

Guidelines on the Development of a Unified Supervision and Inspection System of Economic Activities in Greece



Acknowledgments

The following five guidelines for “the Development of a Unified Supervision and Inspection System of Economic Activities in Greece” have been prepared by a joint team of experts which was composed by members of the Better Regulation Delivery Directorate (BRDD)/General Secretariat for Industry of the MINISTRY OF DEVELOPMENT AND INVESTMENTS and the WORLD BANK Team.

Introduction

This publication presents five horizontal guidelines that settle out the basis for the development and implementation of the new institutional framework for the supervision of economic activities and the product market in Greece¹.

The aim of the guides is to support the country's inspectors and supervisors to develop new inspection methods and tools in order to consolidate and ensure optimal and effective supervisory processes for addressing the risks of doing business. Equally important goal of the guidelines is to provide businesses and their associations with detailed information on the new regulatory framework and its benefits to the entrepreneurial activity in Greece.

The new institutional framework for the supervision of economic activities is one of the three pillars of the reform program which is under implementation by the Ministry of Development and Investments in collaboration with relevant competent Ministries with the aim to strengthen the business environment in Greece, to improve the competitiveness of enterprises, and to facilitate investments.

The other two pillars concern: a) the simplification of licensing procedures for the majority of economic activities in Greece, and b) the development of an Integrated Licensing Information Management System (ILIMS) to support the digitization of the above licensing and supervision of procedures.

The supervision Law introduced a new philosophy for the supervision and inspection of economic activities in Greece with the aim to improve the welfare of citizens by reducing risks (existing or potential) in relation to basic public goods such as, health, safety, and environmental protection. In parallel, entrepreneurial activity and entrepreneurship are facilitated through fair competition and businesses' compliance with transparent, reasonable, and accessible rules.

By developing a predictable system through the implementation of the new institutional framework is intended to make inspections more transparent and effective on the basis of planning, programming, standardization, and disclosure of inspection procedures.

The new framework supports business compliance by introducing innovative tools from public administration, such as a new Enforcement Management Model, the Check Lists e.t.c on inspections while will create a trustworthy and reliable business environment among enterprises, consumers, and citizens by using effectively the available resources.

This new supervision and inspections system will contribute to economic growth and employment, will support the creation of new businesses by facilitating investments and will promote the diversification of production by fostering innovation

The following five guidelines are designed for practical use to support supervision authorities and businesses to cope with the inspection processes in a uniform and consistent manner.

¹ Law 4512/2018 (A'5/17.01.2018), Art. 127-157

Law 4635/2019 (A'167/30.10.2019), Art. 19

Guidelines on the Development of a Unified Supervision and Inspection System of Economic Activities in Greece

Contents

pg. 6 GUIDE 1

**Risk Assessment and Risk-Based
Planning Methodology of Inspections**

pg. 32 GUIDE 2

Development of Checklists

pg. 52 GUIDE 3

**Development of the Enforcement
Management Model**

pg. 82 GUIDE 4

**Development of a Risk-Based Complaint
Management System**

pg. 104 GUIDE 5

Development of Guidance to Businesses

GUIDE 1

Risk Assessment and Risk-Based Planning Methodology of Inspections

Contents

- pg. 9 1. Purpose and scope of the guide**
- pg. 9 2. Why risk assessment and risk-based planning of inspections?**
- pg. 11 3. Key concepts**
- pg. 12 4. Developing a risk-based planning methodology of inspections step by step**
- pg. 18 5. Designing risk criteria and parameters**
- pg. 22 6. Pitfalls in the design of risk criteria and parameters: what not to do**
- pg. 24 7. Risk rating**
- pg. 24 8. Implementation road map for risk-based inspections**
- pg. 25 References**
- pg. 27 Annex**

1. Purpose and scope of the guide

Law 4512/2018 (Art 137) introduced a new legal framework for the supervision of economic activities (hereinafter, inspections) that established the following goals in inspections:

- Improving public welfare by reducing or mitigating existing or potential risks that may endanger key public interests, in particular human health, safety, and the environment;
- Making the best use of available resources through effective and cost-efficient enforcement that increases trust among citizens, businesses, consumers, and so on;
- Using transparent and predictable regulation; and
- Fostering economic growth and employment by facilitating investment, enterprise creation, diversification, innovation, and technology adoption and reducing administrative barriers and costs, ensuring at the same time fair competition and practices in the market.

To achieve these goals, the law stipulates that inspectorates need to base their activities on risk management and proportionality, minimize the burden and costs associated with control activities, and use a wider range of tools to support compliance. More specifically, art. 137 of the law requires that inspections be planned on the basis of risk assessment and risk categorization of economic activities.

The purpose of this guide is to assist inspectorates and inspectors in developing risk criteria and risk planning methodologies for inspection purposes, to ensure optimal decision-making processes for dealing with risks.

This guide will help unify risk assessment and risk planning practices across inspectorates and ensure the consistency, uniformity, and quality of approaches.

The guide is designed for practical use. It presents, in brief, what needs to be done to rate inspection objects (such as establishments and products) in terms of the risks they pose and how to implement this risk assessment to plan inspections. Care should be taken to apply the method and tools in a manner that is suited to the characteristics and circumstances of each inspection domain. The guide will also inform and help businesses and their associations to comprehend the new regulatory framework and the tools available under the new supervision law related to economic activities and products.

2. Why risk assessment and risk-based planning of inspections?

Adopting a risk-based approach involves a shift from covering all economic activities in a uniform way to differentiating among them based on the level of risk they impose on key public interests. It is not feasible, in practice, to inspect all economic activities with the same intensity (for example, by physically inspecting them). The inspectorate instead has to make a decision—and the method of taking such a decision is key—to base the decision of which entity to inspect either on the basis of criteria that are unrelated to risk (for example, inspecting sites that are close by to each other for the purposes of efficiency or focusing on large sites) or by applying a set of risk-based criteria that will allow the inspectorate to choose objects that are most likely to affect the protected public interest. Risk assessment and risk-based planning of inspections can serve four important goals:

2.1. Improve protection of public interests and maximize social welfare

Inspectorates have a duty to plan inspections in a way that maximizes the benefit for the public by mitigating existing or potential risks to key public interests, in particular human health and safety and environment. There is no logic in exercising supervision over all activities in the same way, as supervised activities differ from one another in the level of risk. Inspections should therefore be prioritized based on the level of risk; the higher the potential risk, the greater the need for more frequent inspections. For low-risk activities inspections should be rarer; information campaigns, advice provision and other less interventionist means can instead be used to induce enforcement. A methodology to classify establishments or products according to risk is thus particularly important.

Different establishments/products have different risk levels. If inspections are not adapted to these different risk levels, a universal inspection method or a uniform inspection frequency may be selected for all cases, as depicted by the red horizontal lines. This will result in dangerous establishments/products being inspected too infrequently and less risky establishments/products being inspected too often. Insufficient inspection of risky cases will fail to adequately protect the public interest, whereas overinspection will waste limited resources. Risk-based inspections, on the contrary, will first target high risks and allocate resources accordingly.

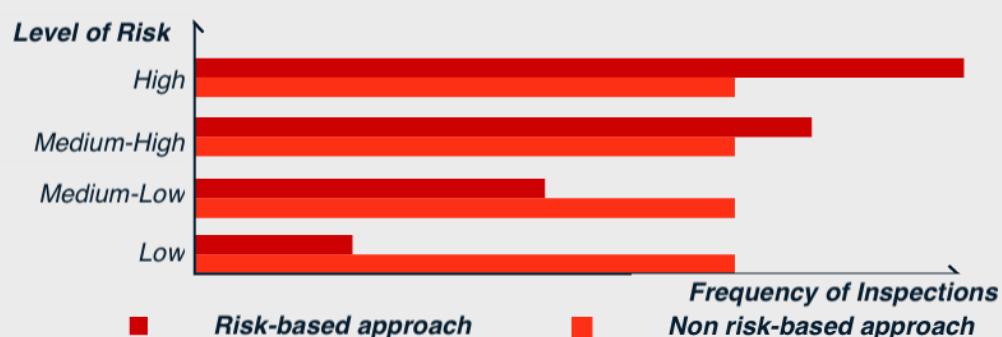


Figure 1: Risk levels and inspection frequencies

2.2 Make the best use of limited resources

Inspectors cannot be everywhere all the time or examine every process, establishment, or product that is involved in risk creation. Existing budgetary constraints and increasing pressures to reduce costs mean that resources such as time, budget, manpower, and professional experience—which are already limited in availability—should be deployed effectively to improve compliance among the economic activities that pose the highest risk to the public interest. Physical inspections are an expensive way to achieve enforcement compared, for example, to the provision of advice and/or training to businesses. Risk-based inspections allow limited resources to “follow” risks by making it possible to direct resources from low-risk activities to high-risk activities and invest them in addressing key problems.

2.3. Establish strategic priorities and improve performance

To identify the key risks that need to be targeted, inspectorates first need to determine the specific positive outcome(s) to be achieved, such as a decrease in labor-related injuries, food-

borne illnesses, or product-inflicted harm. These strategic priorities are frequently coded into the mission of the inspectorates, but need to be translated into specific, real-world outcomes. The adoption of risk assessment and risk-based planning of inspections thus prompts inspectorates to (re)define and concentrate on their strategic goals and objectives. A risk-based approach that involves setting specific goals ex ante can assist in the measurement of performance and improve performance by revealing the sources of failure and success.

2.4. Enhance the transparency and consistency of inspection decisions

A common approach to risk assessment and planning of inspections across inspectorates improves consistency in the assessment of economic activities and ensures that inspection decisions will differ only when justified by the level of risk. Risk assessment establishes a clear criterion for making inspection decisions because the risk criteria on which the assessment is based, and the process followed to make the assessment, are clearly defined in advance. Transparency in the decision making of inspectorates strengthens their legitimacy and allows the public to understand the criteria that underlie inspection decisions, thereby building trust in government institutions and increasing compliance.

| Characteristics | Universal inspections | Risk-based inspections |
|--|---|--|
| <i>Level of clarity for businesses</i> | <i>No clarity, inspection aims and processes depend on individual inspector</i> | <i>Maximum clarity. Inspections are carried out with checklists based on risks</i> |
| <i>Level of effort for inspectors</i> | <i>Huge work load</i> | <i>Inspectors follow checklists that help them focus during inspections</i> |
| <i>Transparency of enforcement and decisions</i> | <i>Decisions are based on discretion, with little guidance</i> | <i>Decisions are based on risks and likelihood of compliance of an operator</i> |
| <i>Effectiveness (result per currency unit)</i> | <i>Expensive – low effectiveness</i> | <i>Very cost-effective</i> |
| <i>Efficiency (ability to protect public interest)</i> | <i>Lack of targeting makes it less likely to produce results</i> | <i>Most efficient – since targeted at risks</i> |
| <i>Transfer of duty</i> | <i>State is liable for everything</i> | <i>Responsibility of the operator</i> |

Table 1: Universal vs. risk-based inspections

3. Key concepts

A unified definition of key concepts that applies across all inspection domains is important to allow for a common approach to risk management, coordination of actions between different inspectorates, and coherence in the supervision of economic activities across government institutions. A limited degree of customization of the key concepts below is allowed when it is required to cope with the needs of specific areas.

Risk

Risk is the combination of the probability that an adverse event will occur and of the magnitude and severity of the harm caused if this adverse event materializes.

$$\text{RISK} = \text{HARM} \times \text{PROBABILITY}$$

Harm

Harm is any form of damage done to a protected public interest. Harm thus includes damage to life, health, and property; damage to the natural and cultural environment; damage to state revenue; and so on. The magnitude of the harm depends on the scope of the damage (for example, the size of the area that is polluted, or the number of consumers or workers affected), and its severity depends on the degree and type of damage.

Hazard

Hazard is a potential source of harm.

Probability of occurrence

Probability of occurrence is the likelihood that an adverse event will occur leading to potential harm.

Risk assessment

The process of identifying, analyzing, and assessing the risks posed by economic activities, establishments, products, and so on, which aims to organize and exercise appropriate enforcement actions, including inspections.

