ready China is to implement this approach in practice was the objective of the survey by the Global Food Safety Partnership to assess the need for capacity-building in both the enforcement and business sides of the food chain. The next sections of this Report explore the key issues involved in making the Food Safety Law operational and how the evidence from the survey indicates it may work in practice.

Key Changes needed under the Food Safety Law

2.30. The new Food Safety Law of 2015 is part of a broader reform that has seen significant restructuring and streamlining of institutions, which have already been implemented down to Township level in most Provinces. This report is not reviewing institutional changes but the changes in regulatory practice that are needed, as set out in Figure 2.

Figure 2. Key Changes in Regulatory Practice

- From products to businesses
- From products to processes
- From coercion to support
2.31. It was mentioned above that the “farm to fork” approach of modern food safety regulation is focused on how the longer and more complex supply chains add danger through the multiple operations applied to the food at each stage and how businesses are responsible for safe management of the food at their stage in the chain. It is businesses that control food safety (or not) and it is therefore businesses that are the primary object of supervision, rather than the food products themselves. It was also shown that testing food products is not an effective form of control, although it can be an invaluable source of information. The way the businesses control food safety is through food management systems, whether at the level of basic food hygiene or advanced HACCP, and it is these systems that are what needs to be tested.

2.32. The third key change in regulatory practice is in enforcement policy.

**Enforcement Policy – Coercion or Support?**

2.33. The traditional view of regulatory enforcement is one of coercion. The model for enforcement agencies has been that of the police rather than that of a consultancy firm. Both models are a little extreme but the current shifts in practice in the study of Regulatory Delivery are moving from policing to enlightened support.

2.34. The key factor in reviewing enforcement policy is whether there is a need to be proactive and deliver positive benefits or whether it is enough to monitor the performance of businesses and impose sanctions when appropriate. The term “enforcement” includes the concept of coercion, of “forcing”, but that is the traditional term used and that has been the traditional approach. But the term “regulatory delivery” includes the concept of delivering something, which is more positive and proactive. Regulatory delivery looks at how to make regulatory systems work, in order that they deliver the regulatory objectives or outcomes.

**Limitations of Coercion**

2.35. Part of the reason for the more proactive approach is an awareness that coercion has not proved to be very effective as a method of securing the outcomes of a regulatory system. It has been the standard model across the world for long enough to prove whether it works or not. When there is nothing to compare it with, it is difficult to say that it doesn’t work. But it has also proved difficult to establish any causal connection between strict enforcement and improvement in public benefits. Part of this is the problem of attribution since so many different factors can contribute to levels of public health and therefore it is difficult to attribute any of them to strict enforcement. Where enforcement removed a clear danger, there is a definite contribution but it still suffers from the point made earlier that removing a danger is not the same as increasing a benefit. Stopping someone selling dangerous food does not establish someone selling safe food.

2.36. In 2003, the “Rose Revolution” in Georgia under Mikheil Saakashvili stopped the enforcement of various regulatory systems, including food safety, and that situation lasted for around ten years. In Armenia, there was a four year moratorium on inspections of small businesses while they moved to a risk-based system. In neither case was there any noticeable difference in levels of public protection. These had been coercive systems although they had also been corrupt and inefficient systems. What is clear is that they had not been doing anything proactive to create benefit. It is easy and dangerous to overstate the example of these cases to condemn any element of coercion and deterrence in a regulatory system and that is not the intention. There is a place for coercion and deterrence but not as the main policy. There will always be some criminals prepared to cause damage in the pursuit of profit and a regulatory

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16 For a modern and comprehensive account of the limitations of deterrence, see Law and Corporate Behaviour: Integrating Theories of Regulation, Enforcement, Compliance and Ethics, Chris Hodges, Hart Publishing, Oxford 2015
system needs to be able to deal with them but they are always a tiny minority and should not be the main focus of attention for the regulatory system.

**Responsive Regulation**

2.37. So who should be the focus of attention of a regulatory system? In Regulatory Delivery, there is an approach known as “Responsive Regulation”\(^\text{17}\) which proposes different ways for an enforcement agency to deal with different types of business. These types of business are categorised according to their attitude to the regulatory system, as follows:

- **Compliant** – these businesses are willing to be compliant and have achieved compliance. They do not need much resource devoted to them, beyond occasional monitoring to ensure that they are remaining compliant.

- **Willing to Comply** – these businesses are willing to be compliant but are having problems in achieving it. The effective response there is to understand the problems and see whether they can be removed or reduced, or whether there are other ways in supporting the business into compliance.

- **Opportunist** – these businesses do not care either way about compliance and will make decisions according to the situation and their self-interest. It is difficult to have any particular response to this type because it depends on the situation but if they can be shown that compliance is in their interest then they will comply.

- **Criminal** – these businesses do not care about the rules and need to be faced with robust enforcement and sanctions.

**Figure 3. Responsive Regulation**

2.38. The key issue in Responsive Regulation is knowing what percentage of the overall businesses fall into these categories. In many countries, there is a perception by the public and by politicians that most businesses are dishonest and that is what makes an enforcement policy of coercion politically popular. But if that is actually the case, it is very bad news for the country's economy and social stability. What is normally the case is that the vast majority of businesses are either willing to comply or already compliant. For a business, there is rarely an issue of principle that they do not want to comply with the rules. Instead, they usually see the rules as another overhead that they need to manage and they want to reduce external interference and possible sanctions from the enforcement authorities. Compliance is the line of least resistance, so long as it is understandable, possible, fair and affordable – and so long as their competitors are doing the same. Understanding compliance can be a complex matter, with various factors sometimes in competition with each other – see Figure 4.

**Figure 4. Managing Compliance**

**Complementary compliance drivers – sometimes in tension**

![Diagram of complementary compliance drivers](image)

- Knowledge
- Financial ability to comply
- Legitimacy of authorities
- Procedural justice in interaction with regulators
- Conformity ("everyone does it")
- Ethics ("this is the right thing to do")
- Dissuasion (control, enforcement)
- Economic benefits of compliance (reputation…)

*Source – Florentin Blanc, “From Chasing Violations to Managing Risks: Origins, challenges and evolutions in regulatory inspections” (in Press)*

2.39. Looking at the factors mentioned above in turn:

- Understandable – the problem may be that the businesses does not understand what to do. This is not solved by punishment but by guidance and training. It may also be a problem with the rules themselves and clarification or simplification may have a big impact on compliance levels, at minimal cost.

- Possible – the business may understand what it needs to do but does not have the capacity, either in terms of skills or human resources (costs are covered separately below). This can be the major problem with many small farmers. What is needed to overcome this is advice and support on working with others in the same position, to make all their businesses more viable. For larger businesses, it may be the challenge of establishing sophisticated food safety management systems. The answer there is training.
• Fair – there have been interesting studies of what is referred to as “procedural legitimacy”\(^\text{18}\). This is the business’s reaction to how it is dealt with by the authorities. It has to have some respect for them and accept the legitimacy of their authority. If the business perceives the authority as being fair and open, it is more likely to accept penalties being imposed on it and more prepared to cooperate with the authorities.

• Affordable – this is the issue of compliance costs. If compliance means that the business is no longer viable commercially, then either the business collapses or it will avoid compliance. It is a vital consideration in the design and operation of a regulatory system. A regulatory system that is not affordable to enough of its target audience will never work. Some compliance costs may be unavoidable but there are many that are avoidable and it is the obligation of those designing and operating the system to avoid them by reducing the costs imposed on business to a minimum. This includes the running costs to business, e.g. time spent on getting licences or on inspections.

• “Level playing field” – the business needs to have confidence that if it bears the compliance costs then its competitors are also bearing them and so it is not disadvantaged by being compliant. This is a major obligation on those operating a regulatory system, to ensure that it is enforced evenly and transparently, giving the businesses that confidence. It is a major element in Procedural Legitimacy. The business not only needs that confidence in order to strengthen its resolve to be compliant but it also needs it to make the important decision to expand, to take on more staff and invest in a higher level of business activity. Well run regulatory systems support economic growth.

2.40. This Report focuses strongly on these issues of enforcement policy in the domestic market. It does not look at the challenges of cross-border trade because that is the responsibility of AQSIQ, a separate government Ministry which focuses on cross-border trade generally, including food products. Nor does it look at the development of third party certification, which is another important international trend, because the focus of the research was on enforcement staff at Township level and above, who are the people primarily responsible for delivering the new Food Safety Law. The main concern of the research was to assess the readiness of these staff to adapt to and adopt the new regulatory approach under the Law.

3. The Inspections and Enforcement System for Food Safety in China

3.1. Before looking at the research results, this section outlines the current administrative structures in which the enforcement staff operate. There are separate structures for primary production, which is still under the supervision of the Ministry of Agriculture and various Agencies under its supervision, and for domestic food safety beyond the farm gate, which is the subject of the Food Safety Law. The administrative structures described are those following the structural changes since 2013 and, subject to some further settling-in, will be structures going forward.

Organization of Provincial FDA and Below

3.2. The organization described in this section does not involve primary production. That remains under the Ministry of Agriculture and has its own specialized supervisory bodies at lower levels of government and is covered later. Primary production stops at slaughter and cutting plants, for animals, and at storage and distribution for non-animal products. Broadly speaking, the division is at the farm gate. There is also a separate inspection and supervisory function for food products intended for export, through AQSIQ.

3.3. At national level is the CFDA. This itself is a streamlined body and that streamlining is intended to be replicated down through the government levels. At Provincial level is the Provincial FDA (PFDA) but it is responsible to the Provincial Government, not to CFDA. CFDA provides guidance and direction but does not directly manage the PFDA. CFDA does not have its own inspectors.

3.4. At National level, there is a Food Safety Commission responsible for coordination of food safety issues across government bodies. This is also replicated vertically. There will be a Provincial Food Safety Commission, led by senior public figures, e.g. mayor, with members from line agencies concerned with food safety, plus public security.

3.5. At Municipal level is the Municipal or City FDA. At County level, there is a new integration of four functions into the Market Supervision and Management Bureau:

- Business registration;
- Food and drug supervision;
- Quality inspection;
- Food Safety Office for coordination (part of the Food Safety Commission vertical structure).

There is no separate body for Township level but instead a sub-organization of the County level, including a Township Food Safety Office coordination body.

3.6. At village level, there will still be a Food Safety Commission organization, responsible for coordination and overall supervision. It will have local dignitaries and professionals such as doctors, working voluntarily. Instead of inspectors, there will be co-inspectors or messengers. They have no authority to sanction but act as supervisors of local conditions, both advising on food safety issues and reporting potential problems to the County level. These could be safety issues discovered in a business or a local event such as a large wedding which may need some checking by County / Township inspectors.

3.7. The structures are a mix of formal inspection bodies with trained inspectors authorized to enter premises, take samples and impose sanctions, and coordination bodies with local representation which provide a forum for general food safety oversight. The coordination bodies do not have powers to direct the formal inspectorates but cooperation between them is likely. China can therefore be seen to be part of the global trend in streamlining food safety enforcement organizations, including merger of smaller specialized inspectorates and limited merger of policy functions at national level.
Inspectors

3.8. An inspector is a person who holds an enforcement certificate. This can take 6 months to a year of on-the-job training by an experienced mentor to achieve, by way of a test. That test also has to be taken and passed each year by all those holding the certificate. It is a generalized test of inspection skills and up to date knowledge of laws and regulations. It is not designed to test specialized knowledge of food safety or food science. Routine inspection of food safety is divided into the supply chain stages of Processing, Distribution and Catering. The test does not differentiate between these functions or require special understanding of them.

- Processing involves all food manufacturing and processing but not primary production.
- Distribution includes storage, transportation, wholesale and retail.
- Catering involves all commercial and public service catering, including schools, but not domestic cooking.

Inspectors will specialise in one of these functions and probably spend an entire career in that function, unless moved to a different function for management reasons. It is unusual for an inspector to be qualified in both food and drugs and these tend to be separate careers. Some senior inspectors may be qualified in both food and drugs and in more than one of the three functions. Some inspectors may also have more specialized qualifications and be used as specialist support on some more challenging inspections or as part of a permitting function for specialized business operations. Inspectors operating in the Processing function should have an understanding of GMP and GSP but HACCP is not required.

3.9. Managers will usually be experienced inspectors but offices will also have professional support and administrative staff, e.g. lawyers, HR, finance, who are not inspectors. Any number quoted for “inspectors” will therefore include more than those who inspect businesses directly. Inspectors also supervise other inspectors, both in terms of experience and government hierarchy. That is, all inspections will be done by a minimum team of two, with an experienced inspector and a less experienced inspector. But Provincial level inspectors will occasionally supervise City/Municipal inspectors during inspections and they, in turn, may supervise County inspections. That supervision also extends to supervising planning and analysis of the work of the lower government levels.

3.10. There is no professional hierarchy of inspectors, e.g. Chief Inspector, but inspectors are part of a management hierarchy. Experience is rewarded by salary rather than rank. All inspectors have to be Civil Servants and so have to pass an entrance exam. There is no specific academic qualification for inspectors but competition is strong and this raises standards. Roughly, one might expect 90% at Provincial level to be undergraduate level and 60% at County.

3.11. A holder of an enforcement certificate carries a warrant card that identifies the holder and his areas of qualification (e.g. drugs, distribution), including a photograph. It outlines his powers and also the rights of the person inspected, both in Chinese and English.

3.12. Numbers of staff are limited by the concept of “staff size” which relates to the population affected by that organization. The ratio is 0.03% staff to the size of the relevant local population. There is no difficulty in recruiting staff in terms of applications but restrictions on the number that can be employed. Staffing at Provincial level is regarded as broadly sufficient but there are concerns about the adequacy of staff numbers at lower levels.

Operations

3.13. Inspectors are responsible for making up annual plans for the businesses to be inspected over the coming year. There will be guidance from senior levels of government up to CFDA on what is to be covered as a minimum. Each business will be inspected at least once a year. There is no limit on the size of a business therefore it can include single individual businesses in Distribution and Catering (though unlikely in Processing). Inspection plans are passed up to senior levels of government for approval.
3.14. There is a territorial grid of the area of jurisdiction and inspection teams are allocated to parts of the grid. These teams will probably have an office in that part of the grid. There may be 8 – 12 inspectors in that office. They will have to include a mix of Processing, Distribution and Catering, although some may have no Processing.

