# POLAND CATCHING-UP REGIONS

# SAFER FOOD, BETTER BUSINESS IN PODKARPACKIE AND LUBELSKIE















# SAFER FOOD, BETTER BUSINESS IN PODKARPACKIE AND LUBELSKIE

RECOMMENDATIONS TO IMPROVE FOOD INSPECTION PRACTICES IN PODKARPACKIE AND LUBELSKIE

Administration Agreement between the European Commission and the International Bank for Reconstruction and Development on the Part II Europe 2020 Programmatic Single-Donor Trust Fund

Trust Fund No. TF072592

May 2018











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Internet: www.worldbank.org

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#### **ACKNOWLEDGEMENTS**

This report was written by a team led by Maciej Drozd, comprising Giedrius Kadziauskas, Gordana Ristic, Goran Vranic, and Marek Zadernowski. The report benefited from comments and insights by Florentin Blanc and peer reviewers Lars Grava and Selma Rasavac. Wojciech Sacha coordinated data collection. Damian Iwanowski assisted with research. Jerzy Toborowicz and Sarah Newman edited the document.

The team would like to thank Commissioner Corina Cretu for starting the Catching-up Regions Initiative, Minister Jerzy Kwieciński from the Ministry of Investment and Economic Development for his invaluable support, and the team at the European Commission for outstanding engagement and support, especially Marc Lemaitre, Erich Unterwurzacher, Christopher Todd, Wolfgang Munch and Justyna Podralska.

The team would also like to thank Arup Banerji, David Sislen, Paulo Correa, Marialisa Motta, John Nasir and Carlos Pinerua for advice and guidance. Paul Kriss, Marcel Ionescu-Heroiu and Grzegorz Wolszczak have been coordinating the Catching-up Regions Initiative.

The team is grateful to entrepreneurs in Podkarpackie and Lubelskie, who shared their perspectives on food control in the two regions. The team is also grateful to the following institutions for sharing information and their active involvement in the Catching-up Regions Initiative: the Ministry of Agriculture and Rural Development, the Ministry of Health, the Office of Competition and Consumer Protection, the State Sanitary Inspectorate, the Veterinary Inspectorate, the Agricultural Trade and Quality Inspectorate, the Trade Inspectorate, the State Plant and Seed Inspectorate, the Lubelskie Voivodship Office and the Podkarpackie Voivodship Office.

The report was completed in May 2018.

### EXECUTIVE SUMMARY

This report provides recommendations to improve food inspection practices in Podkarpackie and Lubelskie, regions in southeastern Poland that represent 11% of the country's population and 8% of its gross domestic product (GDP). The report argues that the enforcement of food-related requirements in southeastern Poland could be less burdensome and more effective if inspectorates fully adopted international best practices in regulatory enforcement.

The food sector in Podkarpackie and Lubelskie is the largest employer and contributor to value added in southeastern Poland. It is undergoing structural transformation as labor gradually shifts from low-productivity agriculture to sectors generating more added value, including food processing and food services. The food sector can further contribute to economic development and provide higher-paying jobs in the two regions.

At the same time, firms in the food sector in Podkarpackie and Lubelskie need to comply with demanding EU-and nation-wide requirements. These requirements help to minimize negative externalities, such as the spread of food-borne illnesses. They are enforced mainly through business inspections carried out by five inspectorates responsible for food control in Poland. They have conducted more than 50,000 inspections in Podkarpackie and Lubelskie in 2016. However, firms struggle to understand requirements and perceive inspections mainly as a burden. More than half of 46 firms interviewed by the WBG indicated that they received five or more inspections in 2016 and that inspections do not help them to comply with requirements.

Poland's authorities have many institutional practices in place to reduce inspection burden and improve compliance with regulations in the country's southeast. The fragmentation of inspections is partly addressed through multi-annual control plans and interinstitutional cooperation agreements. Risk assessment methodologies are used to determine how frequently businesses should be inspected. Inspectorates use checklists to harmonize inspections and occasionally provide guidance to businesses.

However, Poland's authorities can still learn from international best practices in regulatory enforcement to reduce administrative burden and provide firms with more information about requirements. Improvements should focus on strengthening coordination between inspectorates, refining and fully implementing risk assessment, and scaling up compliance promotion (see Box 1).

<sup>&</sup>lt;sup>1</sup> State Sanitary Inspectorate, Veterinary Inspectorate, Trade Inspectorate, Agricultural and Food Quality Inspectorate, State Plant and Seed Inspectorate. Chapter 2.1.1. presents a detailed overview of the responsibilities of individual institutions.

<sup>&</sup>lt;sup>2</sup> The data is not representative of the firm population in Podkarpackie and Lubelskie.

#### BOX 1.

#### WBG recommendations on Safer Food, Better Business in Podkarpackie and Lubelskie

#### Strengthening coordination between inspectorates

- The Ministry of Agriculture and the Ministry of Entrepreneurship should develop in collaboration with the Ministry of Digital Affairs and the Ministry of Investments standard requirements for inspection software and an interoperability platform for inspections.
- On this basis, food inspectorates should standardize and upgrade their existing ICT solutions to support advanced functionalities such as mobile access, automated risk assessment, inspection planning, and information exchange with businesses.
- The Ministry of Agriculture and food safety authorities in Poland should pay more attention to the alignment of processes and resources upon enactment and entry into force of the Law establishing the State Food Safety Inspectorate.
- The Ministry of Entrepreneurship and Technology should improve and strengthen its framework regulation of inspections, in particular Article 33 and 47 of the Entrepreneurs Act.

#### Refining and fully implementing risk assessment

- Food inspectorates should refine and unify their risk assessment methodology; inspection
  frequencies should be reduced for low-risk establishments and more weight should be given to
  compliance records and internal food safety management systems implemented by food business
  operators.
- Food inspectorates should ensure that the risk assessment methodology is fully implemented in Podkarpackie and Lubelskie; more facilities should be covered by risk assessment and unplanned inspections limited; fewer facilities should be rated as high-risk; and risk assessment should be more consistent across regions (voivodships) and districts (poviats); the control of multisite businesses should be streamlined; and investments made into human and technical capacities.

#### Scaling up compliance promotion

• Food inspectorates should scale up compliance promotion by developing and publishing more practical checklists and guidelines; publishing risk assessment methodologies; informing businesses about their risk rating; providing advice through hotlines and websites; limiting the number of inspections and overly punitive sanctions.

The report consists of three chapters. The first chapter presents an overview of the food sector and opinions on food inspections shared with the World Bank Group by companies in southeastern Poland. The second chapter describes how food-related inspections are organized and carried out in Podkarpackie and Lubelskie and how they compare to international best practice. The discussion of inspection practices is organized along three key dimensions outlined in WBG and OECD guidelines: i) coordination; ii) risk assessment; and iii) compliance promotion.<sup>3</sup> Based on the comparison of local and international practices the third chapter concludes with a set of concrete recommendations to be implemented at the national, regional and local levels by Poland's authorities.

World Bank Group. 2014. Food Safety Toolkit: Introduction and Quick Start Guide. World Bank, Washington, DC. https://open-knowledge.worldbank.org/handle/10986/25204. Organisation for Economic Cooperation and Development. 2014. Regulatory Enforcement and Inspections. OECD Best Practice Principles for Regulatory Policy. OECD Publishing, Paris. http://dx.doi.org/10.1787/9789264208117-en

# 1. THE FOOD SECTOR IN PODKARPACKIE AND LUBELSKIE

Poland's southeast undergoes a process of structural transformation as labor gradually shifts from low-productivity agriculture to sectors with higher value added and earnings, including food manufacturing and services in catching-up regions. This chapter presents an overview of the food sector in Podkarpackie and Lubelskie and highlights the importance of local business environment reforms related to food control. The analysis is based on interviews with firms in Podkarpackie and Lubelskie as well as secondary sector- and firm-level data on value added and employment.

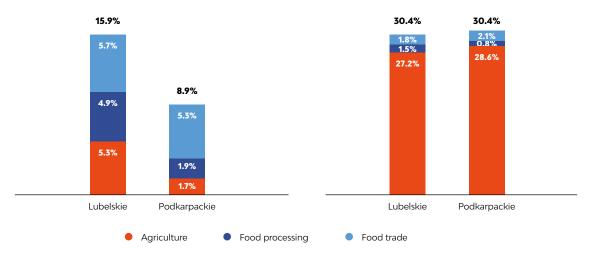
#### 1.1. SECTOR OVERVIEW

# The regions of Podkarpackie and Lubelskie have a long history in food production and trade.

In both regions, the food sector employs more than 600,000 people out of a total workforce of two million and generates over 15 billion PLN (over EUR 3.5 billion) in gross value added. Agriculture has traditionally been the largest sector of the regional economy in terms of output and employment. However, wholesale and retail food businesses have overtaken agriculture output in recent years and food processing is about to do the same. Still, agriculture continues to provide more than one in four jobs in the two regions, suggesting an incomplete structural transformation process.

**FIGURE 1.**Value added of agri-food sector to regional GDP, 2016<sup>4</sup>

FIGURE 2. Employment of agri-food sector in the region, 2016<sup>5</sup>



Source: Central Statistical Office of Poland, Institute of Agricultural and Food Economics, EMIS, World Bank Group staff calculations

<sup>&</sup>lt;sup>4</sup> Agriculture in Figure 1 encompasses value added created by agriculture, forestry, hunting, and fishing activities. Contribution of agriculture to value added was sourced from data published by the Central Statistical Office. Contribution of food processing to value added has been extrapolated by multiplying the share of the manufacturing sector in the regional GDP with the share of regional food manufacturing revenues in regional manufacturing revenues. The latter ratio has been assumed to reflect the proportion of regional food manufacturing value added to regional manufacturing value added. Contribution of wholesale and retail to value added has been estimated on the basis of the ratio of food processing revenues to food wholesale and retail revenues obtained from micro data representing the population of commercial code companies in these sectors in Podkarpackie and Lubelskie.

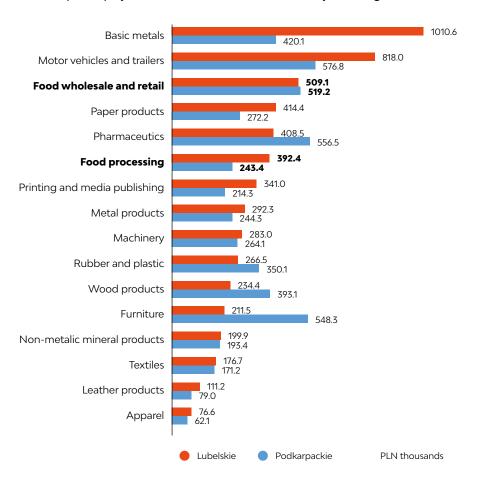
<sup>&</sup>lt;sup>5</sup> Data on employment in agriculture was sourced from the Central Statistical Office. Employment in food processing and food wholesale/retail has been estimated on the basis of micro data representing the population of commercial code companies in these sectors in Podkarpackie and Lubelskie.

Food processing and wholesale/retail are among the manufacturing and trade sectors in Podkarpackie and Lubelskie that generate the most revenue per employee.

In Lubelskie, food outranks other sectors considered revenue generators in Poland, such as furniture, machinery, and metal products. In Podkarpackie, food processing and wholesale/retail is less productive but still generates more revenue per employee than most other sectors.

FIGURE 3.

Revenue per employee across different sectors of economy in the region, 2016

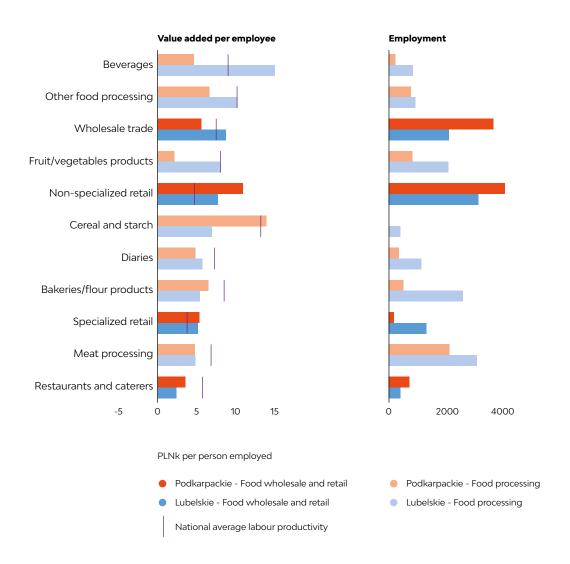


Source: Central Statistical Office of Poland, World Bank Group staff calculations

# There are important regional specializations in food processing and wholesale/retail.

Wholesalers and retailers are among the largest and most productive food firms in the two regions. Their productivity is comparable to or higher than the average in these sectors in the rest of Poland. Other sectors, such as beverages in Lubelskie and cereal/starch in Podkarpackie, are also competitive on a national level. Both regions have traditionally been important suppliers of meat products. The production of bakery and dairy products accounts for half of all jobs in food processing, but companies remain less productive than these sectors in the rest of Poland.

**FIGURE 4.**Value added per employee and employment in food processing and trade per subsector, 2016<sup>6</sup>



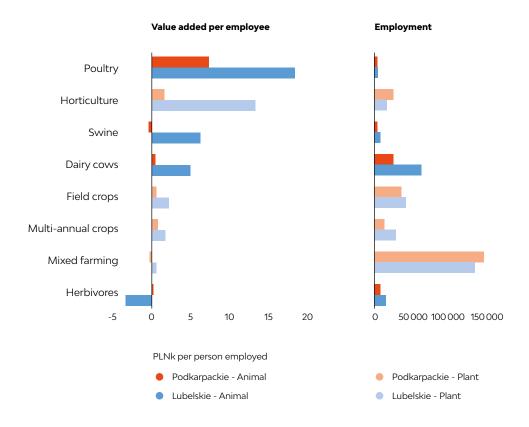
Source: Emerging Markets Information System, World Bank Group staff calculations

<sup>&</sup>lt;sup>6</sup> Value added per employee has been approximated by dividing, at firm level, the sum of operating income (EBIT) and employee benefits (including salaries) by the number of workers. Firm level data represents the population of commercial code companies and has been obtained from publicly available financial statements.

#### Agriculture in both regions is generally unproductive.

Southeastern Poland has the most densely populated farmlands in Poland. The average farm size is five hectares in Podkarpackie and eight hectares in Lubelskie. The small size of farms limits economies of scale and restricts agricultural development to intensive animal farming. Several confined animal feeding facilities are located in Podkarpackie and Lubelskie, of which poultry is the most productive.

**FIGURE 5.**Value added per employee and employment in agriculture per subsector, 2016<sup>7</sup>



Source: Central Statistical Office of Poland, Institute of Agricultural and Food Economics, World Bank Group staff calculations

# The food sector can continue to contribute to economic growth in Podkarpackie and Lubelskie.

Firms in this sector are benefiting from trade. Poland has a comparative advantage in 95% of its food products, offering opportunities to agricultural regions like Podkarpackie and Lubelskie. Approximately 20% of food sector revenues come from export in Poland and exports have been growing at annual rates of more than 6% over the last decade. The success of Poland's poultry producers can serve as inspiration for other food businesses (see Box 2). In addition, firms in the food sector can reap the benefits of consolidation and economies of scale. The share of micro, small, and medium-sized enterprises (MSMEs) exceeds 90% and is higher than in other sectors. Between 2004 and 2014, employment in the Polish food sector grew by 20%, while revenues more than doubled in real terms and the number of firms fell by 20%.