Box 1: Definition of key concepts for risk assessment and risk-based planning of inspections

4. Developing a risk-based planning methodology of inspections step by step

Developing a proper methodology and tools to classify activities according to risk is particularly important for a risk-based inspection system; before taking that step however, it is essential for inspectorates to set the context and define their scope of work.

Step 1: Set a goal of risk reduction

The first step in developing a risk-based targeting method for planning inspections is to define a desired positive outcome that needs to be achieved within a specific time period, usually over a certain number of years (multiannual risk planning). Ideally, the overall positive outcome will be defined quantitatively and broken down into sub-objectives that can be achieved on an annual basis. Each inspectorate targets relevant risks to public interests that are generated by the objects (that is, the products or establishments) under its supervision.

Australian Work Health and Safety Strategy 2012-2022

- The Strategy sets three national targets to be achieved by 2022:
- A reduction in the number of worker fatalities due to injury of at least 20%.
- A reduction in the incidence rate of claims resulting in one or more weeks off work of at least 30%.
- A reduction in the incidence rate of claims for musculoskeletal disorders resulting in one or more weeks off work of at least 30%.

US. Food and Drug Administration (FDA) Strategic Priorities 2014-2018

- Improve response to foodborne outbreaks with rapid tracing of contaminated foods
- Conduct effective risk communications related to outbreaks and contamination incidents.

GR Ministry of Rural Development and Food multiannual national plan (2015-2019)

Strategic goals

1. Monitoring and treatment of zoonoses and zoonotic agents. Eradication of specific zoonoses.
2. Prevention and treatment of chemical and biological risk factors in the food and feed chain.
3. Protection of consumer interests and fighting fraud across the food chain.
4. Ensure effective implementation of EU legislation on phytosanitary control for the protection of national capital, natural resources and the environment.
5. Improving the organization and implementation of official controls on issues related to animal welfare.
6. Protection of public health, animal health and the environment through better management and optimal use of animal by-products.
7. Improving the organization and implementation of official controls for the uniform application of law by:
 - Removing duplications
 - Achieving uniformity in the implementation of official checks
 - Effective supervision of official controls using appropriate verification systems

GR General Secretariat of Industry, Unit of Construction products, Chemicals and Other Industrial Products

Goals for construction products with CE marking available on the market:

1. Minimize the number of non conformity construction products with the Construction Product Regulation (EE) nr. 305/2011, on the greek market.
2. Reduction of deviation of a construction product performance from the declared performance.

Box 2: Examples of goal setting

Step 2: Compile a database of inspection objects

Inspectorates need to compile a database of the objects under their supervision and gather information on the characteristics that are required to assess the objects' risk level. This is necessary so that inspections can be planned correctly. The personnel and material resources available within inspectorates should be matched with the objects to be inspected. It is necessary, therefore, to first identify and keep track of the inspection objects (see Section 5 on necessary criteria for risk assessment). The database need not be sophisticated, but reasonably comprehensive and sufficiently updated. Inspectorates are not expected to achieve a 100 percent accurate list of objects in semi-regulated areas, such as the operation of offices, but it is crucial that—even in these areas—the database does not miss the higher-risk objects. In cases where databases are

incomplete or outdated, inspectorates can use a variety of sources to collect missing information. This could include, for example, exchanging information with other inspectorates or consulting their databases, using publicly available information (such as media reports), systematically collecting data and inputting it into the database when conducting random inspections, and so on.

Notify Business, the information technology (IT) software that currently supports notification in several business sectors (manufacturing, tourism, catering, food retail, logistics, mining, waste management) can be used by inspectorates as a source of information on inspection objects. Notify Business contains information on establishments that started operating from 2016 on, including information on their physical characteristics, which is relevant in assessing risk and targeting inspections.

Law 4442/2016 mandates the creation of a better and more sophisticated information management system to support risk-based supervision. The design of the Integrated Licensing and Inspections Management System is in progress. When completed, the system will comprise a unified database of establishments to be used across several agencies to rank economic activities on the basis of predefined risk factors and their parameters, to generate inspections plans, and to allow inspectorates to list their inspections and view the results of others' inspections.

Box 3. Notify Business

Step 3: Assess risks and classify inspection objects

Once inspectorates have defined the context and their scope of work and created a database of objects, the next step in the process is to assess relevant risks and rate inspection objects according to their assessed risk level. This occurs in three stages:

a. Risk identification

The first stage of risk assessment involves the identification of hazards and of subjects that would be at risk of harm as a result of those hazards.

Methods and sources

To account for as many conceivable hazards as possible, it is suggested to perform risk identification primarily through brainstorming in inspectors' groups. This can be complemented by an examination of historical data on past accidents, by consultation with relevant stakeholders such as business associations, and by using international experiences and data collected by specialized international organizations, where available. The first two columns of Table 2 present examples of hazards and the affected subjects.

| Public interest – affected subject | Hazards | Harm/damage caused |
|---|--|----------------------------------|
| OSH – workers | <i>Bandsaw</i> | <i>Cuts</i> |
| OSH – workers | <i>Asbestos</i> | <i>Mesothelioma</i> |
| OSH – workers | <i>Wet floor</i> | <i>Slips, trips</i> |
| Food safety – consumers | <i>Contaminated water with E. coli</i> | <i>Intestinal infection</i> |
| Food safety – consumers | <i>Infected poultry</i> | <i>Avian influenza</i> |
| Food safety – consumers | <i>Small pieces of broken glass</i> | <i>Gastrointestinal bleeding</i> |
| Product safety - consumers | <i>Short-circuit</i> | <i>Electric shock</i> |
| Product safety - consumers | <i>Overheating</i> | <i>Burns</i> |

| Public interest – affected subject | Hazards | Harm/damage caused |
|---|--|---|
| Product safety - consumers | <i>Toxic material</i> | <i>Poisoning</i> |
| Environmental safety - environment | <i>High energy use</i> | <i>High greenhouse gas emissions</i> |
| Environmental safety - environment | <i>Corroded pipeline</i> | <i>Pollution of aquifer</i> |
| Environmental safety - environment | <i>Illegal waste burning site</i> | <i>Local air pollution, wildfire</i> |
| Technical safety-human life/health | <i>Smoke alarm failure/ nominal activation condition</i> | <i>Smoke inhalation, asphyxiation resulting in death</i> |
| Technical safety-environment | <i>Building burns down</i> | <i>High CO2 emissions, creation of waste</i> |
| Technical safety-economy | <i>Building burns down</i> | <i>High one-time cost for demolition and reconstruction</i> |

Table 2: An example of identification of hazards and subjects at risk

b. Risk analysis

After identification of the relevant hazards, the risks associated with that hazard should be analyzed. Risk analysis involves describing the potential negative consequences—that is, the type of harm or damage that may occur to the subjects if exposed to the hazard (Table 2, Column 3). The type and gravity of the harm are used to understand the nature of the risk and determine its severity.

Methods and sources

This stage can be completed by using data from multiple sources, including the informed opinions of senior officers and experts, academic and research publications, official sources containing current and historical data on accidents, and materials from the EU and other international sources³.

c. Risk evaluation

In the last stage of risk assessment, predetermined risk criteria are used to evaluate the magnitude and probability of harm and arrive at the estimated risk level of the inspection object. To evaluate the risk level of a given object, the probability of harm and the magnitude and severity of harm should thus be combined. This can be performed with the help of a risk matrix, a simple tool that is used to increase the visibility and understanding of risk attributes and assist in decision making.

Each inspectorate should develop and use a fixed set of evaluation criteria that will be applied to all inspection objects under its supervision. All objects under the same inspection domain are evaluated against the same criteria to allow for all supervision objects to be scored on the basis of risk and subsequently to be classified in a specific risk category, usually low, medium, or high risk. It is advisable to use more than three levels, however, such as low, lower medium, upper medium, and high, as shown in Table 3, to allow for greater differentiation among potential inspection objects.

³ For example, EU specialized risk assessment bodies such as the European Medicines Agency (EMA), the European Food Safety Authority (EFSA), and others, and international organizations such as the World Health Organization (WHO), World Organization for Animal Health (OIE), Food and Agriculture Organization of the United Nations (FAO), International Plant Protection Convention (IPPC), International Labor Organization (ILO), and others.

Risk matrices are the primary way of classifying establishments, products, and so on, according to risk. The severity and magnitude of harm are identified on the vertical axis. The probability of occurrence is identified on the horizontal axis. The intersection determines the level of risk.

| Potential severity and magnitude | Probability of harm | | | | |
|----------------------------------|---------------------|--------------|--------------|--------------|--------------|
| | Very low | Low | Medium | High | Very high |
| High | Lower Medium | Upper Medium | Upper Medium | High | High |
| Upper Medium | Lower Medium | Lower Medium | Upper Medium | Upper Medium | High |
| Low Medium | Low | Lower Medium | Lower Medium | Upper Medium | Upper Medium |
| Low | Low | Low | Lower Medium | Lower Medium | Upper Medium |

Table 3: Example of a risk matrix

Methods and sources

In practice, quantitative data are usually combined with a more qualitative assessment to define risk criteria. For a more practical and realistic approach, inspectorates should rely on information from multiple sources—including the Hellenic Statistical Authority (ELSTAT), the Rapid Alert System for dangerous non-food products (RAPEX), the Internet-supported information and communication system for the pan-European market surveillance for products (ICSMS), the Rapid Alert System for Food and Feed (RASFF), the International Plant Protection Convention (IPPC), and others—regarding historical data on accidents, past inspections findings, the understanding and expertise of senior inspectors, examples from other European jurisdictions, and scientific evidence. Specifically with respect to products, the European Commission has recently developed an online tool to facilitate the systematic risk assessment of products, which can also be used as a source of information (EC 2018)⁴. Based on this information, inspectorates can define risk criteria and assign weights to parameters that influence the probability and magnitude of risk. The score for each parameter is then added to reach a total score for the supervision object based on which the object will be classified into a specific risk category (see Annex for examples from Lithuania and the United Kingdom).

Using the risk criteria, risk parameters, and their relative weights over time, and reviewing them when necessary, will result in their refinement, at which point it will be possible to transition from manual implementation of risk assessment to automated implementation of risk assessment performed by the Integrated Licensing and Inspections Management IT system. In some cases, it is possible to use quantifiable indicators from the beginning; these can be incorporated more easily in the IT system, allowing inspectors to promptly categorize and recategorize objects based on their risk level.

Sections 5 and 7 of this guide are devoted, respectively, to the design of risk criteria and their parameters, and the risk scoring of inspection objects.

⁴ European Commission (2018), Risk Assessment Guidelines (RAG) for RAPEX, available at: <https://ec.europa.eu/consumers/consumer-safety/rag/#/screen/home>

Step 4: Match risks with available resources

Risk evaluation will result in the classification of supervision objects into three categories of risk—low, medium, and high—which are usually depicted visually in the form of a risk pyramid, as foreseen in art. 137 of Law 4512/2018. To translate this classification into actual inspection planning, inspectorates will need to link this information with their own resources. This presupposes that inspectorates keep an internal register of their resources—for example, available inspectors and their profiles and skills. After the risk evaluation and the classification of inspection objects into risk categories have been completed, inspectorates should take into account the number of available inspectors, their skills, the average duration of inspections, and the required follow-up desk work in order to estimate how many total inspections each inspector can conduct each year. Based on this estimate, inspectorates should then set a minimum inspection frequency for each risk category. For example, objects in the higher risk category must be inspected at least x times per year, objects in the medium risk category must be inspected at least x times per year(s), and so on. In principle, frequency will be proportional to risk, implying that resources will focus on higher-risk objects, which will be inspected more often. Caution should be exercised in setting the inspection frequency for each category in a way that does not exhaust available resources, in case serious complaints and emergencies arise that will require prioritization.

The risk pyramid depicts the classification of inspection objects (such as establishments and products) into three categories based on their risk level. The type of intervention and frequency to be applied are intensified as the level of risk increases.



