14 International experience on inspection policies and enforcement

This chapter presents three international case studies on regulatory enforcement and inspections: the Environmental Protection Agency in Ireland, the United Kingdoms' Health and Safety Executive and the Lithuanian State Food Veterinary Service. All case studies present the institutional background, followed by practices before, during and after the inspection process.

Ireland: Environmental Protection Agency

The Environmental Protection Agency (EPA) is the institution in charge of protecting and improving the environment in Ireland. The Irish government established the agency in 1993 as a regulatory and oversight body under the Department of the Environment (now the Department for Communications, Climate Action and Environment, DCCAE). The agency's board is composed of a Director General and five directors, each in charge of one of the five offices – Office of Environmental Enforcement, Office of Environmental Sustainability, Office of Evidence and Assessment, Office of Radiation Protection and Environmental Monitoring, and Office of Communications and Corporate Services.

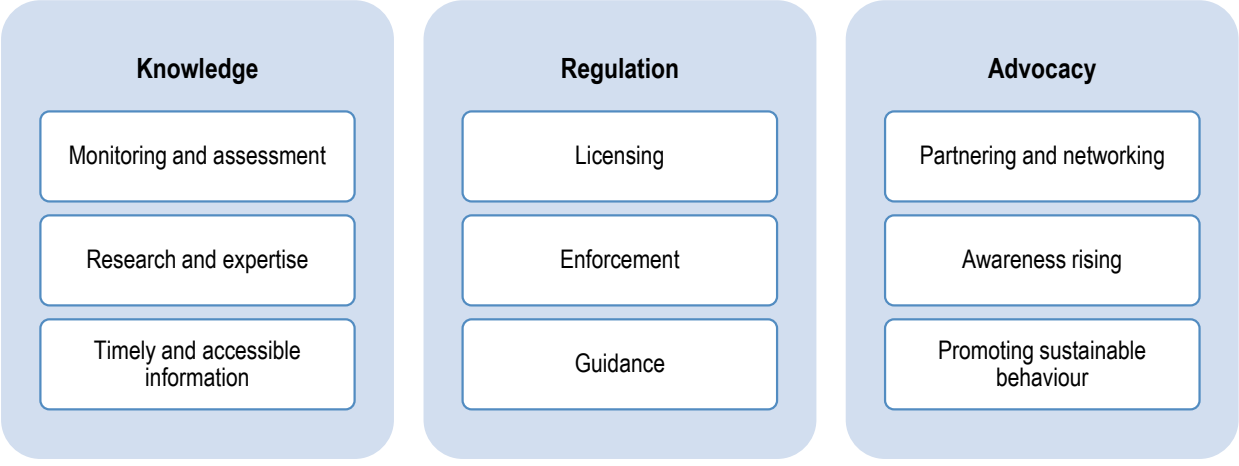
According to the Environmental Protection Act (1992), the EPA is responsible for:

- Environmental licensing, regulation and control of activities
- Monitoring the quality of the environment
- Providing support and advisory services to local authorities and other public institutions
- Promoting and co-ordinating environmental research
- Liaising with the European Environment Agency

The EPA's regulatory functions cover water, wastewater, waste and industrial emissions, dumping at sea, volatile organic compounds (VOCs), sources of ionising radiation, genetically modified organisms (GMOs), dumping at sea and greenhouse gases. In order to carry out its functions, the agency relies on the co-operation with other institutions. The EPA has a dual role regarding its inspection and enforcement duties. The agency directly inspects facilities listed in Table 14.1 and it supervises (and provides advice to) the 31 local authorities who are in charge of enforcing a group of environmental regulations. Local authorities inspect and monitor air quality, noise, small-scale waste facilities, wastewater, and water quality in their jurisdictions.

The agency organises its functions in three broad categories – knowledge, regulation and advocacy Figure 14.1). These functions reflect the EPA's strategic goals for the period 2016-2020 and acknowledge the importance of an integral approach to environmental protection (Environmental Protection Agency, 2016[1]). The EPA obtains the financial resources to carry out its functions from two sources: the Irish government – including the Environmental Fund – that accounts for approximately 80% of the funds, and fees and income derived from the EPA's regulatory activities (e.g. licencing).

Figure 14.1. Main functions of the EPA



Source: Environmental Protection Agency (2016[1]), *Strategic Plan 2016-2020: Our Environment, Our Wellbeing*, https://www.epa.ie/pubs/reports/other/corporate/EPA_StrategicPlanWeb_2018.pdf (accessed 6 September 2019).

Environmental evidence and knowledge is a major focus of EPA. The agency monitors the quality of air and water, co-ordinates research activities, emits technical reports and publishes environmental data. The EPA uses data to improve its performance and to help stakeholders inform their decisions. In particular, the Office of Evidence and Assessment (OEA) provides relevant and accurate environmental data through two initiatives: the water management programme and the environmental evidence programme.

As part of its regulatory activities, the EPA carries out licensing, enforcement of regulations and provision of guidance. According to the Waste Management Act (1996) and the Environmental Protection Act (1992), the EPA is responsible for enforcing environmental licenses through inspections, audits and monitoring (see Table 14.1 for a list of licensed activities). The Office of Environmental Enforcement (OEE), within the EPA, has the task of enforcing and promoting compliance of environmental regulation. Currently, the EPA has five regional inspectorates, all of them supported by an enforcement team, laboratories and field staff.

Table 14.1. Activities licensed and regulated by the EPA

Activities
Large scale waste facilities (landfills, incinerators, waste transfer stations)
Large scale industrial activities (pharmaceutical, cement, manufacturing, power plants)
Intensive agriculture (pigs, poultry)
Contained use and controlled release of Genetically Modified Organisms
Sources of ionising radiation (x-ray and radiotherapy equipment, industrial sources)
Large petrol storage facilities
Waste water discharges
Dumping at sea activities
Volatile Organic Compounds (VOC)
Carbon dioxide emissions trading

Source: Environmental Protection Agency (2019[2]), *The Environmental Protection Agency: Who we are- What we do*, https://www.epa.ie/pubs/reports/other/corporate/WhoweAre_digital_Sept_2019.pdf (accessed 10 September 2019).

The third emphasis of the EPA is advocacy. The agency promotes awareness and good environmental practices through marketing campaigns, including television programmes and resources for schools. In addition, the EPA collaborates with other agencies to foster the inclusion of environmental priorities into sectoral policies.

Evidence-based enforcement

The EPA focuses on environmental pollution prevention. To do this, it follows an enforcement policy based on five principles: risk based, focusing resources and regulatory activities that pose a risk to human health and/or the environment; proportionality in the application of environmental law; consistency in the approach to the use of enforcement powers and in deciding the appropriate enforcement response. In addition, transparency by being clear and open about what is expected of the regulated community, and the polluter pays principle to ensure that polluters are held financially accountable (Environmental Protection Agency, 2019[3])

Regarding the selection of the inspected units, the EPA's approach is to target the sites where the risk of pollution and damage to the environment is higher. The former is done through the collection of data and information that allows the prioritisation of inspections, audits and monitoring activities. The agency produces inspection and enforcement plans following the requirements established by the EU and by other relevant national regulations (The European Parliament and the Council of the European Union, 2001[4]).