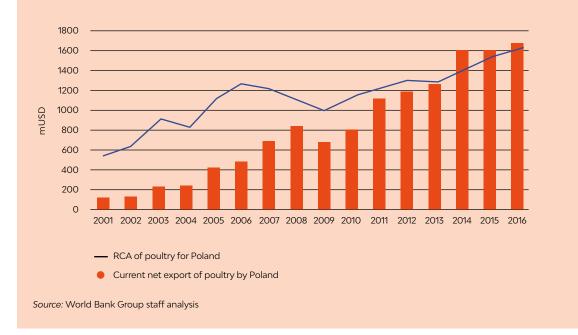
Value added per employee has been approximated by dividing farm profits by the number of workers in each sector. Data on cost and employment structure by sector and region was obtained from farm income surveys and triangulated with information about farm revenues and employment, published by the Central Statistical Office.

#### BOX 2.

#### The success story of Poland's poultry

Today, Poland is the biggest producer of poultry in Europe. Net exports of poultry surpassed USD 1.6 billion in 2016 and accounted for almost half of all revenues of this sector. Polish raised-poultry reached this position after 15 years of dynamic growth, supported by the transformation from family agriculture to intensive animal farming, market consolidation, large-scale investments, and the opening of the Polish economy to trade, first with European countries and later with the rest of the world.

#### Relative Comparative Advantage and net export of poultry, 2001-2016



# Regional business environment reforms should address both economy-wide and sector-specific challenges.

The World Bank Group's 2015 Doing Business in Poland study found that the business environment in Podkarpackie and Lubelskie lags behind other voivodships (regions) in Poland. The gaps in the local business environment affect firms across sectors. While efforts have been undertaken to improve the situation with regards to Doing Business indicators, there are also sector-specific challenges to be met. A challenge specific to the food sector is the proportional food control.

Requirements related to the safety and quality of food are enforced in Poland mainly through business inspections. Enforcement is necessary to minimize negative externalities, such as the spread of food-borne diseases. At the same time, overly frequent, discretionary, and punitive inspections can be burdensome to firms, hamper entry, limit competition, and stall growth. Inspectorates can promote safe food not only through inspections but also by providing information and advice to firms. This function is particularly relevant for MSMEs, which struggle to understand requirements and for which inspections can be relatively more costly than for large enterprises.

# 1.2. FIRM PERSPECTIVES ON INSPECTIONS

Food inspections are frequent and widespread among firms in the food sector in Podkarpackie and Lubelskie.

In 2016, there were more than 50,000 food inspections conducted in the two regions. Approximately three in five establishments in the sector had one or more food inspections. Food inspections are more frequent in Poland than in other EU countries (see Table 1). There are five food inspectorates active in Poland (the State Sanitary Inspectorate, Veterinary Inspectorate, State Plant and Seed Inspectorate, Agricultural Quality and Trade Inspectorate, and the Trade Inspectorate) and all of them have offices at the voivodship level in Podkarpackie and Lubelskie (the Veterinary and State Sanitary Inspectorate have also offices at the district level in the two regions).

**TABLE 1.**Supervision burden among food retailers, caterers, and restaurants in four selected EU countries<sup>8</sup>

	NUMBER OF INSPECTIONS	NUMBER OF FIRMS	RATIO
Netherlands (2014)	36,571	81,119	0.451
United Kingdom (2014/2015)	377,381	591,120	0.638
Germany (North Rhine- Westphalia, 2015)	129,328	157,565	0.821
Poland (2014/2015)	251,152	305,107	0.823

Source: World Bank Group staff analysis on the basis of publicly available annual reports of food and Eurostat businesses statistics (http://ec.europa.eu/eurostat/web/structural-business-statistics).

Firms interviewed by the World Bank Group agree (i) that inspections are disproportionately burdensome, and (ii) that they need more information on how to comply with food regulations.

World Bank Group staff conducted face-to-face interviews with owners and managers of 46 food businesses in the Podkarpackie and Lubelskie voivodships about their experience with food inspections (see Box 3 for an overview of the interview design). While firms provided divergent perspectives on most aspects of inspections, they nearly consistently expressed concern about unnecessary administrative burdens and limited information on how to comply with requirements. The following sections elaborate on these two recurrent themes and specify opinions that were particularly widespread. The information is not representative of the firm population in Podkarpackie and Lubelskie.

<sup>8</sup> Choice of countries based on availability of comparable data. Statistics take into account differences in the size of firm population and mandates of food inspectorates between countries. Estimates for Poland are conservative.

#### BOX 3.

#### Firm interview design

The World Bank Group interviewed owners or managers of 46 firms in Podkarpackie and Lubelskie. The data is not representative of firms in the food sector in the two regions. Firms were sampled selectively based on geography, size and subsector to capture a wide range of views on inspections (maximum variation sampling). The sample was split equally between Podkarpackie and Lubelskie and in a 4:3:2:1 ratio between micro, small, medium, and large enterprises. Firms located outside of the voivodship capital and firms likely to interact with small inspection services were oversampled. One in six firms agreed to be interviewed. The respondents were located in 21 poviats and represented 19 different sectors. The interviews were in person at businesses and interviewees responded to a set of closed-ended and open-ended questions.

After the interviews firm opinions were organized into three groups depending on how widespread they were (very wide-spread, wide-spread, not wide-spread). The first group represents opinions shared by at least 34 out 46 interviewed firms and substantiated by some firms with concrete examples in response to open-ended questions. The following words have been used in chapters 1.2.1-1.2.2 to describe this group: all, almost all, very frequent, very often. The second group represents opinions shared by the majority of respondents (24-34 out of 46 firms) and also substantiated by some firms with concrete examples. The following words have been used to describe this group: most, majority, more than half, frequent, often. The last group refers to all remaining opinions. Words such as minority, less than half, a number of, some, several, at times, occasionally have been used to single out these opinions.

Source: World Bank Group staff analysis

#### 1.2.1. ADMINISTRATIVE BURDEN

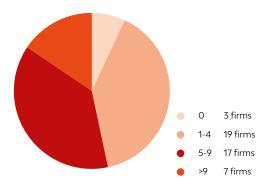
#### Businesses state that inspections are frequent and burdensome.

#### What local businesses say

"Each inspection slows down my business, so my problem is with the frequency of inspections. We have 2-4 general inspections per year and up to 20 special visits."

SMALL BUSINESS

FIGURE 6.
Interviewed firms by number of food inspections in 2016



Slightly more than half of all interviewed businesses reported to have received five or more food inspections in 2016 (see Figure 6). One third of respondents report simultaneous and consecutive inspections by different food inspectorates. Most businesses perceive inspections as a burden, and not an opportunity to improve food safety or quality. Firms explain that they are required to present their premises, designate a member of their staff to support the inspection, provide documents, prepare sample batches of their products for lab tests, and occasionally make other resources available to inspectors (e.g., they are asked to pick up inspectors or to drive them around the premises).

Source: World Bank Group survey of 46 firms in the food sector in Podkarpackie and Lubelskie

# Food businesses do not know their risk rating.

# According to existing rules and regulations, the frequency of inspections is determined by the risk rating given by inspectors. Most businesses are not aware that inspected companies should be chosen on the basis of risk. Most companies pointed out in

#### What local businesses say

"I was not informed about my risk rating or the possibility of changing it by any of the inspectorates. I did not even know that inspectors assess the risk level of facilities."

MICRO BUSINESS

interviews that inspectors do not share information about their assessment of the risk level of the facility, nor do they articulate how this risk is assessed. Seven out of 46 interviewed firms report to have received information on their risk rating from inspectors and three out them were informed about ways to improve their rating.

#### Announcing inspections helps to reduce burden.9

About half of all entrepreneurs stressed that planned and announced inspections significantly help them reduce inspection burdens. Announced inspections allow firms to manage workflow. Companies can secure the presence of key personnel and prepare the necessary documents. Firms noted that would like announced inspections to be more common.

#### Inspections are at times perceived as inconsistent.

Thirteen ouf of 46 companies referred to one or more instances in which controls by different inspectors from one agency or controls by different agencies led to contradictory recommendations for the same company. Cases of different interpretations of regulations amongst: (i) inspectors from the same local inspectorate, (ii) inspectors from different inspectorates in the same region, and (iii) inspectors

#### What local businesses say

"Differences in interpretation of regulations are sometimes very big. A year ago we completed an inspection with no irregularities identified. But, during the next inspection two months later we received an extensive list of things to fix. How is this possible?" MEDIUM-SIZED BUSINESS

from the same inspectorate and different regions were mentioned. Firms indicated that this creates business uncertainty and increases compliance costs. While it is possible to appeal divergent interpretations, businesses prefer to accommodate than challenge inspectorates.

#### The rules concerning sample collection are not clear to all companies.

At least eight companies voiced reservations about the sample collection process, in particular the lack of information from inspectors about the number and origin of samples. Some companies complained that even after the inspection they did not know which samples were collected. According to some firms, there is also no clear sampling procedure for different tests. In some cases, firms say, the sampling is conducted in an inefficient way, blocking entire food consignments (including batches not sampled) for weeks, without giving due reason. Some companies mentioned the need for a sampling process that would allow results to be challenged based on tests from certified labs other than the ones operated by inspectorates.

#### Inspectors' approach is considered rigid by some firms.

At least five companies referred to rigid and formal inspections and substantiated their opinions with examples of problems that had a significant impact on their business. Firms reported that while Hazards Analysis and Critical Control Points (HACCP) requirements can be met in different, technically equivalent ways, inspectors

According to EU law, no notice should be given prior to performing regular controls, unless such prior notice is absolutely necessary for the controls to be carried out (Article 3.2 of the EU Regulation 882/2004). However, audits and other compliance promotion activities may be announced.

have not approached different compliance strategies as equivalent. One company explained that it was required to purchase additional equipment even though its existing equipment met performance standards. Firms would welcome if inspectors were more discerning of internal control systems and procedures.

#### Firms do not mention corruption as a challenge.

Out of 46 interviewed companies, one firm indicated that a bribe was solicited (though it was not a recent incident). Firms have generally not experienced or heard about corruption cases in the sector.

#### 1.2.2. COMPLIANCE PROMOTION

#### The regulatory environment is complicated for most food businesses.

Most firms singled out two key problems: the number of requirements and frequent changes in requirements. Many food businesses were confused by the coexistence of EU regulations that apply directly and national requirements set to conform to EU regulations and directives. One such example is the Law on the Safety of Food and Nutrition and its bylaws, which coexist and to some extent overlap with more than 80 EU regulations and directives. Many companies mentioned that it was difficult to stay abreast with changes in requirements as well as different interpretations of requirements.

#### What local businesses say

"Once, we were preparing a new label and wanted to consult its design to avoid problems in the future. Inspectors refused to help us and told us that their role does not include providing advice."

MICRO BUSINESS

"We would like inspections to have a more advisory and informative role. The role of inspection should be focused on supporting companies in preventing non-conformities, not on discovering them and penalizing."

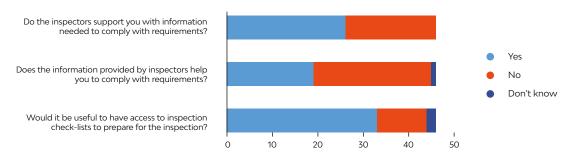
MEDIUM-SIZED BUSINESS

# Companies are willing to comply but need additional information and advice to follow requirements.

Almost all entrepreneurs said that they would like to abide by regulations, but generally do not know how to comply. Most businesses would welcome information from inspectorates that could help them meet requirements. Twenty out of 46 firms indicated that inspectors do not provide them with such information during inspections (see Figure 7). Firms who received such information were generally not satisfied with the advice they received while some firms declared that

their questions were sufficiently answered. Almost all companies confirmed that having access to inspection checklists (a list of items controlled during inspections) and guidelines (instructions for businesses) could help them to comply. Some firms also expressed strong appreciation for inspectors who were willing to share information on how to comply by presenting different compliance options, where possible based on practical examples.

**FIGURE 7.** Firms' perspectives on compliance promotion



Source: World Bank Group survey of 46 firms in the food sector in Podkarpackie and Lubelskie

#### Most companies value inspectors for their knowledge of regulations.

Most entrepreneurs feel that inspectors are privy to more specialized information about regulatory requirements than they could acquire on their own. Firms value inspectors and acknowledge the value of inspections when they receive clarifications on requirements. They also appreciate when inspectors explain how these requirements apply to their situation, e.g. how they should adapt their equipment and their production process. Inspectors can build on the recognition of their regulatory expertise to deepen relationships with firms and expand their efforts to support voluntary compliance.

#### Some companies identify gaps in inspectors' knowledge of food technology.

Several firms, mostly medium and large-sized ones, complained that inspectors are not well prepared to examine their equipment and production process. Companies claim that these gaps in knowledge slow down inspections and may result in judgment errors. At the same time, most firms have not identified this issue as a challenge and several companies were appreciative of inspectors with long work experience in the food sector.

#### The relationship between inspectors and firms is also marked by limited trust.

Several companies reported that inspectors fear that their advice may be misconstrued as a binding recommendation to which they would be held accountable. At the same time, several firms explained that they are afraid to ask questions because they worry that these questions will be held against them and that they may direct the inspector's attention towards potential shortcomings. Several businesses were worried that inspectors were forced to find non-conformities. Firms repeatedly pointed out that they did not feel treated as equals. About half of interviewed companies mentioned that inspections were stressful. The tension associated with inspections appears to limit the potential for compliance promotion by inspectorates and voluntary compliance by firms.

# 2. LOCAL AND INTERNATIONAL INSPECTION PRACTICES

How do food inspection practices in Podkarpackie and Lubelskie compare to international best practices? Can national and regional authorities learn from international experiences to reduce inspection burden and improve compliance in southeastern Poland? This chapter responds to these questions in three parts that correspond to three best practice principles of regulatory enforcement outlined in WBG and OECD guidelines: i) coordination; ii) risk assessment; and iii) compliance promotion. The analysis is based on interviews with representatives of all food inspectorates active in southeastern Poland, official data and documents, as well as interactions with and desk research on inspection services in more than 10 OECD countries.

#### 2.1. COORDINATION

#### 2.1.1. LOCAL PRACTICES

There are five institutions involved in the control of food-related legal requirements in Poland: Veterinary Inspectorate (VI), State Sanitary Inspectorate (SSI), Trade Inspectorate (TI), Agricultural and Food Quality Inspectorate (AFQI) and State Plant and Seed Inspectorate (SPSI).

The Veterinary Inspectorate's primary responsibility is in veterinary control and safety of food of animal origin. It oversees veterinary control in domestic trade and import/export of animals as well as the safety of products of animal origin. It has 5,947 employees (2,249 inspectors) and it consists of the General Veterinary Inspectorate (GVI), nine Border Veterinary Inspectorates (BVI), 16 Voivodship Veterinary Inspectorates (VVI) and 305 Poviat Veterinary Inspectorates (PVI). It supervises farms, slaughterhouses, and producers of food of animal origin.