Adapted from: Ayres Ian & John Braithwaite (1992), Responsive Regulation, Oxford University Press, p. 35

Figure 2: Risk pyramid

5. Designing risk criteria and parameters

The proper design of risk criteria is crucial for the implementation and effective functioning of a risk-based inspection system. Risk criteria and their parameters should be straightforward, concise, and easily identifiable with regard to the inspection object (that is, the establishment, product, process, and so on). Each inspectorate should develop a fixed set of evaluation criteria and a system for scoring based on specific parameters that will be applied to all inspection objects. Though the risk criteria, the parameters, and the scoring method will need to be customized to the inspection domain and type of supervised objects, it is possible to distinguish two groups of criteria that are generally applicable and can be used—with modifications—in most inspection domains.

Group A: Intrinsic characteristics and other (static) risk attributes

Inherent characteristics of economic activities and products, as well as other risk attributes, can be used as criteria for the classification of inspection objects into risk groups. These characteristics usually remain unchanged over time, are easily identifiable and known, and can therefore be assigned scores before any inspection has been conducted. They usually include the following:

a. Type of activity or type of process or type of product

The sector of the activity, the type of activity performed, the processes and equipment used, and the structural characteristics are all important for the risk classification of establishments. Some activities are more dangerous and accident-prone than others, or can lead to more significant harm. For manufacturing establishments in particular, the raw materials used, the manufactured products, the substances stored, and the waste generated will constitute important aspects that affect the risk level and should be included in the parameters to be assigned weights. It is more dangerous, for example, to use pressure equipment, be exposed to high temperatures, and store chemicals than not. The structure of the establishment should also be taken into account when it exacerbates risk, as is the case, for instance, of a multistory hotel or an underground pub, which present difficulties for evacuation. Depending on the inspection domain and the risk to be mitigated, it is possible to identify other, more relevant parameters for risk assessment; in the environmental safety domain, for instance, the age of an establishment is considered to influence the probability of harm.

Intrinsic characteristics are also important for the risk classification of products. The product category or type and other characteristics such as the intended use, overall shelf life, and age of a product can affect the probability and the magnitude of risk and should thus be incorporated into the assessment. Products that have the potential to have a significant impact on the health and safety of consumers will receive a higher risk score. Other important parameters include the frequency of use of the product and its usefulness; a product that is used often entails longer risk exposure for consumers compared to a product that is used less frequently or seasonally, as is the case for instance with holiday ornaments. The existence of risk-mitigating attributes such as warning labels, safe packaging, and so on, as well as compliance with voluntary safety standards, are parameters that should be incorporated into the assessment. More specialized parameters can be identified for product categories with particular characteristics.

b. Size of the activity or scope/volume of operations

The size of the activity or volume of operations can affect the potential scope of harm and are therefore important criteria. In the case of establishments, a larger size implies that inflicted damage will be proportionally higher should an accident occur. The volume of operations is important for products; for example, products that are produced in large quantities and available in many retail stores will pose risk of a higher magnitude compared to products that are produced in small quantities and available in specialist outlets.

c. Characteristics and number of people exposed to risk

The characteristics, function, and number of people that are exposed to risk can influence both the risk magnitude and its probability and should therefore be used as criteria for the risk classification of inspection objects. The larger the number of consumers/users of a product or of people present in an establishment, the higher the number of people who are likely to be injured if the risk materializes. It is also important whether people work in an establishment and are therefore accustomed to its risks—for example, in the case of factory workers or hotel employees—or are present merely as customers. The susceptibility of the population that is exposed to a particular risk should also be taken into account as a parameter; for example, risk is aggravated if the establishment accommodates disabled people or if the product is intended for vulnerable consumer groups such as children or the elderly.

d. Location

Location can affect the magnitude of risk. Parameters that incorporate location characteristics should be used, when appropriate, for the risk assessment of establishments. If an establishment is isolated, for instance, it is likely to have less of an effect on its surroundings if harm materializes. On the other hand, if the establishment is surrounded by densely populated areas or is located near important natural resources such as forests, lakes, other water sources, or sites of cultural interest, the potential harm would be elevated if the risk were to materialize.

The Ministry of Rural Development and Food of the Hellenic Republic has recently defined the following criteria for the risk classification of slaughterhouses. The criteria take into account inherent risks and risk attributes, existence of risk management system and compliance track record:

- a. The risk assessment should take into account the following general criteria:**
- b. The type of food produced and the appropriate use by the consumer.**
- c. Processing methods.**
- d. Business size**

And the following specific criteria:

- a. Risk profile of the establishment according to checklists.**
- b. Implementation of a reliable self-control system according to checklists.**
- c. Recommendations made to the business, corrective measures and administrative and / or criminal sanctions imposed.**
- d. History compliance of the business with released appropriate corrective measures, which result from official controls and confirmed by the Regional Veterinary Authorities.**
- e. Export activity of the business.**

Box 4: Criteria for risk classification of slaughterhouses

Group B: Dynamic risk attributes

The second group of criteria includes risk attributes that are dynamic in the sense that they are not dependent on the inspection object as such, do not receive scores before an inspection has been conducted, and can change over time based on inspection results. These criteria include the existence of risk management measures and the compliance history of the inspection object. The evaluation and scoring of the object with regard to parameters relating to these dynamic criteria are critical in determining the frequency of inspections, which may be increased or reduced depending on the compliance record and the risk management measures in place. For example, inspectorates may set the inspection frequency for a medium-risk business to the same inspection frequency as a low-risk business if its compliance level is found to be high after two consecutive inspections.

The difficulty with dynamic parameters lies in the fact that most inspectorates do not have adequate information systems or prior records to allow them to assess compliance and risk management sufficiently to target inspections accordingly. In such cases, and until information on compliance levels becomes available, inspectorates should base their inspection planning on a preliminary risk categorization of inspection objects according to their intrinsic characteristics (such as type, size, and number of people exposed to risk). This would already present a considerable improvement to inspection planning compared to treating all inspection objects identically. Nevertheless, a full assessment (including the aspects of compliance and risk management) should be completed at the end of the initial inspection of each new establishment and after each full inspection. An assessment should also be completed following a partial inspection if sufficient evidence has been gathered to complete the assessment. Every time the object (that is, the establishment, product, and so on) is inspected, its scoring will be updated based on the results of the inspection, potentially resulting in a reclassification of the object into a different risk category or maintenance of the same level of risk and classification.

a. Existence of risk management measures

The quality of risk management and existence or lack of risk management measures can significantly affect risk and should thus form a separate criterion for evaluating the risk level of establishments. Parameters such as knowledge, managerial rigor and prioritization, the existence of control systems that are designed to detect violations in regular workflow, the external certification of specific risk management standards, the use of protective equipment and machinery, and other means of internal control can reduce the probability of risk and should be included in the assessment. Table 4 shows some of the parameters that could be used to assess risk management capacity. In some cases, the existence of risk management measures or of a risk management system may be not only good practice, but a mandatory legal requirement. In food manufacturing, for example, the implementation of procedures based on Hazard Analysis and Critical Control Points (HACCP) principles are mandatory for most business operators based on EU legislation. The existence of risk management measures and overall effectiveness in how risks are treated in the establishment are ascertained during the inspection.

b. Compliance track record

The compliance record of an inspection object influences the probability of risk. An accident resulting in harm of a public interest is more likely to occur in a business that has been found to commit frequent or repeated violations. Poor compliance history creates an expectation of future violations and implies that the inspection object should be monitored more closely through inspections. The compliance track record will include as a parameter the establishment's approach to findings of non-compliance—for example, whether the business admitted violations and cooperated with the inspectorate, whether the business was willing to act immediately, and so on—which is important in assessing the likelihood of compliance in the future (Table 4). The compliance track record should therefore form a separate risk criterion that can be assessed based on the results of the checklist, after the inspection has taken place. Every time an inspection is performed, the compliance track record will be updated, potentially resulting in a revision of the inspection object's overall risk score.

In the case of products, it is important to take into account the compliance track record not only of the product, but also of the specific producer/trader/importer of the product. Risk assessment for a certain product will therefore combine an evaluation based on risk criteria pertaining to (intrinsic) characteristics of the specific group or type of products and an assessment based on the compliance track record of the respective producer/trader/importer.

| Element | Common criteria to be included |
|---|--|
| <i>1. Track record / history of compliance</i> | <ul style="list-style-type: none">✓ Complaint history;✓ Willingness to act on previous advice and enforcement;✓ Incident history (eg. accidents, food poisonings, pollution incidents, etc) and incidences of non-compliance. |
| <i>2. Current level of compliance</i> | <i>This element reflects the current degree of compliance with relevant legislation and statutory codes of practice and standards. The criteria (which largely already exist in the current risk assessment schemes) should ensure that the findings of the assessment reflect both the number of contraventions that currently exist and their seriousness as determined by the risk involved and the how far they fall below the minimum standard as</i> |
| <i>3. Management assessment: Managers' competence, technical knowledge, leadership & commitment to compliance</i> | <ul style="list-style-type: none">✓ What level of technical knowledge exists within the organisation? Do the key people possess the necessary competence? Where needed, does the organisation have access to contracted external technical knowledge?✓ Do management and key employees have a good understanding of the hazards present and how to control them, and of the relevant legal requirements?✓ Are appropriate training arrangements in place?✓ Is there evidence that managers are demonstrating leadership and commitment to compliance? <i>Consideration of whether the hazards present require innovation or application of standard answers to known problems may also be relevant.</i> |

| Element | Common criteria to be included |
|--|--|
| 4. Management systems assessment: Presence and implementation of effective systems for managing risks | <ul style="list-style-type: none"> ✓ Is there a system for managing the relevant risks? Does it include allocation of key responsibilities to particular members of staff? Is the system being implemented and monitored? Is it effective? ✓ Has the organisation adapted and implemented any relevant management system standards, eg. ISO14001 (Environmental Management); ISO22000 (Food Safety Management); BS/OHSAS 18001 (Occupational health and Safety Management); ISO 9001 (Quality Management)? Where appropriate, is there evidence of recognised external auditing / accreditation?: i.e are there relevant systems subject to external audit, ✓ and has the audit resulted in certification by an accredited (eg. by UKAS) organisation (an example would be the Red Tractor Assurance scheme used for farms)? Have the audit findings been implemented? <p><i>In considering the suitability and effectiveness of the systems used for managing risks, the size of the company will often need to be taken into account. The systems that might be necessary for a large company, particularly in terms of documentation, may not be necessary for a small company. What is appropriate will depend upon the circumstances, and the assessment should be undertaken on this basis.</i></p> |

Table 4: Better Regulatory Delivery Office (BRDO) common criteria for use in helping to assess likelihood of compliance

6. Pitfalls in the design of risk criteria and parameters: What not to do

Using legal requirements as parameters is one of the most common mistakes to avoid in designing criteria for the risk assessment of inspection objects. This results in parameters that are highly specific and therefore of little practical value in assessing risks. Risk criteria and parameters should be easy to understand and fairly generic, in the sense that they can be applicable for the same type of supervised objects of the inspection domain. Using highly specific technical or formal characteristics as parameters should be avoided. For example, using a specific quantity of a flammable substance as a criterion in classifying establishments in terms of fire safety risk will imply that no preliminary risk assessment will be possible and that the risk level of establishments can only be ascertained after inspection.

Formulating parameters in an ambiguous way, so that they become difficult to assess or require subjective judgement, is another frequent and significant error, as it can result in inaccurate classification of inspection objects. Parameters should be formulated by reference to factual characteristics so that it can be objectively determined whether or not they are applicable to a given inspection object.