The EPA has developed inspection or enforcement plans that include a risk-based approach to enforcement activities based on the regulated sector. For example, the National Inspection Plan 2018-2021: Domestic Waste Water Treatment Systems (Environmental Protection Agency, 2018[5]) offers a comprehensive description of the number of inspections to be carried during the year and the criteria used to assess the periodicity and location of site visits to homes with a septic tank system.

Before the inspection

Selection of the inspected units

The EPA selects the inspection sites, the periodicity of the visits and the enforcement mechanism following a risk-based methodology and the legal requirements established in relevant legislation. As the inspection of all regulated entities is not possible, the agency prioritises the use of resources through several initiatives such as the Industrial Emissions Directive and the Remedial Action List.

- The Remedial Action List (RAL) was established in 2008 as a register of public water supplies with the most serious deficiencies and known to be most at risk in Ireland. It gathers data on water supplies at risk and is published every quarter. Since its creation, 92% of the sites have been removed from the list, as the necessary remedial actions have been completed. The dispositions and recommendations included in the RAL are binding.
- Industrial Emissions Directive (IED) is a legal instrument that regulates the release of pollutants from industrial installations across the European Union. Member states should carry out in site inspections of industrial facilities every one to three years following risk-based criteria (The European Parliament and the Council of the European Union, 2010[6]). The Annual Programme of Environmental Inspections is the EPA's inspection plan and ensures the coverage of all licensed installations through routine and non-routine inspections (Environmental Protection Agency, 2014[7]). According to the directive, the environmental inspection programme should consider the following elements:
  - General assessment of relevant significant environmental issues
  - Geographical area covered refers to all Irish counties
  - Register of the installations covered by the plan. The EPA's database of licensed installations is the main input for this point.
  - Procedures for drawing up programmes for routine are based on three criteria: risk analysis, environmental issues at all sites and that are not reflected in the risk analysis and additional sectoral requirements.
  - Procedures for non-routine inspections. Non-routine inspections take place in three different cases: occurrence of serious environmental complaints, incidents, accidents or non-compliances; identification of a significant case of non-compliance and investigation of complaints about licensed facilities.
  - Provisions on the co-operation between different inspection authorities
- Radiation: Inspections of licensees and registrants are determined by the sector, the practices that are carried out at the site and past performance.

In addition to using the methodologies presented above, the EPA also calculates risks using the Risk Based Methodology for Enforcement, which takes into account the following three elements:

- Complexity: Includes six categories, based on the type of activities carried out and the risk that they entail.
- Location: It is based on criteria such as distance to the nearest sensitive receptor, protected sites, groundwater type and vulnerability.

- Enforcement history: It refers the previous 12 months and considers both the non-compliances and the compliance investigations (see Box 14.1 for more information).

Scores achieved in these three categories are allocated into 12 different categories (A1, A2, A3, B1, B2, B3, C1, C2, C3, D1, D2, D3) that determine the enforcement efforts. For example, sites in the A categories are visited more frequently than sites in the B category and so on (Environmental Protection Agency, 2014[7]).

The EPA carries out planned inspections and non-routine environmental inspections, which are the result of specific situations such as complaints, major non-compliance issues or inaction of the local authorities. In order to promote stakeholder engagement, the agency has created a mobile application that allows citizens to submit their complaints to the EPA. The agency assesses the complaints and, when adequate, provides the local authorities with the opportunity to address the issue before getting involved. Additionally, the EPA has put in place a system of compliance promotion using a behavioural insights approach, see Box 14.1.

Box 14.1. Compliance promotion through behavioural change

National Priority Sites

The EPA uses the National Priority Sites System to signal the industrial and waste facilities that do not comply with environmental regulation. Currently, it follows a methodology that measures the performance of licensed sites based on four criteria – compliance investigations, complaints, incidents and non-compliance. Each licensee receives a final score that is the sum of the scores awarded for each individual criterion. If a site scores above the 30 points threshold (the higher the score, the poorer the performance) and has a compliance investigation score above 10 points, it is included in the NPS.

- Compliance investigations (CI): The EPA opens a compliance investigation when it recognises an issue that has the potential to generate environmental damage or identifies a situation that is causing a negative impact on the environment. Compliance investigations are classified according to the environmental risk and the stage of the investigation – open or close. The current methodology for NPS, establishes that CIs related to a nuisance issue can only be scored medium or high if a non-compliant issue has been recorded by the EPA during the previous 12 weeks and/or if a CI has not been addressed to the satisfaction of the EPA

Table 14.2. Compliance investigations

Compliance investigation rating		
	Open CI	**Closed CI**
High	20 points	4 points
Medium	10 points	2 points
Low	3 points	1 point

Note: Only the top three highest scoring Compliance Investigations are taken into account.
Source: Environmental Protection Agency (2014[8]), *Guidance on assessing and costing environmental liabilities*, https://www.epa.ie/pubs/advice/licensee/epa_oee%20guidance%20and%20assessing%20web.pdf (accessed 12 September 2019).

- Complaints: The EPA assesses all the complaints derived from the public, however not all of them derive in a compliance investigation. For the purpose of the NPS, only complaints leading to a medium or high CI are taken into account. In these cases, the methodology assigns one point per complaint and are capped at 20 points.

- Incidents: If there is a breach of a license condition, the EPA classifies the incident according to its impact – Catastrophic (30 points), Very serious (20 points), Serious (10 points), Limited (5 points), Minor (no score).
- Non-compliances: Licensed facilities are required to notify the EPA when license breaches take place. Non-compliance notifications are issued every time a breach occurs. The points assigned in cases of non-compliance depend on whether the licensee notifies the EPA or not. One point is assigned if the incident is notified and five in case it is not communicated to the EPA.

The EPA compiles the list of NPS sites every quarter based on data from the previous six months. As of June 2019, there were five NPS – less than 1% of the total licenced facilities in Ireland. The publication of the NPS has worked as a naming and shaming mechanism, resulting in many licensees improving their compliance.

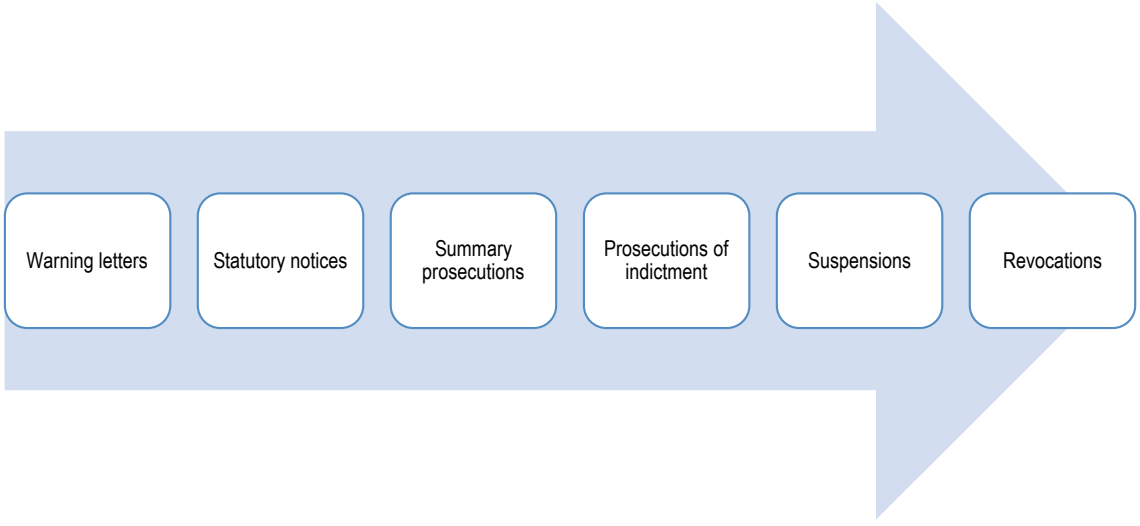
Source: Environmental Protection Agency (2014[8]), *Guidance on assessing and costing environmental liabilities*, https://www.epa.ie/pubs/advice/licensee/epa_oee%20guidance%20and%20assessing%20web.pdf (accessed 12 September 2019).