3.15. Each organization has a database of food businesses, based on registration data and updated with inspection data. The administrative integration at City and County level has not yet extended to integration of databases but work on that continues. Each business has a profile which will include:

- Name, location, size and management team;
- Function and types of food products;
- Compliance history.

3.16. In Catering, food businesses are allocated a rating of A, B, C, or D, according to their last inspection result. All new businesses start with B until first inspection. Inspection frequency is according to that rating:

- A – 2 times a year;
- B – 4 times a year;
- C – 6 times a year; and
- D – monthly.

Businesses are obliged to display their rating. Inspection plans need to apply these frequencies, which can change during the year as ratings change. Inspection planning may therefore already operate to some extent on a risk basis but the process is not as thoroughly based on risk as in international practice. However, the basics are there and could be developed along international lines without radical change.

3.17. In Jilin Province, there are plans to extend this rating system to the Processing and Distribution functions. In Heilongjiang, they started to apply it to Processing in early 2014. They see the potential in applying risk (they already refer to High, Medium and Low Risk rather than A, B, C, and D). Development of a rating system for businesses is a CFDA requirement but there is no detailed guidance on how to do it.

3.18. Unplanned inspections are seen as a problem because a planned system is preferred. These can be follow-up inspections but the main source is complaints or policy direction (in the sense of a sudden focus on one product or event, according to circumstances). There are seasonal factors, such as harvests, festivals and climate but these can be planned for. Every complaint has to be followed up, even if the complaint turns out to be unfounded and there is not even a business at the place specified. Any system of rational planning, whether or not risk-based, is vulnerable to becoming a complaints-based system.

3.19. An inspection can range from an hour to half a day. One average given was between an hour and 90 minutes. Another claimed half an hour for a shop and half a day for a supermarket. An illustration was given of a routine inspection in Distribution, e.g. a shop:

- Documentation – business registration, food distribution certificate, health certificate, any licences;
- Inspecting products – all products have to be inspected but this can be by batch, checking expiry dates, labelling, whether counterfeit, traceability information;
- Sampling – there is a Provincial Sampling and Testing Plan which will have been adapted to local level. The inspector has to pay for samples taken and be reimbursed by his office.
- Regulatory requirements – if there is a corporate production regulation, it needs to be followed, otherwise check compliance with local production regulations (which are advisory).
Sanitation and hygiene – there is a systematic checklist for sanitation and hygiene drafted by central government but adapted locally.

Completion – an inspection log is filled in during the inspection and signed off by the inspector and manager before leaving.

Finalizing – back at the office, data is logged on the information database, after any additional processing or checking is done, e.g. sampling test results.

3.20. One very experienced inspector estimated that only 30% of his time is spent on actual inspection in a business and 70% on planning, transport, reporting, training and other administration. However, he also considered training to be undervalued and proposed 60 hours mandatory training a year as continuing professional development for inspectors who deal directly with businesses. They should be trained in food safety risk and in understanding businesses. The UK “Trading Places” scheme of interchange between inspectorates and businesses seemed attractive to them.

3.21. Inspections may be done jointly with other supervisory bodies, especially from the primary production organizations. In Jilin Province, they said that joint inspections were only with these other bodies but in Heilongjiang they regularly collaborate in joint inspections with up to 16 agencies. Teams may be as large as 20 for a large organization. There was one of 38 but that was searching for dangerous food in a particular spot, rather than an inspection.

**Enforcement Policy**

3.22. There appears to be an “enforcement pyramid” approach\(^\text{19}\) to violations. All violations must be recorded and dealt with but also rectified. The first response is discussion with the business, which will include advice on rectification. It may also involve withdrawal or recall of products. Continuing failure leads to making the violation public through media, including the Party newspaper, the regulatory body’s newspaper and website and other media. Beyond that is punishment.

3.23. In the interviews, there was a belief that it is inspectors that provide safety through their supervision of businesses and, left alone, businesses would become more dangerous. However, on a blind vote, all the four inspectors in one interview considered that businesses are basically honest and willing to comply. Compliance improves with increased size of the business. Large businesses attract skilled staff, care about their reputation and can afford full compliance. The smaller the business the greater likelihood of non-compliance through the lack of these factors.

3.24. Businesses also respond to market conditions. Where there is a shortage, there can be a risk of adulteration in order to extend the available product or to falsify a product. Where there is a glut in the market, competition can drive non-compliance in order to gain competitive advantage. One experienced inspector estimated 30% of violations are intentional and 70% unintentional in Processing and 20:80 in Catering. Cross-contamination through bad practice in smaller businesses remains a key issue.

3.25. One inspectorate has a policy that if a new violation is found then it is looked for in other inspections and, if appropriate, guidance is issued to both inspectors and businesses in order to avoid it.

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\(^{19}\) See again Ayers and Braithwaite, op cit.
Organization of Inspection and Enforcement for Primary Production

Structures and Statistics

3.26. The Ministry of Agriculture operates at the national level but also operates within the Province through Quality Inspection Centres. As an illustration, there are none of these in Jilin for livestock but ten for agriculture, reflecting the overall production of the Province.

3.27. Under the Ministry in each Province there is a Livestock Bureau, an Agriculture Committee and an Aquaculture Bureau. Each has a Provincial, Municipality and County level Bureau. At township level, the Livestock Bureau has a Clinic whereas the Agriculture Committee has a Township Agriculture Committee. Each has a Technical Extension Station. These are also at each level. They include staff who disseminate guidance and staff who inspect and there is not much cross-over during careers.

3.28. The remit for the Livestock Bureau covers meat, eggs and milk at the stages of production and storage. Slaughter was added to the Livestock Bureau in 2014. During “production” of animals, they test urine from the live animals. They also have responsibility for animal health and welfare. Responsibility is only for raw materials and not any processed materials.

3.29. Taking Jilin again as an example, there are over 8,000 scale enterprises in the livestock sector and over 700,000 SMEs. A “small farm” has a minimum of 10 pigs, 5 cattle, 1,000 chicks or 500 egg-laying chicks, or 10 sheep. Anything smaller is not inspected. Jilin has 647 abattoirs, each with freezing facilities.

3.30. The remit of the Agriculture Committee is crops, vegetables, fruits, cash crops and herbs. It covers production and storage, except for granaries which are covered by the Grains Bureau.

Standards

3.31. There are two sets of standards – safety standards and production standards. Safety standards are mandatory and production standards are largely advisory. Safety standards can also include quality insofar as there are different standards for the quality grades of Pollution-Free, Green and Organic. Safety standards are set by the national level, usually by the Health Ministry.

3.32. Production standards prescribe production methods. They can be set nationally or at Provincial level or at corporate level. Provincial production standards can vary national production standards to take account of local factors, such as climate differences in the south and the north. If a company wants to do something different, it can develop a corporate standard for its own process, which is then mandatory within the company. It has no effect on anyone else but may be adopted as a Provincial standard.

3.33. Production standards are developed by research institutes and universities. Because they are not mandatory, they do not need legislation and legal effects. They are formalized by the Provincial Quality Supervision Bureau. They can be amended in the light of experience, every few years. There is no formal process for reviewing standards. It is up to the experts from the research institutes who spend time observing practice and are supposed to be sensitive to the effects of the standards.

3.34. The purpose of production standards is guidance on how to produce products safely, connecting with the mandatory safety standards for each product. Safety standards relate to specific products, rather than, for example, setting minimum levels of specific residues for all products. In addition, large companies can use GAP, GMP, HACCP, ISO 22000 but these are all beyond the capacity of small businesses and most cooperatives. The production standards can be seen as comprehensive guidance to small businesses on how to run their production, rather than as restrictions on large businesses (who can develop their own corporate standards anyway). All large businesses the team visited used quality management systems such as ISO9001 and food safety management systems such as ISO22000. One also had an environmental management systems certified under ISO14001 and one also had Halal certification. All had
QS but that was the minimum. It was claimed that surveys are carried out to see how well the production standards work with small businesses but presumably this is part of the operation of the academics involved in standard-setting.

**Supervision**

3.35. The primary method of supervision is testing of samples. Inspection is carried out by a team, with one checking document records, one taking samples and doing rapid tests and one checking a checklist for the production. The Ministry of Agriculture produce “the inspection file” which is the detailed checklist. Inspection includes giving advice, especially to small businesses. Inspectors are not there to sanction but primarily to take samples and a different part of their organization focuses on disseminating guidance. Small businesses are not sanctioned for violations of production standards (which are advisory) but if products are found to be unsafe, the products will be confiscated and destroyed, along with the relevant batch. This could involve destroying all of that small business’s products. This can also happen through traceability if an unsafe product is traced back to the small business.

3.36. Sanctions are set out in the Food Safety Law and the Agricultural Produce Quality Law.

3.37. The Ministry produces the national level plan for inspections. It is about types of products and not about businesses. It specifies how many types of products are to be tested for particular issues. It is primarily a plan for testing and wholly unrelated to businesses. It has many tables and covers indicators to be tested for, testing methods, types of businesses (e.g. abattoirs) and numbers of samples. Each Provincial Bureau then implements the plan by relating it to businesses. Municipality and County inspections also conduct spot checks in addition, including at the company but also products in free circulation which are then traced back to the primary production stage. But the Quality Inspection Centre (Ministry level) will also carry out inspections according to the national plan, with inspectors employed by the Ministry.

3.38. All scale enterprises will be inspected at least once a year. A “scale enterprise” is a business that requires to be registered, which depends on its size, number of staff, area occupied, equipment, production capacity. Beyond the single inspection, the Livestock Bureau then decides on further inspections at random, including drawing lots. The record of the business can affect that decision but there is not much to distinguish the businesses. Records were started in 2008 and in 2010 there were quite a few problems found but very little since then. A scale business that is found to have unsafe food is more likely to go out of business than continue with a poor record. So the ones left have pretty similar compliance records.

3.39. The Livestock Bureau estimate that an inspection takes between 40 minutes to an hour, with a team of four. The Agriculture Committee talked of covering 20 counties in two weeks, supervising the local governments and picking businesses at random.

3.40. The Agriculture Committee has a graduated approach to enforcement, starting with a reprimand, then a notification and finally a warning which is also circulated to other authorities. It requires all scale enterprises to sign a Letter of Commitment regarding compliance. It also has Letters of Responsibility agreed with the other administrative levels.

**Traceability**

3.41. Traceability operates with pigs, cattle and sheep through individual tagging and meat products can be traced back to a farm and to a batch of animals, although the Livestock Bureau claim that it can also be traced back to the individual animal. Chickens can be traced back to the batch. Milk is received at extraction stations from individual farms. The station keeps a sample of each and forwards the milk to the processing factory which also tests it can trace back to the station and then to the farm. But the traceability then starts again at the processing factory for the rest of the chain, with responsibility resting with the processing factory.
Risk focus

3.42. In Jilin Province, there is a very basic application of risk to inspection planning. The Agriculture Committee focuses on the more risky products. Crops like paddy and corn take a long time to grow and spend a long time in storage so pesticides and other residues can decompose, whereas vegetables, fruits and edible fungi have a shorter life and are more vulnerable to residues. Vegetables are their main focus because of inherent risk and of impact because 70% of the diet is vegetables.

3.43. Inspection planning focuses on the major vegetable growing areas. There will be four inspections a year on vegetables, fruit and edible fungi and also Specific Inspections in addition. These are based on seasonal factors. In Spring, they check greenhouses and film-covered areas. In Summer they look at open air land and in Autumn focus again on vegetables and fruit, especially ones for Winter storage. Routine inspections are done on grain, corn, paddy and soya, with a Specific Inspection for paddy in Summer.

3.44. A vegetable producer can expect one or two inspections a year but there can also be rapid testing spot checks – “fast detection”.

3.45. The Ministry of Agriculture has responsibilities that go beyond food safety. It is responsible for animal and plant health, not just as an element in the safety of food for humans but as a value in its own right. It therefore has its own risk analysis system, separate from the CFSA risk assessment system. The Provincial Food Safety Committee has a third. There is an intention to integrate them at some point. The Ministry focuses on risks to products whereas CFSA is looking at risks to humans. They also have an early warning system based on risk, which also allows quick response to an emergency.
4. Interviews with the Regulatory Staff

The team had the opportunity to meet a great variety of people from a wide range of regulatory bodies in five Provinces during its missions. Some provisional observations about the current Chinese system of inspection and enforcement can be drawn from the discussions with various counterparts in Provinces.

Risk-based approach to inspections and enforcement

4.1. One of the main areas in which the team suggests further development is in applying risk as a primary basis for inspection activity – the “risk-based approach to inspections”. Under this, each business is given a risk rating and the frequency of inspection depends on the level of risk, with high risk having more attention. At the start of the visits to the Provinces, the team was looking for any aptitude for applying a risk-based approach, but by the end it was observing what seemed to be well established risk-based systems.

4.2. Throughout the visits, the team has been looking for aptitude, rather than operational systems, in order to see where lessons from international practice could best make a contribution. The team would expect to see some cases of low capacity in terms of individual inspectors and systems, but if it were to see ability, aptitude and even operational risk-based practice then that would be positive. Accordingly, there was no attempt to make an assessment of how far a risk-based system has been developed or how much capacity there is in individual inspection teams, but instead this summary of observations looks at potential for further capacity building. The results of the survey itself will give greater depth of evidence to make a broad assessment.

4.3. In Heilongjiang and in Jilin, the team had detailed conversations with front-line inspectors. These were probably the best inspectors, and they showed how experienced inspectors think and how they see their job. They did not talk in terms of risk but the practical approach they took to their job was in various ways consistent with the risk-based approach applied in many other countries. At a basic level, it appears to be a fairly universal approach to similar problems. Experienced inspectors know where the main problems are, understand why these problems exist and, in many cases, will be sympathetic and supportive to businesses that try to improve their performance. They also see that dealing with the people is as important as testing the products.

4.4. That suggests that a more expressly risk-based system should not create difficulties for many inspectors and is likely to be welcomed. The Food Safety Law is moving towards more open discussion about risk as a basis for inspection and enforcement so this is a move that will happen and is one where international experience from applying such a system in many other countries can help.

4.5. The challenge is that the application of the risk-based approach will have to compete with other innovations. It is more difficult to change ways of thinking about inspections than it is to install technological solutions. At the management level in Heilongjiang and Jilin, there was some understanding of the risk-based approach but also a desire for technological answers, especially portable rapid-testing equipment. In Jilin, senior management is very innovative in its approach to enforcement, as illustrated by its growing use of video-cameras in kitchens, and that may make it easier to adapt to a new approach. In Heilongjiang, senior management was aware of the need to develop risk profiles of businesses in production and distribution, because of the Food Safety Law, but specifically asked for help in how to develop these profiles. A willingness to adopt new approaches still needs to be supplemented by training. Most enforcement bodies in China have experience of applying an A, B, C, D rating to catering businesses but not to production and distribution.