The State Sanitary Inspectorate is designated to protect public health. Besides the food sector, it is responsible for oversight of schools and health care facilities, as well as workplace hygiene and disease prevention. Its specific functions entail: oversight of the hygiene of foodstuffs; pesticide residues in food; contaminants and imports of food of non-animal origin, materials and articles intended to come into contact with food, food additives, genetically modified organisms (GMOs) in food, supplements, and novel food.10 They supervise establishments involved in food production, trade, transportation, and storage. There are 10 Border Sanitary and Epidemiological Stations (BSES), 16 Voivodship Sanitary and Epidemiological Stations (VSES) and 318 Poviat Sanitary and Epidemiological Stations at the district level (PSES). There are 3388 employees (2524 inspectors) in food safety field at the State Sanitary Inspectorate.

The Agricultural and Food Quality Inspection supervises the quality of agricultural and food products in Poland. It performs controls at the production stage, import, export, and trading stages: supervision of the fruit and vegetable market, classification of bovine and porcine carcasses in the EUROP system, organic farming standards, and wine and hop markets. The Agricultural and Food Quality Inspection consists of the Central Inspectorate and 16 voivodship inspectorates, with 659 employees (549 inspectors) working in the food control area and functions. The primary aspects of quality control are proper packaging, labeling and classification. The agency oversees farmers, producers and traders of food products.

The Trade Inspectorate is part of the Office of Competition and Consumer Protection. It is tasked with the protection of consumer rights in the field of services, food, and non-food products. It employs 345 staff (277 inspectors) across Poland. TI oversees sellers. In the field of food products, the main concerns of the TI are: marketing and information, labeling, weight of the product.

The State Plant and Seed Inspectorate oversees regulations for plant health, seeds, and the marketing, trade and use of plant protection products. At the regional level, there are 16 voivodship inspectorates (VSPSI), 255 field units and 13 border inspection points. The total number of staff is 1832 (1569 inspectors). SPSI oversees sellers of seeds, seedlings and plant protection products, and farmers.

A simplified overview of the institutions responsible for food and feed safety, animal health, animal welfare, and plant health is presented in Table 2.

<sup>10</sup> According to EU law, novel food is defined as food that had not been consumed to a significant degree in the EU before 15 May 1997, when the first regulation on novel food came into force. Novel food can be newly developed, innovative food, food produced using new technologies and production processes, as well as food which is or has been traditionally eaten outside of the EU. Examples of novel food include food derived from new production processes (UV-treated milk, bread, mushrooms and yeast), extracts from existing food (Antarctic Krill oil) or agricultural products from third countries (chia seeds, noni fruit juice). Novel food requires pre-market authorization in the EU so that it is safe for consumers, properly labelled, and if they is intended to replace another food, it is not nutritionally disadvantageous.

**TABLE 2.**Competent authorities by inspection domain

	AREA	POLICY CO-ORDINATION	CO-ORDINATION OF INSPECTIONS	IMPLEMENTATION OF INSPECTIONS
1.	Animal Health	MARD	GVI ARMA	VVI / PVI
2.	Food of Animal Origin	MARD MH	GVI SSI	VVI / PVI VSES / PSES
3.	Imports of animals and food of animal origin	MARD MF	GVI Customs Service	BVI / PVI Customs Service
4.	Feedstuffs	MARD MF	GVI Customs Service	RVI / PVI / BVI Customs Service
5.	TSEs/ABP	MARD	GVI ARMA	RVI / PVI / ARMA Regional Offices
6.	Veterinary medicines: authorization, marketing & distribution	MH MARD	MPI GVI	VPI RVI
7.	Foodstuffs and food hygiene	МН	SSI	VSES / PSES
8.	Import of food of plant origin	MH MARD MF	SSI Customs Service	VSES / BSES Customs Service
9.	Plant protection products: authorization, quality control, marketing and use	MARD	SPSI	VSPSI: Field Units
10.	Animal Welfare	MARD MI	GVI	VVI / VVI / BVI
11.	11. Plant Health	MARD	SPSI	VSPSI: Field Units

Source: European Commission, Directorate-General for Health and Food Safety

Abbreviations: TSEs - Transmissible Spongiform Encephalopathies (including BSE, bovine spongiform encephalopathy), ABP - animal by-products, MARD - Ministry of Agriculture and Rural Development, MH - Ministry of Health, MF - Ministry of Finance, MI - Ministry of Infrastructure, GVI - General Veterinary Inspectorate, ARMA - Agency for Restructuring and Modernization of Agriculture, SSI - State Sanitary Inspectorate, MPI - Main Pharmaceutical Inspectorate, SPSI - State Plant and Seed Inspectorate, VVI - Voivodship Veterinary Inspectorates, PVI - Poviat Veterinary Inspectorates, VSES - Voivodship Sanitary and Epidemiological Stations, BSES - Border Sanitary and Epidemiological Stations, PSES - Poviat Sanitary and Epidemiological Stations, VPI - Voivodship Pharmaceutical Inspectorate, VSPSI - Voivodship State Plant and Seed Inspectorates.

# The division of responsibilities creates fragmentation of food control and oversight.

Five agencies supervising the food sector fragments control of food and foodstuffs. Fragmentation affects food safety, creates unnecessary costs and may create confusion for consumers. According to the most recent country report by the European Commission's Directorate General for Health and Food Safety (DG SANTE),11 fragmented control between agencies requires a significant level of coordination and strong dedication to information exchange.

<sup>&</sup>lt;sup>11</sup> Food and Safety country profile, Ref Ares (2017)2205255 -28/04/2017.

# Fragmentation results in parallel controls and increases the possibility for duplication.

Duplication of control occurs when two agencies oversee the same establishment/process/product against the same risks. In Poland efforts have been made to avoid duplications, mainly through legislation delineating functions of different agencies and interinstitutional agreements.

Parallel control occurs when two or more agencies carry out controls of the same establishment/process/product for different risks; or two agencies carry out inspections of the same establishment/product for the same risks but during different stages of the food chain. Parallel controls, a direct consequence of fragmentation, are common in Poland. The following examples illustrate this problem:

- Control of labeling is done by three inspectorates: health claims are checked by the State Sanitary
  Inspectorate; correctness, language, signs and obligatory information is checked by the Agricultural and
  Food Quality Inspectorate during manufacturing and processing, while the Trade Inspectorate does so
  at retailers.
- Weight of products (as an element of commercial quality) is controlled by the Agricultural and Food Quality Inspectorate and Trade Inspectorate.
- During import procedures, fruits and vegetables are inspected by the State Plant and Seed Inspectorate
  for pests and diseases, while the Agricultural and Food Quality Inspectorate checks size, shape, caliber
  and freshness.
- Raw berries and leafy vegetables are inspected by the State Plant and Seed Inspectorate and State Sanitary Inspectorate at the production place (sometimes even at the same time).
- Control of raw meat and meat for processing in the marketplaces responsibilities are divided between the Veterinary Inspectorate and State Sanitary Inspectorate.

The negative consequences of parallel controls are not immediate and obvious, but widespread:

- It is difficult to ensure that requirements are applied consistently when the same products are controlled by different agencies at various stages in the value chain (production, marketing, trade).
- Public resources are used inefficiently, since inspections are carried out by different agencies but focus
  on the same premises and products.
- Business face additional burdens as they need to understand which aspect of the same product/ establishment is controlled by which agency and need to host more inspections and provide more samples.

As shown in Table 2, inspections in Poland are further fragmented by the split of responsibilities between 16 voivodships and 379 poviats (districts), opening ground for inconsistencies among various levels of the same agency.

# Problems resulting from fragmentation are addressed through multiannual control plans and interinstitutional cooperation agreements.

In order to ensure coordination and effective control among different agencies, EC Regulation 882/2004 requires each member state to establish and implement a multi-annual national control plan for animal health, welfare, feed, and food. Each country provides an annual implementation report with the results of the official control. Poland's multiannual control plan covers all five institutions involved in food inspections.

In addition, Polish inspectorates conclude interinstitutional cooperation agreements to coordinate food inspections. Interinstitutional agreements delimit competencies, clarify responsibilities of institutions in emergencies, and set procedures for joint planning, joint controls, and information exchange.

Interinstitutional agreements have been implemented in Podkarpackie and Lubelskie. There are agreements between the State Sanitary Inspectorate and Veterinary Inspectorate of 2007 and the State Sanitary Inspectorate, State Plant and Seed Inspectorate, Agricultural and Food Quality Inspectorate, and Environmental Inspectorate of 2015. Interinstitutional agreements are concluded at the central level and similar agreements are subsequently signed at voivodship and poviat levels. Implementation of agreements varies and depends largely on local leadership.

# There is growing recognition that institutional consolidation could remedy the fragmentation of food inspections in Poland.

In June 2017, the government of Poland adopted the draft Law on the Creation of the State Food Safety Inspectorate (or National Food and Veterinary Inspectorate).12 It consolidated the institutions related to food safety in Poland. The new State Food Safety Inspectorate (SFSI) will subsume the Veterinary Inspectorate, Agricultural and Food Quality Inspectorate, and State Plant and Seed Inspectorate, as well as parts of the State Sanitary Inspectorate and Trade Inspectorate related to food.

The draft law draws on the experiences of 23 European countries, which consolidated several food safety institutions to ensure effective coordination. The State Food Safety Inspectorate would be responsible for food safety (animal and non-animal origin), some food quality issues, veterinary matters (animal health, animal welfare, feeds), and plant health (seeds, plant protection products, fertilizers).

# Fragmentation could be further reduced by standardizing operating procedures, e.g. for risk assessment.

As shown in chapter two of this report, procedures for risk assessment, categorization of establishments, collection of data from inspections, and complaints management vary significantly between inspectorates. These differences hamper the effective exchange of information related to inspection objects. For example, the State Sanitary Inspectorate and Veterinary Inspectorate supervise meat-related risks in supermarkets and markets, however the information collected is not shared across agencies. Existing risk assessment matrices are based on rules and forms set by different inspectorates. In some cases, inspectorates collect the same pieces of information, such as the type or the size of the establishment.

#### ICT tools can also help to streamline food inspections but are underutilized.

All food inspectorates in Poland developed elementary record-based software applications for inspections. These tools help to manage registries of establishments, record the number of inspections and outputs (non-conformities, fines), and generate statistical reports. Several software developers created existing applications in-house.

Technically, intrainstitutional communication between all administrative levels in the Veterinary Inspectorate and State Sanitary Inspectorate is by e-mail, conventional mail, and/or fax. The exchange of information between agencies is also carried out in the same manner. All existing means of communication rely on inspectors personally forwarding information. For instance, information about new establishments is shared in scanned portable document format (PDF), which makes it time-consuming and error-prone to find and copy information. Day-to-day cooperation and exchange of information relies heavily on personal relations between officials.

Inspectorates develop and use IT systems separately. The software applications implemented by inspectorates are used within inspectorates only, and without automated data exchange with external information systems. As a result, businesses are repeatedly asked to provide information about their operations and inspectorates lack the necessary data to plan their activities. Existing software applications were developed independently by inspectorates, and are hosted in separately administered server rooms, increasing the cost of operations.

<sup>&</sup>lt;sup>12</sup> At the time of writing (May 2018), the Law on the Creation of the State Food Safety Inspectorate was not enacted by the Polish parliament.

There are few online services provided by the inspectorates. Two-way communication with businesses and other institutions is mainly manual, using paper-based documents. Only very limited data is publicly available. There is no data published online for use by business operators, except for the Veterinary Inspectorate, which publishes the registry of establishments.

Risk assessment and inspection planning are not automated. While some of the existing software applications provide basic information to facilitate risk assessment, the process is still conducted manually, leaving room for subjectivity and errors. The selection of businesses and objects for inspections is also done manually, and inspection schedules are only entered into the software programs. The relation between the risk assessment and scheduled inspection is not recorded in software applications used by inspectorates.

Inspectors only have desktop computers. They do not have mobile devices or applications to retrieve or upload information during inspections. Inspection checklists are not automated in the implemented software packages. The Veterinary Inspectorate initiated a pilot of electronic checklists with basic questions structured according to sections of existing checklists and answers recorded in the form of the confimed non-conformities (not weighted by risk). However, inspectors still record outcomes of field visits with paper-based documents and input the data into the inspection software only when they return to their offices. Also, inspectors enter data into several software packages (e.g., veterinary inspectors into the inspection software and the Animal Identification and Registration System), creating duplicate entries, which require additional overhead and increase the possibility of data errors.

#### 2.1.2. INTERNATIONAL PRACTICES

# As per EU rules, control of food is to be organized along the food chain in a way that ensures unbroken information flow.

Food labeling is an important element of food safety and a way to secure traceability. To maintain unbroken information flow, either one agency controls both labeling and food safety, or a robust exchange of information between agencies is secured. In France, one competent authority (Directorate-General for Competition Policy, Consumer Affairs and Fraud Control) plans and enforces control of food safety in processing facilities (except slaughterhouses) and labeling (including nutritional labeling and health claims). The Directorate General for Food oversees primary production control, in approved facilities, whereas the National Institute for Origin and Quality manages labeling of organic primary and processed products, and pre-market quality control. Information between the two agencies is exchanged regularly. In the United Kingdom, at the local level, food safety inspectors and Trade Standards inspectors (who control labeling) perform joint control. Instructions for control are developed centrally, by the Food Standards Agency.

#### Institutional consolidation is common to improve coordination.

Safe food can only be achieved by ensuring the integrity of the food chain, i.e. food is kept safe at each a step "from farm to fork" and "from stable to table". This basic premise has resulted in good practice recommendations by international institutions engaged in this area, in particular the Food and Agriculture Organization of the United Nations, to unify all food safety regulatory control under one authority. In the EU, a consolidated food safety system is the most prevalent. Denmark, Sweden, Finland, Lithuania, and Ireland, among others, have consolidated food safety enforcement in one institution. Yet, consolidation is not always achieved as a number of existing food safety systems have institutional structures rooted in the past. At a minimum the responsibilities of the different institutions involved in controlling the food chain should be clearly defined and integrated.

#### Legal obligations to conduct risk assessment and promote compliance through means other than sanctions are also used to stimulate coordination.

In recent decades, countries have introduced business regulations that are applicable to all inspectorates in various fields of control- food, fire, health, environment, and occupational safety. Countries that embarked to improve the work of inspectorates realized that, despite technical differences, all supervisory institutions share the same core function in the state administration system and therefore the rules pertaining to inspections, planning and publicity requirements should be similar.

The United Kingdom adopted the Regulator's Code in 2008 and revised it in 2014. The Code provides a flexible and principles-based framework for regulators that covers relations with businesses and citizens, establishes duty of regulators to support growth and voluntary compliance. Italy adopted guidelines on inspections in 2013, the Netherlands in 2017. Slovenia and Lithuania adopted horizontal, inspection-related provisions in its framework legislation in 2007 and 2010 respectively. An inspection law was also adopted recently by the Greek parliament.

# Countries establish umbrella bodies, which foster cooperation on inspection practices and general policy matters.

For instance, in 2007 In the Netherlands' Inspection Council (Inspectieraad) was created to foster communication and cooperation among inspectorates in different fields of supervision. It addresses issues common to inspectorates, ranging from monitoring practices and implementing shared IT projects, to restructuring and consolidating institutions as well as changes in staffing. Lithuania created the Committee of Experts on Improvement of Inspection Practices in 2010 under the Ministry of Economy, with participation of major inspectorates. Although the committee does not have formal decision-making powers, it became the first-ever peer-learning forum for inspectorates in the history of the country. This forum allows inspectorates to share challenges, identify regulatory gaps, test reform tools and ideas, and consolidate the approach to inspections.