Basing risk assessment on the size of the activity or scope/volume of operations and compliance history, while omitting parameters pertaining to the type of activity/object, ignores parameters that are fundamental to risk assessment, as they affect both the magnitude and the probability of risk. This mistake occurs because the type of activity is regarded as a dimension that requires technical expertise, such that inspectorates may abstain from using it. As discussed in Section 4, however, senior inspectors' experience and examples from other European jurisdictions can enable the design of parameters that largely reflect the characteristics of the activity, establishment, product, and so on, that are important for risk classification and allow for a relatively easy determination of

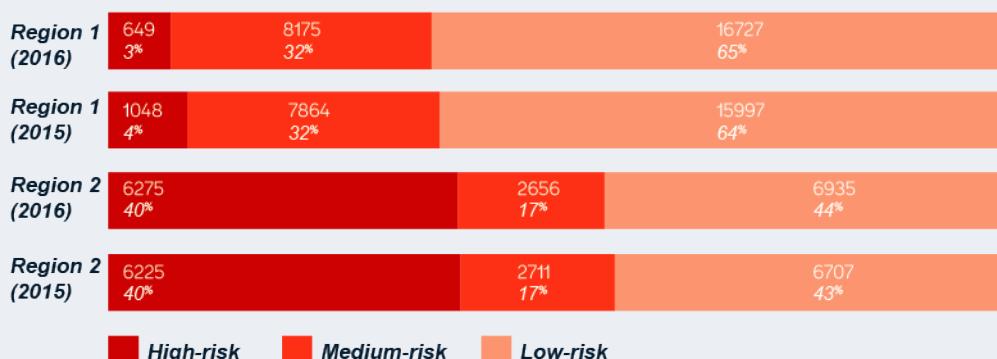
which inspection objects are inherently more or less hazardous.

Classifying too many establishments/products in the high-risk category is another common mistake. In the early stages of introducing risk-based inspections, it is common to develop risk criteria in such a way that a large proportion of establishments/products are automatically classified as high-risk category (see, for example, Figure 3). This results in a distribution of objects into risk categories that does not correspond to a “risk pyramid” and implies that resources will be spent on objects which are of lower risk.

Considering the duration of business operation as a decisive criterion. In some countries, as in Moldova, new businesses are categorized as high-risk, by definition, while old businesses are considered to be of low risk. Such a simplistic classification clearly disregards intrinsic characteristics and other risk attributes that are important for correctly assessing risk. The argument is that the lack of experience of young businesses makes them risky. As in Moldova, however, this is not backed by empirical evidence.

The bar chart shows that the Sanitary Inspectorate of Region 2 categorized 40 percent of supervised facilities as high-risk and 43 percent as low-risk, leaving about one-fifth of all facilities in the medium-risk category. In a different region, however, the distribution of facilities across risk categories by the same inspectorate was consistent with the pyramid approach, ensuring that a minority of facilities would be categorized as high-risk and a majority treated as low-risk.

Supervised facilities by risk category, State Sanitary Inspectorate, 2015-2016



Source: World Bank Group (2018, 32).

Figure 3: Polish State Sanitary Inspectorate distribution of facilities in risk categories—regional differences in the proportion of high-risk facilities

7. Risk rating

Once inspectorates have designed the risk criteria and parameters that are relevant for the specific inspection domain, they should assign a weight to each risk parameter that corresponds to its significance. Higher weights will imply a higher level of risk. The weights will then be translated into risk bands, so that a predetermined range of weights will correspond to a risk category. Depending on available resources, each inspectorate will subsequently decide on the frequency of inspections corresponding to each category.

Several inspectorates across European jurisdictions implement such intervention rating schemes to plan inspections. The Lithuanian Food Safety Authority and the United Kingdom Food Safety Authority are prominent examples (Annex 1). Using this scheme, each inspection object receives an aggregate score, on the basis of which it is placed in a different risk category with corresponding inspection frequencies.

8. Implementation road map for risk-based inspections

Summarizing the steps that need to be followed to develop a risk-based planning methodology for inspections, it is proposed that each inspectorate adhere to the following sequence of actions:

- Determine the desired positive risk reduction outcome to be achieved within a specific time period.
- Compile a database of objects (and their characteristics) under its supervision.
- Identify the hazards and the subjects that would be at risk from those hazards.
- Determine the type of harm/damage that may occur to the subjects if exposed to the hazard.
- Develop a set of risk criteria, parameters, and respective weights to use in evaluating the magnitude and probability of harm posed by the inspection objects under the supervision of the inspectorate.
- Evaluate all objects against the same criteria and classify them into specific risk categories.
- Match the number and type of objects in each risk category with available resources.
- Set the inspection frequency for each risk category.
- Conduct risk-based inspections.
- Revise the risk criteria and parameters and inspection frequencies when/if necessary.

References

- Ayres, Ian, and John Braithwaite. 1995.** Responsive Regulation: Transcending the Deregulation Debate. Oxford University Press.
- Better Regulation Delivery Office.** Proposals for developing a common approach to risk assessment, available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/263921/risk-assessment-paper.pdf
- Blanc, Florentin. 2018.** From Chasing Violations to Managing Risks: Origins, Challenges and Evolutions in Regulatory Inspections. Elgar Studies in Law and Regulation. Cheltenham, UK: Edward Elgar Publishing.
- European Commission. 2016. "EU general risk assessment methodology," available at: <http://ec.europa.eu/DocsRoom/documents/17107/>.
- . 2018a. "Commission Implementing Decision No. 2018/C7334/EU, 2018, C(2018) 7334 final," available at: https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/docs/Guidelines_en.pdf.
- . 2018b. "Risk Assessment Guidelines (RAG) for RAPEX," available at: <https://ec.europa.eu/consumers/consumer-safety/rag/#/screen/home>.
- European Union Network for the Implementation and Enforcement of Environmental Law. 2013.** Guidance for the implementation of the IED in planning and execution of inspections, available at: <https://www.impel.eu/tools/guidance-implementation-ied-planning-execution-inspections/>.
- Hellenic Ministry of Rural Development and Food. 2015.** "Multi-Annual Integrated National Control Plan 2015-2019," available at: http://www.minagric.gr/images/stories/docs/politis/Trofima_Ygeia/POESE_2015-2019.pdf
- Organisation for Economic Co-operation and Development (OECD). 2010.** Risk and Regulatory Policy: Improving the Governance of Risk. Paris: OECD Publishing, available at: <https://www.oecd.org/publications/risk-and-regulatory-policy-9789264082939-en.htm>.
- Organisation for Economic Co-operation and Development (OECD). 2014.** Regulatory Enforcement and Inspections. OECD Best Practice Principles for Regulatory Policy. Paris: OECD Publishing, available at: <https://www.oecd.org/gov/regulatory-enforcement-and-inspections-9789264208117-en.htm>.
- Organisation for Economic Co-operation and Development (OECD). 2016.** "Product Risk Assessment Practices of Regulatory Agencies." Summary of Discussions at Workshops and Meetings of the OECD Working Party on Consumer Product Safety, available at: <https://www.oecd.org/sti/consumer/product-risk-assessment-practices-regulatory-agencies.pdf>
- Organisation for Economic Co-operation and Development (OECD). 2018.** OECD Regulatory Enforcement and Inspections Toolkit. Paris: OECD Publishing, available at: <https://www.oecd.org/gov/regulatory-policy/oecd-regulatory-enforcement-and-inspections-toolkit-9789264303959-en.htm>.
- Safe Work Australia. 2012.** Australian Work Health and Safety Strategy 2012-2022: Healthy, safe and productive working lives, available at: <https://www.safeworkaustralia.gov.au/system/>

files/documents/1804/australian-work-health-safety-strategy-2012-2022v2_1.pdf

Stefanov, Ruslan, Daniela Mineva, and Stefan Karaboev. 2018. “Risk Assessment for More Efficient Inspections.” A Learning Resource from the Thematic Review Workshop, 14-15 June, Madrid, Spain.

United Kingdom Better Regulation Delivery Office. 2012. “Proposals for Developing a Common Approach to Risk Assessment,” available at: <https://www.gov.uk/government/publications/common-approach-to-risk-assessment>.

United States Food and Drug Administration. 2014. Food and Drug Administration Strategic Priorities 2014-2018, available at: <https://www.fdanews.com/ext/resources/files/07/07-14-14-priorities.pdf>

World Bank Group. 2013a. “Implementing a Shared Inspection Management System: Insights from Recent International Experience.” Investment Climate: Nuts & Bolts Technical Guidance for Reform Implementation, available at: <http://documents.worldbank.org/curated/en/190851468152706158/Implementing-a-shared-inspection-management-system-insights-from-recent-international-experience> .

World Bank Group. 2013b. “Introducing a Risk-Based Approach to Regulate Businesses: How to Build a Risk Matrix to Classify Enterprises or Activities.” Investment Climate: Nuts & Bolts Technical Guidance for Reform Implementation, available at: <http://documents.worldbank.org/curated/en/102431468152704305/Introducing-a-risk-based-approach-to-regulate-businesses-how-to-build-a-risk-matrix-to-classify-enterprises-or-activities> .

World Bank Group. 2018. Poland Catching-Up Regions: Safer Food, Better Business in Podkarpackie and Lubelskie, available at: <http://documents.worldbank.org/curated/en/289891529314549019/pdf/127296-WP-P165726-Activity-9-Inspections-Report.pdf>.

Annex

Table 5: Example of UK Food Establishment Intervention Rating Scheme

| Element | | Food Hygiene Scoring System |
|--|-----------|---|
| Type of food and method of handling | 40 | <i>Manufacturers of high-risk food, wholesalers and packers who re-wrap or re-pack high-risk foods. In this context, high-risk foods may be regarded as foods which support the growth of micro-organisms, and are ready to eat without further treatment that would destroy pathogenic micro-organisms or their toxins.</i> |
| | 30 | <i>Preparation, cooking or handling of open high-risk foods by caterers and retailers, except caterers that prepare typically less than 20 meals a day (see below).</i> |
| | 10 | <i>Preparation, cooking or handling by small caterers of open high-risk foods but serve less than 20 meals on a single day; Handling of pre-packed high-risk foods;</i> <i>Other wholesalers and distributors not included in the categories above;</i> <i>Manufacture or packing of foods other than high-risk;</i> <i>Establishments involved in the filleting, salting of fish for retail sale to final consumer.</i> |
| | 5 | <i>Retail handling of foods other than high-risk, and other ambient shelf stable products.</i> <i>Any other businesses not included in the categories above.</i> |
| Method of processing | 20 | <p><i>The overriding principle to assess is whether the process itself creates an increased risk and /or the intention is to increase the shelf life of the product by applying it.</i></p> <p><i>Below is a non-exhaustive list of processing types that should be allocated an additional score of 20. Authorised officers will need to make a judgement regarding additional processing types not listed below.</i></p> <ul style="list-style-type: none"> ✓ Canning or other aseptic packing of low-acid foods; ✓ Vacuum packing; ✓ Sous-vide cooking; ✓ Manufacture of cook/chill food, i.e. cooked and prepared meals or foods which may be eaten cold or after reheating. (The simple reheating of cook-chill meals is excluded from the scope of this paragraph.); ✓ Fermentation of meats e.g. to produce salamis and other fermented sausages; ✓ Air drying e.g. dried hams, biltong, jerky; ✓ Freeze drying; ✓ Addition of salt and/ or other preserving agents; ✓ The cooking and cooling of meat products prior to service e.g. production of hams by retailers, including butchers; This is not intended to be applied to simple catering operations where foods may often be pre prepared and subsequently re heated. ✓ Establishments that manufacture, prepare, or serve high risk uncooked or lightly cooked ready to eat food of animal origin whose nature poses a residual microbiological food safety hazard. This is intended to include caterers/manufacturers producing foods such as steak tartare and other raw meat dishes, fish and meat carpaccio, types of sushi or sashimi, ceviche, and burgers less than thoroughly cooked. |
| | 0 | <i>Any other case not included above.</i> |