Responsive regulation

The EPA sanction scheme provides the agency with different enforcement methods, based on the severity of the infraction. This allows for a balanced and proportionate enforcement, particularly if risk criteria are used to target inspections. Figure 14.2 shows the mechanisms that the Office of Environmental Enforcement uses. These tools range from warning letters up to revocations (the hardest sanction).

The EPA follows the polluter pays principle, which states that the company or person that pollutes should pay for the damages. Given that remediation of environmental damages requires a significant amount of resources, the Environmental Protection Agency has mandated the creation of financial provisions – insurance, bond, guarantee, fund – to deal with environmental incidents and closure costs. The amount of the provision is based on the assessment and costing of environmental liabilities. As of 2019, the EPA had secured more than EUR 700 million in financial provisions for environmental liabilities (Environmental Protection Agency, 2020[9]) (Environmental Protection Agency, 2018[10]).

Figure 14.2. Enforcement actions used by EPA



Note: More severe actions to the right of the figure.
Source: Environmental Protection Agency (2019[2]), *The Environmental Protection Agency: Who we are- What we do*, https://www.epa.ie/pubs/reports/other/corporate/WhoweAre_digital_Sept_2019.pdf (accessed 10 September 2019).

Co-ordination with other agencies

The EPA has formal collaboration agreements with a broad number of government institutions, regulators and stakeholders. Currently, the agency has 21 Memoranda of Understanding (MoU) with 23 different entities. Furthermore, the EPA has co-operation arrangements with enforcement institutions such as the National Bureau of Criminal Investigation, the Criminal Assets Bureau and the Office of the Director of Corporate Enforcement. Coordination with these agencies reduces inconsistencies and promotes a better use of resources in the public administration (see Box 14.2 for an example of co-ordination with local authorities) (Environmental Protection Agency, 2006[11]).

One of the co-ordination fora in which the EPA participates is the Network for Ireland's Environmental Compliance (NIECE). The NIECE was established in 2004 with the objective of improving environmental protection in the country. It gathers relevant stakeholders for environmental enforcement – local authorities, the EPA, the County and City Managers Association, Inland Fisheries Ireland, the Health Service Executive, DCCAE, DHPLG, among others. NIECE's structure includes a steering committee (chaired by the EPA) that is in charge, among other things, of identifying the priority areas. The NIECE has defined three thematic areas of interest (waste, water and air/climate), each area has an assigned working group inside the network. Working groups integrate relevant stakeholders from different institutions and levels of government and work collaboratively to address specific environmental issues (Network for Ireland's Environmental Compliance & Enforcement, 2018[12]).

Box 14.2. Inspection of the domestic waste water treatment systems

According to the Water Services (Amendment) Act 2012, the EPA should prepare a national inspection plan of domestic wastewater treatment systems (DWWTS), or septic tank systems. Local authorities are in charge of the inspection of the DWWTS, while the EPA provides guidance, establishes the responsibilities and attributions of the relevant parties (homeowners, DHPLG, local authorities and EPA) and determines the minimum number of inspections that local authorities should conduct per year.

Using the information available and a risk-based methodology, the EPA defines the minimum requirements that local authorities should fulfil. In 2016, approximately 489 669 households had a septic tank system in Ireland (Environmental Protection Agency, 2018[13]). According to the National Inspection Plan 2018-2021, local authorities should carry out at least 1 000 DWWTS inspections per year. The EPA audits local authorities

Each local authority is responsible for the selection of the sites and the allocation of resources for enforcement. Local authorities document the justification and methodology followed for the selection of priority inspection areas in the local site selection plan. On the other hand, the EPA audits local authorities and evaluates their compliance with the requirements established in the National Inspection Plan. If a local authority fails to perform its functions, the EPA may take enforcement action. Moreover, the EPA helps the 31 local authorities through workshops for the inspectors, letter templates, and guidance. Additionally, the agency publishes rankings and reports that describe the local authorities' performance concerning the requirements established in the National Inspection Plan (Environmental Protection Agency, 2018[13]).

Source: Environmental Protection Agency (2018[13]), *National Inspection Plan 2018-2021: Domestic Waste Water Treatment Systems*, http://www.epa.ie/pubs/reports/water/wastewater/NIP%202018%20to%202021_web.pdf (accessed 10 September 2019) and Environmental Protection Agency (2017[14]), *Focus on Local Authority, Environmental Enforcement 2014-2016 Performance Report*, https://www.epa.ie/pubs/reports/enforcement/performanceframework/Focus_on_Local_Authority_Environmental_Enforcement_2014-2016_Performance_Report.pdf (accessed 13 September 2019).

During the inspection

The EPA's inspection and enforcement system includes on-site inspections, audits, desk-based assessments and monitoring. Regarding on-site visits and audits, the EPA prepares guidance for inspectors, offers training and provides kits with useful information, both for representatives of the agency and for regulated subjects.

The inspection procedure and visit frequency depend on the nature of the regulated sector. For example, on-site visits to facilities with an industrial and waste license (1 472 sites in 2019) include sample collection, monitoring, incident investigations and complaints investigations. In 2019, an EPA inspector visited at least 74% of these locations (Environmental Protection Agency, 2019[15]).

The inspection process of licensees and registrants that are subject to Ionising Radiation Regulations is comprised of two elements: administrative details and audit of equipment/facilities. The former comprises a revision of the relevant documentation, testing results, and dosimetry, among others. The latter refers to an on-site visit that allows the inspector to examine visually the equipment and protective gear. The inspector may make measurements if she deems it appropriate.

Local authorities are required to send homeowners a pre-inspection letter for the inspection of domestic wastewater treatment systems. This document informs regulated subjects about the on-site visit. Local inspectors are responsible for checking the septic tank system and producing a report within 21 days. If the homeowner desires to have a re-inspection, there is a EUR 20 fee to be covered by the regulated subject. Depending on the household income, the government provides grants aimed at easing the cost of fixing the issues (Environmental Protection Agency, 2018[13]).

After the inspection

The EPA elaborates an inspection report after each visit. These documents are publicly available and consist of a template where inspectors can explain the compliance breaches (if any) found during the inspection visit. Regulated subjects are allowed to submit a response to the report prepared by the EPA (this document is also public). The EPA also uses the information and data gathered through the inspections as input for the design of inspection plans and strategies.

The EPA's enforcement policy promotes the *polluter pays principle*, which aims at holding those responsible for environmental damages accountable for their actions. To do so, the agency imposes sanctions and fines proportional to the harm from profiting of the damage. Although, in 2017, the EPA awarded sanctions for EUR 390 074 (Environmental Protection Agency, 2018[10]), legislative limits on fines are deemed too low by legal experts. The EPA publishes relevant data regarding the punitive action and prosecution process for each sanction that it imposes – dates in which main events took place, charges, name of the judge and the amount of the fine.