# The United Kingdom developed an innovative approach to improve coordination between territorial units: the Primary Authority scheme.

In 2010, the United Kingdom's Better Regulation Delivery Office introduced the Primary Authority scheme. This scheme allows companies operating in different local authorities to establish a special agreement with an inspectorate in a single territorial unit that would govern all the relations with the regulator in all other territorial units. The substance of the agreement between the regulator and the company is that assured and tailored advice on complying with environmental health, trading standards, or fire safety regulations of local authorities are adhered to by other local regulators. The scheme provides more confidence to businesses about their obligations towards the state and the consumers.

# IT tools implemented in the Netherlands, Croatia, and Bosnia and Herzegovina help to coordinate inspections.

The Inspection View, implemented in the Netherlands 2013 and leveraged in different inspection domains, is an integration platform that enables data exchange and horizontal coordination between Dutch inspectorates. It designates a virtual file in which inspectors can consult information on inspected objects. In Croatia, inspectorates within the Ministry of Agriculture use the e-Inspector tool to plan inspections based on risk assessment. Usually the frequency of inspections is determined based on risk, inspection history and knowledge base, as well as evidence of actions taken to rectify non-compliances and reduce risks. There are several indicators used to estimate risks, including the data collected on the basis of inspection checklists. In Bosnia and Herzegovina, the existing Inspection Management IT solution allows recording inspection results in the field using inspection checklist and notebook computers. Data are instantly uploaded and synchronized with the central database and available for statistical reporting.

#### 2.2. RISK ASSESSMENT

#### 2.2.1. LOCAL PRACTICES

#### 2.2.1.1. Methodology

#### All food inspectorates in Poland have developed risk assessment methodologies.

Risk assessment is the process of identifying food safety hazards, assessing the likelihood of occurrence and severity, and evaluating significance.13 Risk assessment involves categorizing supervised facilities according to levels of risk and making comparisons between businesses on the basis of this categorization. Risk assessment helps to decide about the optimal allocation of scarce resources for food safety enforcement. To ensure accuracy and consistency, risk assessment should be conducted based on a methodology that combines inherent indicators (e.g., owing to the type of business activity microbiological risks are larger for slaughterhouses than for kiosks) and compliance indicators (e.g., risks are higher in facilities with a history of non-conformity than in facilities with a "clean" record).

In Poland, risk assessment methodologies are set by central inspectorates and applied nationwide. These methodologies are then used by regional inspectors to assess the risk level of individual facilities.

The two largest inspectorates, the State Sanitary Inspectorate and the Veterinary Inspectorate, rely both on risk assessment methodologies, which are based on inherent indicators and compliance indicators. In the case of the State Sanitary Inspectorate, inherent indicators include types of production/products, volume of production/turnover and information on consumers. Compliance indicators are based on actual inspections and include information on how requirements regarding infrastructure, hygiene, microbiological indicators and internal control system were met. Each compliance indicator is assigned a weight (a maximum number of points). The sum of points for all indicators represents the degree of compliance. The instructions of the State Sanitary Inspectorate for the assessment of compliance indicators, however, are not precise enough to ensure consistent grading by inspectors. For instance, there are indicators that deal with several different topics and it is not clear which topic should prevail when assessing whether requirements are met. There are also no clear criteria to assign weights each of the indicators.

The Veterinary Inspectorate also developed a risk assessment methodology based on inherent indicators (type of activity) and compliance indicators (infrastructure, practices, internal management system), as well as weights (points) assigned to each indicator. Small producers are automatically classified as low-risk, while other types of businesses are rated either as high-, medium-, or low-risk. Inspectors determine the risk category of a facility by aggregating the total number of points after a site visit. Several checklists are used and findings recorded in protocols.

The Agricultural and Food Quality Inspectorate and Trade Inspectorate determine risk for commodities at the central level on the basis of information on non-conformities identified by regional inspectors during the previous year as well as other sources of information (e.g., RASFF, trade partners, complaints, information from other inspectorates). Trade inspectors target facilities based on information about the type of activity, the scope of inspection, the probability of non-conformities, history of inspections and how long a facility has been in business. Agricultural & Food Quality inspectors also prioritize facilities that have not been inspected or facilities that have been inspected but have a history of non-conformities.

<sup>15</sup> In this chapter, risk assessment is understood as subsuming risk management, which is the coordinated and economical application of resources to minimize and monitor the impact of food-borne incidents and to maximize opportunities for growth in the food sector.

The State Plant and Seed Inspectorate categorizes businesses by risk related to the use and handling of pesticides but does not apply risk assessment in the area of plant health and seeds, largely due to data limitations. The State Plant and Seed Inspectorate also highlights nationwide priority areas in any given year, including areas of highrisk, and requests regional inspectors to take these areas into consideration when preparing annual inspection plans. The Plant and Seed Inspectorate categorizes farms and businesses according to risk in terms of use/handling of pesticides.

# Risk assessment methodologies are in general used to determine how frequently businesses should be inspected.

Risk assessment methodologies developed by central inspectorates are widely used to determine the frequency of inspections by regional inspectors. The lowest frequency for veterinary inspections is at least once in 12 months (low-risk facilities) and the highest is at least once in three months (high-risk facilities). For sanitary inspections, the highest frequency is at least once in 12 months for production facilities, at least once in 18-24 months for trade facilities, and at least once in 66 months for primary producers that sell low-risk products directly to customers. Since frequencies are specified as minimum, inspections can take place more often and opens the possibility for unnecessary controls.

Other inspectorates do not apply risk levels to determine the frequency of inspections per establishment. Risk assessment systems in these institutions are based on a top-down approach. In the case of the Agricultural and Food Quality Inspectorate, risk levels and related frequencies of controls are determined by the priorities of particular control programs, which are then used to identify relevant facilities. Similarly, the State Plant Health and Seeds Inspectorate determines the number of farms to be inspected annually, per region, based on national statistics of farms, number of farms, quantity of pesticides applied per crop, and statistics on violations (per region). Additionally, the type of crop and related biological characteristics of potential hazards determines the frequency of controls. The Trade Inspectorate focuses mostly on alerts from consumers and does not maintain separate databases. Necessary information is acquired from general business registers (CEIDG or National Court Register).

**TABLE 3.**Frequencies of inspections by risk category

LEVEL OF	FREQUENCY OF CONTROL		
RISK OF FACILITIES	STATE SANITARY INSPECTORATE	VETERINARY INSPECTORATE	
HIGH-RISK	At least once every 12 months for production facilities	At least once every 3	
FACILITIES	Every 18 months for trading facilities	months	
MEDIUM- RISK	At least once every 18 months for production facilities	At least once every 6	
	At least once every 24 months for trading facilities	months	
	At least once every 24 months for production facilities		
LOW-RISK	At least once every 36 months for trading facilities		
	At least once every 66 months for primary producers which sell directly products which have low microbiological risk	months	

Source: Veterinary Inspectorate, State Sanitary Inspectorate

#### 2.2.1.2. Implementation challenges: coverage, categorization, consistency, capacity

Not all facilities have been assigned risk categories by food inspectorates and inconsistencies remain in the process of risk categorization.

According to internal regulations, all facilities under the supervision of the State Sanitary Inspectorate should be subject to risk assessment, 14 while in the Veterinary Inspectorate, 6 out of 38 categories of facilities under

<sup>&</sup>lt;sup>14</sup> Appendix No. 1 to Order No. 104/17 of the Chief Sanitary Inspector from May 8, 2017.

supervision are excluded from risk assessment (e.g., smallholders, retailers).15 However, the share of facilities under supervision covered by risk assessment varies between regions. While this difference may be due to variations in characteristics of the firms, it is more likely due to incomplete coverage and inconsistent risk ratings. In the case of the Veterinary Inspectorate, the share of supervised facilities in one region was more than double the share of supervised facilities in another region in 2016. In the case of the State Sanitary Inspectorate differences in risk assessment methodology were confirmed between regions and poviats in the same region.16 There have also been coverage and consistency gaps confirmed in the case of other food inspectorates.

# Many food inspections are unplanned. One of the drivers of unplanned inspections is complaints.

The two largest inspection bodies, the State Sanitary and Veterinary Inspectorates, conducted over 12,000 unplanned food inspections in Podkarpackie and Lubelskie in 2016, accounting for about one third of inspections by these institutions. Unplanned inspections were mostly caused by outbreaks, alerts from the Rapid Alert System for Food and Feed (RASFF) or trade partners, information from other inspectorates, and complaints filed by consumers or competitors. Unplanned inspections are ad hoc and therefore not risk-based. They are necessary in the case of emergencies, but are harder to justify in less acute situations.

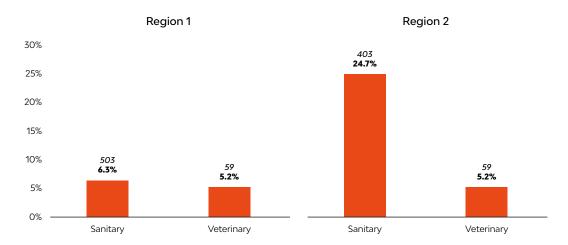
#### What local businesses say

"There should be a mechanism to assess the seriousness and truthfulness of consumer complaints. We have experienced many inspections due to complaints but during inspections all complaints turned out to be unfounded."

MEDIUM-SIZED BUSINESS

In 2016, complaints were responsible for 2-25% of unplanned inspections by the Veterinary and the State Sanitary Inspectorate in Podkarpackie and Lubelskie. Complaint-based inspections were most frequent in the State Sanitary Inspectorate. In addition, the majority of inspections performed by the Trade Inspectorate were due to consumer alerts.

**FIGURE 8.**Share of unplanned inspections triggered by complaints, 2016



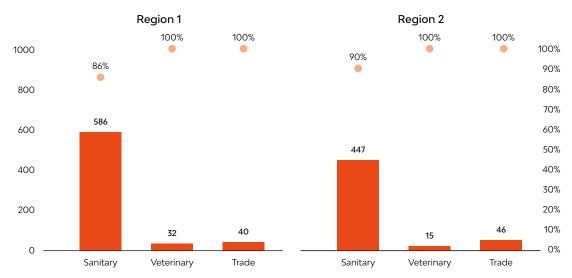
 $Source: Voivodship\ Veterinary\ Inspectorate\ and\ Voivodship\ Sanitary\ and\ Epidemiological\ Stations\ in\ Podkarpackie\ and\ Lubelskie\ Podkarpackie\ and\ Lubelskie\ Podkarpackie\ Podkarpackie\$ 

<sup>15</sup> The list of facilities excluded from risk assessment has been determined on a basis of Appendix No. 1 to Ordinance of the Ministry of Agriculture and Rural Development from December 15, 2016 (determining groups of all facilities under supervision of Veterinary Inspection) and Instruction No. 500 – 2/11 from September 1, 2011 (determining groups of facilities which are subject to risk assessment).

<sup>16</sup> In several poviats, risk was rated only on the basis of information gained in the most recent inspection. Thus, there were as many risk ratings as inspections. Information gained earlier about facilities, including its historical compliance record, was disregarded. In other poviats, the risk assessment process included information on historical compliance as well as other information about facilities under supervision.

The number of complaints received varied significantly between each inspectorate, as did the reaction of inspectorates to complaints. While the State Sanitary Inspectorate in both regions received more than 1,000 complaints in 2016, the Trade and Veterinary Inspectorates received 86 and 47 complaints, respectively. In the State Sanitary Inspectorate, 88% of complaints resulted in unplanned inspections. In the Veterinary and Trade Inspectorates all complaints triggered physical inspections.





The majority of complaints filed with the Veterinary and State Sanitary Inspectorates were anonymous compared to about one third in the Trade Inspectorate. Businesses confirmed in interviews that anonymous complaints are frequent and suggest that complaints are often not related to public health but driven by rivalry between competitors.

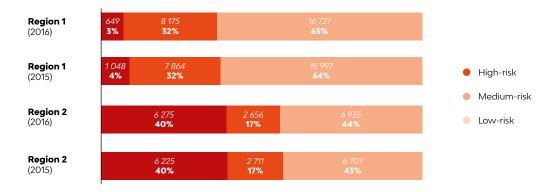
Policies to address complaints differ among inspectorates. There is not a unified methodology for complaint triage and management. Some institutions have basic complaint management mechanisms, such as the Plant and Seed Inspectorate, which interviews both the complainant and the complainee. The Agricultural and Food Quality Inspectorate has also a basic management mechanism that takes into consideration if the complaint is anonymous, the inspectorate is the competent authority, and the facility in question was included in the annual plan of inspections.

# The distribution of companies into risk categories does not always correspond to a "risk pyramid".

There are to be differences between inspectorates and regions. The distribution of risk categories in the State Sanitary Inspectorate in one of the regions covered by this report is consistent with the pyramid approach of ensuring that a minority of firms is categorized as high-risk while a majority is treated as low-risk. However, in the other region, 40% of supervised facilities were categorized as high-risk and 43% as low-risk, leaving about one fifth of all facilities in the medium-risk category.

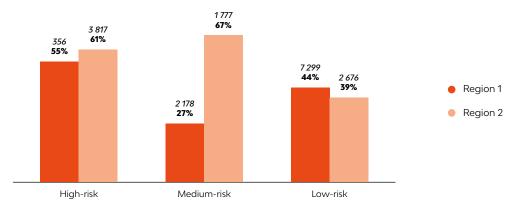
The differences between regions were also reflected in the statistics on actual inspections by the State Sanitary Inspectorate. High-risk facilities in one of the regions were on average controlled 50% more often than low-risk facilities. However, the frequency of controls of medium-risk companies varied significantly, with two thirds of all medium-risk establishments controlled in one of the regions and less than one third of all medium-risk establishments controlled in the other region. The distribution of inspected companies by risk category has been generally found to be stable across time.

**FIGURE 10.**Supervised facilities by risk category, State Sanitary Inspectorate, 2015-2016



Source: Voivodship Sanitary and Epidemiological Stations in Podkarpackie and Lubelskie

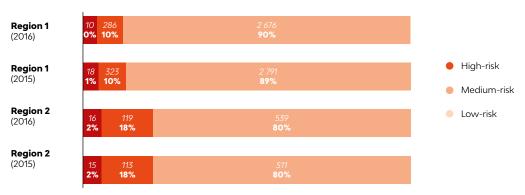
**FIGURE 11.**Share of facilities inspected by risk category, State Sanitary Inspectorate, 2016



Source: Voivodship Sanitary and Epidemiological Stations in Podkarpackie and Lubelskie

In the Veterinary Inspectorate, the distribution of companies into risk categories is pyramid-shaped, with the smallest number of companies in the high-risk group and the majority categorized as low-risk. There are also no major differences between the two regions regarding the frequency of inspections by risk category. In both regions, all high-risk companies, more than 95% of medium-risk facilities, and more than 88% of low-risk facilities were inspected in 2016.

FIGURE 12.
Supervised facilities by risk category, Veterinary Inspectorate, 2015-2016



Source: Voivodship Veterinary Inspectorates in Podkarpackie and Lubelskie

Region 2

Share of facilities inspected by risk category, Veterinary Inspectorate, 2016 15 **100%** 16 **100%** 283 **99**% 2 571 **96%** 473 88%

Region 1

Source: Voivodship Veterinary Inspectorates in Podkarpackie and Lubelskie

FIGURE 13.