4.6. In Shandong, the team had less direct engagement with inspectors and most contacts were with bodies coming under the Agriculture Committee, rather than the FDA. However, the team was pleased to observe the close working relationship between the two regulatory bodies. The team did also have one very useful discussion with the senior management of the Provincial FDA. They showed a clear understanding of the risk-based approach and were also concerned about the impact that inspections have.
When discussing the role of inspections in dragonhead companies, it was recognized that they had to think carefully how they could add value to the operation through inspection and they saw the answer as identifying weaknesses in management systems, rather than looking for technical violations. These companies are fully focused on safety, especially the exporting ones that have to be compliant with multiple regulatory systems, and rely on the quality of their management to maintain compliance and cost-effective safety. The Provincial FDA manager saw that as the appropriate level of engagement for a high quality enforcement service.

4.7. In Sichuan, there was some evidence of risk being important to operational decisions. A County level senior manager in Distribution saw the main problem as being with the smaller businesses and that was where he tried to focus resources. In his view, the bigger the company the better the compliance and the less risk, therefore these companies were urged to maintain their compliance levels, but the main efforts were in supporting the smaller businesses into higher levels of compliance. A discussion with another County FDA established that they had been operating an A-C risk grading system since 2009, where any business scoring D would soon be eliminated. The Provincial FDA Director claimed that all businesses have had a risk rating for many years, but this may apply only to the catering operations, as is the case in other provinces, or perhaps some counties are more advanced than others. He also said that inspectors use checklists when conducting inspections but he acknowledged that there will be room for improvement in both the risk rating systems and the checklists.

4.8. In Fujian, however, the Provincial level FDA described a comprehensive risk-based system which has been the basis of its approach to inspections since 2010. All businesses (other than in distribution) have a risk rating and that determines the frequency of inspection, which is taken into account in the primary inspection plan, as well as in any discretionary additional inspections. The risk criteria for allocating a risk rating had the main factors that would be found in other countries experienced in a risk-based approach, apart from the level of potential impact, i.e., how many people might be affected by something going wrong.

4.9. Even if a risk-based approach were to be adopted, it still has to be balanced with the product testing. Although final product testing has been abandoned by most risk-based systems used in developed countries as a method of control, there is enough of an established danger in many raw materials being contaminated at primary production stage due to overuse of agrichemicals, antibiotics or pollution that China will need to maintain a more extensive testing regime than other countries. However, risk analysis can still be applied to sampling and product testing, rather than trying to test as much as possible, and this is an area of operation that will require further study and discussion. The team observed too many cases of testing of end-products, taken from the retail stage, which have no preventative value because they come far too late in the chain. To be effective, testing needs to be done before the product is subject to further processing, such as the stage of raw materials entering a processing plant. Testing also has to be appropriate to the stage of processing, yet the team came across cases of samples taken at the end of a processing operation being tested for elements that could not have been added at the processing stage, e.g., pesticide residue. There is a concern that the current system may be either inefficient or ineffective (or both) in its approach to testing, and application of a risk-based approach to testing could improve the system.

4.10. It may be that further study from Fujian Province could demonstrate how best to find that balance, through their experience of both systems. Such study should also look at who does the testing. In developed economies, there is still an enormous amount of testing carried out, but it is done by the producer and not by the State. As part of the principle of producer responsibility (which the Food Safety Law is also promoting), the producer does its own testing as a matter of routine and testing by the State is only done for confirmation if the inspector has reason to challenge the safety of a product. Such a change would have a significant economic impact because of the current levels of State investment in laboratories. However, many of these laboratories are also providing testing services to the private sector so, for them, it may be an opportunity to obtain a higher level of financial support and allow expansion and improvement of standards and services.
4.11. **There may be instances where inadequate food standards create impediments to market access, because they were outdated or not evidence-based.** One example was observed in Fujian, where the standards for tea included unreasonably low thresholds of rare-earth metals – not fully justified by risk assessment. Such a situation highlights the necessity to

- plan for enhanced coordination between food safety regulatory partners locally and nationally and
- follow a “life-cycle” approach in food regulatory development.

By “life-cycle” approach, we mean that the implementation of regulatory requirements by enforcement agencies on the ground may lead to identifying issues which call for the intervention of other players in the food safety system e.g., food risk assessors, as demonstrated in the instances of inadequate standards for maximum levels of rare earth elements in tea, witnessed in Fujian Province. These standards set earlier need to evolve (as part of a life-cycle) involving a risk assessment and an updated impact evaluation. It will be important that food regulators plan for such interventions when considering the implementation of food regulatory provisions.

4.12. **In summary, there is evidence of a risk-based approach to inspections already being applied at different levels in different Provinces.** It is clearly not an alien concept operationally, and therefore it should be capable of being applied successfully. Where international practice can help is in refining the approach in those Provinces where it is already established, especially in terms of risk criteria for allocating risk ratings, database systems for recording risk profiles and development of checklists for different types of inspection.

**Focus on results through co-governance**

4.13. **Determining inspection and enforcement systems on a risk basis goes beyond using risk to allocate resources through inspection plans.** It includes being focused on results and outcomes rather than on process. An effective enforcement agency will measure its success in terms of final outcomes rather than operational inputs. That is, it will seek to reduce the amount of food-borne illness, strengthen the internal control systems used by producers and also work with consumers in order to deliver results. This is in contrast to measuring the number of inspections, violations and penalties. An enforcement agency focused on results will look for ways of working with partners – local government, other agencies, consumers and also the businesses themselves. This is all included in the concept of social co-governance that underpins the China Food Safety Law and is also good international practice.

4.14. **There is no doubt that China needs to get tougher with food processors and retailers, partly because of the low level of penalties and partly because of the low capacity of businesses.** The new Food Safety Law now has penalties that are sufficiently high to act as a deterrent to deliberate violations. At operational level, there is a limit to the usefulness of deterrence. In most countries, the common experience is that the great majority of businesses are willing to be compliant but face various barriers to compliance. These include compliance costs but also capacity, whether in terms of awareness, understanding or skills. In these cases, deterrence is irrelevant and penalties do not solve the problems. In these cases, the businesses need support to overcome the barriers to compliance and for overall compliance levels to rise. Best international practice is to focus on compliance management rather than coercion and to work in partnership with businesses rather than in confrontation.

4.15. In Heilongjiang, the mission team asked a group of inspectors to vote whether they thought most businesses were deliberately dishonest or whether most were prepared to be compliant but faced problems in doing so. They all chose the latter. The County FDA in the distribution sector in Sichuan mentioned that the main effort needed was with small and medium businesses that had capacity issues, and he said his task as helping them into compliance. Also mentioned above, in Shandong the Provincial FDA saw it as a challenge how their inspection activities could help large international businesses. In Fujian, the Vice President of the Provincial FDA made a presentation in which she was acting as advocate for the local tea industry.
4.16. These are all good examples of enforcement agencies recognizing the benefit in working with businesses in support rather than confrontation. However, the development of compliance records for each business is also intended as a further deterrent, through the intention to publish compliance records online so that consumers and the general public can be informed of the compliance record of any business. For a business with a good record, this can be a benefit and perhaps even give some competitive advantage, similar to the “Smiley Face” scheme in Catering, so it is not wholly a “naming and shaming”, coercive approach. But developing these compliance records is also demonstrating that the enforcement system is giving much greater recognition to the importance of the business as opposed to the product. The previous approach used in China was to focus on the products, with businesses having a secondary importance. The international approach is to put the business at the center of enforcement since it is the business that has control over the food and therefore it is what the business does that increases or weakens safety.

4.17. Co-governance is also vital between enforcement agencies, with the bodies under the Ministry of Agriculture, those under the CFDA and also AQSIQ needing to collaborate in order to deliver results. At national level, collaboration is also needed with the Ministry of Health and Family Planning Commission for the purposes of risk assessment. Collaboration is needed in determining standards at national level and also to some extent at Provincial level but collaboration is also vital at operational and enforcement policy level. The approach taken to enforcement should be consistent across primary production and then through the rest of the value chain.

4.18. The team saw good examples of collaboration at the provincial and county levels – between FDA and Agriculture Committee bodies in Shandong, Sichuan and Fujian. In Sichuan, it was noticed that representatives from each agency were not seated in their groups but were comfortably mixed around the table. There was a greater separation at plenary meetings in Jilin and Heilongjiang but the team was assured that in each of these Provinces joint inspections are very common, showing strong operational collaboration.

4.19. Co-governance is also necessary to provide a responsiveness to the priorities of the local government. This can be a significant issue in many countries, where a desire to centralize inspection and enforcement in a vertical model does not fit well with managing horizontal relations with local government. There can be political interference in operational decisions for personal or commercial gain because the local government does not consider itself a partner in delivering the regulatory results and therefore not accountable for these results. The Food Safety Law requires collaboration between enforcement bodies and local government, and the extent to which this will be implemented to give greater local autonomy or whether a more centralized approach is taken is one of the strategic implementation decisions still to be taken by CFDA.

4.20. Best international practice tries to find a balance between national and local priorities and tries to be responsive to local needs. This also depends on the quality of the local government and the accountability of inspectors, i.e. whether they are employed by the local government or by a national government body. The best example seen of close cooperation between the County government and County FDA was in Anxi County in Fujian, with the Deputy Mayor being an integral part of the local/provincial food safety team.

Risk Communication

4.21. Compared to other developed countries, there are still relatively weak links with consumers. One of the implications of a greater focus on businesses, rather than products, as the central factor in food safety is that consumers have a very powerful role in the food safety system in holding businesses to account. They do this through their buying choices, to the extent that a business should be much more worried about its customers than about its inspectors. Where enforcement agencies can work with consumers, they obtain far greater leverage and control over businesses than just using inspectors. Chinese consumers have been very responsive to negative information about food businesses, to the extent that
the dairy industry has still not really recovered from the melamine incident. But that is not healthy for the dairy industry and shows how the relationship with consumers requires more careful management.

4.22. **Risk communication is another aspect of applying risk to the delivery of regulatory results.** At one level, it is about awareness raising and education of businesses and consumers about the realities of food risks. To that extent, it fits with co-governance with businesses and compliance management. It also fits with working with consumers.

4.23. But risk communication is also about crisis management. There are some who say that risk communication is only valid during “peacetime” and does not apply to crises. But a major feature of Chinese food safety is food safety crises. The melamine scandal was only one incident, yet the media have been trying to find similar dramatic stories ever since. The messages sent during these crises wipe out calmer messages in “peacetime” and strengthen the overall message that Chinese food is generally unsafe because Chinese businesses cannot be trusted. The reality is somewhat different but it will be difficult to convince the skeptical public.

4.24. The team did not have an opportunity during the visits to the Provinces to discuss the impact of risk communication in a crisis, but it is an important element in an overall risk-based approach to delivering regulatory systems. Both the UK and the Netherlands have had programs devoted to how to help politicians handle crises in a way that does not lead to negative impacts on business sectors. The impact on the dairy industry of the handling of the melamine scandal is still negative, so this may be another area in which international experience can benefit the Chinese system.

4.25. At a simpler level, the risk communication message was demonstrated in various Provinces through two factors. First, in Sichuan and Fujian, when asked to identify the main hazards facing food safety in the Province, the Provincial and County FDAs were quick to identify capacity issues in small and medium sized businesses (after the primary hazard of contamination of raw materials). Second, they were also able to outline the programs they had to reach out to these businesses in order to strengthen internal control systems and better basic hygiene. But in Jilin and Heilongjiang there is also a high level of support being given to small farmers by the bodies coming under the Agriculture Committee.

4.26. **The picture of food safety in China as presented by the media in relation to scandals in the food industry is not reflected in reality.** The media emphasizes largely the negative messages about the level of food safety whereas there are many positive messages which go ignored. What there has been evidence of – and this does not mean that it is common practice across China – is some good, or even high, capacity in senior management and at least some strong capacity at inspector level that recognizes the realities of regulatory enforcement systems:

- They recognize that what matters are final outcomes, which is what gives them professional satisfaction.
- They recognize that most businesses are not dishonest but their honesty levels need occasional encouragement or practical help.
- They recognize that the results from product testing come from what people do and not from a table of statistics.

4.27. The above observations do not mean that international practices are automatically valid in Chinese context, but it encourages the view that experience from international practice can benefit not only the current Chinese system but also the direction that the Food Safety Law is taking China.

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20 For a very recent Handbook on Risk Communication applied to Food Safety from FAO / WHO, see - http://www.fao.org/3/a-i5863e.pdf
5. The Survey Results

Enforcement Policy

The Inspectors’ Perceptions of Businesses

5.1. Fundamental to the Responsive Regulation approach is the actual attitudes of the businesses in a particular country. The image of Chinese food businesses that is often reinforced in the media is one of dishonest or even criminal businesses that endanger their customers but that is unlikely to be the reality. The survey of those involved in the enforcement system is better evidence of the attitudes of Chinese food businesses since the respondents in the survey work with them every day.

5.2. The methodology and the survey size is set out in Annex B to the Report. It is enough at this stage to say that this was a survey of the attitudes of those involved in enforcement and it covered four levels of staff, at different levels of government from Provincial to Township, across five Provinces. The numbers alone are not statistically significant but that is not the point of the survey. What is looked for in a survey of attitudes is not numbers but consistency. If similar attitudes are found across a wide range of respondents, the results are valid.

5.3. The respondents were given the four categories used in Responsive Regulation (Criminal, Opportunist, Willing To Comply, Compliant) and asked to rate the businesses they deal with according to these categories. There was a very high degree of consistency. Overall, 94% of respondents see Chinese food businesses as Compliant or Willing to Comply. The Criminal category came out at 1%. This is an extremely encouraging result. It shows that, in the view of those working with them every day, Chinese food businesses are basically honest and trying to get it right. That has enormous implications for planning the implementation of the new Food Safety Law and fully justifies the proactive, supportive approach in Article 36.