Feedback mechanisms

The EPA carries out efforts aimed at improving the quality of their services, reducing environmental damage and increasing efficiency in the use of resources. The agency's use of IT systems has created feedback loops where data collected through inspection procedures can be analysed and processed, thus informing the policy design.

A clear example of the former is the licensing process for Industrial Emissions Licensing (IEM), Integrated Pollution Control Licencing (IPC) and Waste Licencing applications. Currently, the application process is available online, which has promoted a better allocation of resources and has compelled the EPA to analyse the rationale behind the licencing procedure. This assessment was used to modify, and improve, the application template.

United Kingdom: Health and Safety Executive

In the United Kingdom, all employers must protect their workers from hurts and ills through work. Otherwise, a regulator such as the Health and Safety Executive (HSE) or any local authority can take actions against the employer under criminal law (Health and Safety at Work Act 1974 - HSWA).

Under the scope of the criminal law, when employers do not comply with the HSWA, they can get an improvement notice (see section 21 of HSWA), or they can be prosecuted. The authority in charge of enforcing HSWA depends on the industry. For instance, local authorities are responsible for retailing, wholesale distribution, warehousing, hotel and catering premises, offices, and consumer or leisure industries. In the remaining industries, the HSE is the oversight body.

Moreover, any affected person can submit a compensation claim under the civil law. In this case, an employer may have to pay the worker a compensation due to hurts or ills at work. In most cases, employers must have an employer's liability insurance – it is a criminal offense not to have it. If the claim is successful, a court may rule in favour of the victim and award money as compensation.

About the Health and Safety Executive

According to the HSWA, all businesses must have a health and safety policy explaining how the employer will manage hazards and stakeholders' roles – if the business has more than five employees, it has to write down the policy. Thus, HSE supports business compliance publishing a concise guideline on how to write the policy, which must have at least three parts: statement of intent, responsibilities and arrangements. HSE also publishes an example and a template of an ideal policy (Health and Safety Executive, 2019[16]), (Health and Safety Executive, 2019[17]).

HSE also promotes the compliance of employers' obligation to assess risks affecting themselves and other people. HSWA indicates that an employer must assess and control risks at work, identifying the potential sources of harm and actions to prevent it. The results of the assessment must be recorded if the business has more than five employees. HSE publishes a risk assessment guide with templates, examples and a toolbox for risks control (Health and Safety Executive, 2019[18]).

HSE's enforcement activities

According to HSE, it emphasises prevention but it will enforce the HSWA when it is deliberately ignored. HSE secures compliance through inspections, other regulatory contacts, investigations and formal enforcement work. Actually, for some activities involving significant risks, hazards or public interests, the HSE provides permissions in forms of consents, licences, letters of conclusion, or acceptance of safety cases or reports.

Table 14.3 presents the strategy of HSE to accomplish its mission. The document indicate that the inspection process is a relevant tool to achieve one of the main objectives of the institution: secure effective management and control of risks.

HSE however, recognises that it is impossible to inspect all of 2.5 million business in Great Britain and consequently, it targets sectors and activities with the most serious risks – Table 14.3 indicates as a priority, targeting inspections on specific issues and activities. Box 14.3 presents the HSE's strategy to target priorities.

The objectives and tasks of HSE require fit-for-purpose financial resources. In 2018/2019, HSE's budget was GBP 223 million. The funding scheme of HSE for this period included several sources: parliament (59% in 2018/19), regulatory fees (33%) and commercial work (8%). Correspondingly, the operating expenditure was GBP 217.5 million – GBP 140 million were for staff salaries and GBP 78 million for other

operation costs as rentals, travel, accommodations, training, legal, shared services, technical support, scientific equipment, research and development, IT, etc.

HSE prioritises the use of financial resources according to the most serious risks, the industries with the greatest hazards and the sectors with the lower risk management records. According to HSE, inspections provide information to assess if the risk management is adequate, and if it finds any misconduct, investigations help to get the truth and increase the learning experiences. Furthermore, when the HSE assists employers with the setting of their health and safety obligations, the employer has to pay an intervention fee. In the period of 2018/2019, the income from this label was GBP 14 million.

Table 14.3. Health and Safety Executive's strategy

The prevention of death, injury and ill health to those at work and those affected by work activities			
↑			
Our objectives			
Lead and engage with others to improve workplace health and safety	Provide an effective regulatory framework	Secure effective management and control of risk	Reduce the likelihood of low-frequency, high-impact catastrophic incidents
↑			
Our priorities for 2019/20			
Continue to focus our activity on tackling ill health as part of the Health and Work Programme Promote proportionality in health and safety management Share the learning from our expert science and research with those who can influence workplace health and safety performance	Support the government's fundamental reform of the building safety system following the Grenfell Tower disaster Contribute to government-wide activities on the UK's departure from the EU	Target our inspections on specific issues and activities, including a sustained focus on work-related ill health Investigate to swiftly tackle and reduce risks, securing accountability for victims and their families Operate effective statutory schemes, ensuring the safe use of potentially harmful substances	Provide assurance that dutyholders are identifying and managing the major hazard risks they create Strengthen major hazard leadership and worker engagement Deliver robust and consistent regulation for decommissioning and dismantlement of offshore oil and gas infrastructure Secure improvements in the effective management of network assets including gas risers in high-rise homes Drive dutyholders to reduce the risk of offshore hydrocarbon releases Raise operators' focus on cyber security to ensure appropriate protection against major incidents
↑			
Enable improvement through efficient and effective delivery			
↑			
Our enablers			
Develop our strategy and put in place the building blocks to ensure we are fit for the future	Support our people to be the best they can	Secure a sustainable financial future for HSE	

Source: Health and Safety Executive (2018[19]), *Health and Safety Executive Annual Report and Accounts 2018/19*, Health and Safety Executive, http://www.hse.gov.uk/aboutus/reports/ara-2018-19.pdf (accessed 28 August 2019).

Box 14.3. HSE's strategy to target priorities

The HSE targets duty holders according to sectors with serious risks. The HSE has developed specific strategies for 19 categories of industry sectors (Health and Safety Executive, 2018[20]). The strategy includes a plan to cover, the health and safety performance, the top three priorities for five years and proposed actions. The priorities of each sectors are defined according to:

- The size of the industry and its demographics
- Death, ill and injury rates
- Potential risks

Other prioritisation's criteria is when information and intelligence indicates that health is a serious concern. The sources of information in this case are:

- Previous performance of duty holders
- Explicit concerns raised by workers or other stakeholders
- Investigations
- Reports of injuries, diseases and dangerous concerns – employees should report certain incidents at the workplace. See the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (HSE, 2013[21])).

Source: Health and Safety Executive (2018[20]), *Operational Guidance: Inspection Procedure*, http://www.hse.gov.uk/foi/internalops/og/ogprocedures/inspection/inspection-procedure.pdf (accessed 20 September 2019).

On average, the number of full-time equivalent staff in HSE during 2018-19 was 2 453 employees. As of March of 2019, 1 066 workers out of 2 426 were inspectors, visiting health, and safety staff – about 44% of the total headcount.