High-risk

#### Risk assessment is applied differently in different regions.

Medium-risk

Inspectors interpret the risk assessment methodology differently across regions. This can be demonstrated by the McDonald's test, i.e. comparing risk assessments of near-identical franchises of the same company. According

to large and medium-sized businesses, which operate the same food safety management system across regions, their facilities are graded differently because of differences in interpretation by inspectors. This leads to unnecessary high-frequency inspections in some cases. There is also no coordination mechanism in place that would allow inspectors from region A to draw on information collected by inspectors in region B related to the same business entity and thus potentially minimize the number of inspections.

#### What local businesses say

"Facilities belonging to our global retail chain were categorized differently in different poviats."

LARGE BUSINESS

Low-risk

"Identical practices of one farmer with farms in two districts were accepted in one poviat and declared non-conformant in another poviat."

MEDIUM-SIZED BUSINESS

#### The implementation of risk assessment is constrained by limited technical and human resources.

Currently, there is no integrated software application used by inspectors for risk assessment in Poland. As outlined in chapter 2.1., risk assessment and inspection planning are not automated. The process is conducted manually, leaving room for subjectivity and errors. Inspectors do not possess laptops/mobile devices to record data during field inspections. Inspectors document their results with paper forms and input rudimentary data into basic record-keeping software upon return to their office. Some information is entered into several systems.

In some areas, registers maintained by inspectorates contain insufficient data. For instance, the Plant and Seed Inspectorate does not have a complete registry of farms, nor exhaustive information on crops, making it difficult to sample farms for inspections and locate farms that grow high-risk crops.

The application of risk assessment is also constrained by difficulties in attracting and retaining talent. Food inspectors are among the lowest-paid government workers in Poland. According to data from the Chancellery of the Prime Minister of Poland and the Ministry of Health, veterinary inspectors earned in 2016 on average 62% of the average government salary of 5266 PLN gross (around EUR 1250). This metric was lower for sanitary inspectors (53-61%), agricultural food quality and trade inspectors (50%), and phytosanitary inspectors (49%). Depending on the inspection service, average salaries of food inspectors ranged in 2016 between 140% and 173% of the minimum wage in Poland.

There are also limited training opportunities for inspectors and few occasions to work in interregional and interdisciplinary teams to unify the approach to risk-based inspections. Inspectors confirmed that trainings are regularly conducted when new regulations enter into force. There were, however, limited trainings available on technical topics and inspectors expressed interest in learning more (e.g., effectiveness of different HACCP-based systems in facilities, food safety implications of technological innovations in food production and processing) and improving their communication skills.

#### 2.2.2. INTERNATIONAL PRACTICES

#### 2.2.2.1. Methodology

## Risk-based enforcement is based on a clear methodology and criteria to assess businesses.

The level of risk posed by business operations can be calculated using the simple formula: hazard x likelihood of non-compliance. The accuracy of this formula depends on the availability of information on hazards (which is a fact-based assessment) and the ability of inspectors to assess the likelihood of non-compliance in a business (which is a judgment-based assessment).

In assessing hazards, most criteria take into consideration:

- · sector of activity;
- · specific processes used;
- scope of operations;
- number of people affected (or potentially affected) by its operations; and
- geographic locations (for example, close to sources of pollution, or likely to cause pollution to critical sources such as drinking water).

In assessing the likelihood of non-compliance, relevant factors include:

- · food safety knowledge and awareness of management;
- implementation of compliance systems; and
- records of previous inspections and responses to previous advice.

Scores for both hazard and likelihood of non-compliance can be given and then translated into a risk-assessment matrix, such as the one shown in the table below. This allows the categorization of businesses into high, medium and low-risk categories.

**TABLE 4.** Sample risk matrix

	<b>VERY LOW</b>	LOW	MEDIUM	HIGH	<b>VERY HIGH</b>
нісн	LOWER MEDIUM	UPPER MEDIUM	UPPER MEDIUM	HIGH	HIGH
UPPER MEDIUM	LOWER MEDIUM	LOWER MEDIUM	UPPER MEDIUM	UPPER MEDIUM	НІСН
LOWER MEDIUM	LOW	LOWER MEDIUM	LOWER MEDIUM	UPPER MEDIUM	UPPER MEDIUM
LOW	LOW	LOW	LOWER MEDIUM	LOWER MEDIUM	UPPER MEDIUM

#### Risk assessment allows to deploy inspections where they are most needed.

The basis for risk assessment and the targeting of inspections is that it is impossible to control everything and capacities need to be focused where the need is greatest. Once a problem has been solved, the inspection effort is to be moved elsewhere. This helps to shift from an excessively frequent and broad scope to inspections that bring measurable progress.

Robust risk assessment should lead to the emergence of a risk pyramid, i.e. a distribution of supervised facilities in which there are few high-risk businesses. When implementing risk assessment, care should be taken to avoid an overly cautious approach where low-risk becomes medium-risk and many businesses are rated as high-risk.

# Good practice examples are the United Kingdom's Food Establishments Intervention Rating Schemes<sup>17</sup> and the Danish rating scheme.

Countries with sophisticated risk assessments publicly present the methods to determine the risk of facilities and frequencies of inspections. In both countries company practices and management systems are assessed and taken into consideration when determining the risk level. The use of internal control systems is encouraged and rated when categorizing facilities.

In the United Kingdom, hygiene risk is determined by inherent indicators (type of food and method of handling, method of processing, and consumers at risk) and compliance indicators (level of current compliance according to results of the last inspection, confidence in management/control procedures in place). All indicators are assigned a certain number of points. Additional points are given for food that is a potential carrier of Clostridium Botulinum, Verotoxic Escherichia Coli, Salmonella sp. or Bacilus Cereus. Total score of points determines the level of risk (A the highest – D the lowest) and frequency of inspection. For the facilities classified in the lowest risk group, alternatives to inspection are suggested.

The Food Law Code of Practice in England,18 for instance, provides detailed information on Food Establishment Intervention Rating Schemes (separate ratings for hygiene and adherence to market standards and labeling) and minimum frequencies for controls for all food establishments, with the exception of primary production and animal feed establishments.

<sup>17</sup> https://www.food.gov.uk/enforcement/codes-of-practice/food-law-code-of-practice-2015/5-6-food-establishment-intervention-rating-schemes#toc-1

<sup>18</sup> https://www.food.gov.uk/enforcement/codes-of-practice

**TABLE 5.**Frequencies for hygiene inspection in the United Kingdom

CATEGORY	SCORE	FREQUENCY	
A	92-100	At least once in 6 months	
В	72-91	At least once in 12 months	
С	52-71	At least once in 18 months	
D	31-51	At least once in 24 months	
E	0-30	A program of alternative enforcement strategies (non-official control) official control every three years	

Food standards risk is determined using inherent indicators (risk to consumers/other businesses; activities of businesses; complexity of products, processes and services including the consistency of raw materials; consumers at risk) and compliance indicators (present compliance as per results of the last inspection and confidence in management/control system, track record, and presence of management systems).

**TABLE 6.**Frequencies for food standards inspections in the United Kingdom

CATEGORY	SCORE	FREQUENCY	
A	101-180	At least every 12 months	
В	46-100	At least every 24 months	
С	0-45	A program of alternative enforcement strategies (non-official control) or official control every five years	

The Danish Veterinary and Food Administration (DVFA) prepared its rules for the classification of facilities along similar lines as the United Kingdom. In Denmark, the frequency of inspections is strongly determined by compliance and type of activity. An enterprise with third party certification and a standard annual inspection frequency of once per year can reduce the frequency of inspections by achieving the so-called elite status, i.e. having passed the last four inspections with only minor violations and one inspection in the previous 12 months with no remarks.

**TABLE 7.** Inspection frequencies in Denmark<sup>19</sup>

RISK GROUP	STANDARD ANNUAL INSPECTION FREQUENCY	ELITE INSPECTION FREQUENCY	TYPE OF BUSINESS
VERY HIGH	3 or 4	3 (2 after one year with elite status)	Only wholesalers (B2B). E.g., slaughterhouse, fish product establishment, dairy
HIGH	2	1	Brewery, egg packing establishment, butcher (retail)
MEDIUM	1	0.5	Production of vegetable products, cold store, restaurant, baker (retail)
LOW	0.5	0.5	Storage – no temperature regulation, grocer's shop (retail)
ULTRA LOW	As and when required	-	Food trade without storage, wine shop (retail)

 $<sup>^{19}\</sup> https://www.foedevarestyrelsen.dk/english/Inspection/Inspection\_of\_food\_establishments/Pages/default.aspx$ 

#### 2.2.2.2. Implementation: complaint management, consistency, capacity

#### Anonymous complaints are filtered.

In countries with the most developed risk assessment systems, inspectorates have discretion about handling anonymous complaints.

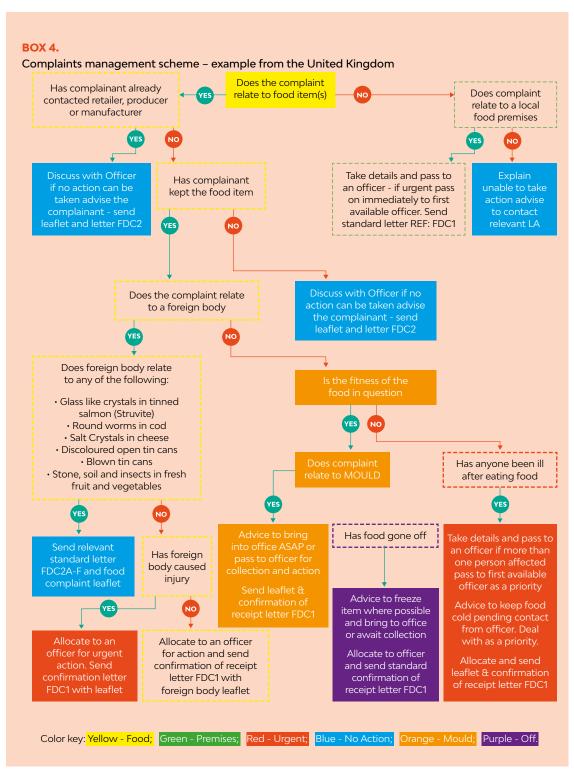
In some agencies, such as the Food Safety Authority of Ireland, such complaints cannot be investigated.<sup>20</sup>

In the United Kingdom, counties have flexibility over their complaint management system and broadly categorize them into the following groups:

- Minor complaints: If they pose little to no public risk. Such complaints may not trigger an in-depth investigation (e.g., low-risk foods beyond best before date, minor labelling offences etc.). Officers are to inform the complainant that they will address the problem during the next planned inspection to a facility on which the claim has been filed.
- Potentially serious, but not corroborated complaint: For example, concerning cleanliness or management concerns, no temperature checks, etc. If the next planned inspection is not imminent, the business is informed of the complaint and a written response requested. If the agency is satisfied with the response, the case is closed. When the response is not satisfactory, an inspection is conducted to investigate the problem. If the regular/planned inspection is imminent, the problem is investigated during the regular inspection.
- Potentially serious and corroborated complaint: This includes mouldy food, foreign bodies, food sold beyond use by date. An investigation begins immediately. A witness statement is obtained from the complainant. The complaint material is stored, marked, and handled with best practices. Careful and minimal handling of the complaint material should take place and consideration should be given to photographing it. Foreign bodies should be photographed in situ, on no account should the complaint material be removed from the food. Samples should be transferred to a designated laboratory and handled according to best laboratory practices.
- Food-borne diseases: The agency is to respond in accordance with established procedures for investigation of food-borne diseases, conduct an epidemiological investigation, include other relevant authorities and ensure that the source of contamination is found and appropriately managed. Sanctions can be issued only in situations in which the link between the cause and the disease is established and the business/person responsible for the outbreak is identified.<sup>21</sup>

<sup>20</sup> https://www.fsai.ie/make\_a\_complaint/anonymous\_complaint\_policy.htm

<sup>&</sup>lt;sup>21</sup> http://www.moray.gov.uk/downloads/file81862.pdf



 $\textit{Source}: \textbf{Bath and North East Somerset Council Equality Impact Assessment Toolkit}^{22}$ 

<sup>&</sup>lt;sup>22</sup> www.bathnes.gov.uk/sites/default/files/.../food\_complaints\_procedure\_aug\_2009.doc

# The Primary Authority Scheme in the United Kingdom ensures a uniform approach to inspections, including of facilities belonging to the same company.

The Primary Authority Scheme<sup>23</sup> gives a legal opportunity to businesses, or groups of businesses, to choose any local authority that will create a model of compliance for a business/group of businesses. The model will be used as the standard for other local inspectorates examining the same business/group of businesses. After considering all the available information, the Primary Authority can reduce the frequency of visits to firms covered by the scheme. The scheme is further implemented through a national inspection strategy.<sup>24</sup>

The program can be adapted to different institutional systems. The key is to ensure a uniform approach to a company's practices nationwide. For example, in Denmark and Norway,<sup>25</sup> a food chain's headquarters is responsible for and manages relevant parts of the food safety management system control in all branches. The combined inspection frequency for a chain is reduced by a third if the chain as a whole has high compliance (few sanctions were issued). In Portugal, the National Authority for Safety of Food and Economy (ASAE) takes into consideration the same food safety management system applied in a chain of restaurants and selects only one sixth of facilities belonging to the chain for annual control (out of 12 restaurants belonging to the same chain, only two are inspected in one year, unless the control results give reason to deviate from this policy).<sup>26</sup>

## Inspectors receive the training and equipment that they need to manage food safety risks.

Inspection activities depend on adequate resources. Human capacities are developed by scouting for qualified professionals and on-the-job training. For example, in the Norwegian Food Safety Agency's training is regarded as a means to enhance staff capabilities and morale. In 2015 a two-year project was started to turn the agency into a learning organization and to educate managers as agents of change. This included increasing management responsibilities, strengthening the expertise of inspectors, and training in statutory provisions and control methodology. Also, inspectors were taught how to implement the new national public awareness program and communicate during inspections.

Lack of resources is sometimes overcome by contracting third parties to perform inspection activities (implementation of animal health measures, ante and post-mortem meat control,<sup>27</sup> control of organic products,<sup>28</sup> etc.). Having appropriate guidance documents, standardized tools, and proper training ensures that the approach of inspectors and third parties is synchronized.

<sup>&</sup>lt;sup>23</sup> The Primary Authority scheme was established by the Regulatory Enforcement and Sanctions Act 2008 (as amended). It is overseen by Regulatory Delivery (RD) on behalf of the Secretary of State for the Department for Business, Energy and Industrial Strategy.

<sup>24</sup> https://www.food.gov.uk/enforcement/regulation/regulating-our-future/ primary-authority-national-inspection-strategy-feasibility-study

<sup>&</sup>lt;sup>25</sup> Norway Annual Food Safety Authority Report, 2015.

<sup>26</sup> DG(SANTE) 2017-6062

<sup>27</sup> http://www.oie.int/fileadmin/Home/eng/Publications\_%26\_Documentation/docs/pdf/EN\_role\_des\_services\_veterinarie\_securite\_sanitaire\_des\_aliments.pdf

<sup>28</sup> The authorities in charge of the control system for organic production may confer their control competences to one or more public control authorities and/or delegate their control tasks to one or more private control bodies, according to Article 27(4) of Council Regulation (EC) No 834/2007 of June 28, 2007 on organic production.