Figure 5. Perceptions of Compliance – Overall

5.4. The survey was designed to probe further into attitudes in order to be more confident that the answers were genuine and not what the respondents thought was expected as the “right” answer. There are many statements in the data about the great majority of businesses being honest and largely compliant. Question 12 was designed for a slightly different purpose but the actual responses had many statements about the majority of businesses being compliant. Where there is a rating scheme (which was the original purpose of question 12), the majority seem to be in category B (where A is the best out of A, B, C and D).

5.5. That overall figure of 94% is an average across the Provinces, which break down as follows:
Table 1. Perceptions of Compliance by Province

<table>
<thead>
<tr>
<th>Province</th>
<th>Compliant</th>
<th>Willing to Comply</th>
<th>Opportunist</th>
<th>Criminal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heilongjiang (97%)</td>
<td>46</td>
<td>51</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Jilin (93%)</td>
<td>41</td>
<td>52</td>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>Shandong (95%)</td>
<td>57</td>
<td>38</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Fujian (90%)</td>
<td>55</td>
<td>35</td>
<td>7</td>
<td>3</td>
</tr>
<tr>
<td>Sichuan (95%)</td>
<td>57</td>
<td>38</td>
<td>4</td>
<td>2</td>
</tr>
</tbody>
</table>

5.6. The variation in overall percentages of those Complaint and Willing to Comply is small (7%) and it is remarkable that they are all at least 90%. This is not just a majority of results indicating the enforcement staff’s combined perception of business but a very clear indicator of a shared perception. When looking at the split between Compliant and Willing to Comply, there is a mixture of results. The highest percentage of the combined score, from Heilongjiang, has the majority within that combination being only Willing to Comply whereas the next highest, from Shandong, has those actually Compliant in the majority.

5.7. This result was also analysed according to the size of the business. Large businesses were seen as the most compliant and micro as the least. Aggregating all Provinces, 80% of Large businesses were seen as already being Compliant and 62% of Medium businesses. The number of those Willing to Comply increases significantly as the size of business decreases and this shapes the challenge facing the enforcement agencies in raising overall compliance levels. Little needs to be done with those in the Compliant category and those in the Opportunist category are probably not worth bothering about. The tiny Criminal element still needs attention but of a different sort. The real challenge, in terms of delivering maximum public benefit, is moving the Willing Comply into Compliant, and there the main challenge lies with Micro businesses.

Figure 6. Perceptions of Compliance by Size

5.8. These results were also tested by Question 21, which asked whether the violations found were deliberate or unintentional. Although there were slight differences across the Provinces, the overwhelming majority of violations were seen to be unintentional, which also supports the view that the vast majority of businesses are either Compliant or Willing to Comply. The results of this question exclude the compliant businesses and are looking only at where violations have been found. Across the Provinces, there is also a slight convergence of these results from Large down to Micro, i.e. there is a slightly greater number of deliberate violations in small and micro businesses than in large and medium.
5.9. The variation across the Provinces is not significant insofar as the same overall graph applies, i.e. a large gap between Unintended and Deliberate at Large, narrowing slightly towards Micro. The most extreme version of this was from Fujian, as shown below:

**Figure 8. Unintended and Deliberate Violations – Fujian**

5.10. These figures were also broken down across the types of activity, which showed very little difference:

**Figure 9. Unintended and Deliberate Violations by Type of Activity**

5.11. “Deliberate violations” do not mean criminality. Where compliance costs are too high, the business may consciously violate a requirement that it cannot afford to comply with. This might include structural changes to the premises that are required for hygiene reasons. It is not the same thing as deliberately poisoning food. Clearly the inspectors do not see it as criminal since the overall results show that only 1% of businesses are seen as criminal. It is also clear that the incidence of deliberate violations increases as the size of business gets smaller which is probably because of the higher impact of compliance costs. The main message from these results is to identify very clearly a major target for capacity-building, namely helping those willing to comply into compliance. That is a message both for the business side and for the enforcement side, where resource is needed in the enforcement staff finding better ways to support businesses into compliance.
5.12. “Compliant” may also need some qualification. It is unlikely that inspectors consider that the “Compliant” businesses are 100% compliant. It is fairly rare to find such perfection. In 2008, the UK government adopted the concept of “broadly compliant” when looking at food businesses and set targets for increasing the numbers of businesses being “broadly compliant”\(^{21}\). In terms of regulatory systems, this is usually good enough to deliver the regulatory outcomes. The inspectors in this survey are likely to have adopted a similar assessment when distinguishing between those Willing to Comply and those judged to be Compliant.

5.13. These results refer to the perceptions of the respondents and are not a statement of actual levels of compliance. However, these are the people who test compliance every day so their perceptions should be a reliable guide to the actual compliance levels. In terms of measuring compliance, the best measurement is through inspection results. In a sense, an inspection system is also an ongoing survey of business compliance. The respondents did not have their own data to consult when answering the questionnaire therefore these results are still perceptions rather than data drawn from the records of the enforcement bodies. Although such data would give more accurate figures on actual compliance, division into the remaining categories of Willing to Comply, Opportunist and Criminal can only be a matter of perception. It is worth repeating that what this survey was seeking to assess was the capacity of the current enforcement system to move to a risk-based and business-focused system, rather than being a statistical study of business behaviours.

5.14. It is difficult to find actual figures for levels of compliance with food regulations in other countries but the UK has been gathering data on this and publishing it for many years, through the Local Authority Enforcement Measurement System (LAEMS). When the concept of “broadly compliant” was first applied in 2008, the percentage of broadly compliant food businesses was 86%. In 2014-2015, the figure was 93%\(^{22}\), which is very close to the average perception of the Chinese inspectors in this survey.

**Attitudes to Punishment**

5.15. Question 22 was designed to assess the enforcement staff’s attitude to punishment. The traditional approach to inspections and one that still holds popular appeal to the public in most countries is the approach of “catching bad guys”. It is similar to a policing function. It is also tied up with the idea of imposing punishment as the outcome of a successful inspection. This is also the view that comes across from much of the popular discourse in Chinese media on food safety issues. The danger is presented as companies that deliberately poison food for profit and must be stopped and punished. The new Food Safety Law significantly increases many penalties for food safety violations, which is justifiable when looking at the fairly low penalties that existed previously, but it also rewards “whistle-blowers” and others who bring to the attention of the authorities businesses that are violating the law.

5.16. It was argued above that the main effort in making regulatory systems work is in increasing compliance rather than reducing cases of non-compliance, which runs counter to the approach of maximising punishment. The level of punishment is a measure of the failure of the regulatory system, not its success. The better measure of success is the level of positive compliance. Punishing a business for non-compliance without also ensuring that the violation is remedied does not deliver the regulatory outcomes. It is the remedying that matters. But imposing punishment may also be important, as an additional incentive to be compliant.

5.17. Question 22 gave respondents three choices in how to deal with a violation:

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\(^{21}\) “Broadly Compliant” is equivalent to scoring between a 3 to a 5 on the Food Hygiene Rating Scheme, which goes from 0 to 5, with 5 being outstanding.

• Advise them on how to remedy it;
• Impose a penalty for the violation; or
• Both.

It was expected that most respondents would choose “Both” but the question was designed to see how many would choose either of the other two alone. The vast majority did indeed choose “Both” but there were many who chose only punishment and many who chose only to advise on remedies. Of these, around twice as many chose advising on remedies than chose punishment. What this shows is that there are still many enforcement staff who believe in the traditional view of catching and punishing bad guys. It also shows that there are many who see their job as supporting compliance rather than punishing. So both the traditional and modern attitudes are represented.

Figure 10. Responses to Violations

5.18. Answers to Question 25 supplement this. That was an open question, asking for a description of what constitutes an effective inspection. There were many answers that referred only to punishment and a few that talked about helping businesses raise their compliance levels. The picture that emerges is of a group already in transition from one approach to another, with a mix of attitudes. What is encouraging is that the vast majority chose “Both” in question 22.

Conclusion on Enforcement Policy

5.19. The Food Safety Law is a mixture of deterrence and support, encouraging consumers to identify bad practice but also providing for a proactive delivery level at County government and above. The perceptions and attitudes of enforcement staff are fundamental to the success of a policy of supporting compliance and the survey of enforcement staff in five Provinces shows that they are already sympathetic towards the food businesses they deal with. This provides a sound foundation for enforcement staff working with businesses to raise compliance levels and ensure the success of the new regulatory system. In terms of further capacity building, the clear area of need is in helping these businesses overcome whatever the current barriers to compliance are, with support from the enforcement bodies.

Technical Aspects of Enforcement Systems

Streamlining Administrative Structures and Coordination

5.20. Locating Food Safety within government structures is always challenging because food connects with so many aspects of government. There is no single model that stands out as the best way to do it but, looking across international developments in the last 20 years, the following picture has emerged:
• It has become common to create a specialized agency for Food Safety. The US model of a “Food and Drugs Agency” has been followed in a small number of countries but of the 28 Member States in the EU, 16 have created specialized agencies focusing on Food Safety.

• There is no single model for a specialized agency but it is very common for it to deal only with the food chain beyond the primary production stage, leaving Food Safety enforcement at primary production to the agriculture Ministry (as is the case in China).

• These specialized agencies may also cover an additional subject, such as Drugs (China, US, South Korea), Veterinary Services (Canada, Iceland, Romania and Lithuania), non-food product safety (Netherlands) or even Environmental Protection and Occupational Safety (France).

• Some specialized agencies have policy responsibility for Food Safety and also responsibility for delivery. Some employ inspection staff directly and others work through local government staff. The size of the population is crucial. It is only in relatively small countries that enforcement staff are directly employed by the national agency (Canada, Netherlands and Greece) and it is more common for the national agency to direct and delegate enforcement to local government (China, Australia and UK) or, in federal countries, a mix of Federal and State level (USA).

5.21. China’s re-structuring of Food Safety responsibilities across all levels of government has built on international experience and, once the restructuring is fully completed in all Provinces, it will have a remarkably simple structure, given the size and complexity of public administration in China.

5.22. The alternative to creating specialized agencies has been developing systems of coordination of enforcement bodies or functions. But these are also needed even where there has been streamlining, in order to coordinate between Food Safety and other public safety regulatory systems. One of the best has been the Dutch “Domain” system23 which organises enforcement bodies locally around a topic (North Sea Mining) or a place (e.g. Schiphol Airport), rather than a single regulatory system. The UK has created a specialized government Directorate - Regulatory Delivery24, in the Trade Ministry – with the express task of coordinating regulatory delivery at ground level. But the Chinese system of Food Safety Commissions is also amongst the best practice for integrating Food Safety enforcement with other safety and community issues and for bridging the gap between primary production and the rest of the food chain. There is a strong tradition of joint inspections between inspection teams on either side of the farm gate. The model of having these coordination committees at each level of administration is unique in large countries.

The Risk-based Approach to Enforcement

5.23. Although China has in the past relied heavily on product testing as an approach to ensuring food safety, it has developed disciplines in the field of enforcement that will make it easier to adapt to a risk-based, preventive approach to enforcement. In the rest of this section, what is being explored is the degree of discipline applied to enforcement activities, even although these activities are not the risk-based activities that they need to move to under the new Law. Skills in planning workflow can be applied to different activities that constitute the work and it is that sort of capacity rather than the work activities themselves that this section is mainly concerned with.

5.24. Risk-based planning is a way of focusing resources on where they will be most effective, by identifying the areas of greatest risk. Businesses are seen as the main source of risk, rather than products,
since businesses control the products. They may control them through processing them into new products, through using them to provide meals, through selling them to the public or even through how they transport or store them. The level of risk presented by a business also of course includes the level of risk in the food products it works with so this approach does not ignore the importance of the risk levels of food products. However, it treats that risk as only one of a collection of risks that together make up the risk profile of a particular business. The main factors usually used to determine the risk level of a business are:

- the risk level of the food product and the risk level of the process applied by the business;
- the extent of potential damage that could be caused; and
- the compliance history of the business.

5.25. A food business that processes milk into other dairy products will score a high level under the first category whereas a food business that only sells pre-packaged dairy products from a chilled compartment will be low risk. A bottling plant for drinking water may be high risk, not because of either the risk in the product or the process but because a very large number of people would be affected if anything goes wrong. Both of the first two criteria combine to form the magnitude of the potential risk whereas the compliance history provides the probability of the risk materialising. The compliance level of the business can include the overall quality of management and of management systems, both quality management systems (such as ISO 9001) and food safety management systems (such as HACCP). Ways of defining the risk criteria for awarding a risk profile to a business vary across countries but they broadly follow the approach set out above. The common factor is that what is seen as the primary object of inspection is the business and not the product.

Risk-based Planning

5.26. The risk-based approach applies to both testing and to inspections. By targeting where the resource is best applied, better results can come from fewer resources. But all this requires careful planning. So planning of enforcement activities is vital to an effective enforcement system. China already has a highly disciplined planning system for inspections and for testing, which is an enormous advantage.

5.27. Question 15 of the Survey asked what percentages of inspections in a typical year are planned and unplanned. This is the test of whether there is an effective planning system in practice. There will always be some unplanned inspections because new situations arise during the year that cannot be foreseen but there are many other factors as well. The primary one is responding to complaints from the public. This may be a useful source of intelligence but more often it is a distraction from risk-based planning because it relates to low risk businesses. The best example is street traders who are very visible to the public and often the source of complaints but they are low risk in terms of public health because each street trader affects a small number of people. Cumulatively, they are more important but that cumulative risk cannot be dealt with effectively by individual inspections. There has to be a system for responding to complaints from the public but that should not always require an official inspection or even anything using inspection resources. A complaints-based system is the opposite of a risk-based system and there exist in some countries risk-based systems that have become complaints-based in practice.
5.28. The aggregated answers over the five Provinces to question 15 show a ratio of 72:28, which shows good discipline. The reasons for unplanned inspections were given as follows:

Figure 12. Reasons for Unplanned Inspections

5.29. Complaints are the main reason, at 38% of the unplanned inspections, but that is well controlled in terms of the overall planning system. The planning system itself is not fully risk-based but adjusting to a risk-based system is much easier when that discipline is there. The breakdown of the figures across the Provinces is shown below:

Table 2. Planned:Unplanned Inspections by Province

<table>
<thead>
<tr>
<th>Province</th>
<th>Planned</th>
<th>Unplanned</th>
<th>Public Complaints</th>
<th>Seasonal events</th>
<th>Unforeseeable events</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jilin</td>
<td>80%</td>
<td>20%</td>
<td>37%</td>
<td>39%</td>
<td>11%</td>
<td>5%</td>
</tr>
<tr>
<td>Shandong</td>
<td>68%</td>
<td>32%</td>
<td>44%</td>
<td>31%</td>
<td>13%</td>
<td>12%</td>
</tr>
<tr>
<td>Fujian</td>
<td>73%</td>
<td>27%</td>
<td>37%</td>
<td>38%</td>
<td>20%</td>
<td>5%</td>
</tr>
<tr>
<td>Sichuan</td>
<td>63%</td>
<td>37%</td>
<td>47%</td>
<td>23%</td>
<td>15%</td>
<td>15%</td>
</tr>
<tr>
<td>Heilongjiang</td>
<td>79%</td>
<td>22%</td>
<td>26%</td>
<td>29%</td>
<td>22%</td>
<td>28%</td>
</tr>
</tbody>
</table>
5.30. The variation is between 80:20 in Jilin and close to 60:40 in Sichuan. In Sichuan’s case, the percentage of unplanned inspections due to complaints is very high, as it also is in Shandong which has the second lowest ratio. Managing complaints appears to be the determining factor. The new provisions in the Food Safety Law on encouraging complaints may change these performance figures if both the numbers and the profile of complaints increases.