HSE's long term vision

The HSE publishes a business plan on a yearly basis. In such document, the regulator explicitly states the challenges ahead and its plans to address them. In the 2019/2020 business plan (see Box 14.4), HSE published data on illnesses and work related deaths, as well as the main regulatory actions to reduce such figures (Health and Safety Executive, n.d.[22]). For example, in the United Kingdom, over 2015-16, there were around 12 000 deaths per year from occupational lung disease, 1.4 millions of workers with work-related illnesses, 144 people killed at work, 30.7 millions of lost working days, amongst others. The actions of the HSE included 19 500 intelligence-led inspections, which ended in 91% of duty holders taking actions after the inspections over 2017-18. The HSE also recorded 6 000 investigations, 8 940 enforcement notices and 517 prosecution cases.

Box 14.4. The HSE's business plan of 2019/2020

The business plan for 2019/20 focuses on priorities to provide an effective regulatory framework, secure an effective management of risks, reduce the likelihood of low-frequency high-impact catastrophic incidents and promote improvement. Some of the priorities are the following:

- Support the government's reform of the building safety system.

- Contribute to government-wide activities on the UK's departure from the EU.
- Target inspections on specific issues and activities.
- Investigate to tackle and reduce risks, and securing accountability for victims and families.
- Operate effective statutory schemes and ensure the safe use of harmful substances.
- Assure that duty holders identify manage major hazards.
- Strengthen major hazard leadership and worker engagement.
- Deliver robust regulation of decommissioning and dismantlement of offshore oil and gas infrastructure.
- Improve the management of network assets including gas risers in high-rise home.
- Drive duty holders to reduce the risk of offshore hydrocarbon releases.

Source: Health and Safety Executive (n.d.[22]), *HSE Business Plan 2019/20*, http://www.hse.gov.uk/aboutus/strategiesandplans/businessplans/plan1920.pdf (accessed 23 September 2019).

Co-ordination and consolidation

The HSE works closely with other regulators and public agencies to ensure the most appropriate intervention – (Health and Safety Executive, 2018[19]). The objective is to lead and engage with others to improve workplace and health and safety. According to the HSE, it sets arrangements where laws overlap to promote co-operation, minimise duplication, co-ordinate joint regulatory activities, and share information and intelligence.

Local authorities focus on managing health and services in low-risk workplaces as offices, shops, warehouses and consumer services. The *Health and Safety (Enforcing Authority) Regulations 1998: A-Z guide to allocation* sets the limits in competences between the HSE and local authorities.

The HSE also controls major hazards in co-operation with the Environmental Agency, the Scottish Environmental protection Agency and the National Resources Wales. Besides, the HSE and the Department for Business, Energy and Industrial Strategy regulate oil and gas hazards jointly. The HSE also supports the Office for Nuclear Regulation, the Office of Road and Rail Regulation, the Driver and Vehicle Standards Agency, the Civil Aviation Authority and Maritime Coastguard Agency.

A complete list of agreements and memoranda of understanding is available in https://www.hse.gov.uk/aboutus/howwework/framework/f-2001-3.htm.

Information integration

HSE's policy is active on informing duty holders, workers and other stakeholders about the processes followed during inspections, complaints, expectations, duties, reports of incidents, objectives, and outcomes, amongst others. In http://www.hse.gov.uk/pubns/leaflets.htm, there are available pamphlets published by the HSE that are free of charge.

For example, the HSE publishes documents to inform the duty holders what to expect if an inspector calls. This document explains the objectives of the inspection, the information to be required, the information received after the visit, amongst others, (Health and Safety Executive, n.d.[23]). The document also provides information about disagreements with HSE's inspection decisions and the rights of duty holders on this matter.

Alternatively, HSE may endorse guidance publications made by other institutions when there is a joint participation, common topics, sectors, etc.

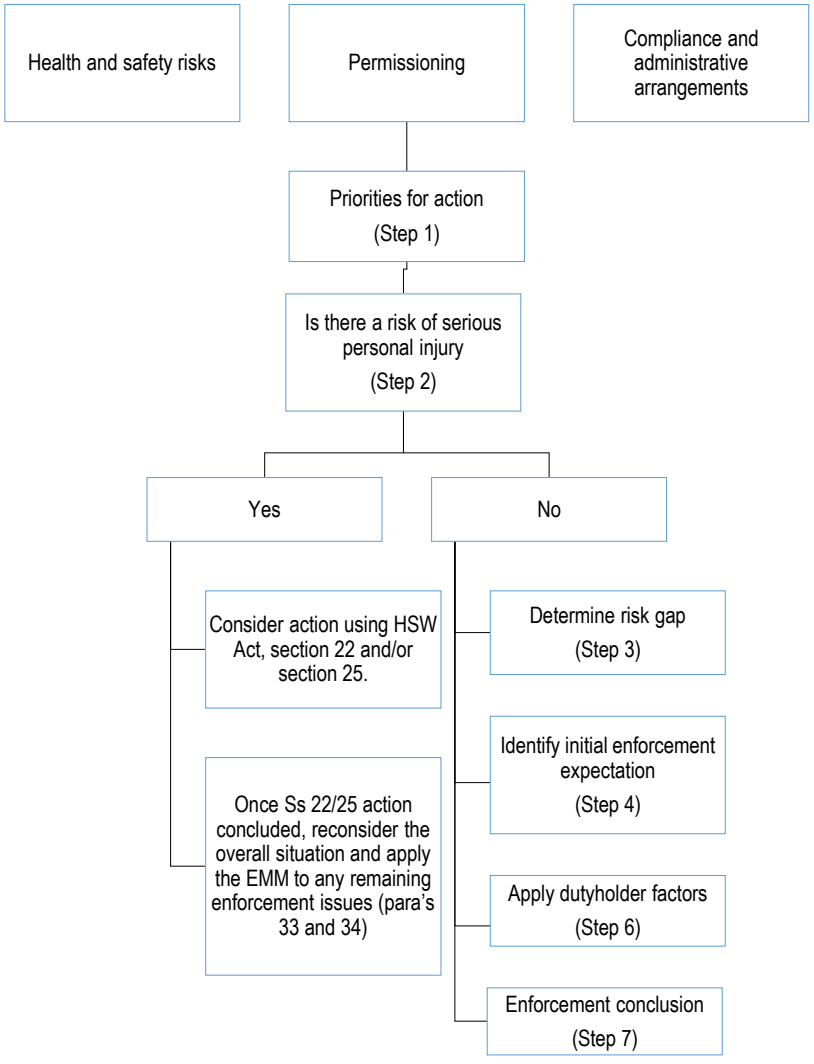
Before the inspection

Professionalism

The *Operational Guidance: Inspection Procedure* (Health and Safety Executive, 2018[20]) sets the foundations for inspections planning. It indicates the steps to carry out before any inspection event. Moreover, it suggests that inspectors align their duties with the Enforcement Management Model (EMM) (Health and Safety Executive, 2013[24]) and with the Enforcement Policy Statement (EPS) (Health and Safety Executive, 2019[16]).

The EMM is a system that supports inspectors in making enforcement decisions, according to the priorities stated in the HSE´s strategy and the specific programmes (see the step 1 of the Figure 14.3). However, the inspectors have discretion to define such priorities. In order to assess them, inspectors must collect information about hazards and control measures during regulatory contacts. Thus, after analysis they can make judgements about risks associated to activities.