### 2.3. COMPLIANCE PROMOTION

### 2.3.1. LOCAL PRACTICES

### 2.3.1.1. The compliance challenge

The legal environment for food businesses in Poland is complex and inconsistencies in inspectorates' approaches create burdens to businesses.

#### What local businesses say

"If we have a hierarchical structure of inspectorates, then it should be used to have instructions for local inspectorates on how to apply law and these instructions should be publicly available for entrepreneurs. EU regulations are written in a technical language, full of cross-references and very general. Therefore, if EU law is applied directly in Poland, then more information on how to interpret the law and translate it into business practice should be provided. Instructions are rarely published and even when they are, the contents are very generic." LARGE BUSINESS

EU food legislation is based on performance standards (established goals), rather than specification standards (prescribing the exact procedures) which is both more flexible and effective (results rather than inputs), but can be more difficult to understand, particularly for smaller businesses with limited capacity. Furthermore, since the implementation of regulations such as the 2004 "Hygiene Package", EU food laws are among the most restrictive worldwide, for specific hygiene outcomes and internal controls. When EU legislation is transposed into national legislation, and particularly when controlled by several agencies, it may pose difficulties for MSMEs to understand and comply with regulations.<sup>29</sup>

For instance, different requirements imposed by veterinary inspectors (who control establishments handling food of animal origin for approvals required under EC Regulation 853/2004) and sanitary inspectors (who have the authority to approve plans for construction permits of buildings intended for handling food of animal origin) may increase costs for Podkarpackie and Lubelskie businesses, and discourage them from compliance (or even deter investments). Labelling fragmented between three inspectorates (State Sanitary Inspectorate, Agricultural and Food Quality Inspectorate, Trade Inspectorate) and quality split between two inspectorates (Trade Inspectorate and Veterinary Inspectorate for food of animal origin, and Trade Inspectorate and Agricultural and Food Quality Inspectorate for fruits and vegetables, processed food of plant origin and composite products) opens the ground for additional differences in approach by inspectorates.

Businesses in southeastern Poland confirmed in interviews different approaches to sanctions, both between individual inspectors within the same inspectorate and inspectors from different inspectorates. Businesses also expressed the need to unify how requirements are interpreted. These opinions confirm the findings of DG SANTE published in the country profile for Poland.<sup>30</sup>

#### 2.3.1.2. Sanctions

To ensure compliance, some inspectorates resort to sanctions frequently while other institutions use them as a last recourse.

As DG SANTE noted in the country profile for Poland, "there is a considerable amount of legislation which defines enforcement and measures to be taken in case of non-conformities, yet, not a single law covers all sectors and it is unclear, how and whether, the impact of enforcement is formally measured."<sup>31</sup>

<sup>&</sup>lt;sup>29</sup> https://www.oecd.org/gov/regulatory-policy/1910833.pdf

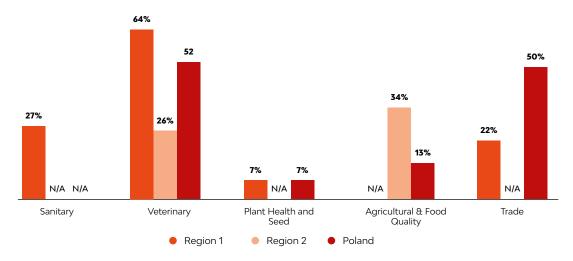
<sup>&</sup>lt;sup>30</sup> Food and Safety country profile, Ref Ares (2017)2205255 -28/04/2017

<sup>31</sup> Ibidem

As a result, the share of inspections, during which non-conformities were identified, varies across inspectorates in Poland. In 2016, the State Plant and Seed Inspectorate identified the lowest number of non-conformities. The Agricultural and Food Quality Inspectorate found countrywide non-conformities in about 13% of inspections. No data could be obtained for the State Sanitary Inspectorate at central level, but data from one of the regions covered by this report suggests that about 25% of sanitary inspections resulted in administrative measures. In comparison, the Trade Inspectorate and the Veterinary Inspectorate detected problems in more than half of all of its inspections in Poland.

There are also differences between regions and within the same institution. For example, veterinary inspectors in one of the regions identified non-conformities in about two thirds of all controls, while in the other region, non-conformities were more than two times less prevalent.

FIGURE 14.
Ratio of non-conformities to inspections in 2016<sup>32</sup>



Source: Multi Annual National Control Plan, Veterinary Inspectorate, Agricultural & Food Quality Inspectorate, Voivodship Sanitary and Epidemiological Stations in Podkarpackie and Lubelskie,

# Non-conformities are either substantial and need to be addressed through sanctions, or they are minor and sanctions are not necessary.

Article 55 of EC Regulation 882/2004 provides that sanctions should be "effective, proportionate and dissuasive". The new Regulation 625/2017 has identical language on penalties in Article 139, which states that financial penalties for violations "perpetrated through fraudulent or deceptive practices" should at least reflect "the economic advantage for the operator or, as appropriate, a percentage of the operator's turnover". It also emphasizes that penalties should not be the sole or main response to "established non-compliance" (Article 138) but rather, the competent authorities should take "appropriate measures to ensure that the operator concerned remedies of the non-compliance and prevents further occurrences of such non-compliance" and, in so doing, "take account of the nature of that non-compliance and the operator's past record with regard to compliance". In other words, not only should penalties and other sanctions be proportionate, but they should be responsive to the situation and track record, and the main objective is to promote compliance. When penalties can work as deterrence, they should be used, but this is not always the case, and they are not always the most appropriate tool.

DG SANTE found that "overall it is not clear that the requirements of the Article 55 of Regulation EC 882/2004 on the effectiveness, proportionality and dissuasiveness of sanctions are met in all sectors and by all competent authorities." Disproportional fines and penalties were identified by businesses as one of the most negative

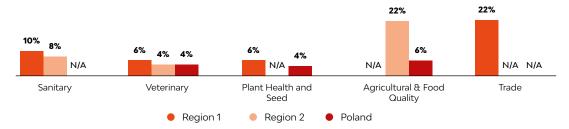
<sup>52</sup> The number of non-conformities was estimated based on the number of administrative sanctions taken by inspectorates. When multiple non-conformities were found during one inspection, they were added.

<sup>33</sup> Ibidem

aspects when dealing with official food control agencies. Such practices diminish trust in inspectorates, build a sense of injustice and undermine the legitimacy of inspectorates. Too frequent fines may encourage businesses to comply less than in cases when they trust inspectorates.

In general, inspectorates focused on the safety of food, animals and plants (State Sanitary Inspectorate, Veterinary Inspectorate, State Plant Health and Seed Inspectorate) impose less fines in the regions covered by this report than inspectorates focused on the commercial quality of food (Agricultural and Food Quality Inspection and Trade Inspectorate). One in five inspections by Trade Inspectorate and Agricultural and Food Quality Inspection resulted in a fine. In interviews, many food producers associated inspections with inevitable punishment and pointed out the Agricultural and Food Quality Inspection most frequently issues fines.

FIGURE 15.
Ratio of fines to inspections in 2016<sup>34</sup>



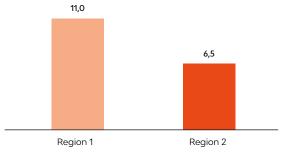
Source: Multi Annual National Control Plan, Veterinary Inspectorate, Agricultural & Food Quality Inspectorate, Voivodship Sanitary and Epidemiological Stations in Podkarpackie and Lubelskie,

About five percent of inspected businesses were fined by the Veterinary Inspectorate at an average amount of EUR 35 in 2016. The State Sanitary Inspectorate fined more often. About nine percent of all their 2016 inspections resulted in fines, ranging from an average of EUR 40 for employees to EUR 400 for establishments. Sanitary inspectors informed World Bank Group staff that such fines were issued mostly in cases when a repetitive non-conformity was found and they were mostly directed at employees, not businesses (e.g. workers not wearing work clothes, not washing their hands regularly). When workers are fined, businesses are not required to address individual transgressions and therefore violations can continue. Business owners/managers are required to provide all tools and preventive equipment and to train and oversee workers performing operations. Businesses are not motivated to invest significantly in practices/equipment/infrastructure when fines are low. Thus, such fines could be replaced with alternative measures that could help to increase compliance (e. g., provision of advice, warning letters, agreement dates to remedy non-compliance). An administrative measure should follow only in cases when these measures have been exhausted.

The number of non-conformities identified per fine can be an approximation of the proportionality (or lack thereof) of enforcement practices. On average, veterinary inspectors in one of the regions covered by this report issued fines almost two times more often than their colleagues in the other region. This suggests that veterinary inspectors in the first region may be less inclined to issue penalties for minor violations and that sanctions standards are not integrated between regions.

FIGURE 16.

Non-conformities per fine issued by veterinary inspectors, 2016



Source: Voivodship Veterinary Inspectorates in Podkarpackie and Lubelskie

<sup>&</sup>lt;sup>34</sup> Where multiple fines were issued during one inspection they have been added. Multiple fines are common, e.g. the Veterinary Inspectorate can fine the establishment for different violations. Multiple fines occur also when one inspectorate, e.g. the Sanitary Inspectorate, fines one or several individual employees and the establishment for a sanitary violation. National-level data from the Plant and Seed Inspectorate refers to pesticide inspections.

### 2.3.1.3. Alternatives to sanctions: guidance, checklists and ratings

# Inspectorates provide guidance to businesses occasionally and this practice should be mainstreamed and improved.

Food inspectorates in Poland follow the requirements of Regulation EC 178/2002 and publish guidance documents. The clarity of the guidance documents varies. Some documents are practical and easy-to-understand while others are theoretical and not easily applicable. In several cases, guidance documents quote regulations without providing additional information. Micro and small businesses in Podkarpackie and Lubelskie expressed during interviews a desire for practical guidance, especially regarding the implementation of Good Manufacturing Practices and Hazard Analysis and Critical Control Points (HACCP). Veterinary inspectors, in both regions, also expressed the need for user-friendly instructions/toolkits for farmers and micro and small producers, such as those on pesticide use and Good Hygiene Practices and Good Manufacturing Practices for small dairy producers.

**TABLE 8.**Selected examples of guidelines published or recommended by inspectorates

INSPECTORATE	TITLE/CONTENT
VETERINARY	Direct sales of animal products - food safety requirements
	Veterinary requirements for the production and sale of animal products in marginal, local and limited activities
	Guidelines for dairy farms selling raw milk
	Guide to Good Hygiene Practices for the production of cheese and other dairy products in farms and artisanal milk processing.
SANITARY	Code of Good Hygiene Practices for the European Milling Industry
	Guide to Good Hygiene Practices for the fruit juice industry
	Hygiene Code for margarines and spreadable fats
	Food contact materials
	GMO Food
	Guidelines for setting tolerance limits for the nutrients mentioned on the labelling
AGRICULTURAL & FOOD QUALITY	Guidelines to the Regulation 1169/2011
	EU Commission Allergen Guidelines
PLANT AND SEED	Minimum requirements for fertilisers and plant protection products
	Classical methods of isolation and identification of species from the genus Phytophthora - advantages and disadvantages - presentation from the conference
TRADE	Consumer guidance

Source: Veterinary Inspectorate, State Sanitary Inspectorate, Agricultural & Food Quality Inspectorate, Plant and Seed Inspectorate, Trade Inspectorate

Advice offered by inspectors in Podkarpackie and Lubelskie ranges from disciplinarian to consultative, as illustrated by inspectors' comments shared with World Bank Group staff. Businesses in Podkarpackie and Lubelskie confirmed in interviews instances when inspectors had offered advice and that it was increasingly common. The State Plant and Seed Inspectorate in Lubelskie, for instance, recognizes the need for inspectors to play a consultative role, and management encourages inspectors to provide advice to farmers. To ensure professionalism, inspectors in Lubelskie received on-the-job training but still need practical training in communication skills to improve their ability to consult effectively.

Inspectors use checklists, but they are underutilized as tools to promote voluntary compliance.

#### What local inspectors say

"I provide advice to avoid a situation in which businesses later have to undertake costly reconstruction to fulfil requirements."

"We are policemen, we are here to enforce laws and we are not supposed to provide advice." Checklists are used to standardize inspections. Existing checklists range from specific and practical to generic and sometimes abstract. They are developed at the central level for implementation at the local level.

Both the State Sanitary Inspectorate and Veterinary Inspectorate have used checklists for several years. The publicly available Veterinary Inspectorate's checklists are

both general (applicable to all facilities under Veterinary Inspectorate supervision when assessing hygiene and HACCP) and industry-specific. The inspectorate's other checklists are for regulatory requirements and practices and are publicly available for business use.

The State Sanitary Inspectorate's checklists are instructions for inspectors. They are not industry-specific, nor available to the public. They generally summarize regulations and do not provide businesses details about inspections.

All questions in existing sanitary and veterinary checklists are given the same weight and non-conformities are not differentiated by the significance of hazards. Inspectors make their own judgements about hazards and non-conformities, thereby creating the opportunity for subjective judgments.

Both sanitary and veterinary inspectors in Podkarpackie and Lubelskie expressed the need for additional checklists to help them control HACCP-based system in small facilities, which require more flexibility. Poviat veterinary inspectors also expressed the need to develop checklists to control of good practices and direct sales at farms.

The Plant and Seed Inspectorate also developed checklists for the control of pesticides. While generic protocols are used for other areas under their purview, tailored checklists are in development for these. The Agriculture and Food Quality Inspectorate and the Trade Inspectorate use inspection protocols.

Regional businesses with advanced food safety management systems expect checklists to evaluate their effectiveness. Micro and small-size businesses prefer checklists that only assess minimum requirements to assure proper safety of their products. Both groups expect checklists to address business practices and how businesses implement regulatory requirements.

### Businesses are not aware of their risk categorization.

There are no public ratings schemes in place in Podkarpackie and Lubelskie. In addition, businesses do not know about the risk assessment undertaken by inspectorates or its implications (e.g. the frequency of inspections). Only about one in six businesses in Podkarpackie and Lubelskie surveyed by the World Bank Group was aware of their risk rating and less than half of these firms knew what to do to transfer to another risk category.

### 2.3.2. INTERNATIONAL PRACTICES

#### 2.3.2.1. Sanctions

# Sanctions and inspections are proportionate to risk levels of hazards and the history of violations.

The United Kingdom's Food Law Code of Practice<sup>35</sup> defines the principle of proportionality in food inspections: Authorized agents take into account the full range of enforcement options. This includes educating food business operators, giving advice, informal action, sampling, detaining and seizing food, serving Hygiene Improvement Notices/Improvement Notices, Hygiene Prohibition Procedures/Prohibition Procedures and prosecution procedures. Except where circumstances indicate a significant risk, officers should operate a graduated and educative approach (the hierarchy of enforcement) starting at the bottom of the pyramid i.e. advice/education and informal action and only move to more formal action where the informal action does not achieve the desired effect. This should lessen the likelihood of a legal challenge.<sup>36</sup>

FIGURE 17.
The enforcement pyramid



Source: Ayres and Braithwaite (1992)

This approach follows the enforcement pyramid developed by John Braithwaite and Ian Ayres in their seminal 1992 study "Responsive Regulation"<sup>37</sup> which has been influential in the redesign of enforcement agencies around the world. It departed from the premise that there are only two types of agents (compliant and non-compliant) towards the realization that compliance is continuous and can be influenced by gradual enforcement actions.