| Element | | Food Hygiene Scoring System |
|--|-----------|--|
| Consumers at risk | 15 | <i>Food businesses involved in either the manufacture, distribution, packing or wrapping operations of food which is distributed nationally or internationally.</i> |
| | 10 | <i>Businesses serving a substantial number of customers, including a significant proportion from outside the local area, e.g. superstore, airport caterer, motorway service area caterer; Manufacturers not included in the category above.</i> |
| | 5 | <i>Businesses, most of whose customers are likely to be living, staying or working in the local area, e.g. supermarket or shop, local convenience store or high street or local restaurant.</i> |
| | 0 | <i>Businesses typically supplying less than 20 consumers each day.</i> |
| | 22 | <i>Production and/or service of high-risk foods in establishments where the ultimate consumers of the product produced include a vulnerable risk group of more than 20 persons.</i> |
| | 0 | <i>Any other case not included above.</i> |
| Level of (current) compliance | 25 | <i>Almost total non-compliance with statutory obligations.</i> |
| | 20 | <i>General failure to satisfy statutory obligations – standards generally low.</i> |
| | 15 | <i>Some major non-compliance with statutory obligations – more work required to prevent fall in standards.</i> |
| | 10 | <i>Some non-compliance with statutory obligations and industry codes of recommended practice* that are not considered significant in terms of risk (but may become significant if not addressed). Standards are being maintained or improved.</i> |
| | 5 | <i>Good standard of compliance with statutory obligations and industry codes of recommended practice* with only minor contraventions.</i> |
| | 0 | <i>High standard of compliance with statutory obligations and industry codes of recommended practice*; conforms to accepted good practices in the trade. *where a relevant code/industry guide has been published.</i> |
| Confidence in management/control procedures | 30 | <i>Poor track record of compliance. Little or no food safety knowledge and understanding. Little or no appreciation of hazards, risks or quality control. No food safety management procedures. Does not recognise or accept the need for food safety and hygiene controls.</i> |
| | 20 | <i>Significantly varying record of compliance. Insufficient food safety knowledge and understanding. Poor appreciation of hazards and control measures. No food safety management procedures or unsatisfactory progress in terms of developing, documenting and implementing food safety management procedures, commensurate with type of business, since the last intervention rating. Some reluctance in recognising or accepting the need for food safety and hygiene control procedures.</i> |

| Element | Food Hygiene Scoring System | |
|--|------------------------------------|--|
| Confidence in management/control procedures | 10 | Satisfactory record of compliance. Access to relevant food safety advice source and/or Guides to Good Practice or assurance schemes commensurate with type of business. Understanding of significant hazards and control measures in place. Has implemented satisfactory food safety management procedures or is making satisfactory progress towards documented food safety management procedures, commensurate with type of food business. Officers will need to ensure that a business is demonstrating it is actually 'making satisfactory progress' towards food safety management procedures. A score of 10 can be awarded for more than one intervention cycle if: <ul style="list-style-type: none"> ✓ the previous non-compliances have been addressed but different non-compliances have arisen; and ✓ the overall risk has not increased. |
| | 5 | Good record of compliance. Food safety advice available in-house or access to, and use of, technical advice from a Primary or Home Authority, trade associations and/or from Guides to Good Practice or assurance scheme commensurate with type of business. Effective management control of hazards. Having effective self-checks with satisfactory documented food safety management procedures commensurate with type of business. Audit by Competent Authority confirms general compliance with procedures with minor non-conformities not identified as critical to food safety. |
| | 0 | Excellent record of compliance. Food safety advice available in-house or access to, and use of, technical advice from a Primary Authority or Home Authority, trade associations and/or from Guides to Good Practice or assurance schemes commensurate with type of business Food Business Operator/ Manager knowledgeable and competent. Has effective self-checks with satisfactory documented food safety management procedures commensurate with type of business, and may have external audit processes in place. Audit by Competent Authority confirms good compliance with food safety procedures. |
| | 20 | Significant risk of food being contaminated with <i>Clostridium botulinum</i> , and the organism surviving any processing and multiplying; or Significant risk of ready-to-eat food being contaminated with micro-organisms or their toxins that are pathogenic to humans. |
| | 0 | Any other case not included above. |

SCORE:

Food hygiene intervention frequencies

| Category | Score | Minimum intervention frequency |
|-----------------|--------------|--|
| A | 92 or higher | At least every 6 months |
| B | 72 to 91 | At least every 12 months |
| C | 52 to 71 | At least every 18 months |
| D | 31 to 51 | At least every 24 months |
| E | 0 to 30 | A programme of alternative enforcement strategies or interventions every 3 years |

Establishments rated as low-risk (30 or less) need not be included in the planned inspection programme, but must be subject to an alternative enforcement strategy at least once in every 3 years.

Table 6: Example by Lithuanian State Food and Veterinary Service - risk assessment of food production and packaging companies

| Criteria for risk assessment | | |
|-------------------------------------|---|---------------|
| A | <i>Type of food being managed</i> | <i>Weight</i> |
| I. Animal Food | | |
| 1 | <i>Meat</i> | 25 |
| 2 | <i>Milk</i> | 20 |
| 3 | <i>Fish</i> | 20 |
| 4 | <i>Eggs</i> | 15 |
| 5 | <i>Culinary mixed animal food</i> | 20 |
| 6 | <i>Other animal food</i> | 15 |
| II. Non-animal food | | |
| 1 | <i>Fruit, vegetables</i> | 5 |
| 2 | <i>Frozen, salad</i> | 20 |
| 3 | <i>Non-alcoholic beverages, juices, mineral water</i> | 10 |
| 4 | <i>Grain crops, cereals, flour</i> | 5 |
| 5 | <i>Products from flour</i> | 5 |
| 6 | <i>Creamy confectionery</i> | 20 |
| 7 | <i>Sweets</i> | 10 |
| 8 | <i>Sugar, salt</i> | 5 |
| 9 | <i>Sauces</i> | 10 |
| 10 | <i>Spices, condiments, tea, coffee</i> | 5 |
| 11 | <i>Food additives</i> | 15 |
| 12 | <i>Food supplements</i> | 10 |
| 13 | <i>Alcoholic beverages</i> | 5 |
| 14 | <i>Drinking water</i> | 10 |
| 15 | <i>Publicly supplied drinking water</i> | 15 |
| 16 | <i>Other non-food</i> | 10 |
| B | <i>Scale of food management activities</i> | <i>Weight</i> |
| 1 | <i>Food is delivered directly to the consumer or distributed through stores of the producer</i> | 5 |
| 2 | <i>Food distributed directly to other stores Cafes</i> | 10 |
| 3 | <i>Publicly supplied drinking water</i> | 10 |
| 4 | <i>Food distributed through wholesale companies in the territory of Lithuania</i> | 15 |
| 5 | <i>Food is supplied to the European Union and other third countries</i> | 20 |

| C | Status of implementation of the HACCP system or GHP rules* | Weight |
|---|--|--------|
| 1 | <i>The system does not work: unmanaged critical control points (hereinafter referred to as CCPs), the entity does not take corrective action, does not carry out risk analysis and monitoring, does not ensure safe food management</i> | 20-30 |
| 2 | <i>The system is fully operational: targeted laboratory food studies are being conducted, CPP is managed, timely adoption of corrective measures, ongoing monitoring, registers, periodic HACCP system internal audits and assessment of procedures. Employees periodically raise qualifications</i> | 11-19 |
| 3 | <i>The system is not fully operational: food laboratory tests are performed irregularly, unsupervised CCP monitoring, timely corrective measures are not taken, the HACCP system internal audit does not cover essential food safety requirements</i> | 0-10 |

* - If there is no self-regulation based on the HACCP principles based on the HACCP principles applicable to the food business operator, a score of "0" is given.

| D | Inspection results | Weight |
|---|--|--------|
| 1 | <i>Rugged violations that pose a risk to food safety and consumer health have been identified. Consumer complaints have been received concerning the activities of the food business operator, the product that it has produced, which has been verified by the inspectorate</i> | 20-30 |
| 2 | <i>Several violations that could affect food safety or which could harm consumers' interests have been identified. Also, several of the same violations that were detected during the previous check are detected</i> | 11-19 |
| 3 | <i>Identifying minor damage that does not pose a risk to the safety or quality of a food does not mislead consumers</i> | 0-10 |

| Food business risk group | Score | Frequency of food and veterinary control |
|--------------------------|-------------|--|
| High risk | 60 and more | Twice per year |
| Medium risk | 46-59 | Once per year |
| Low risk up to | 45 | Once in two years |

GUIDE 2

Development of Checklists

Contents

- pg. 35 1. Purpose and scope of the guide**
- pg. 35 2. Checklist definition**
- pg. 35 3. Goals and principles of the checklists**
- pg. 37 4. How to decide on the scope to be covered by checklists**
- pg. 39 5. How to develop a checklist**
- pg. 50 References**

1. Purpose and scope of the guide

According to art. 147 of Law 4512/2018, inspections must be carried out using checklists. The purpose of this guide is to help authorities and inspectors develop checklists that are to be used to inspect economic activities and to achieve a coherent way of assessing business compliance.

This guide is designed for practical use and outlines how checklists are developed at both the organizational and the content level. Particular attention should be paid, however, to the application of the methodology and tools used in relation to the characteristics and conditions of each economic activity.

The purpose of the guide is also to inform companies about the use of this new tool by the supervisory authorities, which can be used for self-assessment and compliance in accordance with legal requirements.

2. Checklist definition

A checklist is a tool that controlling agencies (inspectorates or supervision authorities) use while inspecting business entities. Checklists contain both questions that are geared to elicit detailed information about the inspected entity and questions that help the inspector to examine the business entity's compliance with legally set standards (IFC 2010). The checklist is a compliance assessment sheet that contains the minimum main requirements or categories of requirements with which businesses must conform as regards their products, services, or operations.

Checklists are used in a number of developed and developing countries (including Great Britain, Germany, France, Lithuania, Belgium, Austria, Canada, and Mexico) as an efficient inspection mechanism. They are also used to collect and process information about the condition of a certain sector of the national economy. In addition, checklists can promote compliance, if made available to businesses so that they can access them easily and understand the legal requirements for a particular activity and what inspectors will focus on during an inspection.

3. Goals and principles of the checklists

Checklists can be an effective tool for addressing a number of problems that are frequently encountered in inspections, including:

- **Lack of uniformity and consistency**, for example when different inspectors act differently during inspections or they prioritize different things to inspect;
- **Lack of clarity** when requirements are interpreted differently from how inspectors view them, creating difficulties for businesses to comply with rules.
- **Lack of focus** on which rules are important in tackling hazards when inspectors focus on some requirements over others
- **Lack of compliance**, since businesses become confused about how to implement requirements, do not understand which are important for risk mitigation in their activities, and eventually do not comply.

Checklists are used in a number of developed and developing countries (including Great Britain, Germany, France, Lithuania, Belgium, Austria, Canada, and Mexico) as an efficient inspection mechanism. They are also used to collect and process information about the condition of a certain sector of the national economy. In addition, checklists can promote compliance, if made available to businesses so that they can access them easily and understand the legal requirements for a particular activity and what inspectors will focus on during an inspection.

Checklists need to clearly emphasize the core requirements -the principal and most important requirements for risk mitigation- as inspections will be carried out according to that checklist. Checklists are also used to promote business compliance in general, because as the checklists are available to businesses (e.g. by uploading them on the website of competent authorities) businesses are now able to understand better and easier the legislative requirements and can be aware of the critical points of inspection and of the main requirements to which the inspectors will focus on during an upcoming inspection (which, as mentioned, also relates to the key risk points) of the particular activity. Finally, the checklists also serve as a basis for the level of activity's compliance and for the choice of action the inspector will make, and the measure he will impose on the activity (from the simplest one, that is simple advice and guidance, to the strictest one where there is an imminent threat to public interest).

There are two major goals in introducing a checklist: (1) simplification and improvement of the inspection procedure as an integral component of the inspection system; and (2) increasing compliance levels by achieving uniformity and informing businesses about the main elements of inspections.

Simplification and improvement are achieved by consolidating the main legal requirements into a single document, thus facilitating efficient and expedient inspections.

Increased compliance is achieved by introducing a uniform and focused tool that offers greater clarity and certainty to businesses. Greater legal awareness among businesses will, in turn, help them to perform self-checks and eliminate non-conformities that they themselves find before a controlling agency's inspector visits (IFC 2010).

An indirect positive impact is that developing checklists will help the supervision authority to understand whether the requirements are too complex or detailed (which makes it difficult for the inspected entities to comply) and, accordingly, whether it is necessary to clarify or simplify requirements (or even eliminate them if they are obsolete and do not address risk) to encourage compliance.

Checklists were part of the reform of the supervision process (inspections and enforcement) in Lithuania, which itself was part of an overall regulatory reform agenda initiated in 2008. Authorities in Lithuania adopted checklists for all major inspectorates, covering the most widespread types of economic activity. Lithuania adopted 65 checklists in 2012 and 148 in 2015.