5.31. It is interesting how little effect “unforeseeable events” have on the figures. These can include new intelligence about hazards or even new hazards, plus new businesses starting up. A very low score in this category may raise questions about the quality of risk assessment and flexibility of the planning to adapt to changing circumstances. It is also interesting to see how significant “seasonal events” can be. In a sense, these are not unplanned in that the type of events and their timing are predictable but what may be difficult to plan is the detail. Food businesses spring up to feed large numbers of people suddenly coming together for events so although the events may be predictable, the actual businesses involved may not be.

Classification of Businesses

5.32. Questions 10 to 13 looked at the actual planning system, asking first whether there is a classification of food businesses based on their performance. The next asked what classification of businesses is used if not based on performance. The third then asked which classification applies to the majority of the businesses they cover. Finally, respondents were asked to set out their priorities for inspection.

5.33. The first question relates to a fact, i.e. whether there is a system of classification according to performance, and the great majority responded with “Yes”. It is interesting that a few responded with a “No”, indicating that perhaps a different system applied to them. The answers to Question 11 on different types of classification revealed some interesting views. They were not all simply where they had answered “No” to question 10, with some volunteering to describe their classification system. Where systems were described, there appears to be quite a lot of confusion about how exactly it works. In Shandong, for example, one said that there are four levels of classification for processing businesses and another said five levels for processing. Some gave a good and concise description of risk-based planning, such as this one from Shandong:

*Have preliminary judgment of a food manufacturer’s risk level through food risk classification and the company’s ability in production management. Then adjust the level according to its record of food safety and quality.*

5.34. The answers to these questions again show a system in transition. Some of the confusion may be due to the scale of the recent mergers of bodies and consequent mergers of staff from different backgrounds and different professions. They may be correct in describing conflicting classification systems in that their organizations have still to settle the system, rather than giving “wrong” answers. But the system of classification is also going through change. Catering businesses have had a risk-based classification for a few years now but it is only recently that this approach is also being applied to Distribution and Processing. The introduction of these new classification systems may be proceeding at different speeds in different Provinces or even within Provinces. There is not enough uniformity in the responses to construct useful charts. Instead the main message is to note the variation expressed by the respondents but whether that should be ascribed to the respondents or whether that indicates administrative flux is unclear.

5.35. The answers to Question 12 were both surprising and insightful. The question asked which class within the classification system applied to the majority of their food businesses. The most common answer was a variation on “compliant”. That is not part of the classification but it is a strong indicator that the earlier answers on perceptions of businesses are genuine. Many respondents gave a rating, e.g. “mostly B”, which is the sort of answer that was being looked for, but those answering either mostly A or mostly B were also confirming either Compliant or Willing to Comply. Some answered according to the
type of business, e.g. catering or processing, or the size of business. Again, this type of response to question 12 was found in all five Provinces, showing that most respondents interpreted it as asking about the compliance levels of the businesses.

5.36. Question 13 asked “When you are making the annual inspection plan, how do you prioritize which food businesses to inspect?”. The answers were a mixture of prioritization according to risk, compliance record, size of business, nature of the food, formal classification or no prioritization at all. Prioritization according to risk included both references to risk classification or to levels of danger to the public, including vulnerable groups, e.g. high volume production, such as bottled water, or canteens in kindergartens. A particularly interesting response was this one from a Manager at County level in Heilongjiang:

“1, level 1 – high risk: department stores and supermarkets that larger than 6000 m2, wholesalers that have storage area larger than 2000 m2, bulk food sellers that have been warned or punished in the past year, enterprises that were punished to close down or revoke license in the past 2 years, enterprises that were punished twice in the past year; 2, level 2 – medium risk: business area is less than 6000 m2 and more than 500m2, food additives business, dairy business, edible oil business, bulk food business, food business within 100 m2 distance to schools, been punished in the past 2 years, been ordered to rectify in the past year; 3, level 3 – low risk, all others.”

5.37. This refers to a 3 level system of risk applied to Distribution, which is different to the more normal A – D system. It is a very detailed answer (and illustrates how seriously many of the respondents took the exercise) with a mix of size, nature of food and compliance history for each of the levels. This looks more like a summary of the respondent’s understanding of the system than copying out an official guide (which was noted in some answers across the Provinces). It captures some of what is involved in risk assessment of businesses although the actual risk criteria are not what would be recommended. It demonstrates more an aptitude for risk management than a command of risk management.

Announced and Unannounced Inspections

5.38. Question 18 asked whether inspections are usually notified in advance.

5.39. Probably the most highly contentious issue with regard to inspections and enforcement in any country is whether inspections should be notified to the business in advance or should be unannounced. Having a planning system allows notification since the inspection is scheduled anyway. The argument in favour of not announcing an inspection is that the inspector will see a more realistic and accurate picture of the operations of that business. This view is strongly supported by FAO for food safety inspections (and by the International Labor Organization for occupational safety inspections) and is mandatory under the EU system. The contrary view argues that inspections are disruptive to businesses and can be inefficient if the correct staff are not available. Since most businesses are usually trying to be compliant, inspections should be a partnership approach to raising compliance levels and not adversarial. If a business gets everything in order because it knows an inspection is coming, then it seems odd to see that as in some way cheating. Experienced inspectors can also tell what has been done for show and what underlying problems remain.

5.40. There are arguments both ways and their validity really depend on the type of business and the violations being checked. Using child labor is something that can be covered up with warning of an inspection but running a full HACCP operation in a large processing businesses is not something that can be switched off and on. Underlying the debate, however, is often an assumption about whether businesses are honest and deserve consideration or dishonest and need to be caught out.

5.41. The overwhelming response across all five Provinces was in favour of unannounced inspections. This came not only from the answers to this question but also the answers to question 25 on what constitutes an effective inspection. For question 18, the results aggregated across all five Provinces were as follows:
5.42. There is a clear variation of approach according to size of business, with the chance of notification increasing with the size of the business. That fits with the argument that inspection of large and complicated businesses are usually more efficient with notification and preparation. There is little difference, however, between Small and Micro.

5.43. When looking at the answers to Question 25 on what constitutes an effective inspection, the overwhelming majority of answers were around unannounced inspections. There were a few who argued for well prepared and notified inspections but, across all five Provinces, there is very clear resistance to announced inspections.

**Duration of Inspections**

5.44. Question 17 asked how long an inspection takes, on average. Answers ranged from around half an hour for some Micro Catering businesses to almost seven hours for a Large Processing business. Processing takes significantly longer than either of the other two types of business, in each size.

5.45. These figures are short compared with EU inspections, indicating that there is less inspection of food safety management systems and more inspection of physical characteristics (in addition to documentary checks and sampling). Inspecting a large EU processor using HACCP would be measured more in days than hours. This has significant implications for resources once the Chinese enforcement system focuses more on food safety management systems.

**Figure 14. Duration of Inspections**
Table 3. Duration of Inspections in Hours

<table>
<thead>
<tr>
<th></th>
<th>Large Processing</th>
<th>Large Distribution</th>
<th>Large Catering</th>
<th>Medium Processing</th>
<th>Medium Distribution</th>
<th>Medium Catering</th>
</tr>
</thead>
<tbody>
<tr>
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<td>2.38</td>
<td>3.15</td>
<td>2.51</td>
<td>1.96</td>
</tr>
<tr>
<td>Manager of Inspectors</td>
<td>5.19</td>
<td>2.01</td>
<td>1.58</td>
<td>2.92</td>
<td>1.19</td>
<td>1.21</td>
</tr>
<tr>
<td>Inspector of Businesses</td>
<td>6.45</td>
<td>3.40</td>
<td>4.00</td>
<td>3.92</td>
<td>2.06</td>
<td>2.03</td>
</tr>
<tr>
<td>Co-Inspector</td>
<td>2.45</td>
<td>2.60</td>
<td>2.60</td>
<td>1.89</td>
<td>1.98</td>
<td>1.98</td>
</tr>
</tbody>
</table>

### Preparation for Inspections

5.46. Question 14 asked what information is checked before an inspection.

5.47. Many began with the practical basics about location and contact points but the majority took that as given and went for more substantial issues. The primary one that nearly all referred to was the operator’s licence, to ensure that it was properly licensed and to see what conditions attached to the licence. Some detailed various other documents, such as staff health certificates or even staff training logs. The compliance history was very commonly referred to but not automatically in all responses. A few in Sichuan expressly referred to checking any complaints made against the business but this was rarely mentioned. Only two mentioned recall history. Those preparing for a processing inspection tended to have more detail than the others, with some referring to flowcharts for the process.

5.48. Perhaps the most detailed response was from a Manager at District level in Shandong who responded with:

> “Production and distribution enterprise qualification, goods supply check and inspection, production process control, food out of plant inspection implementation, sub-standard products management, waste management, food label compliance, sales log records, standards implementation, unsafe food recalls management, staff food safety knowledge training, contracted processing, registration and handling of consumer complaints, records on collection of risk monitoring and evaluation, food safety incidents treatment etc.”

5.49. The answers show that there does tend to be some preparation beyond checking the address and the licence but there is clearly no common practice.

### Proportion of Time Spent on Inspections

5.50. Inspectors should do much more than just inspection visits, e.g. preparation, follow-up, analysis, training, surveillance, monitoring. In many OECD systems, inspection will be a minority of the inspector’s time – perhaps as low a ratio as 30:70 of inspection to other activities. Question 19 asked “What percentages of your time are spent on the following, in your type of activity:

- Inspection of Businesses;
- Other functions, such as preparation, follow-up, travel, training etc.”.
5.51. The data on that ratio is far too varied to produce useful charts. A small number said 100% of their time was on inspections (which is unlikely to be correct) and the highest percentage claimed for “other” activities was 90%, in a very small number of cases. There was no particular difference according to the role of the respondent so the figures were averaged over all respondents in each province, according to size and type of business.

5.52. Only in Fujian is the ratio ever in favour of more time spent on other activities and even then it is fairly well balanced, up to 42:58 at the most extreme. There is little difference in terms of the size of the business or the category. The province with the highest ratio in favour of inspections is Heilongjiang, at 81:19 in Distribution and similar in Catering but dropping to 64:36 for Processing. In Heilongjiang, Large businesses give a markedly lower ratio than the others. Shandong also has a clear leaning towards inspections but again the lowest ratio is with Processing.

5.53. There is certainly a recognition that inspection is not the only activity but it is still seen as the major activity in terms of time, except in Fujian where more time is spent on other activities.

**Conclusion on Technical Aspects**

5.54. The administration of inspection and enforcement in China at present is well-settled and disciplined. The figures for most of the technical aspects would be higher than for some EU countries and at best would stand comparison with some of the better EU countries. The system that is being administered is also emerging from a challenging set of mergers of organizations so, overall, they show that the technical aspects are robust. However, the system is not fully risk-based and there is still considerable work to be done in terms of developing risk criteria and updating the risk ratings of businesses. But when these aspects are fed into the current system, there should be a smooth transition. There are many indications that the system is already in transition to a more risk-based approach.
5.55. It should be repeated that this section is looking at the capacity of the regulatory bodies to run a disciplined enforcement operation, even if the enforcement tasks are not the ones that the new system will require. Skills in workflow are essential regardless of the nature of the specific work activities. But having the capacity to run efficient operations and also noting that some bodies are already in transition to new methods does not mean that they are currently operating a risk-based enforcement system.

5.56. There are resource implications for moving from testing products to testing systems. Inspecting complex food safety management systems will be a significant challenge in terms of expertise but also in terms of staff time and therefore staff numbers. Audits of HACCP systems can take days and that is outside the normal range of time spent on individual inspection visits. For most countries, an important driver for adopting a risk-based approach to inspection is to be able to reduce staff costs by employing fewer staff but, through better targeting of resources, increasing effectiveness. This is less of a driver in China, which is prepared to put resource into Food Safety, but it means that there will be choices available as the focus of enforcement changes. Some resource should be saved from reducing product testing, although that is not necessarily staff time. That can be saved by reducing the supervision of low risk businesses. Targeting of resources through risk analysis not only shows where more resource is needed (high risk) but also shows where resource is not really needed at all (low risk).

5.57. More resource may also be needed on compliance support, as opposed to conventional inspections. The percentage of time spent on inspections as opposed to other activities is likely to shift, as it has already done in Fujian Province which appears to be further through the transition to a risk-based approach than other Provinces. Less time spent on inspections again raises the issue of whether to have fewer inspections. The lesson from the countries that have adopted a risk-based approach is that inspection of low risk businesses can be cut back very significantly without any loss of effectiveness in the overall regulatory system.

5.58. However, all these changes will need to be accompanied not only by training for the enforcement staff but also awareness-raising and education of the general public. No matter how sound the theories may be in adopting new safety practices, changes in safety practices can lead to public anxiety. The public has become used to particular ways of doing things and has little interest in understanding new theories. Reducing both product testing and inspections will require very skilful communication to the public. That is why the EU system of risk analysis includes Risk Communication along with Risk Assessment and Risk Management.

Training Needs and Priorities

5.59. The previous two sections of this Report concluded that the enforcement staff are well-prepared to move to an enforcement policy that has a more positive, supportive approach to food businesses and also concluded that the administrative structures and disciplines already developed should also facilitate a transition to a risk-based, preventive approach to Food Safety. However, there is still a need for training.