A similar understanding of the principle of proportionality underpins the work of the Danish Food and Veterinary Authority, which recommends that an inspector's reaction should be tempered, though sanctions must have sufficient impact to ensure that regulations are followed. If the establishment or primary producer fails to comply with the control authority's sanctions, the punishment should be escalated.<sup>38</sup>

Applying the proportionality principle offers inspectorates a range of responses to minor and major violations. Given that a large number of violations occur because of limited knowledge and difficulties dealing with a complex web of requirements, food inspectorates in many jurisdictions have developed alternatives to administrative measures such as guidance documents and rating systems.

 $<sup>{\</sup>color{red}^{35}} https://www.food.gov.uk/enforcement/codes-of-practice/food-law-code-of-practice$ 

<sup>&</sup>lt;sup>36</sup> Food Law Code of Practice (England), 2008

<sup>37</sup> Ayres, Ian and John Braithwaite (1992) "Responsive Regulation: Transcending the deregulation debate". New York: Oxford University Press.

<sup>38</sup> https://www.foedevarestyrelsen.dk/english/Inspection/Inspection\_principles/Pages/default.aspx

### 2.3.2.2. Alternatives to sanctions: guidance, checklists, ratings and hotlines

# Guidance documents are widely used by inspectorates and businesses to reduce uncertainty.

The 2009 Anderson Review<sup>39</sup> conducted for the British government found that the impact of regulatory uncertainty was high for business, government, and citizens and added to existing compliance costs for small and medium-size enterprises (SMEs). In comparison to larger businesses, SMEs were found to be more limited in their capacity and budgets to address complex regulations. SMEs faced up to seven times higher costs per employee to comply with regulation. Micro businesses (less than ten employees) used no government guidance about regulations because of: uncertainty whether all inspectors would accept the same guidance; difficulties to find and/or to understand guidance; and inconsistencies by different authorities.

The United Kingdom's Food Standards Agency (FSA) developed and widely promoted the use of "Safer Food, Better Business" packs for caterers, retailers, child caretakers and care homes. It was developed to translate "abstract" regulations (in particular, the 2004 EU Hygiene Package) into understandable, concrete steps. Rather than following the structure of regulatory texts, its chapters correspond to fundamental aspects of food safety (temperature control, cross-contamination, personal hygiene, etc). Impetus to develop this tool came from a pilot in Westminster City where repeated inspections and sanctions failed to improve conditions in non-compliant Chinese restaurants (and resulted in increased resistance to regulators perceived as "aggressive"). Providing, clear and specific guidance, in the chef's native language, led to rapid and major improvements in compliance. Along these lines, "Safer Food, Better Business" was translated into 16 languages (including Polish).

In Denmark, the national guidelines, "sector codes for good hygienic practice" help companies develop internal checks and accountability. <sup>41</sup> In Italy, the Lombardy region (the country's most populated and richest) developed a practical guidance on food safety for processors, which is similar to the United Kingdom's "Safer Food, Better Business". <sup>42</sup> Guidance on labelling in Portugal is practical and helpful to businesses. In France, the food control agency and agency for control of labelling produced a common guidance on food information. <sup>43</sup>

In Canada<sup>44</sup> and France<sup>45</sup>, guidelines for the implementation of practices and technological solutions in various industries are published on the inspectorates' websites. The Los Angeles County Public and Environmental Health Authority<sup>46</sup> publishes informative guidelines for restaurants and small food producers. The Australian Food Authority of New South Wales published a generic model for implementation of HACCP<sup>47</sup> and the United States Federal Inspection Service produces generic HACCP models for all types of industries under its surveillance.<sup>48</sup>

#### Quantifiable and publicly available checklists are used by businesses for self-control.

Publicly available guidelines are complemented with easy-to-follow checklists to help businesses assess their practices. Making guidelines and checklists public helps businesses to understand requirements and to increase the safety and quality of food. Checklists and other instructions are published by inspectorates at all levels of government both within and outside the EU. Good practice examples can be drawn from institutions, such as the Luxembourg

<sup>39</sup> http://webarchive.nationalarchives.gov.uk/20090609052836/http://www.berr.gov.uk/files/file49881.pdf

<sup>40</sup> https://www.food.gov.uk/business-industry/sfbb

 $<sup>{\</sup>color{blue}^{41}} https://www.foedevarestyrelsen.dk/english/Inspection/Own\_checks\_in\_food\_establishments/Pages/default.aspx$ 

<sup>42</sup> http://www.regione.lombardia.it/wps/portal/istituzionale/HP/DettaglioServizio/servizi-e-informazioni/imprese/ sicurezza-ambientale-e-alimentare/sicurezza-degli-alimenti/ser-buone-pratiche-igiene-microimprese-alimentari-sal

<sup>43</sup> https://www.economie.gouv.fr/files/files/directions\_services/dgccrf/documentation/fiches\_pratiques/fiches/etiquetage-denrees-alimentaires.pdf

<sup>44</sup> http://www.inspection.gc.ca/industry-guidance/food-guidance/eng/1374178718703/1374508433359

<sup>45</sup> http://agriculture.gouv.fr/vade-mecum-dinspection-de-lhygiene-des-denrees-alimentaires-0

<sup>46</sup> http://publichealth.lacounty.gov/eh/docs/ffipFinal.pdf

<sup>47</sup> http://www.foodauthority.nsw.gov.au/ip/food-safety-programs-haccp

<sup>48</sup> http://haccpalliance.org/alliance/haccpmodels.html

Organization for the Security and Quality of the Food Chain,<sup>49</sup> the Belgian Food Control Authority,<sup>50</sup> the Lithuanian State Food and Veterinary Service,<sup>51</sup> the Los Angeles County Public and Environmental Health Authority<sup>52</sup>.

### Businesses are rated publicly for hygiene and food safety standards.

The first public rating scheme of hygiene and safety standards was developed and published by the Los Angeles County Public and Environmental Health Authority.<sup>53</sup> There are many examples of public programs, including the Smiley (Denmark) and Scores on doors (United Kingdom). The Danish Food and Veterinary Authority uses the Smiley Scheme<sup>54</sup> to rate all food facilities. Administrative measures are determined and frequency of inspection adjusted based on a business' rating. Smiley marks are publicly displayed and businesses use them for marketing purposes. Based on Danish success, Norway developed the same program in 2014.

#### FIGURE 18.

The Smiley ranking in Denmark



No remarks



Minor non-conformities described in the report, no order



Injunction or prohibitory order



Administrative penalties, reported to the police, or approval withdrawn.



Enterprises with only happy smiles on their last four inspection-reports – and no remarks during the last 12 months – may use the elite-smiley in their marketing

#### FIGURE 19.

United Kingdom Food Hygiene Rating



The Food Hygiene Rating in England, Wales and Northern Ireland<sup>55</sup> and the Food Hygiene Information scheme in Scotland,<sup>56</sup> both run by food standards agencies, provide information to consumers about adherence to good practices in restaurants, takeaway businesses, and food shops. Upon official inspection, inspectors give marks from "1 to 5" to businesses for food handling practices, infrastructure and the management system in place. If the top rating is not given, the inspector will inform the business representative what improvements need to be made

and what action they can take to improve their hygiene rating. Ratings are displayed visibly in businesses and consumers can find them published on the agency website, too. $^{57}$ 

The Lithuanian Food Department adopted a "name and shame" approach, to increase adherence to requirements; egregious violators are listed on the State Food and Veterinary Service website. In New South Wales, Australia, violations and court fines are publicly displayed on the food control authority website.<sup>58</sup>

<sup>49</sup> http://www.securite-alimentaire.public.lu/professionnel/checkliste/secualim/index.html

<sup>50</sup> http://www.afsca.be/autocontrole-fr/guides/distribution/

<sup>&</sup>lt;sup>51</sup> http://vmvt.lt/node/848?language=lt

<sup>52</sup> http://publichealth.lacounty.gov/eh/docs/booklet.pdf

<sup>53</sup> https://ehservices.publichealth.lacounty.gov/ezsearch

<sup>54</sup> http://www.findsmiley.dk/english/Pages/About.aspx

https://www.food.gov.uk/multimedia/hygiene-rating-schemes/ratings-find-out-more-en#toc-1

<sup>&</sup>lt;sup>56</sup> http://ratings.food.gov.uk/search-a-local-authority-area/en-GB/Scotland

<sup>57</sup> http://ratings.food.gov.uk/

<sup>58</sup> http://www.foodauthority.nsw.gov.au/

### Businesses are also informed of their risk rating and how to be reclassified.

Inspectorates also share risk ratings with businesses to encourage them to become compliant and thus influence the frequency of inspections. For instance, in Portugal, businesses have access to their own inspection reports and compliance rating in the veterinary inspection IT system (SIPACE).<sup>59</sup> Businesses in Scotland receive an inspection report with clear information on the criteria according to which business compliance is assessed and the frequency of control determined. The report also provides information on all non-compliance cases and the consequences.<sup>60</sup> The Danish Veterinary and Food Administration also explains through its Elite Scheme how compliance can affect risk category.<sup>61</sup> This practice is also encouraged by regulation 652/2017 which will replace EC Regulation 882/2004 from December 2019 (see Box 5).

#### BOX 5

#### EC Regulation 652/2017 on official control, preamble, point 39

Competent authorities should also, subject to certain conditions, be entitled to publish or to make available information about the rating of individual operators based on the outcome of official controls. The use of rating schemes by Member States should be allowed and encouraged as a means to increase transparency along the agrifood chain, provided that appropriate guarantees of fairness, consistency, transparency and objectiveness are offered by such schemes. The competent authorities should have the necessary arrangements in place in order for the rating to reflect accurately the actual level of compliance; in particular, competent authorities should be encouraged to ensure that the rating is based on the outcome of several official controls or, when the rating is based on the outcome of one single official control and the findings are unfavorable, that subsequent official controls are carried out within a reasonable time. The transparency of rating criteria is particularly necessary so that best practices can be compared and, in time, the development of a consistent approach at Union level considered.

# To improve compliance promotion, inspectorates learn from questions asked by firms through hotlines and internet queries.

Hotlines are a good way to spread information on how to implement requirements. They also allow to collect frequently asked questions and later publish responses to questions online. Lithuania uses hotlines as an alternative to inspections. Et in 2012, the government in Vilnius adopted guidelines on hotlines and decided to: (1) direct most inquiries to one number; (2) designate and train staff to handle calls; (3) keep logs of inquiries; (4) develop questions and answers trees and (best practice is to publish the tree online); (5) record conversations for reference and quality management purposes; (6) monitor the quality of answers and customer satisfaction. In 2016, the Food and Veterinary Safety Authority responded to 2897 telephone inquiries via its hotline.

Communication tools can be integrated into performance management systems of inspectorates. For instance, one of the key performance indicators for Norway's food safety inspectorate is the number of visits to its website. The inspectorate also tracks how many non-conformities were avoided/resolved thanks to the information made available on its website. 63

### Compliance promotion is reinforced through behavioural training of inspectors.

The behavioral competencies of inspectors are a key factor to the success of inspections. Collecting and evaluating information, communicating with businesses, providing advice, managing emergencies, all require "soft" skills. In the United Kingdom, a "competency model" was developed for regulators, in which technical skills and "core skills" (soft skills) are considered equally important. A self-assessment tool underpins this model for inspectors and a set of training resources.<sup>64</sup>

<sup>&</sup>lt;sup>59</sup> DG Sante: Ref.Ares (2016)6133070 - 26/10/2016

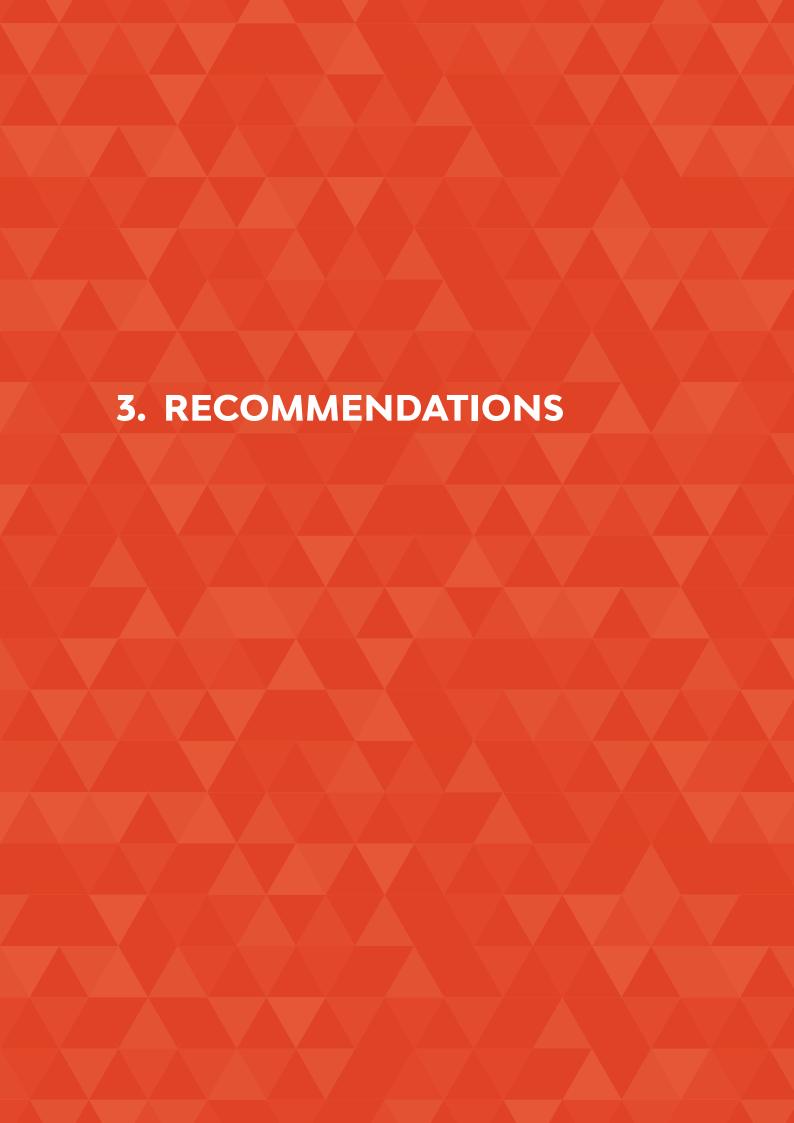
 $<sup>^{60}\,</sup>http://www.foodstandards.gov.scot/business-and-industry/safety-and-regulation/approval-of-meat-plants$ 

<sup>61</sup> https://www.foedevarestyrelsen.dk/english/Inspection/Inspection\_of\_food\_establishments/Pages/default.aspx

<sup>62</sup> http://vmvt.lt/?language=en

<sup>63 2015</sup> Annual Report of the Norwegian Food Safety Authority

<sup>64</sup> http://rdna-tool.bis.gov.uk/



## Poland and the regions of Podkarpackie and Lubelskie should complete the transition to coordinated, risk-based food control.

The first responsibility of public authorities is to safeguard public health and enable consumer choice. It should be pursued in a way that limits burden to businesses and encourages economic growth. When applied properly, risk-based enforcement reduces administrative burdens, since scope, frequency and length of control is commensurate with the risk level of facilities and hazards. The same is true of a strategy that prioritizes compliance promotion over the punishment of violations. Stimulating compliance promotion helps to secure safe and quality products and enables firms to be competitive. According to most UK firms participating in the "Safer Food, Better Business" program, 65 the guidance provided as part of the scheme helped them to improve not only compliance but also efficiency and profitability. Thus an approach that prioritizes outcomes and not "conducting inspections" or "finding infringements", can achieve higher safety, less burden to businesses and stronger growth.