Figure 14.3. Risk-based inspection process of the HSE



Note: This figure is an edited version, for brevity and clarity.
Source: Health and Safety Executive (2013[24]), *Enforcement Management Model*, HSE, http://www.hse.gov.uk/enforce/emm.pdf (accessed 18 September 2019).

Risk focus and proportionality

The EPS indicates that the HSE adopts a proportionate approach to enforce the laws across different industries and sectors. It establishes that the HSE applies enforcement actions that are proportionate to the health and safety risks and potential harms due to breaches of the law and seriousness of the risks. The principle of proportionality takes into account both, duties which are specific and absolute, but also reasonably practicable actions, which requires the exercise of judgement (Health and Safety Executive, 2019[16]).

Box 14.5. Activities before inspection visits

The Operational Guidance: Inspection Procedure suggest the following activities before the inspector conducts a visit

1. Selection of duty holders, which inspectors should target according to:
   a. The alignment with divisional working plans
   b. Sectors of higher risks or activities where local knowledge suggests that it is a priority for inspection or when there is an investigation on course
2. Gather information to achieve objectives and priorities. The collection of information should rely on:
   a. Records of previous interventions, enforcements and ratings
   b. Site-specific information, work activities and process risk
   c. Local arrangements with employees or safety representatives
   d. Liaison with other regulators
3. Identify clear objectives and outcomes of the inspection (aligned with divisional working and sector plans and the operational guidance). Besides, the objectives must be related to the most relevant hazards known or potentially to be present. Finally, the objectives should focus on the management of health and safety to achieve compliance.
4. Afterwards, a method of inspection should be selected according to the size and structure of the organisation, the level of risks associated to the working activities and the organisational complexity. It also has to take into account the most efficient path to achieve the objectives of the inspection.
5. Finally, the inspector should prepare the inspection taking into consideration:
   a. The address of significant risks and underlying management systems
   b. The resources, knowledge, skills or specialist inputs required for the inspection
   c. The timing of the visit or consider an appointment
   d. If there is are complex inspections that require more than one day inspection
   e. Making provision for personal health and safety

Source: Health and Safety Executive (2018[20]), *Operational Guidance: Inspection Procedure*, http://www.hse.gov.uk/foi/internalops/og/ogprocedures/inspection/inspection-procedure.pdf (accessed 20 September 2019).

On the other hand, the Operational Guidance: Inspection Procedure indicates the fulfilment of five steps before any inspection event. The principles of risk focus and proportionality are present in several of the activities suggested – see Box 14.5.

During the inspection

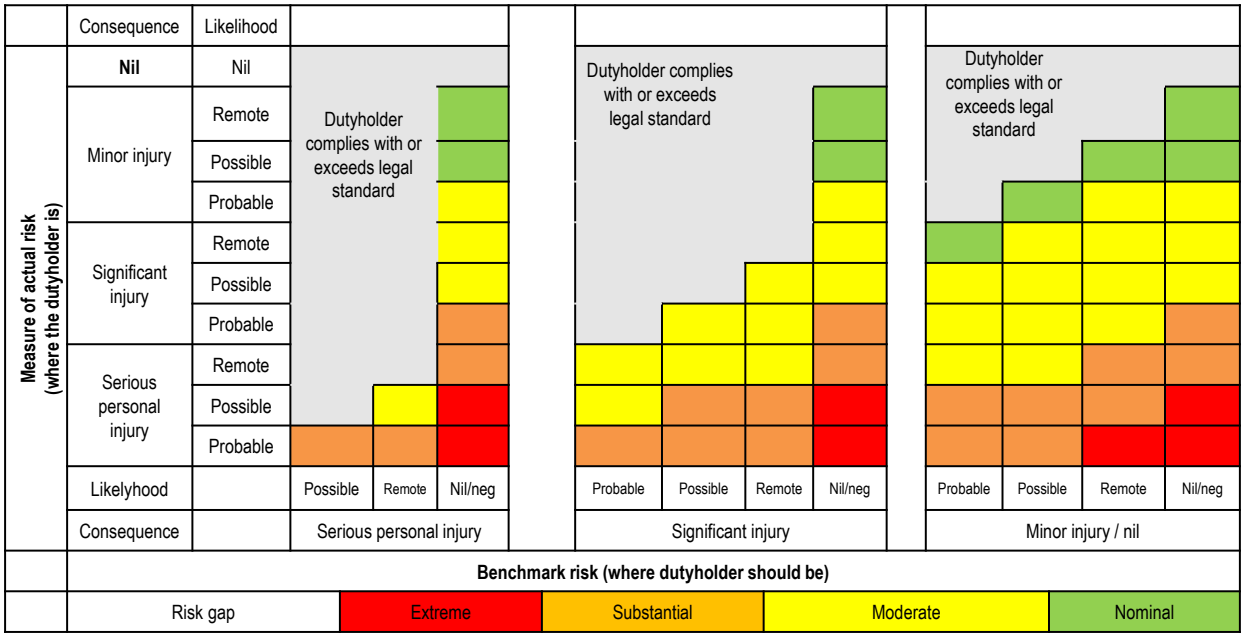
Risk focus and proportionality

According to the EMM, inspectors always have to understand and assess the actual risk that a person might be injured (step 2 of Figure 14.3), taking into account the consequences, the likelihood of occurrence and the extent, in order to prohibit the activity or make safer the origin of risks. Therefore, inspectors should identify risk gaps of the activities (step 3 of Figure 14.3).

The gap analysis is a fundamental concept of the inspection process at HSE. For instance, inspectors have to make an initial assessment of hazards based on the information collected during regulatory contacts and determine the actual risk. Then, they have to compare the risk with the levels defined in the guidelines and decide the benchmark risk. The benchmark is the remaining risk after the duty holder deployed the standards required by law.

The build-up of the risk table is a useful tool to identify priorities. This table matches the consequence and likelihood of the actual risk with the consequence and likelihood of the benchmark risk. Figure 14.4 presents an example of a risk table and the critical areas.

Figure 14.4. Risk tables



Note: This table is an edited version, for brevity and clarity.
Source: Health and Safety Executive (2013[24]), *Enforcement Management Model*, HSE, http://www.hse.gov.uk/enforce/emm.pdf (accessed 18 September 2019).

Clear and fair process

HSE promotes standard practices and transparent processes for inspection activities. For instance, the Operational Guidance: Inspection Procedure (OGIP) incorporates four recommendations to conduct during the HSE's inspection activities (Health and Safety Executive, 2018[20]).

The first recommendation is starting the process explaining the reason of the visit, the role of the inspector and how the official visit will be conducted – on this matter, the inspector should agree on who is the best suited person to assist to the inspection. The OGIP suggests an early contact whenever possible to explain

the reason of the visit, to find out the involvement of the employees in the management of safety and health, to provide a space to raise health and safety concerns in private and discuss about the information provided at the end of the inspection.

The inspector should encourage the duty holder on taking notes, engage in the inspection process and discuss the main hazards on site and the actions to control them. Besides, the parties may discuss about the policy and the findings. Finally, the inspector should provide information about the *fee for intervention policy*.

The *fee for intervention policy* is a cost recovery device used by the HSE for carrying out regulatory functions if duty holders are on material breach of the health and safety law (Health and Safety Executive, 2012[25]). In order to promote transparency, the HSE publishes a guide to make duty holders understand what is the *fee for intervention* and how it fits the enforcement policy (Health and Safety Executive, 2012[26]). Additionally, the HSE publishes a leaflet about the query and dispute process of the fee for intervention (Health and Safety Executive, n.d.[27]).