Source: OECD (2015) Regulatory Policy in Lithuania

Box 1: The Case of Lithuania

Checklists are useful to help inspectors weight risk. This is achieved by weighting control questions, for example by using scoring and allocating more weight to questions regarding non-conformities that will increase the risk level of the activity.

The following principles should be applied in the development of checklists and the questions included in them:

- a) Clarity:** questions should be clear and easy for both inspectors and businesses to understand;
- b) Simplicity:** questions should be simple, not strictly repeating legislative norms but practical and easily answered in real time;
- c) Risk-based approach:** questions should focus on the main requirements related to risk, not repeating or replicating legislative norms but working as a tool to identify whether the main hazards are controlled in the business activity; and
- d) Publicity:** Checklists should be publicly available, allowing businesses to identify the checklist, understand where the focus of an inspection is, and use the checklist to self-check in preparation for an inspection, as well as to check regularly how they perform in terms of legal requirements. As already mentioned, this will help businesses to increase compliance levels on their own which is also a matter for an effective supervisory system.

4. How to decide on the scope to be covered by checklists

One of the most important questions to address before starting to develop checklists is what scope the checklists will cover. If an inspectorate checks more than one object (that is, more than one type of installation) or different areas (for example, both safety and quality issues for consumer protection), it is important to be in a position to select correctly which objects should be covered by the checklists.

Ideally, the inspectorate will decide on how to define the checklist's object by defining which **risks to mitigate through inspections**.

Furthermore, the inspectorate can group objects if similar hazards apply to more than one object, especially if they are similar or if the same regulatory requirements apply to them.

To frame this question, the following criteria are recommended in deciding on the object (and groups of objects) of the checklist (Figure 1):

- a) Domain of inspection⁵:** Inspectorates could define the object per domain of inspection (such as product safety), especially if an inspectorate deals with different domains at the same time.
- b) Sector:** Inspectors could group together all objects within a sector⁶ (for example, food retail) that is subject to the same regulatory requirements linked to risk.
- c) Activity:** Within the sector, there may be different requirements related to the activity of

⁵ As per the Law 4512/2018, there are 8 domains (art. 127).

⁶ A sector of businesses usually corresponds to a sector or subsector of the economy. A helpful guide in defining a sector is EC (2008), which classifies businesses into divisions, groups, and classes and is also used in the licensing simplification Law 4442/2016.

the business. For example, if one business deals with processing and another with trade (for example, in food sector) and therefore justify a different checklist. If more than one activities meet the same requirements, they can be grouped into one checklist.

d) Product category: Even under the same domain, there may be cases in which a product category is subject to different rules or different production procedures that generate different threats and hazards. For example, the formulation of a checklist per product category (e.g. specific type of toys).

e) Business activities with fewer requirements: Even if all of the above (domain, activity, sector, and product category) are similar, it is common for some businesses to potentially be subject to fewer requirements. This may be the case for small businesses or businesses that offer only a small variety of products. and are not expected to cause risk of equal scale to the corresponding medium or large activities within the same industry or sector. These may be subject to fewer requirements in infrastructure or processing. In such cases, the inspectorate may decide to separate the objects of a checklist by creating a shorter and simpler checklist for this “niche” market of businesses. Even if the checklist (as seen below) includes “not applicable” as an option in replying to a control question, it is usually more practical and user-friendly to create a separate checklist for these businesses, especially in sectors where both types of businesses (using the full and the smaller questionnaire) are expected to be inspected⁷.

It should be noted that Law 4512/2018 does not specify how to develop a checklist per inspection object, thus allowing the Greek authorities to decide with discretion on how to group (if they decide to group) the applied fields of the checklists.

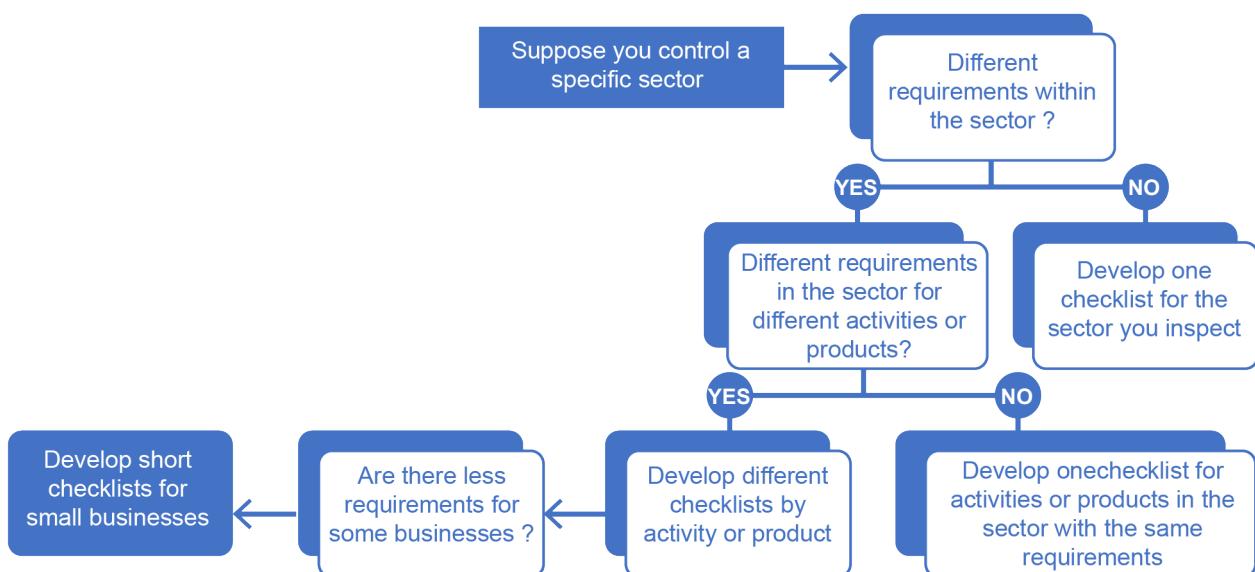


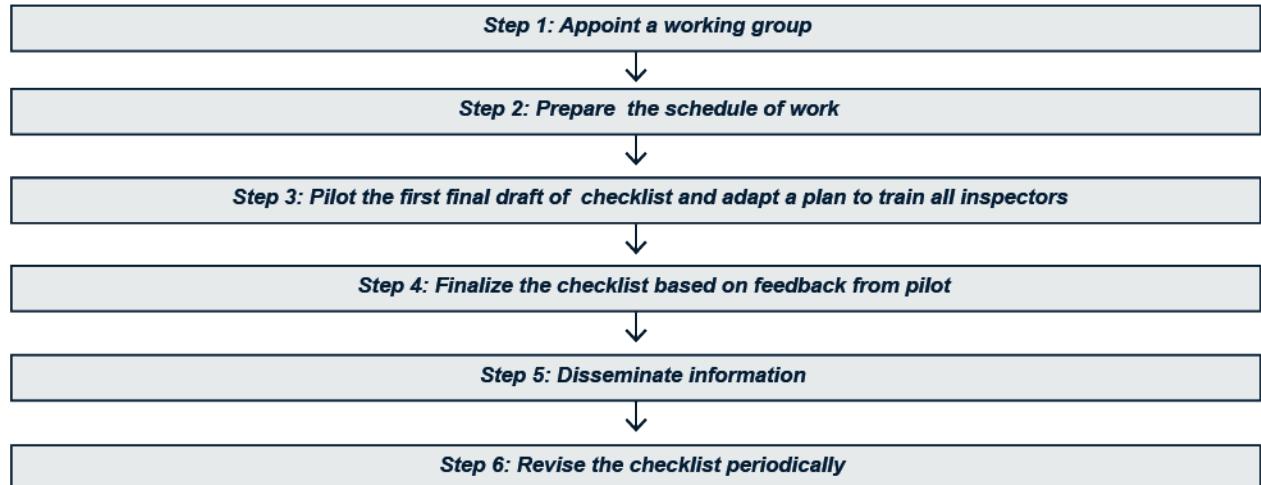
Figure 1: Object decision tree

⁷ For example, a different checklist may apply to large restaurants serving 200 consumers compared to a small fast-food restaurant with a capacity of 20 people per day.

5. How to develop a checklist

In developing a checklist, it is recommended that inspectorates follow the next two actions, which are further divided into steps. Action A refers to the organizational part (how to organize the work for the development of checklists) and Action B refers to the substantive part (how to develop the content of the checklists). It should be noted that Step 2 of Action A is implemented through Action B. The following figure depicts the two Actions.

Action A: How to organize the work for the development of checklist



Action B: How to prepare the content of the checklist

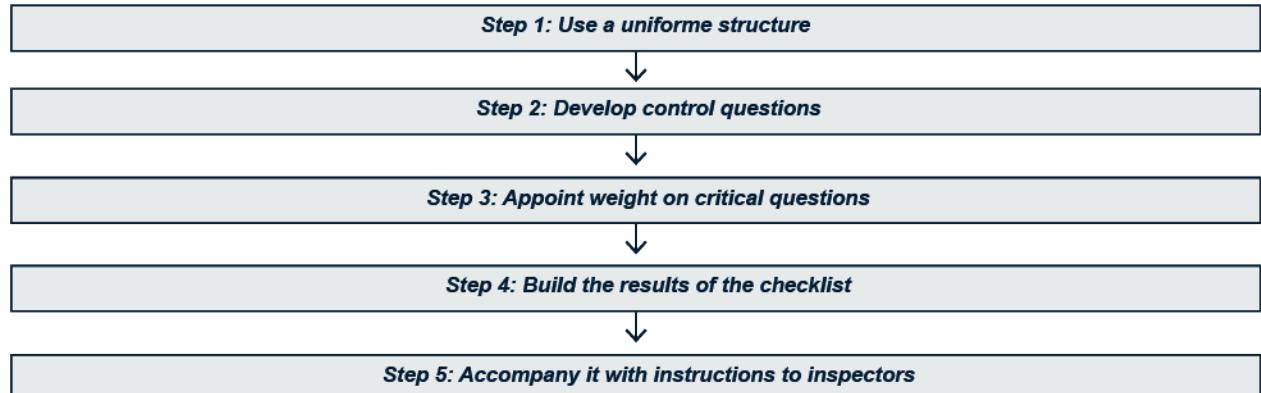


Figure 2: How to develop the checklist

A. Action A: How to organize the work of developing the checklist

The following actions are recommended in initiating and organizing the process of developing a checklist:

Step 1: Appoint a working group and adopt a work time schedule

The first step is to appoint a small working group of three to ten people who will be dedicated to the development of a checklist. It is important to keep in mind that:

- The working group will need to brainstorm on the practical and technical parts of the checklists. It is important, therefore, that the inspectors who are actually experienced in

conducting inspections participate in the development of the checklist. Inspectors of the particular inspectorate are the most competent to develop a checklist and include the most critical questions that need to be answered and are related to risk, and are best aware of the potential difficulties that they may face during an inspection.

- The working group will be required to draft, discuss, revise and finalize the checklist.
- The working group should participate in the training of other inspectors once the new checklist is implemented. The working group will thus act as the direct “owner” of the checklist by responding to questions from other inspectors.

Step 2: Develop the draft of the checklist

Having in mind the goals and main principles (as explained above) of the checklist, the working group will prepare the content of the checklist. In practical terms, it is important to keep in mind that:

- The working group should meet regularly, adopt a flexible way to communicate (such as by e-mail), and act quickly to incorporate changes.

The working group will prepare a time schedule reflecting the key milestones and deadlines related to the preparation of the checklist. The following milestones of Table 1 should be included in the time schedule:

| Schedule of work for the development of the checklist on ... (domain, sector, activity, category of products) | | |
|--|--------------|------------|
| Milestones | Start | End |
| <i>Working group conducts brainstorm regular meetings</i> | | |
| <i>First draft of checklist</i> | | |
| <i>Provide time to review the first draft (this will require back and forth meetings and contacts within the working group and with external parties, e.g. other inspectors or businesses)</i> | | |
| <i>Revise checklist</i> | | |
| <i>Final draft of the checklist</i> | | |
| <i>Pilot the checklist (including on the job training of inspectors)</i> | | |
| <i>Collection of feedback</i> | | |
| <i>Final checklist for adoption</i> | | |
| <i>Disseminate information to the private sector – intermediate steps for the involvement of the private sector are highly recommended</i> | | |

Table 1: Work time schedule for development of the checklist

Step 3: Pilot the draft of the checklist and adopt a plan to train all inspectors

When the working group’s draft is ready, it is important to test the draft checklist in actual inspections. This can be achieved through mock inspections, as well as on-the-job training on the use of the checklist in real-time (field) inspections, preferably unofficial inspections that will not have legal implications for businesses. Based on this activity, corrections and comments will be collected and used to further refine the checklist. It is important the participation inspectors from different regions to the pilot process, as they will be able to serve as trainers for other inspectors, before and after the adaptation of the checklists.