Poland and the regions of Podkarpackie and Lubelskie have made significant strides to introduce risk-based enforcement. Methodologies to assess risks are in place and thousands of facilities are graded according to risk every year based on checklists and other tools. However, the transition to coordinated risk-based enforcement is not complete. The following sections provide more details on the changes necessary to complete this transition. All of these recommendations are addressed to ministries and central inspectorates and require countrywide action. At the same time the recommendations on risk assessment and compliance promotion should be piloted by regional inspectorates before being rolled out across the country. Through these pilots, Podkarpackie and Lubelskie have a unique opportunity to boost the competitiveness of their regions and lead the way for food inspectorates across the country.

### 3.1. COORDINATION

### Poland should leverage and improve its framework regulation of inspections.

There are two critical horizontal principles which should guide business inspections in general and food inspections in particular in Poland: 1) the obligation to apply risk assessment to various stages of supervision (planning, inspections, sanctioning); and 2) the obligation to promote voluntary compliance through provision of information and advice to businesses.

The first principle is enshrined in sectoral EU law and national law related to food safety since Poland's accession to the European Union. It was upheld by recent legislation (amendments to the Freedom of Economic Activity Act, in force since January 1, 2017, as well as subsequent changes adopted as part of the Poland's new Business Constitution<sup>66</sup>). However, as shown in chapter 2.2, these rules have not been consistently implemented in the food safety area. To close the implementation gap, legislation (in particular Article 47 of the Entrepreneurs Act) should be revised, risk assessment methodologies and tools aligned by inspectorates under the leadership of the Ministry of Entrepreneurship or another coordinating institution, and significant resources invested in trainings of inspectors and improved technology. Funding for these investments is available from the Operational Program Digital Poland and the Operational Program Knowledge, Education and Development. Poland can also draw on the experiences of the Lithuanian Ministry of Economy in unifying risk assessment across inspectorates using hard and soft law as well as performance management and coordination of inspectorates.

<sup>65</sup> See chapter 2.3.2.2. for details about "Safer Food, Better Business".

<sup>&</sup>lt;sup>66</sup> The Business Constitution is an informal term describing a set of new horizontal laws governing business operations in Poland, of which most have been adopted and have entered into force in April 2018. The Business Constitution upholds existing horizontal provisions with regards to business inspections.

The second principle is reflected in Article 33 of the Entrepreneurs Act, which requires public bodies to issue practical guidance for businesses about legal requirements. Compliance promotion is also encouraged under EU regulations. However, for compliance promotion to be effective, the advice given by inspectorates should not only be scaled up but also pooled. Poland should follow the example of Lithuania by creating a central hotline and post online manuals, checklists, risk ratings, frequently asked questions, and so on. Efforts to promote voluntary compliance are likely to free up resources dedicated to inspections, allowing inspectorates to finance new activities from existing budget allocations. At the same time, EU funds are available to finance start-up expenses related to the standardization of processes, retraining of staff, software development, and purchase of equipment.

## Poland should develop national requirements for inspection software and an interoperability platform.

Poland's inspectorates use basic software programs that are not connected and do not offer critical functions, such as automated risk assessment, inspection planning, and information exchange with businesses. Records are generally paper-based and mobile access to view and record inspection findings is not supported. As a result, coordination is challenging and more time than necessary is spent on inspections.

Upgrading or designing new inspection management systems by inspectorates individually is costly and does not improve coordination. Thus, the first step should be the development of standard requirements for inspection software in Poland's inspectorates. Standard requirements should pave the way to implement automated, real-time data exchange between business registries, inspectorates, and other users (e.g., laboratories and the Agency for Restructuring and Modernization of Agriculture). Standard requirements should be one of the priority tasks of the planned State Food Safety Inspectorate. If it is not established this task can be carried out by the Ministry of Agriculture or the Ministry of Digitization.

Ultimately, Poland should aim to create an interoperability platform to business registries, inspectorates, and other data users. The platform should also enable businesses to provide information only once to all inspectorates using a single point of access integrated with the e-government system e-PUAP. The interoperability platform can also introduce shared software functionalities for inspectorates (e.g., risk assessment modules which can be customized to specific risk indicators used by inspectorates). The Ministry of Digitization (in charge of e-PUAP) or the Ministry of Entrepreneurship and Technology (in charge of the Central Business Registry) could operate this platform. The planned State Food Safety Inspectorate could also play a leading role in the development of the platform in the food safety area.

When designing standard requirements for its inspection software and interoperability platform, Poland can draw on international reference examples, such as the Company Dossier (Ondernemingsdossier) and the Inspectionview (Inspectieview) systems introduced by the Dutch government or the Shared Inspection Management System implemented with World Bank Group support in Bosnia and Herzegovina.<sup>67</sup>

## Once the State Food Safety Inspectorate is established, attention needs to be paid to the alignment of processes and resources.

The draft Law establishing the State Food Safety Inspectorate sets a broad framework for operations of the joint inspectorate but does not provide many important details on how to integrate the five institutions responsible for food safety inspections in Poland. While common, mergers of food safety authorities have proven challenging and can fail to achieve synergies if not enough attention is paid to post-merger consolidation of core functions. Protocols of five separate institutions will need to be aligned by the State Food Safety Inspectorate and tools unified. For instance, inspectors should be recruited and trained to control both food safety and quality as without such training inspections are likely to remain fragmented.

<sup>67</sup> For more reference examples see John Wille and Florentin Blanc. 2013. Implementing a Shared Inspection Management System: Insights from recent international experience. Nuts & Bolts Technical Guidance for Reform Implementation. Washington D.C.: World Bank Group. http://documents.worldbank.org/curated/en/190851468152706158/pdf/907550BRI0Box30ment0System0apr02013.pdf

### 3.2. RISK ASSESSMENT

### Risk assessment methodologies should be refined.

The instructions for risk categorization should be clear to allow uniform use by all risk assessors, no matter whether the assessment is done manually, through an IT-based system or as a combination of both. The risk assessment methodologies should allow for the identification of high-risk facilities and prioritization of resources aligned with the "risk pyramid", which presumes that as the risk increases, fewer facilities will be deemed as high-risk. This enables inspectors to limit the time spent in firms with a positive track record or otherwise low-risk profile and to dedicate more resources to others enforcement actions, including business analytics, monitoring and surveillance of hazards and compliance promotion. For instance, the State Sanitary Inspectorate should consider differentiating traders into high, medium, low and no-risk categories and define maximum (not minimum) frequencies of inspection. The frequency of inspections for some facilities (e.g., shops selling prepacked products with long shelf life at ambient temperatures) should be reduced to once in 36 months.

In addition, compliance records should be used more broadly when rating the risk of facilities. Compliance records should take into account internal control systems of food business operators and should be weighed against intrinsic risk. Safety and quality of food is controlled by companies via their internal management systems, based on critical control points and prevention of hazards. Frequency and scope of inspection should be determined along with the effectiveness of preventive systems in place. Use of third-party audit reports will allow for more precise insight into the level of compliance of businesses and the extent to which they effectively ensure that their products are consistently safe. Having compliance records and internal control indicators complement intrinsic risk indicators (type of facility, production and type of process, size) allows differentiation among businesses within the same inherent risk group and recategorize individual businesses based on their behaviors. For example, the Veterinary Inspectorate should reduce the frequency of inspections for low-risk facilities and facilities with a strong record of compliance. It should also reclassify frequencies as maximum (not minimum).

### Unplanned inspections should be limited.

A large share of unplanned inspections is caused by complaints, of which most are anonymous. Complaints constitute an important source of information on potential violations. However, automatic inspections following every complaint from consumers or competitors are not proportional and do not lead to substantial gains in public health or consumer safety. Policies and protocols regarding the triage and handling of complaints need to be developed by all inspectorates. Protocols should define how to handle anonymous complaints, how to distinguish between important and less important complaints, and which actions to take. Protocols written in narrative form and/or as flow charts should be publicly accessible.

The monitoring of contaminants, animal/plant diseases, and pests is usually conducted through unplanned inspections. Triggers of such unplanned inspections, such as notifications via RASFF on non-conformities of exported products, outbreaks of diseases or pests in previously pest-free areas, as well as bio-security alerts may be also resolved by requests to businesses to explain the situation and other measures. The choice of interventions should be case-by-case and depend on the gravity of the problem and an earlier assessment of internal management systems in the business.

#### The control of multisite food safety management systems should be streamlined.

Currently there are inconsistencies in the assessment of internal multisite food safety management systems. Food inspectorates in Poland can achieve better results by: 1) assessing and approving the multisite management system as a model (preferably in the main place of production); 2) stimulating the multisite business to follow this model; and 3) ensuring that inspectors in different locations accept the approved model. The frequency of inspections for businesses with multisite food safety management systems should be synchronized and increased only if authorities have reason to believe that the approved model is not applied uniformly across sites.

### Inspectorates need to scale up investments in technical and human capacities.

Training in communication skills, production technologies and the assessment of internal management systems are needed to update the knowledge of inspectors. Addressing the gap in compensation between inspectors and other civil servants in Poland is also critical to ensure that inspectorates can attract and retain talent. Similarly, providing inspectors with the necessary equipment to conduct inspections (transportation, sampling equipment, laptops, software) is essential to ensure professionalism. Funds for most of the above investments are available through the Operational Program Knowledge, Education, Development administered by the Ministry of Investments and Development.

### 3.3. COMPLIANCE PROMOTION

### Compliance promotion needs to be scaled up by all inspectorates.

Enforcement should not rely on inspections alone as other means of ensuring compliance are often more cost-effective. Providing information and advice to businesses should be embraced by all inspectorates to address the lack of knowledge as a significant driver of non-compliance. Ultimately, compliance promotion should reduce the number of repeated non-conformities. Advice can be provided through hotlines, websites, during inspections, and in all other situations in which inspectors are in contact with businesses. Improvements to risk assessment and thereby a reduction in the number of inspections will free up more resources for compliance promotion.

### National-level guidance on sanctions should be adopted to ensure coherent enforcement.

This guidance should aim to avoid excessive discrepancies between different agencies, regions, and inspectors and achieving higher levels of proportionality and responsiveness. A gradual approach to sanctions (from recommendations, through notices, warning letters, temporary or permanent closure, and fines) should be well defined in a single guidance for the food area and integrated into inspectorates' policies. New businesses, first-time offenders and non-conformities that do not pose significant public health or consumer hazards should not be sanctioned. If a sanction is needed, it should be proportional to infringement. In the case of the State Sanitary Inspectorate, the practice of sanctioning employees for non-conformities should be discontinued and businesses should be instead held accountable for violations.

#### Inspectorates should inform businesses about their risk rating.

Risk ratings of individual establishments could be published online and shared individually with inspected businesses. Publishing the risk assessment methodology and instructions related to risk assessment would also help businesses to understand their risk rating and improve the methodology based on user feedback.

## Inspectorates should develop more practical, publicly available checklists and guidance documents.

Checklists should entail sets of clear questions and weights for non-conformities. Checklists should also include references to particular regulatory provisions (but not just quote these provisions). Not all non-conformities have the same importance for food safety/animal/plant health/consumers. Businesses and inspectors need to be able to distinguish, in a transparent and consistent way, between critical/major and minor non-conformities. Instructions how to grade non-conformities should be given to inspectors and firms as separate attachments to every checklist. Checklists should be published to support voluntary compliance by businesses.

Besides access to full texts of legislative documents and checklists, businesses need simple explanations and indicative examples to understand how requirements are to be implemented. This is particularly important for small and some medium-sized businesses, which do not always have enough knowledge to implement requirements and adequately control hazards.

Checklists and guidance materials should be developed together with business associations to ensure that inspectors and businesses share interpretations of legal requirements. Trainings in risk-based approaches to control hazards, business advisory panels, and regular meetings with business associations should help to achieve this objective. Check and guidance documents should be updated and revised regularly. Inspectorates should seek the opinions of businesses about the usefulness of existing documents, and encourage the use of practice-oriented guidance.

#### BOX 6.

#### Pilots of inspection checklists in Podkarpackie and Lubelskie

To demonstrate the value added of inspection checklists the World Bank partnered together with businesses in Podkarpackie and Lubelskie as well as the State Sanitary Inspectorate and the Veterinary Inspectorate to develop checklists in two subsectors: meat processing and food service. Both subsectors are large employers in southeastern Poland but lag furthest behind the national average in labor productivity. The reference checklists have been distributed by regional authorities to encourage voluntary compliance and they were tested in real-life inspections. These pilots demonstrated that international best practices in the field of regulatory enforcement are adaptable to circumstances in Poland and its less developed regions. The State Sanitary Inspectorate, the Veterinary Inspectorate and other authorities in Poland should build on the experiences gained in Podkarpackie and Lubelskie to design, adopt and publish practical checklists covering other sectors.

# **ANNEX I.** OECD BEST PRACTICE PRINCIPLES ON REGULATORY ENFORCEMENT AND INSPECTIONS<sup>68</sup>

- Evidence-based enforcement. Regulatory enforcement and inspections should be evidence-based and measurement-based: deciding what to inspect and how should be grounded on data and evidence, and results should be evaluated regularly.
- Selectivity. Promoting compliance and enforcing rules should be left to market forces, private sector and civil society actions wherever possible: inspections and enforcement cannot be everywhere and address everything, and there are many other ways to achieve regulatory objectives.
- 3. Risk focus and proportionality. Enforcement needs to be risk-based and proportionate: the frequency of inspections and the resources employed should be proportional to the level of risk and enforcement actions should be aiming at reducing the actual risk posed by infractions.
- 4. Responsive regulation. Enforcement should be based on "responsive regulation" principles: inspection enforcement actions should be modulated depending on the profile and behavior of specific businesses.
- Long-term vision. Governments should adopt policies and institutional mechanisms on regulatory enforcement and inspections with clear objectives and a long-term road map.
- Coordination and consolidation. Inspection functions should be coordinated and, where needed, consolidated: less duplication and overlaps will ensure better use of public resources, minimize burden on regulated subjects, and maximize effectiveness.
- 7. Transparent governance. Governance structures and human resources policies for regulatory enforcement should support transparency, professionalism and results-oriented management. Regulatory enforcement should be independent from political influence and compliance promotion efforts should be rewarded.
- 8. Information integration. Information and communication technologies should be used to maximize risk-focus, coordination and information sharing, as well as optimal use of resources.
- 9. Clear and fair process. Government should ensure clarity of rules and process for enforcement and inspections; coherent legislation to organize inspection and enforcement needs to be adopted and published, and clearly articulate rights and obligations of officials and of businesses.
- 10. Compliance promotion. Transparency and compliance should be promoted through the use of appropriate instruments such as guidance, toolkits and checklists.
- 11. Professionalism. Inspectors should be trained and managed to ensure professionalism, integrity, consistency and transparency: this requires substantial training focusing not only on technical but also on generic inspection skills, and official guidelines for inspectors to help ensure consistency and fairness.

<sup>&</sup>lt;sup>68</sup> Organisation for Economic Cooperation and Development. 2014. Regulatory Enforcement and Inspections. OECD Best Practice Principles for Regulatory Policy. OECD Publishing, Paris. http://dx.doi.org/10.1787/9789264208117-en