Afterwards, the inspector should assess specific risk control systems and the adequacy for health and safety management arrangements.

The OGIP indicates that inspections have to consider the inspector's own safety and health. The inspector should implement the inspection plan (which can be adapted if necessary) identifying and prioritising a sample of control-risks systems to assess how the duty holder is managing the health and safety. The number of systems to assess will depend on the nature or site of the business, the complexity or scale of the risks and the time to assess the duty holder.

Furthermore, inspectors should follow up on the concerns raised by employees or safety representatives during inspections, identify the strength and weaknesses in the risk control systems and report good practices. The OGIP also indicates that inspectors have to review the progress of the inspections against the level of compliance, the discovery of breaches and the effectiveness of the safety arrangements.

Ending the process in time, the inspector should finish with an appropriate explanation if there is evidence that inspected units manage risks adequately.

At the end of the process, the inspector should assess the findings and make regulatory decisions.

Responsive regulation

Inspectors should take actions in relation to risks and determine the level of enforcement using the principles of the EMM and the EPS. Moreover, the inspector must be sure that the information collected is enough to support the proposed arrangements. Besides, the inspector should decide if any specialist in needed or extend the inspection beyond a single visit. The types of the HSE's enforcement include:

- providing information and advice
- serving notices on duty holders
- withdrawing approvals
- varying licences, conditions or exemptions
- issuing simple cautions
- prosecution

HSE however, after an enforcement action, gives duty holders advice about their right to challenge or appeal any decision.

The inspector should communicate the outcome and conclude the visit, demonstrating failings, setting expectations for improvement and explaining the immediate actions to implement.

After the inspection

Information integration

After the inspection, the inspector should report and record the findings, follow up, closing out and evaluate the process.

1. The inspector must complete the reports using a do it inspection-recording tool, ensuring that all information required by the operational guidance is included. Afterwards, the inspector should assign a performance rating to each risk control system and prepare written correspondence and notices, which will be sent within 10 working days.
2. The follow up is specific for every issue raised during the inspection process. It should consider further activities, including visits, specialists' support to confirm that inspected units took remedial actions, and all issues were adequately solved. In addition, the inspector should consider potential notices, material breaches, etc. During the follow up process and the closing out, the inspector must communicate with other regulators and the sector about any significant issues found – novel solutions or relevant challenges to enforcement benchmarks.
3. Finally, the evaluation should consider if inspections achieved its objectives.

Lithuania: State Food and Veterinary Service

Background

The State Food and Veterinary Service (SFVS) is the regulatory agency of Lithuania in charge of implementing and designing food sanitation and animal health policy. While this is not a standardised institutional setting, it does allow SFVS to follow the governance cycle discussed in Chapter 1. The SFVS main legal framework is the Statute of the State Food and Veterinary, which defines the responsibilities of the SFVS (SFVS, 2000[28]) Table 14.4 outlines SFVS main responsibilities, including licensing, defining quality requirements, conducting inspections. Most of these tasks revolve around different sectors within the food and animal industries. However, SFVS also has a commitment to work with a focus on consumers rights.

The statute also defines legal structures relevant to the agency's operation. This includes financial matters, which mostly comes from the national government's budget and the European Union. Additionally, the statute outlines specific activities that SFVS has to undertake, beyond the broad mission of the agency. This is relevant as the SFVS defines two-year plans on yearly basis that must match the activities defined in this statue.

In 2017, the SFVS had an approved budget of 28.5 million EUR (including provisions from the European Union) with total expenses amounting to 26.8 million EUR. While the SFVS has technical independence, the Head of the SFVs, the Chief Veterinary Officer (CVO), is accountable to the Minister of Agriculture. The Minister of Agriculture appoints the CVO to lead the SFVS in four-year periods. The agency has four deputy directors heading the organisational departments directly accountable to the CVO. The SFVS totals 1 675 employees, including 309 that work for the National Food and Veterinary Risk Assessment Institute.

Table 14.4. Policy Responsibilities of SFVS

Safeguard interests of consumers and protect infringed rights	Food sanitation policy	Animal health policy	Additional tasks
Investigate complaints from consumers and stakeholders	Manage hygiene and control requirements for safety, quality, handling and placing of food	License to engage in veterinary practice	Performing smell control in residential houses and public building
Register, analyse and monitor consumer complaints	Introducing systems for analysis and management of risk factors in food handling practices	Permission to conduct laboratory trials on animals	Implement and maintain information systems and databases
Inform consumers and businesses about SFVS' tasks	Establish mandatory requirements to mark animal products	Certificates for animal transporters	Submit proposal to other ministries, regarding topical problems on food and veterinary research
Offer consultations and guidance to regulated entities	Establish procedures to control food, materials, and articles in contact with food and drinking water	Certificates for road vehicles intended for transport of animals	Maintain contacts with relevant institutions of other countries and international organisations
	Approval of food handling businesses	Approval of control programmes of contagious animal diseases	Collaborate with mass media, and research institutions
	Establish requirements for import, export and transit of non-animal food, animal products and materials in contact with food	Establish mandatory requirements for the protection of animals' welfare	Represent the country in pertinent EU commissions
		Establish mandatory requirements for trade in animals	
		Licence to engage in veterinary pharmaceutical activity	
		Carry out scientific evaluation of risks related to feeds, feed additives and veterinary appliances	

Note: This table is an edited version, for brevity and clarity.
Source: SFVS (2000[28]), *Statute of the State Food and Veterinary Service [Valstybinės Maisto Ir Veterinarijos Tarnybos Nuostatai]*, https://vmvt.lt/sites/default/files/statute_sfvs_2011.doc?language=en

Before the inspection

Risk focus and proportionality

In order to define the periodicity of inspections, the SFVS has a methodology to categorise business units by risk. The methodology, available online, allocates risk in different industries by looking at the specific products being produced, managed and transported. In the case of food products, SFVS has a different consideration for food business operators, for caterers and for traders.

Table 14.5 gathers the risk criteria and the frequency of inspections for each risk category. Products with the lowest risk are those with minimal or no likelihood of people getting a disease as well as products having physical/chemical properties that do not allow microorganisms to reproduce. The SFVS inspects business units that meet these criteria every six years. Conversely, the agency inspects once a year those with the highest risk associated.

Table 14.5. SFVS Risk Matrix for Food Safety

	Very low risk	Low risk	Medium risk	High risk
Criterion 1	There is minimal or no likelihood that people will become ill from food when handling food.	There is little likelihood of contamination, microbial growth and toxin and mycotoxin levels in food management.	While food is likely to cause contamination, food properties do not facilitate the growth of microorganisms and the growth of toxins and mycotoxins, and the application of heat treatment or other more efficient food processing processes can reduce microorganisms to an acceptable level.	There is a high risk of contamination, multiplication of microorganisms and increased levels of toxins and mycotoxins in the final product or food processing (e.g. long food production, supply chain).
Criterion 2	Physical-chemical properties of the product do not allow microorganisms to multiply or increase toxins and mycotoxins	The physical and chemical properties of the product do not allow microorganisms to multiply or increase levels of toxins and mycotoxins.	The physical and chemical properties of the product do not favour the growth of microorganisms or the increase of toxins and mycotoxins.	The product is inherently risky (readily multiplies microorganisms, increases toxins and mycotoxins), is intended for direct consumption, is a perishable food or is intended for infants and young children.
Frequency of inspection	Once every 6 years	Once every 3 years	Once every 2 years	Once every year

Source: SFVS (2019[29]), *Breakdown of Food Management Sub - items into Risk Groups [Maisto Tvarkymo Subejktų Suskirstymas Į Rizikos Grupes]*, http://vmvt.lt/opendata/mtsr/index.php (accessed 24 January 2020).