According to the IFC Checklist Guidance (IFC 2010), developing effective and efficient checklists requires close cooperation between controlling agencies and business entities. The following approach can be applied during the checklist introduction phase:

- 1. Select a pilot region to analyze the efficiency and effectiveness of the developed checklists (it is better to select the region with the highest concentration of checklist-specific business entities).*
- 2. Discuss the developed checklists in the pilot region with business entities and business associations and make appropriate adjustments on the basis of these discussions.*
- 3. Based on checklist discussions and the adjustments that have been introduced, run a number of inspections in a pilot region.*
- 4. Introduce the developed checklist on a national level.*

Box 2: IFC piloting approach

While initial feedback is being collected from the piloting of the draft of the checklist, the working group should develop a plan for training inspectors across the country in the use of the checklist. The inspectors trained in the pilot phase can serve as trainers for the remaining inspectors.

Step 4: Revise the draft of the checklist based on feedback from pilot

The working group will incorporate comments made on the draft of the checklist, as well as those made during the training (which can generate more comments and suggestions for changes) and will subsequently revise the draft of the checklist.

Step 5: Disseminate the revised draft of the checklist to the private sector and collect feedback

The private sector should be involved in the development of checklists, to the maximum extent possible. This can be accomplished during the pilot testing of the checklist, by initiating discussions with inspected entities and business associations.

Also, before the legal adoption of the checklist authorities should disseminate information about the checklists to the private sector. This will help businesses understand what the new tool is about, encourage them to use it as a self-assessment instrument before an official inspection, and help them focus on the main requirements of inspection to increase compliance levels. In this way, it is also expected that a relationship of trust will be built between inspectors and inspected entities. As suggested by IFC (2010), there are various methods for distributing checklists' information, with the most important being the publication of the checklist on the official website of the authority, enabling businesses to download it at any time.

According to the IFC Checklist Guidance (IFC 2010), possible methods of checklist distribution include:

- 1. In national print media or publications that are popular in business circles.*
- 2. Through government offices that interact with business entities on a daily basis (for instance, business registration and licensing departments).*
- 3. Through business associations and other nongovernmental organizations.*
- 4. On the official websites of the state control agencies/supervising authorities.*

Box 3: IFC piloting approach

Apart from providing direct information and enabling businesses to download the checklist from various sources, it is also recommended that—in light of the new supervision framework in Greece—the authorities organize seminars, workshops, and focus groups with the business community to explain the new tools and how both parties can benefit from the efficient use of checklists in inspections.

Step 6: Finalize and adopt the checklist

Legal adoption of the finalized checklist will follow under this activity as foreseen in the legislation of Law 4512/2018 (art. 147) through a Ministerial Decision or a decision of the Head of the competent authority.

Step 7: Revise the checklist periodically

The checklists should be reviewed periodically by the inspectorate to:

- a) reflect accumulated experience from both inspectors and businesses;
- b) introduce new legislative norms to mitigate hazards;
- c) adjust to new technologies and updated methodologies used by businesses that fall under the categories addressed by the checklists; and
- d) remove obsolete or negligible requirements.

Checklists should be reviewed and revised on a regular basis, drawing on the feedback of inspectors who have used the checklist and of businesses that were subjected to it. Inspectors can identify problems in the use of the checklists, particularly concerning the items and the procedure used during the inspection. For example, the checklist may not efficiently reflect actual hazards or new hazards may have come into play as a result of a new regulatory prioritization (EU or national). These remarks should be part of the review process.

Feedback from the private sector should also be taken into consideration. For example, businesses may report to inspectors that checklists are too strict, do not accurately reflect risk, or impose an unnecessary regulatory burden. Businesses' feedback can be used fruitfully by inspectors to update and improve checklists. The checklists should thus be seen as a dynamic tool, which also acts to build a relationship of trust between the public and the private sector, with the goal of mitigating risks and increasing compliance.

There is no specific guide for the time frame of these periodic reviews. The ideal frequency of review could be divided into two types: low-intensity review on an annual basis (especially when the checklist is first being used), where comments from inspectors will be incorporated, and high-intensity review every three years, where a focus group with the involvement of the businesses will conduct the review. The above duration gives a reasonable time for authorities to collect feedback from inspectors and businesses and examine the actual need for renewal, always keeping in mind that amendments should follow the same principles to mitigate risk and increase compliance. Longer review periods pose the risk of rendering the checklist obsolete, whereas review periods that are too short may cause confusion and fail to provide adequate compliance intervals.

B. Action B: How to develop the content of the checklist

Step 1: Adopt a uniform structure for the checklists

The form of the checklist should be built so that inspectors can use it easily and so that businesses can easily understand the requirements and use it for self-checks. It is strongly recommended that the checklist form (its layout and structure) be homogeneous across the same inspectorate and –to the extent possible- across all domains of inspection falling under Law 4512/2018.

A checklist could be structured in the following form:

- a) Introductory part
- b) Control questions (which can be grouped into chapters)
- c) Results
- d) Recommendations or next steps.

The introductory part (usually short) includes information on the inspectorate, name of inspector(s), and date of inspection. The cover sheet should also include key details on the inspected entity, including the name of the business, an ID indicator for the business (such as its Tax ID number, GEMI number, notification number, or any other code approval number that could be useful for the inspectorate to track the business), the address of the business, contact details, and the name of the responsible person of the particular business.

| | |
|---|--|
|  <p>ΕΛΛΗΝΙΚΗ ΔΗΜΟΚΡΑΤΙΑ ΠΕΡΙΦΕΡΕΙΑ: ΠΕΡΙΦΕΡΕΙΑΚΗ ΕΝΟΤΗΤΑ: Δ/ΝΣΗ ΑΓΡΟΤΙΚΗΣ ΟΙΚΟΝΟΜΙΑΣ & ΚΤΗΝΙΑΤΡΙΚΗΣ ΤΜΗΜΑ ΚΤΗΝΙΑΤΡΙΚΗΣ</p> | <p>Ημερομηνία Εξέγουν:</p> <p>Επιθεωρητής (εζ) Κτηνιατρος:</p> |
| <p>ΕΝΤΥΠΟ ΕΠΙΘΕΩΡΗΣΗΣ ΣΦΑΓΕΙΟΥ ΟΠΛΗΦΟΡΩΝ</p> | |
| Επανομία Επιγείρσης: | |
| Κωδικός Αριθμός Κτηνιατρικής Εγκρισης: | |
| Διεύθυνση | |
| Τηλεφωνο(α), Τηλεομοτουπικό (Φαξ) | |
| e-mail | |

Table 2: Introductory part of the pilot checklist for slaughterhouses



ΦΥΛΟ ΕΛΕΓΧΟΥ ΤΟΥΡΙΣΤΙΚΩΝ ΚΑΤΑΛΥΜΑΤΩΝ

ΑΡΙΘΜΟΣ ΑΠΟΦΑΣΗ....., 2018

| | |
|--|--|
| Ημερομηνία Αυτοψίας; Ώρα έναρξης αυτοψίας; Ώρα λήξης αυτοψίας; | |
| Στοιχεία Ελεγκτικών Οργάνων: | |
| Στοιχεία Επιχείρησης: Επωνυμία Επιχείρησης: ΑΦΜ: Στοιχεία Εγκατάστασης: Διεύθυνση: | |
| | |
| | |
| | |
| | |

Table 3: Introductory part of the pilot checklist of the fire service for tourist accommodation

Step 2: Develop control questions of the checklists

Proper design and definition of control questions is a key element of a checklist. Control questions should be defined narrowly, strictly following the mandatory requirements defined by laws and regulations and technical standards (and not optional).

The checklist should NOT, however, be an exact blueprint of all requirements described in the legislation, as not all of them may be related to the risks that the inspectorate is trying to mitigate. The questions should enable verification of compliance with essential requirements—those for which the failure to comply could have consequences with regard to risk or could create the conditions for such consequences. Inspectors are experts on the subject of the supervision they perform and, in practice, even without checklists, one could expect them to focus on the main hazards that are identified in a business. Performing checks of all legal requirements is practically impossible in terms of time and human resources.

According to the IFC Checklist Guidance the process of formulating questions and assigning weights to each of them can be conveniently broken down into four major phases:

- 1. Classification of business activities by sector, since each sector and type of activity requires a separate checklist (gas stations and oil refineries require different checklists that take into account the specifics of their activities).**
- 2. Selection of questions for each sector that the inspectorate deems adequate for conducting an analysis and inspection of the business entity (only those questions that are the most essential for control should be included).**
- 3. Classification of the selected questions for groups depending on their importance and the potential risks that could result from failure to comply with a certain condition (question). The questions may be classified on the basis of the following criteria:**

- a. Probability of emergency due to risk factors (high, average);
- b. Likely direct or indirect harmful impact on those being protected (society, consumers, workers, the natural environment);
- c. Global or local extent of consequences with a focus on the entity being protected.

4. Assignment of a weighting to each question based on its importance, which is determined by applying the criteria described above.

Box 4: IFC Checklist Guidance on formulating questions⁸

International experience shows that the list of questions should not be overly extensive (in order to reduce the workload for both inspectors and business entities and focus attention on the most important questions). A way to verify that the checklists do not contain excessive requirements that deal with non-hazardous issues, and thus have low overall effect on the risk of the inspected entity, is to test them in a limited number of mock inspections. If the inspector confirms that the inspection with a checklist(s) does not extend the time for inspection, the number of questions is not excessive. Grouping questions into thematic chapters can help to organize the checklist, reducing repetition between questions and allowing for sequencing that follows the natural flow of the inspection. For example, one chapter may address documentation requirements and the files kept by the business, another chapter may deal with safety in production processes and procedures, the next may assess certificates and training of personnel, and another one may deal with equipment. Tables 3 and 4 provide some examples of chapters and questions in a checklist.

Control questions should:

- a) Be defined strictly on the basis of mandatory requirements as defined by laws, regulations, and technical standards—that is, select requirements that address hazards and mitigate them;
- b) Formulate requirements into simple and clear questions, providing for non-equivocal responses (yes, no, not applicable) that do not allow for ambiguous interpretation or using a fixed scoring system (see Step 3);
- c) Be specific and avoid generalizations about requirements;
- d) Avoid vague formulations such as “etc.” or “et al.,” which may result in non-transparent questions and, thus, in ambiguous interpretations; questions must also not include statements like “should” because, in this case, the answer of “yes, no, and not applicable” is not direct (that is, “should” may be yes or may be no); instead, they should be phrased in a way that illustrates the real-time situation (Box 5);
- e) Use common and understandable terms and definitions (derived either from legislation or from common practice);
- f) Record the real-time assessment rather than repeat the legislative norm (Box 5);
- g) Be in a positive and not a negative form (Box 5); and
- h) Be defined with a hypothetical inspection in mind, focusing on the most crucial points that need to be checked to mitigate hazards.