5.60. This section looks at the needs of the enforcement staff as seen from their point of view through the Needs Assessment Survey, and also covers the training currently received. It looks also at training needs identified for some food businesses from another part of the survey. It closes by analysing the results when enforcement staff were asked what they saw as the main spending priorities for their work in the future.

Training needs for enforcement staff

5.61. Question 23 asked the respondents to confirm whether they had received training in six specific areas, plus “other”, namely:

- Risk Assessment
• Risk Management
• Principles of Food Safety
• Food Safety Systems (e.g. GHP, HACCP)
• Laws and Regulations
• Food Safety Standards

5.62. They were not asked how much training they had received or how often. The question was designed to see what had been covered and, in particular, whether there had been specific training in Risk. The overall results came out as follows:

Figure 16. Areas of Training Already Provided – Overall

5.63. There is relatively little training in Risk, although more for Managers than for others. The main training is in Laws and Standards, but also some in Principles and Food Safety Systems. There are significant difference across the Provinces but the top three are Laws and Regulations, Standards and Principles. Annex F gives more detail on both the training provided and the training asked for broken down by Province.

5.64. Question 24 then asked respondents to rank from 1 to 6 their priorities for future training, spread across the same subjects. The overall results came out as follows:

Figure 17. Priorities for Future Training – Overall
5.65. The most notable result is the recognition of the need for training in Food Safety Systems, which is clearly needed at a strategic level but it is good to see that also being recognised on the ground. There is also an appetite for training in that the Inspectors have a more even spread across the subjects than in the chart for training already received. It is also reassuring that “other” does not figure very much in either chart so the subjects chosen appear to be the central ones. As regards Risk specifically, in Shandong, Fujian and Sichuan, Risk scores quite highly.

Training needs for businesses

5.66. In addition to looking at training needs for enforcement staff, it is helpful to cross-refer to some results from the linked survey into the Value Chains in the same Provinces, which looked at how the businesses perceived their own needs. Surveys were done for Farming, Distribution and Manufacturing in each of the five Provinces in which the Regulatory survey was carried out. Examples here are taken from the Distribution results. Farming is not covered by the Provincial FDA and below enforcement staff but by regulatory agencies under the Ministry of Agriculture.

5.67. The businesses were asked to assess themselves against good practice. While being strongly positive, they did admit to some areas that need improvement, as seen below:

Figure 18. Self-Assessment of Product Controls and Management Systems
5.68. But this largely positive attitude is in contrast to the next result which looked at the strengths and weaknesses of their facilities (see Figure 19). There was much greater acknowledgement of weaknesses there. However, the results of the regulatory questionnaire suggest strongly that there remain significant weaknesses in their management practices as well as in their facilities. Admittedly, the businesses that took part in the Value Chain survey were Large or Medium, where the assessment of the enforcement staff was more positive but still identified a significant area of “Willing to Comply” but not compliant and significant unintentional violations, even at Large level as well as at Medium.

Figure 19. Self-Assessment of Facilities
**Spending Priorities for the Future**

5.69. The final question in the survey of enforcement staff, Question 26, asked respondents to rank from 1 to 6 five specific spending needs plus “other”, as follows:

- Additional Staffing
- Testing Equipment
- Better Data
- Training
- Vehicles and other equipment
- Other operating costs

5.70. Averaged out across the five Provinces, the results were as follows:

**Figure 20. Future Spending Priorities**

5.71. Unfortunately, the “other” category received some of the strongest support therefore there is at least one other factor not mentioned that is of some importance.

5.72. It is worth noting that “Training” is the highest priority for Inspectors and, excluding “other”, for Managers and Members of the Food Safety Commissions. It is also worth noting that “Additional Staffing” is not a high priority for Inspectors or for Managers but is for Members of the Food Safety Commissions. For Jilin, however, it was by far the clear priority, as shown below:
5.73. The Jilin contrast with the overall result indicates that this question led to sharply differing priorities across the Provinces and the full spread is set out in Annex G. There is no reason why all the Provinces should have the same priorities so inconsistency is not a great concern.

**Conclusions on Training and Priorities**

5.74. Even before the adoption of the new Food Safety Law, there was already training offered in Risk Assessment, Risk Management and Food Safety Systems but the three of these scored below Law, Standards and Principles. What the staff see as priorities should be reassuring because they can see the switch of focus from products to food safety systems and the increasing importance of Risk. Article 3 of the Food Safety Law puts “risk management, whole-process control” as two of the principles on which the new Law is based.

5.75. The training needs of the businesses are not as clear as for the enforcement staff because they are likely to have overstated how good their present systems are but they still admit to areas where they are more in the “Willing to Comply” category than being fully compliant.

5.76. Finally, the question to the enforcement staff on what they see are spending priorities for the future missed an important factor because of the support for “other” and it is not easy to see what that factor might have been. It was also the question that showed the biggest variations across the Provinces, although a fair amount of consistency within each Province. Aggregating all five results therefore is less useful for this question, which is why the individual results are also supplied in the Annexes. The lesson from this, however, is that we can still expect some divergence in implementation of the new Law across the Provinces. Underlying issues such as the perceptions of the staff and the level of discipline in the practices are very reassuring as a foundation for a successful transition to the new system but there is still likely to be differences of interpretation and differences of priorities in how the new Law is implemented and enforced across all Provinces.
6. Conclusions and Recommendations

Conclusions

6.1. The main conclusions from this research into attitudes towards adopting a preventive, risk-based and proactive approach to food safety are:

- The attitudes of the overwhelming majority of enforcement staff surveyed and interviewed are aligned with the main principles on which the new Food Safety Law is built;
- The perception that the enforcement staff have of the businesses they supervise is positive and supportive, which provides a strong foundation for the social co-governance approach of the Food Safety law and for a modern approach to compliance management;
- The system of enforcement of food safety regulation is well disciplined, even if its practices and principles have not been those on which a risk-based system is built, and transition to a different set of practices and principles should not be a major challenge;
- At operational level, the system is already well into transition, with different Provinces progressing at different paces and even exhibiting sound risk-based practice in places, but there is still a long way to go in developing the new approach.

6.2. There is learning and experience available from other countries in how to develop this new approach but it will also need adaptation to Chinese circumstances. Indeed, a common feature of that learning is that risk assessment has always to be tailored to the specific circumstances in which it is being applied. For China, that is not just “China” but will be an extremely wide range of circumstances, not just between Provinces but also within them.

Dangers of divergence in implementation

6.3. Although the survey showed remarkable consistency in perceptions and attitudes, it showed significant diversity in the question about Spending Priorities. This is a reminder that common principles and attitudes do not necessarily lead to uniform practice. Even a single legal framework can still lead to wide diversity in implementation and enforcement, as seen in the EU in each of its regulatory systems. The CFDA Study Tour to the EU was very struck by the challenge of potentially wide divergence of practices across China when faced with the divergence of practices between Member States. The Food Safety Law provides that implementation will be at County level government and above and does not attempt to impose a uniform, top-down approach from CFDA. That is very wise but there are dangers in allowing total delegation of regulatory delivery issues. In particular:

- Managing supply chains will become more difficult if different practices and interpretations apply in different places along that chain;

Value Chains

An interesting result from the Value Chain survey that was carried out in parallel to the Regulatory survey was the discovery that, for both Distribution and Manufacturing, the main supply chains were less than 100 kilometres. This is much less than had been expected and it may help to mitigate some of the potential dangers of divergent interpretations of the Food Safety Law across different local government boundaries.

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25 The dangers of divergence are already being reported in some cases - https://foodindustry.asia/confusion-over-implementation-of-new-food-safety-law-at-provincial-level-in-china
• This will be particularly burdensome for businesses that operate across local government boundaries, as well as across Provincial boundaries;

• It may affect further moves towards vertical integration of value chains.

6.4. This has been the experience in other countries but that also means that there is learning on how to manage or mitigate some of the risks arising from this diversity of practices. The CFDA Study Tour to the EU was very interested in the UK’s attempt to deal with this issue even within one Member State through its “Primary Authority” approach. Although comparatively small even by Provincial standards, the UK has 433 local government boundaries and each local government has separate delegated responsibility for delivering food safety. The Primary Authority approach allows consistency of interpretation and practice for large, cross-boundary businesses while still allowing a high degree of autonomy and local variation for local governments.

Recommendations

6.5. The main recommendations arising from the Food Safety Capacity Development Assessment are:

• Deepen the risk-based, preventive approach to inspections and enforcement;

• Support businesses who are willing to comply into fuller compliance;

• Embed good practices and food safety management systems in as many businesses as possible; and

• Adapt learning and experience of regulatory delivery from other countries in order to manage the potential dangers of divergent interpretations and practices.

These are of course high level recommendations and require to be unpacked.

Deepen the risk-based, preventive approach to inspections and enforcement

6.6. This approach has already been mandated in the Food Safety Law so this is not an experiment. There are already many elements of a risk-based approach in place so it is primarily a matter of extending and developing what is there already. Provinces are moving at different speeds (and may even be moving at different speeds within a Province). What was seen in Fujian Province was far more advanced than in others. The World Bank Group (WBG) has experience of assisting the development of risk-based systems in many countries and that experience could add value to CFDA and PFDA efforts to deliver a fully risk-based system. The main development needed is in risk-based planning, which depends on better risk profiling of businesses. This in turn requires a recognition that the main object of supervision is the business and not the product. There is already experience of applying an A to D classification of catering businesses so the principle is in place but developing risk criteria for applying that approach to production and distribution is a specialized task. There are different risks at each stage of the supply chain and risk profiling of businesses depends on a good analysis of the hazards and risks in the particular operations at each stage. Risk criteria that are well established for catering do not transfer to transport, for example.

6.7. In addition to risk profiling, risk-based checklists are central to a risk-based approach. The checklists currently used need considerable development because the Food Safety Law is still a very recent Law and there has been limited experience so far of specialized checklists being used. Checklist development should involve feedback from the inspectors using them and it can take years to refine effective and efficient checklists. Risks also change with time and circumstances, which also requires regular review and updating of checklists.

6.8. The WBG can also add value through specialized IT systems for integrated inspection management systems. These have been developed in a variety of countries and have been proven to work in practice. They support building a database of businesses according to risk profiling and compliance record that allows much more targeted planning of inspections (or other interventions) but is also integrated
with workflow systems that make deploying specific staff more efficient. They can also be used to digitize the inspection process itself, to the extent of being accessible through an Android app on a smartphone.

6.9. Risk also needs to be applied to product testing. As explained in paragraph 2.11 above, at present the main testing resources are spent at the wrong end of the supply chain. Testing end-products at the retail stage is needed as part of a surveillance programme, as a check on levels of safety, but it is of very little use as a method of control. Where it is most effective is where action can be taken on the basis of the results, to prevent damage. That is particularly the case at the primary production stage. Yet more resource is currently applied to end-product testing at the retail stage.

6.10. Risk is also at the basis of food safety management systems and, just as businesses need to adopt and master food safety management systems of varying complexity, the inspectors also need to have enough understanding of these systems to carry out supervision.

6.11. China also has serious issues over Risk Communication. It is another element in a fully risk-based approach to food safety. Food safety “scare” can be enormously damaging economically because public anxiety is also consumer anxiety, which will lead to buying decisions that have enormous impact on the sector subject to the scare. The reality of the situation is often far less of a danger than the public understands but the phenomenon of that high public / consumer anxiety can be a serious issue in its own right. The survey result that showed that inspectors see food businesses as basically honest and trying to do a good job is what most countries can expect of their food industry but the public rhetoric around food scares in China has distorted the public perceptions of the industry. As with other aspects of applying risk to food safety, there is learning available from other countries on how to manage food scares effectively and to build trust on the part of the public / consumers.

6.12. To deliver a more developed risk-based approach involves both systems development and training. Risk analysis and risk assessment is needed to develop risk criteria for profiling and for checklist development. This is specialized work, as opposed to skills that need to be developed in all front-line staff. But because of the size of China, there is still a significant training challenge in training the specialists. In addition, all front-line staff do need at least a basic skill level in understanding risk and how it applies to their work. “Risk” is not as common a part of daily conversation in China as in many OECD countries but that is largely a matter of vocabulary rather than understanding. It has been observed in many countries that experienced inspectors who care about what they are doing often adopt what can be described as a risk-based approach, even although they may not talk about it in such terms. Effective training of front-line staff requires a very practical approach that makes it relevant to their day-to-day work.

Support businesses who are willing to comply into fuller compliance

6.13. A fully risk-based approach to regulatory delivery covers risk management as well as risk assessment. In addition to using risk criteria, risk-profiling and checklists, all of which derive from risk assessment, an enforcement agency also has to have ways of managing the risks that are identified and prioritised. Risk-based planning is one form of risk management, with resources targeted where they are most effective. But inspection is only one form of intervention. An enforcement agency should also be considering other ways of delivering safety outcomes.

6.14. The most effective intervention can sometimes be a form of compliance support, rather than inspection. Where a food business is willing to comply but is not compliant in some ways, what is needed to deliver the safety outcomes is increased compliance levels, not sanctions that do not improve the business’s performance. The survey has shown that China is a particularly good case for developing compliance support programs, on the basis of the perceptions of the inspectors who work with them.
6.15. As explained in paragraph 5.13, these are not actual compliance records but the perceptions of the inspectors. However, these perceptions are unlikely to be far out since they are the people who inspect these businesses for compliance. The orange part of the graph above at Figure 22 shows those businesses who are willing to comply but are prevented from better compliance by some factors. The size of that group expands as one goes from Large down to Micro businesses, indicating the main area of work to be addressed.

6.16. Understanding how to improve compliance can be a complex matter. Fundamentally, it is a matter of understanding the barriers to compliance, with a view to removing them and allowing the businesses to raise its performance. But the barriers that operate can be complex. Sometimes, they can be simple matters of understanding, caused by unclear regulations or continuing to use traditional methods. But others can be more complex and may even interact with each other. Procedural legitimacy has been shown to be a strong factor in compliance and enforcement that is seen as too coercive can reduce that legitimacy and build resistance. But when it is handled well, Procedural Legitimacy can also help relationships. Discovering the real barriers to compliance requires dialogue with businesses and this is an area where trade associations could be valuable. Businesses are understandably reluctant to talk openly to regulators about compliance issues yet what is needed is exactly that candour.