Forward planning

Every year the SFVS publishes a two-year *Strategic Action Plan* that outlines specific actions to undertake in order to achieve the stated policy goals. The plan has five chapters the mission; operational priorities; strategic objectives and programme; human resources and management expenditure, and operational efficiency. The plan outlines its 2019-2021 mission: Implement the procedures for placing on food safety and quality, labelling, animal health and welfare, labelling and registration to protect and defend consumer rights in the provision of food and food-related services areas (SFVS, 2019[30]). Table 14.6 lists the directives of both operational priorities and strategic objectives. Regarding operational efficiency, SFVS focus on conciliating personnel functions and asset management.

Table 14.6. SFVS's Strategic Action Plan 2019-2021

Operational priorities	Strategic objectives
Control the implementation of biosecurity and veterinary requirements to prevent the transmission and spread of infectious animal diseases	Maintaining a high level of animal welfare and health, while avoiding contagious animal diseases
Development of export markets for food and animal food products	Ensuring and maintaining a high level of food safety and quality, consumer rights to food and food advocacy in food-related services
Safety and quality control systems for food and food contact materials	Development of international co-operation in the fields of food and veterinary control
Increasing the effectiveness of controls on food supplements and their labelling	Improving the efficiency and transparency of the SFVS's management process.
Improving the efficiency and transparency of service, management processes and quality systems. Improving consumer confidence	

Source: SFVS (2019[30]), *Strategic Action Plan 2019-2021 [2019–2021 Strateginis Veiklos Planas]*, https://vmvt.lt/sites/default/files/zum_patvirtintas_2019-2021_vmvt_strateginis_veiklos_planas.pdf?language=lt

A key aspect is financial transparency. In this report, the SFVS states the expenses in the past year by specific goal purposes. SFVS also presents the expected expenses for the next two years.

These plans go beyond stating policy actions and their rationale. For example, the 2019-2021 plan states the following priority: carry out and co-ordinate controls on food supplements and their labelling. To explain the motivation of this policy action, the agency points to the rising consumer complaints on labelling. This example highlights two important features: forward planning and responsive regulation. The regulatory agency shows openness to the consumers, as it continuously receive comments, and adopts them to design policy going forward.

During the inspection

Clear and fair process: inspection acts

The SFVS publishes inspection acts for every inspection carried out. This transparency practice promotes good policymaking as it lets the industry prepares its quality practices beforehand, and it avoids potential authority abuses. As the acts are public, any business unit is able to complain if an inspector is asking for any additional information or requirements.

As an example, SFVS' *Retail Trade Inspection Act* is available in its website. The document incorporates identification information of the inspecting officer, the purpose of the inspection, consumer complaints (if any) and date of the inspections. The act consists of 44 question divided in four sections: general requirements, requirements for handling of food contact materials, liquor handing requirements, and products with protected indications.

After the inspection

Information integration: risk-related databases

The SFVS has a list of food business operations, categorised by risk groups (the same risk groups from the matrix presented beforehand). The SFVS match information from the inspections and from their own record. The database has updated information of the companies' licenses, so that the public can research whether companies are in good legal standing. This database (SFVS, 2019[31]), available for the public, contains the following information:

- Name of the company;
- Commercial activities;
- Range of products approved for the business operator;
- Address;
- Authority who issued license or permits;
- Date of issue of certificate;
- Food Management Certificate number;
- Risk group (very low, low, medium, high).

Annual evaluation

The SFVS prepares and publishes an annual activity report, available online for the public to download. As part of the report, the SFVS holds a self-evaluation with criteria that measure the progress of strategic goals of the agency (see Box 14.6). The report couples each criteria with several indicators to measure the agency's performance.

The goals are consistent with the OECD best practice principles in inspections in two ways. The SFVS's self-evaluation addresses policy objectives, such as "Control of the implementation of biosecurity and veterinary requirements in order to prevent the spread of contagious animal diseases". In addition, it addresses its own operational performance, as goal 6 states: "Open and effective public governance, with increased public confidence and reducing the burden on small agricultural operators."

While the SFVS achieved most of the expected targets in 2018, it was also transparent with those not met. Several goals contained underperforming indicators, and for all of them, the SFVS explained the reason. In some cases, the SFVS was clear on how institutional or technological changes modified its role on inspections. Overall, this practice renders SFVS as a good example of accountability to the public.

Box 14.6. SFVS annual evaluation indicators 2018

1. **Goal:** Strengthen prevention and control of antimicrobial resistance in the veterinary and food sectors.
    a. **Indicators:** 10% reduction in antibiotic use in food and veterinary use; selected samples for antimicrobial resistance of zoonotic and symbiotic bacteria materials tracking number (575 pieces).
2. **Goal:** Development of export markets for animal food products
    a. **Indicators:** Number of harmonised animal health certificates for animal food exports in 2018: 4 units; Countries with which veterinary sanitary negotiations started and have requirements for animal food (28).
3. **Goal:** Control of the implementation of biosecurity and veterinary requirements in order to prevent the spread of contagious animal diseases.
    a. **Indicators:** Analysed samples selected for state surveillance of infectious animal diseases programme: 297 894 units. Commercial pig farms with fully implemented biosecurity requirements: 100%. Selected samples for antimicrobial resistance of zoonotic and symbiotic bacteria materials tracking number: 575 pieces.
4. **Goal:** A plan of measures to combat food counterfeiting, illegal food processing, consumers cheating and food safety offenses.
    a. **Indicators:** Detection of food samples in food processing companies for possible tampering number: 129 units. Evaluation of distance selling of food products: 838 units. Meetings organised by Internet Service Providers and Portal Managers (0 out of 3). Regular inspections of markets and temporary markets for illegal activities or number of detection of food counterfeiting: 115 units. Control of incoming food at wholesale companies (cold stores) ensuring the traceability of the product stores: 162 units.
5. **Goal:** Food and alcoholic beverages registered in Protected Destination of Origin, the Register of Protected Geographical Indications, and the Register of Traditional Specialties Guaranteed market control.
    a. **Indicators:** Conformity samples of food products selected by food business operators to Protected Origin local destination, and quality of traditional specialties guaranteed number of requirements: 50 units. Done food and spirits registered 919 units.
6. **Goal:** Open and effective public governance, with increased public confidence and reducing the burden on small agricultural operators.

a. **Indicators:** Independent Consumer Satisfaction Index: 6.4 (expected 7). Users of electronic public and administrative services: 43% (expected 20%). Number of electronic services provided to business entities and residents: 85 392 (200 units expected). Eighty two percent of control questionnaires reviewed and updated (80% planned). Responding appropriately and timely to consumer inquiries: 65% (expected 90%).

Source: SFVS (2018[32]), *State Food and Veterinary Service Activity Report 2018 [2018 2018 Metų Veiklos Ataskaita]*, https://vmvt.lt/sites/default/files/veiklos_ataskaita.2018m.pdf.

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