6.17. The survey has clearly shown the area of need in terms of capacity development but meeting that need will be very challenging, through developing compliance management strategies which, in turn, require research into the current barriers to compliance. But this also expands the skill set of the managers of enforcement agencies, as they start to think beyond traditional methods of inspection to get a better understanding of how to deliver safety outcomes.

Embed good practices and food safety management systems in as many businesses as possible

6.18. The value chain survey became a self-assessment exercise for the businesses that responded. In their view, they did not place much importance on developing their food safety management systems but were more concerned with the state of their facilities. To some extent, this could be explained as an astute business reaction to being asked by a project backed by the World Bank what their main development needs are. There may be a need for better facilities but it was considered by the team that they overestimated their skills in food safety management systems. The view taken by the inspectors was similarly skeptical about the standard of food safety management systems.
6.19. This recommendation fits well with the previous one since a common barrier to compliance is limited capacity to comply. The solution to this may be training in good practices (GMP, GHP, GAP) for small businesses or in more sophisticated food safety management systems (including HACCP) for the larger businesses. Developing a program of training in these skills should be coordinated with any compliance management strategies being developed in response to the previous recommendation.

6.20. Another GFSP program currently running in China is the China Supplier Food Safety Training Program. This fits exactly with this recommendation as its aim is to increase compliance levels of businesses — not just to provide training but to deliver increased compliance.

- The objective of the program is to establish sustainable, self-sufficient food safety training resources for suppliers and SMEs, starting in Shanghai, with the intention of demonstrating concrete results which can be scaled up. Key partners are the GMA Science and Education Foundation, SSAFE (Safe Supply of Affordable Food Everywhere) and the Shanghai Food Safety Federation, who have established a working relationship with Shanghai Jiao Tong University (SJTU). GFSP funding is considered to be critical seed funding to establish the program and facilitate further investments and scaling up the program throughout China and regionally. GFSP financing is supporting international trainers, the Online learning platform and training to establish the Monitoring and Evaluation (M&E) platform.

- Training consists of a one month on-line program, intensive face-to-face food safety technical training and advanced principles for training and mentoring. A core group of 18 Lead Trainers are being trained through SJTU in key elements of training approaches and adult learning so that the training has the intended impact to ensure retention, change behavior and, ultimately, to ensure improved food safety compliance in targeted companies and operations. Their training is being completed in June 2016.

- The Lead Trainers will be evaluated for their ability to ensure that a comprehensive food safety plan is in place and appropriately documented in a given company with which they will be working. For the company, the desired result is to be in compliance with food safety requirements of their respective audits, meet food safety specifications of their buyers and customers and/or comply with recognized government auditing programs and produce safe food. A comprehensive set of metrics for the program has been developed in collaboration with the Global Food Safety Partnership M&E working group and this will be the initial program for utilizing this guidance.

6.21. Having this training provision available is good but it is better if it can be utilized as part of a wider program, in order to maximize its impact. Connecting it with compliance management strategies of enforcement agencies has potential to increase its impact. Although it is aimed at food businesses, it was also intended to provide training for regulatory bodies.

The potential dangers of divergent interpretations and practices

6.22. Within a year of adoption of the new Food Safety Law, there are already cases arising of different interpretations of the Law by different agencies, or different ways of implementing the Law. These early examples have been reported by Food Industry Asia:

- Traceability is providing some problems where 16 Provinces still have not developed a consistent approach to tracing systems;

• In Qian’an, it is reported that there is discriminatory application of food safety regulation to favour local companies over companies with a national scope, through the action of a local Market Supervisory Authority;

• Shandong and Xizang Provinces are reported to have different labelling requirements arising from slightly different interpretations of the same regulation;

• Problems can also arise in interpreting the interaction between the new Food Safety Law and existing Laws: in Sichuan Province, there is a report of a conflict with local SME protection laws.

6.23. These sort of problems of implementation are of a different type to the earlier recommendation about deepening the technical approach to a risk-based, preventive approach. But they are also part of the practice of regulatory delivery and some assistance can be provided from experience and from institutional solutions in other countries.
### Annex A - Reform of Inspection and Enforcement: International Perspective

<table>
<thead>
<tr>
<th>Type of Reform</th>
<th>Examples</th>
<th>China’s Progress</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Streamlining administrative structures</td>
<td>Creating a lead agency for Food Safety is the most common model and it comes in different variations. But many countries fail to integrate at levels below National, e.g. UK.</td>
<td>Completed at National and Provincial level and in progress in integrating structures at City and County levels. Township also integrated into County operations. Primary production remains outside the integrated system.</td>
</tr>
<tr>
<td>2 Coordination across inspection bodies</td>
<td>Coordination can be an alternative to creating a lead agency, e.g. Germany. But it is also used to direct collaboration between all major inspection bodies, e.g. Dutch Inspection Council and “Domain” system. The UK has a looser system under a special government department, the Better Regulation Delivery Office.</td>
<td>Concept of Food Safety Commission present at all levels from National to Village. Provides coordination rather than direction but engages with local communities. Only deals with Food Safety. Joint inspections between agencies common.</td>
</tr>
<tr>
<td>3 Risk profiling of businesses</td>
<td>Detailed risk criteria developed for both food products and types of business and then combined with compliance record to form a risk assessment matrix to allow fairly precise calibration of risk levels presented by any company. Best examples in Netherlands and UK.</td>
<td>The A/B/C/D system in Catering has been in use for many years in some parts but it is based only on the last inspection. Currently planning to extend business profiling to Processing and Distribution, with some Provinces further developed than others. Risk criteria still relatively simple and capable of considerable development.</td>
</tr>
<tr>
<td>4 Risk-based planning of inspections</td>
<td>Inspections are targeted at High Risk businesses and even High Risk is then prioritized individually. Low Risk businesses are largely ignored. Unplanned inspections reduced through applying same risk criteria when responding to complaints. One of the best studies of problems of unplanned inspections is from Mongolia.</td>
<td>Frequency and order of inspections can be determined by business profile (A/B/C/D) but no prioritizing within each category. Frequency of inspection still high and every business is inspected at least twice a year. High ratio of unplanned to planned inspections so system is not primarily planned.</td>
</tr>
<tr>
<td>5 Resource reduction</td>
<td>Risk-based targeting allows reduction in resources since only a small number of businesses need to be inspected. Also political pressure in many countries to reduce burdens on business drives reduction in inspections. Poland has shown dramatic results in reduction without losing effectiveness.</td>
<td>China does not have the same resource constraints and is increasing resources applied to Food Safety. Chinese public not ready for any reduction in inspection levels and economic growth is not as strong a driver.</td>
</tr>
<tr>
<td></td>
<td>Application of risk treatment strategies</td>
<td>Regulatory organization is focused on delivering public goods through managing risks on behalf of the public. Uses strategies other than enforcement to manage these risks, e.g. compliance assistance, co-regulation, consumer empowerment. The USA, Canada and Australia have good examples of compliance management systems.</td>
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<tr>
<td>7</td>
<td>Performance management</td>
<td>Regulatory organization has clear strategic and annual objectives, with specific performance indicators linked to risk criteria. These are reflected in performance indicators for staff that drive staff behavior in line with the organization’s objectives, i.e. raising compliance levels rather than imposing penalties. The UK is particularly strong on this approach but Estonia has shown how well it can be applied in recently developed economies.</td>
</tr>
<tr>
<td>8</td>
<td>Providing assured advice on request</td>
<td>Regulator provides advice to business on which business can rely in order to ensure compliance. Can be at inspector level or at corporate level or telephone help line. Best examples in UK and Lithuania.</td>
</tr>
<tr>
<td>9</td>
<td>Personalized regulation</td>
<td>The UK’s “Primary Authority” scheme approves a partnership between a regulatory body to a large company with many outlets and both agree detailed compliance plans. The company ensures compliance with the detailed plan and all other regulators have to consult its partner before taking action.</td>
</tr>
<tr>
<td>10</td>
<td>Export-led drive to raise standards and encourage compliance</td>
<td>Benefits of compliance seen as allowing access to new markets, especially foreign markets. Domestic inspection then becomes supportive, to help meet foreign standards.</td>
</tr>
</tbody>
</table>
The aim of the Regulatory survey

7.1. The aim of the Regulatory survey was to assess the capacity of the current food safety enforcement system in China to adapt to a risk-based and business-focused system of enforcement.

7.2. The World Bank Group has experience of working with countries in applying a risk-based approach and this has shown that one of the biggest challenges in changing a system of enforcement is the mindset of those involved. New practices can be introduced but successful implementation depends on those applying the practices understanding and supporting the new practices. New practices can also be undermined by practitioners sticking to previous values and attitudes.

7.3. For these reasons, the survey assessed the capacity to move to a new system through examining current attitudes and current practices of those involved. It is not looking at the level of technical knowledge, such as food science, or advanced practices, such as auditing HACCP control systems, but at perceptions of businesses and day-to-day operations of inspection.

7.4. The survey consisted of a questionnaire (attached at Annex C) and semi-formal interviews, as explained further below. It does not claim to be statistically robust because of the scale of numbers needed to carry out statistically robust surveys in China. For example, Question 8 on the number of Food Business Operators (FBOs) operating in the area of the respondent is not trying to establish the actual number of FBOs but is merely further information regarding the overall responses of that one respondent. Because it is an attitudinal survey, the main check on validity is the diversity of the respondents. If there are common results emerging from across a diverse group, these results are significant. If the diversity of the group leads to complete diversity in results, the only lesson is that there are no clear common approaches.

7.5. The survey did show many common results, with significant conformity across the group. By contrast, there was one question (19) which showed no clear trends at all, even within Provinces. The final question (26) on spending priorities showed significant variations across Provinces but there were common trends within each Province. Combining the results of each Province to that final question may not be very helpful but the results for each Province remain valid. It is also less surprising that there may be variations across Provinces on what are seen by each as current priorities.

The respondents

7.6. The total sample size was 237, spread across five Provinces and across the range of enforcement staff. The Provinces were Jilin, Heilongjiang, Shandong, Sichuan and Fujian. From each Province, there was a spread across Provincial FDA, Municipalities, Counties, Districts and Towns. Most are FDAs but there are also some respondents from Livestock, Agriculture or Aquaculture Bureaus. The results have not been analysed at this stage according to local government level or by the FDA / Agriculture function but by Province and by the role of the respondent in the enforcement system. These roles can apply at each local government level (apart from co-inspector, which is only at township level) and were:

- Member of the Food Safety Commission (21%);
- Manager of Inspectors (35%);
- Inspector of Business (39%);
- Co-Inspector (4%).
7.7. Jilin had the largest number of respondents and by far the largest number of Co-Inspectors. The others rarely had more than one Co-Inspector so the results for Co-Inspectors mainly reflect those in Jilin.

7.8. The respondent’s educational background was asked by Question 7 and the result was almost wholly “Undergraduate”. There were no more than one or two “Masters” or “PhD” from each Province.

7.9. The data is also rich in the detail of the types of businesses being referred to in the answers. The FDA inspection system is split across Processing, Distribution (Retail, Storage and Transportation) and Catering, with inspectors specialising in one for most of their career. Businesses were split into Large, Medium, Small and Micro, according to the National Bureau of Statistics classification (see Annex D).

The methodology

7.10. With the assistance of CFDA, the Provincial FDA in each of the five Provinces brought together a range of staff as described above and they sat together to complete the questionnaire. Each session took around an hour in total but many respondents completed the questionnaire more quickly. Each session was supervised by a national expert from the CFDA team who also explained the guidelines for completion of the questionnaire.

7.11. The handwritten results were transcribed into Excel worksheets in Chinese by CFDA and, after review, given to GFSP who translated them into English. The international experts from GFSP analysed the data into the current charts and prepared a report on preliminary findings which was shared with the national experts from CFDA.

7.12. There was a question for the respondent’s name but it was made clear that there was no obligation to complete it. The information about the respondent’s role and the respondent’s location in local government mean that it could be possible to narrow the number of potential respondents to a small number and then refine that by whether their answers to detailed questions showed that they operated in, say, Distribution, and primarily in, say, Small and Micro businesses. So it cannot be claimed that the respondents would have felt secure about anonymity. They were also completing and handing in the questionnaire in full view of their colleagues. (It was clear that various answers were also being copied by two or three respondents so there was obviously some discussion and collusion.) However, the questions were designed to check responses from different angles in order to check consistency and credibility.

7.13. Both the national and international experts were present at each of these sessions in the different Provinces and spent time in discussion with groups of enforcement staff as semi-formal face to face interviews. These discussions were either parallel to or following the completing of the questionnaire so would not have influenced the responses. The results from the questionnaire support what the experts learned from the discussions.

7.14. There was also a parallel questionnaire on the Value Chain, completed by representatives of businesses in chosen value chains in each Province. Some of the results of that questionnaire which support the findings of the Regulatory questionnaire are referred to in this report.

7.15. A copy of the Guidelines for the Regulatory questionnaire is attached to this report at Annex E.
### Annex C – The Regulatory Questionnaire

**CHINA: FOOD SAFETY CAPACITY DEVELOPMENT NEEDS ASSESSMENT**

**REGULATORY ANALYSIS QUESTIONNAIRE**

**Version 8.0**

<table>
<thead>
<tr>
<th>Name of the Regulatory Agency</th>
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<tbody>
<tr>
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</tbody>
</table>

1. Province

2. City / County

3. Town / Village

4. Name (optional)

5. Reporting Organization

6. Your identify

<table>
<thead>
<tr>
<th>Check one</th>
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<tr>
<td></td>
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<tr>
<td>a</td>
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<tr>
<td>b</td>
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<tr>
<td>c</td>
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<tr>
<td>d</td>
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</tbody>
</table>
7. What is your educational background?

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>a</td>
<td>Undergraduate (7A.1)</td>
</tr>
<tr>
<td>b</td>
<td>Masters (7A.2)</td>
</tr>
<tr>
<td>c</td>
<td>PhD (7A.3)</td>
</tr>
</tbody>
</table>

8. How many Food Business Operators are in your area of operation?

<table>
<thead>
<tr>
<th></th>
<th>Large (8.1)</th>
<th>Medium (8.2)</th>
<th>Small (8.3)</th>
<th>Micro (8.4)</th>
<th>Total (8.5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Processing</td>
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<tr>
<td>Distribution</td>
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<tr>
<td>Catering</td>
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</tbody>
</table>

9. Do you think there are enough inspectors in your area to deal properly with the number of FBOs?

Yes (9.1) No (9.2)

10. Does your agency have a classification of FBO in your area, based on their performance on food safety?

Yes (10.1) No (10.2) Don't know (10.3)

11. If the last answer was No, please explain the classification your agency uses
12. If you apply this classification, which class applies to the majority of FBOs in your area?

13. When you are making up the annual inspection plan, how do you prioritize which FBOs to inspect?

14. What information do you check before conducting an inspection (if any)?

15. In a typical year, what percentage of inspections are unplanned, rather than planned?

| Planned (15.1) | Unplanned (15.2) | Not Applicable (15.3) |

16. What are the main causes of unplanned inspections?

<table>
<thead>
<tr>
<th>Cause</th>
<th>Rough Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>a Complaints from the public</td>
<td>16.1</td>
</tr>
<tr>
<td>b Seasonal events, such as holidays</td>
<td>16.2</td>
</tr>
<tr>
<td>c Unforeseen events</td>
<td>16.3</td>
</tr>
<tr>
<td>d Other, please specify . . . .</td>
<td>16.4</td>
</tr>
</tbody>
</table>

17. How long do inspections take, on average? (Answer in the appropriate column, for your type of activity)

<table>
<thead>
<tr>
<th>Size</th>
<th>Minutes (17.1)</th>
<th>Hours (17.2)</th>
<th>Days (17.3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a Large</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b Processing</td>
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<tr>
<td>c Distribution</td>
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<tr>
<td>d Catering</td>
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</tbody>
</table>
18. Are inspections usually notified in advance?

<table>
<thead>
<tr>
<th>Size</th>
<th>Yes (18.1)</th>
<th>No (18.2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a Large</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b Processing</td>
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<td></td>
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<tr>
<td>c Distribution</td>
<td></td>
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</tr>
</tbody>
</table>
19. What percentages of your time are spent on the following, in your type of activity?

<table>
<thead>
<tr>
<th>Size</th>
<th>Inspection of Businesses (19.1)</th>
<th>Other functions, such as preparation, follow-up, travel, training etc. (19.2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a</td>
<td>Large</td>
<td></td>
</tr>
</tbody>
</table>
20. How do you see the FBOs in your area?

<table>
<thead>
<tr>
<th>Size</th>
<th>Compliant (20.1)</th>
<th>Trying to comply (20.2)</th>
<th>Opportunist (20.3)</th>
<th>Criminal (20.4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>b  Processing</td>
<td></td>
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<td></td>
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<td>c  Distribution</td>
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<tr>
<td>d  Catering</td>
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<td>e  Medium</td>
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<tr>
<td>f  Processing</td>
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<td>g  Distribution</td>
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<td>h  Catering</td>
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<td>i  Small</td>
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<td>j  Processing</td>
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<td>k  Distribution</td>
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<td>l  Catering</td>
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<tr>
<td>m  Micro</td>
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<tr>
<td>n  Processing</td>
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<td>o  Distribution</td>
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<tr>
<td>p  Catering</td>
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</tbody>
</table>
21. Of the violations found, what percentage are deliberate and what percentage are unintended?

<table>
<thead>
<tr>
<th>Size</th>
<th>Deliberate (21.1)</th>
<th>Unintended (21.2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a Large</td>
<td></td>
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<td>b Medium</td>
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<tr>
<td>c Small</td>
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<td>f Processing</td>
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<td>h Catering</td>
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<td>i Small</td>
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<td>j Processing</td>
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<tr>
<td>k Distribution</td>
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</tbody>
</table>
22. Where there are unintentional violations, what action do you take?

<table>
<thead>
<tr>
<th>Size</th>
<th>Advise them on how to remedy it (22.1)</th>
<th>Impose a penalty for the violation (22.2)</th>
<th>Both (22.3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a Large</td>
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</tr>
</tbody>
</table>
23. Do you receive training in any of these topics? (Please tick all applicable)

<table>
<thead>
<tr>
<th>Risk Assessment (23.1)</th>
<th>Risk Management (23.2)</th>
<th>Principles of Food Safety (23.3)</th>
<th>Food safety systems (e.g. GHP, HACCP) (23.4)</th>
<th>Laws and regulations (23.5)</th>
<th>Food Safety standards (23.6)</th>
<th>Other (23.7)</th>
</tr>
</thead>
</table>

24. Please rank these according to what you see as training priorities. Number those that matter to you personally in order of priority, starting with 1 (can be multiple choices)

<table>
<thead>
<tr>
<th>Risk Assessment (24.1)</th>
<th>Risk Management (24.2)</th>
<th>Principles of Food Safety (24.3)</th>
<th>Food safety systems (e.g. GHP, HACCP) (24.4)</th>
<th>Laws and regulations (24.5)</th>
<th>Food Safety standards (24.6)</th>
<th>Other (24.7)</th>
</tr>
</thead>
</table>

25. Describe what you consider to be an effective inspection?
26. What do you see as the main spending priorities in your organization, in order.

<table>
<thead>
<tr>
<th>Spending Needs</th>
<th>Priorities</th>
</tr>
</thead>
<tbody>
<tr>
<td>a Additional Staffing</td>
<td>26.1</td>
</tr>
<tr>
<td>b Testing equipment</td>
<td>26.2</td>
</tr>
<tr>
<td>c Better data</td>
<td>26.3</td>
</tr>
<tr>
<td>d Training</td>
<td>26.4</td>
</tr>
<tr>
<td>e Vehicles and other equipment</td>
<td>26.5</td>
</tr>
<tr>
<td>f Other operating costs</td>
<td>26.6</td>
</tr>
</tbody>
</table>
Annex D – National Bureau of Statistics Classification of Businesses

The standard of categorizing Large, medium, small and micro enterprise in statistics

<table>
<thead>
<tr>
<th>Industry</th>
<th>Indicator</th>
<th>Unit</th>
<th>Large</th>
<th>Medium</th>
<th>Small</th>
<th>Micro</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agriculture</td>
<td>Sales revenue (Y)</td>
<td>10 thousand RMB</td>
<td>(Y \geq 20000)</td>
<td>(500 \leq Y &lt; 20000)</td>
<td>(50 \leq Y &lt; 500)</td>
<td>(Y &lt; 50)</td>
</tr>
<tr>
<td>Wholesale</td>
<td>No. of Employee (X)</td>
<td>People</td>
<td>(X \geq 200)</td>
<td>(20 \leq X &lt; 200)</td>
<td>(5 \leq X &lt; 20)</td>
<td>(X &lt; 5)</td>
</tr>
<tr>
<td></td>
<td>Sales revenue (Y)</td>
<td>10 thousand RMB</td>
<td>(Y \geq 40000)</td>
<td>(5000 \leq Y &lt; 40000)</td>
<td>(1000 \leq Y &lt; 5000)</td>
<td>(Y &lt; 1000)</td>
</tr>
<tr>
<td>Retail</td>
<td>No. of Employee (X)</td>
<td>People</td>
<td>(X \geq 300)</td>
<td>(50 \leq X &lt; 300)</td>
<td>(10 \leq X &lt; 50)</td>
<td>(X &lt; 10)</td>
</tr>
<tr>
<td></td>
<td>Sales revenue (Y)</td>
<td>10 thousand RMB</td>
<td>(Y \geq 20000)</td>
<td>(500 \leq Y &lt; 20000)</td>
<td>(100 \leq Y &lt; 500)</td>
<td>(Y &lt; 100)</td>
</tr>
<tr>
<td>Storage</td>
<td>No. of Employee (X)</td>
<td>People</td>
<td>(X \geq 200)</td>
<td>(100 \leq X &lt; 200)</td>
<td>(20 \leq X &lt; 100)</td>
<td>(X &lt; 20)</td>
</tr>
<tr>
<td></td>
<td>Sales revenue (Y)</td>
<td>10 thousand RMB</td>
<td>(Y \geq 30000)</td>
<td>(1000 \leq Y &lt; 30000)</td>
<td>(100 \leq Y &lt; 1000)</td>
<td>(Y &lt; 100)</td>
</tr>
<tr>
<td>Catering</td>
<td>No. of Employee (X)</td>
<td>People</td>
<td>(X \geq 300)</td>
<td>(100 \leq X &lt; 300)</td>
<td>(10 \leq X &lt; 100)</td>
<td>(X &lt; 10)</td>
</tr>
<tr>
<td></td>
<td>Sales revenue (Y)</td>
<td>10 thousand RMB</td>
<td>(Y \geq 10000)</td>
<td>(200 \leq Y &lt; 10000)</td>
<td>(100 \leq Y &lt; 2000)</td>
<td>(Y &lt; 100)</td>
</tr>
</tbody>
</table>
Annex E – Guidelines for Completion of the Questionnaire

CHINA: FOOD SAFETY CAPACITY DEVELOPMENT NEEDS ASSESSMENT

REGULATORY ANALYSIS QUESTIONNAIRE (v8.0)

FREQUENTLY ASKED QUESTIONS

How the questionnaire is organized?

The questionnaire contains 26 sets of questions.

Who should complete the questionnaire?

The questionnaire should be completed by the regulatory specialists. Their TORs are provided.

What is the role of the World Bank?

This is a joint effort by the CFDA and World Bank teams for the Food Safety Capacity Development Needs Assessment in China. The entire effort is co-led and coordinated by the CFDA and World Bank/GFSP leadership. Technical teams operate under the leadership’s guidance. Final output is a joint analytic report (25 pages) to describe the food safety capacity development needs for the selected value chain.

Who should be interviewed?

The questionnaire covers many aspects of the enforcement system, including the management and planning of inspections and the carrying out of inspections. It has not been split into separate sections for different regulatory functions because there may be a significant amount of crossover. There are unlikely to be many people who can confidently answer all the questions but they should only answer those questions which they feel are appropriate. Some of the questions are trying to understand the perception that regulatory staff have of businesses and these perceptions are relevant at any level of operation.

What information should be provided to the interviewees beforehand?

The following statement should be read aloud to interviewees before the start of the interview:

“Thank you very much for agreeing to participate in this interview.

This interview is part of a larger effort lead by the China Food and Drug Administration to improve the food safety system in China through improved regulatory/inspection system, as well as through targeted support to selected priority value chains. The interview is the integral part of the joint World Bank/GFSP and CFDA food safety capacity development needs assessment process.

The results of the interview will be only used for the analytical work to understand the key challenges faced by various regulatory actors when it comes to food safety, and to design a food safety capacity development action plan for the regulatory function. All individual responses will be fully confidential and will not be shared outside the interview group. Only the summary results of all interviews will be used for analytical purposes, and no specific attribution to individual responses will be made. The data output will
only have a numerical key to the individual interviewed, and all specific attributable information will be hidden in a separate file.

The interview will consist of a face-to-face discussion through a structured questionnaire.

The interview should take no more than 45 minutes.”

Interviewees should give formal consent before the start of the interview.

**What time-period is covered in the interview?**

The interview should cover the latest full calendar year (2013) if possible. In case data is available on a fiscal year basis, the interview should cover the latest fiscal year. This should be noted on the questionnaire.

**How long should the interview last?**

The interview should not exceed 1.0 hour.

**How the interviewees should be selected?**

The regulatory enforcement system is complicated by the levels at which different regulatory bodies operate and also by the different responsibilities and functions within the system. All those involved, however, have a part to play in the overall system so the study needs to cover as representative range of levels of government and regulatory functions as possible. This includes both management and operational staff. Identification of appropriate bodies to interview will be done by discussion with CFDA and individual interviewees will be identified partly with the assistance of the Provincial level government and then with each level below that has been chosen to take part.

**Who will schedule the interviews?**

The interviews should be scheduled by the assistance of the Provincial government.

**Should there be a pre-test?**

Yes. First three interviews should be considered pre-test and the questionnaire should be revised after these interviews.

**How is data processed?**

Data will first be entered in spreadsheet software (Excel). A data entry model will be provided.

**Accuracy of answers**

We are not looking for accuracy but for the interviewee’s estimate. This is primarily a survey of attitudes and practices, not statistics.

**What is a Food Business Operator?**
An FBO is an individual or a corporate body that operates a business involved in food or food products. That can cover production, processing, transportation, storage, wholesale, retail and catering. The questionnaire looks for information relating to the size of the FBO, using standard definitions of Chinese companies as Large, Medium, Small and Micro. It may not be possible to provide accurate information about every level of FBO but it will be useful to understand how the interviewee’s perception changes across that range. Actual hard statistical data will be obtained elsewhere and will not rely on these interviews.

Sizes of FBOs

The categories of Large, Medium, Small and Micro are set out by the National Bureau of Statistics at - [http://www.stats.gov.cn/statsinfo/auto2073/201310/t20131031_450691.html](http://www.stats.gov.cn/statsinfo/auto2073/201310/t20131031_450691.html).

Types of Inspection Activity

Many questions are divided into separate cells for not only the size of companies but also the type of inspection activity – Processing, Distribution and Catering. Inspectors who inspect businesses directly will normally operate in only one of these activities. They should therefore ignore all the cells for the other activities but just answer (as far as they can) according to the size of the companies. Managers of inspectors may be able to answer more widely.

Percentages of time spent by inspectors

Question 19 asks inspectors to set out how much time they spend on various activities, as percentages rather than actual hours or days. It would be a percentage of the time spent in an ordinary week or perhaps month, if that is easier to estimate.
Annex F – Training Received and Training Desired by Province
Annex G – Spending Priorities by Province

Spending Priorities - Jilin

- Other operational costs
- Better data
- Vehicles and other equipment
- Training
- Testing equipment
- Additional staffing

Co-Inspector | Inspector of Businesses | Manager of Inspectors | Food Safety Commission

Spending Priorities - Shandong

- Other operational costs
- Better data
- Vehicles and other equipment
- Training
- Testing equipment
- Additional staffing

Co-Inspector | Inspector of Businesses | Manager of Inspectors | Food Safety Commission

Spending Priorities - Fujian

- Other operational costs
- Better data
- Vehicles and other equipment
- Training
- Testing equipment
- Additional staffing

Co-Inspector | Inspector of Businesses | Manager of Inspectors | Food Safety Commission

Spending Priorities - Sichuan

- Other operational costs
- Better data
- Vehicles and other equipment
- Training
- Testing equipment
- Additional staffing

Co-Inspector | Inspector of Businesses | Manager of Inspectors | Food Safety Commission

Spending Priorities - Heilongjiang

- Better data
- Vehicles and other equipment
- Training
- Testing equipment
- Additional staffing

Co-Inspector | Inspector of Businesses | Manager of Inspectors | Food Safety Commission