⁸ The International Finance Corporation of the World Bank Group (2010). Guidance on Development and Introduction of Checklists by Controlling Agencies [διαδικτυακό] available at: https://www.wbginvestmentclimate.org/uploads/check%20lists%20manual_en.pdf, Washington D.C.: The World Bank Group

| <i>Unclear Question</i> | <i>Clear Question</i> |
|--|---|
| <i>Emergency exit doors should open outwardly from the building.</i> Yes No N/A | <i>Emergency exit doors open outwardly from the building.</i> Yes No N/A |
| <i>As a firefighting measure, a 20 m3 reservoir with a feeding pipeline connected to the facility water supply should be installed at the drilling site.</i> Yes No N/A | <i>As a firefighting measure, a 20 m3 reservoir with a feeding pipeline connected to the facility water supply has been installed at the drilling site.</i> Yes No N/A |
| <i>Ice is not produced from drinking water.</i> Yes No N/A | <i>Ice is produced only from drinking water.</i> Yes No N/A |
| <i>Consumers are well informed as per "X" Law provision</i> | <i>Consumers are well informed about "....." (the specific requirement)</i> |

Box 5: Unclear vs. clear questions

A common concern in selecting questions under a risk-based approach is how inspectors will deal with legal requirements that are not included in the checklist.

First, it is expected that requirements that are left out of the questionnaire are not linked to high-risk hazards; otherwise they should have been included in the checklist. Second, excluding questions from the checklist does not mean that business operators are no longer obliged to comply with them. Law 4512/2018 gives the solution by defining in art. 147 that:

“If non-compliance is identified with requirements that are not included in the check list, and only if these fall under the inspector’s supervision area, the inspector notes the non-compliance with these requirements in the inspection report, and recommendations are then made for compliance within a fixed time limit.”

In this way, business operators can be assured that in fulfilling the requirements of the control questionnaire in the usual case (as defined in the checklist), they will not be forced to stop or suspend their activities or be subject to fines or sanctions.

Nevertheless, neither the legislation nor the checklist limits the inspector to respond immediately to exceptional circumstances. If, during the inspection, the inspector observes a high risk imposed by a specific violation or the condition for a high-risk probability, he or she can act immediately. This is likely to mean that the particular requirement was more important in this type of business, and authorities should rethink whether this should be included in the checklist. If it falls under the competence of another inspectorate, the inspector will inform the other authority accordingly (per art. 152, “In the event that, during the inspection, they should discover information useful for another competent supervisory authority, they shall immediately inform the said authority”).

Ultimately, what inspectors and inspectorates should care about most is mitigating risks that are linked directly to safety and other public interest issues and are legally binding. This is exactly what the checklist should focus on, as it is primarily a tool for enhancing the inspection process and helping businesses understand the crucial points to be addressed through inspections. Indeed, if

businesses comply with these requirements (and questions) and increase the level of compliance, instead of dealing with details that are not linked to actual hazards, inspectors and inspectorates will generally be successful in their goals.

Finally, checklists are not only memos for inspectors, but official proof that the inspector performed an inspection, checked particular requirements, and identified non-conformities as noted in the checklist.

Step 3: Appoint weight on critical questions of the checklists

As mentioned above, the main answers to the questions of the checklist should be formulated as No, Yes, and Not Applicable. In addition, it is important for the authority to distinguish critically important questions from questions of regular importance. This can be achieved by appointing a weight to each question based on its importance. A good way to achieve this is either to use a scoring system or by highlighting critical questions that will lead to more rigorous assessment.

A scoring system, while not mandatory, is a useful tool and a logical extension of the application of the risk-based approach in the control questions. Scoring on the checklist has to be in line with what the inspector has identified, and the score may reflect either the total number of negative answers, which qualifies the result of control for a certain type of decision, or a numerical score (in case each negative answer is given a numerical value).

Weights can range from minor, medium, and major to critical non-conformities. Non-conformity with critical requirements (some or all) may even result in suspension of activity (or part of the activity or operation), according to the measures decided by the inspectorate or the competent authority.

| PART 5 Special places for staff only e.g. kitchen or launderette, linens storage cupboards | THE MOST ESSENTIAL FIRE SAFETY INSPECTION POINTS: NON-COMPLIANCE WILL HAVE TO BE REMEDIED IMMEDIATELY | Score | Non-compliance class | Comment | | | | |
|---|--|-------|----------------------|---------------------------------|------------------|-------------------|-----------|----|
| | | | | | 0 | 5 | 10 | 20 |
| | | | | Non – Applicable / Non Existent | Low risk | Medium risk | High risk | |
| | Where the Law dictates, an active fire suppression system (local to the stove or room-wide) is present. And 1 there is proof that this system is inspected Compartmentation (such as fire dampers and walls) appears to be satisfactory to prevent the spread of fire 2 and smoke to other areas | | | IF YES, GO TO QUESTION 4. | | | | |
| | 3 Highly flammable materials (e.g. chemicals and fuel) are stored according to the regulations The fire alarm system is adequate (detection and audio warning supplemented by visual warning devices where 4 appropriate) | | | | | | | |
| Shared spaces for guests like corridors, restaurant or underground parking | Where the Law dictates, an active fire suppression system (local to the stove or room-wide) is present. And 4 there is proof that this system is inspected Compartmentation (such as fire dampers and walls) appears to be satisfactory to prevent the spread of fire 5 and smoke to other areas Floor, wall and ceiling linings are of non-combustible nature. This includes any accumulation of combustible 6 waste The length of the escape route till the next smoke compartment is less than 25 m and there is emergency 7 lighting Exits are satisfactory. (All exits lead to a place of safety. Exit doors open in the escape direction. Emergency 8 exits are adequately marked) The fire alarm system is adequate (detection and audio warning supplemented by visual warning devices where 9 appropriate) | | | IF YES, GO TO QUESTION 8. | | | | |
| | | | | | 1 Low Compliance | 2 High Compliance | | |

Table 4: Chapters used in the pilot checklist for fire safety

Step 4: Build the results of the checklists

Checklists are official documents to be used during inspections, and they need to indicate the inspector's final conclusion, such as non-conformities observed and measures that need to be implemented before the next regular inspection. Of course, checklists are not only memos for inspectors, but official proof that the inspector performed an inspection, checked particular requirements, and identified non-conformities as noted in the checklist.

The checklist should: (a) indicate the most important requirements for both the business and the inspector; (b) use the results for enforcement decisions(ratification, recommendation or other measures to be imposed on the company); and, (c) use the inspection result for further risk assessment and reprogramming the inspection of the establishment.

The usual way to build the outcome of the checklist is to define compliance levels as per the overall assessment of the risk of the business—for example low, medium, or high risk. If the checklist uses a scoring system, this could easily be calculated using the sum of the scores calculated for each question or chapter. In this case, the checklist should initially define the scores correspond to each risk category. Another solution is to calculate the percentage of conforming answers (yes) over the total number of questions, either by chapter or overall, and define which percentages correspond to high, medium, and low compliance.

Example of risk calculation and compliance level

Option 1: Use risk percentage for each chapter of the checklist

For each chapter there is a specific overall score, which is assessed according to the principle: High risk: over 60% - Medium risk: 30% - 59,9% - Low risk: below 29,9% of the maximum achievable score

TOTAL LOW DANGER: out of 10 chapters, up to 7 low risk and up to 3 medium risk (no high) - or percentage position

TOTAL MEDIUM RISK: out of 10 chapters, up to 2 high risk and any combination (low, medium) of the remaining 8 - or percentage position

TOTAL HIGH RISK: out of the 10 chapters 3 or more chapters are at high risk and any combination (low, medium) of the remaining funds - or percentage position

Option 2: Use percentages of conformities over all questions of the checklist

Box 6: Example of risk calculation in two options

Once the business's overall compliance has been calculated, it is recommended that a separate sheet with recommended actions to be introduced in the checklist (Table 6). A follow-up inspection then needs to be organized to inspect whether the areas of non-compliance have been addressed and inspection measures followed. The checklist will help in recording changes in compliance status after a follow-up inspection related to checks (questions) for which non-compliance was detected, including the implementation of prescribed inspection measures. At this point, and for facilitating both inspectors and businesses, we are referring to the Guide for the Development of the Enforcement Management Model.

Finally, there should be two copies of the checklist, one of which is left to the business after the inspection. The checklist should include a field for the signatures of all parties, including inspectors and inspected entities (Table 5).

| | |
|--|--|
| Signature(s) of Inspector(s): 1. 2. | |
| Singature(S) of subject or representative of subject. | |

Table 5: Signature part of the checklist

Step 5: Accompany the checklists with instructions to inspectors

It is recommended to draft a separate sheet of explanations and instructions to inspectors on how to use the checklist. Instructions should focus on how to interpret a question (especially if questions correspond to ambiguous legal provisions), which alternatives exist or can be accepted during inspections, and how to assess the business in a particular situation. This will give a framework for any conditions that would require the discretion of the inspector. It will also boost uniformity in the use of checklists across different inspectors and inspectorates across the country, one of the major goals of the checklist. Instructions are highly recommended when inspectors are many and the inspectorate (or competent authority) is aware that different interpretations may occur due to variations in inspectors' practices. As an alternative to a detailed list of instructions, authorities can use the Guidance to Businesses as a reference to resolve issues on interpretation.

| INSPECTION RESULTS – PLAN OF CORRECTIVE ACTIONS | | | | | |
|---|-----------------|------------------------------|---|--------------------------------------|--|
| No. Findings | Non-Compliances | Suggested corrective actions | Person in charge and time schedule for implementation | Approval of corrective actions' plan | Confirmation of completion of corrective actions |
| 1. | | | | Date: Signature: | Date: Signature: |
| 1. | | | | Date: Signature: | Date: Signature: |
| Date of follow-up inspection | | | | | |

Table 6: Recommended actions section in the checklist

References

Guidance on Development and Introduction of Checklists by Controlling Agencies [on line], The International Finance Corporation of the World Bank Group (2010),: https://www.wbginvestmentclimate.org/uploads/check%20lists%20manual_en.pdf, Washington D.C.: The World Bank Group.

Regulatory Policy in Lithuania, Focusing on the Delivery Side, <https://www.oecd.org/gov/regulatory-policy-in-lithuania-9789264239340-en.htm>

Statistical classification of economic activities in the European Community, <https://ec.europa.eu/eurostat/documents/3859598/5902521/KS-RA-07-015-EN.PDF>

The International Finance Corporation of the World Bank Group (2010). Guidance on Development and Introduction of Checklists by Controlling Agencies [διαδικτυακό] available at: https://www.wbginvestmentclimate.org/uploads/check%20lists%20manual_en.pdf, Washington D.C.: The World Bank Group

GUIDE 3

Development of the Enforcement Management Model

Contents

- pg. 55 1. Purpose and scope of the guide**
- pg. 56 2. The Enforcement Management Model**
- pg. 57 3. Enforcement**
- pg. 64 4. Overview of the EMM**
- pg. 69 5. Developing the EMM step by step**
- pg. 73 6. Review of the EMM**
- pg. 73 7. Dissemination of the EMM**
- pg. 74 References**
- pg. 75 Annex**

1. Purpose and scope of the guide

As it is not feasible in practice to inspect all economic activities with the same intensity, **risk-based planning**—along with the outcome of the Complaint Management System—assists supervision authorities in planning inspections to maximize the public benefit by mitigating existing or potential risks to key public interests, particularly with regard to human health, safety, and the environment. Inspections are conducted with the use of checklists, which ensure an optimal process for decision making to deal with hazards while inspecting businesses. Following an inspection, enforcement actions decisions are made with the use of the **Enforcement Management Model (EMM)**, which guides inspectors in imposing appropriate sanctions.

More specifically, art. 149 of Law 4512/2018 requires that each supervision and coordination authority develop an EMM to guide inspectors' decisions and actions following an inspection. In parallel, art. 151 of the law introduces a unified approach to measures and sanctions that must be adopted by all supervision authorities within two years after adoption of the law. To this extent, the EMM is the tool that helps inspectors to implement the revised sanctioning system set out in Law 4512/2018 and to use their discretionary powers in a uniform way.

The purpose of this guide is to assist supervision authorities in developing an EMM for inspection purposes, and to ensure consistency, uniformity, and quality in the approaches taken across authorities. In parallel, the guide provides the basis for revising existing sanctions systems.

The guide is designed for practical use. It presents, in brief, what needs to be done to develop an EMM that clearly sets out the principles that inspectors are to apply when determining what enforcement action to take in response to breaches in compliance with legislative requirements. Care should be taken to apply the method in a manner that suits the characteristics and the special circumstances of each inspection domain. Figure 1 outlines the supervision cycle and the supervisory tools used in each step of the inspection process.

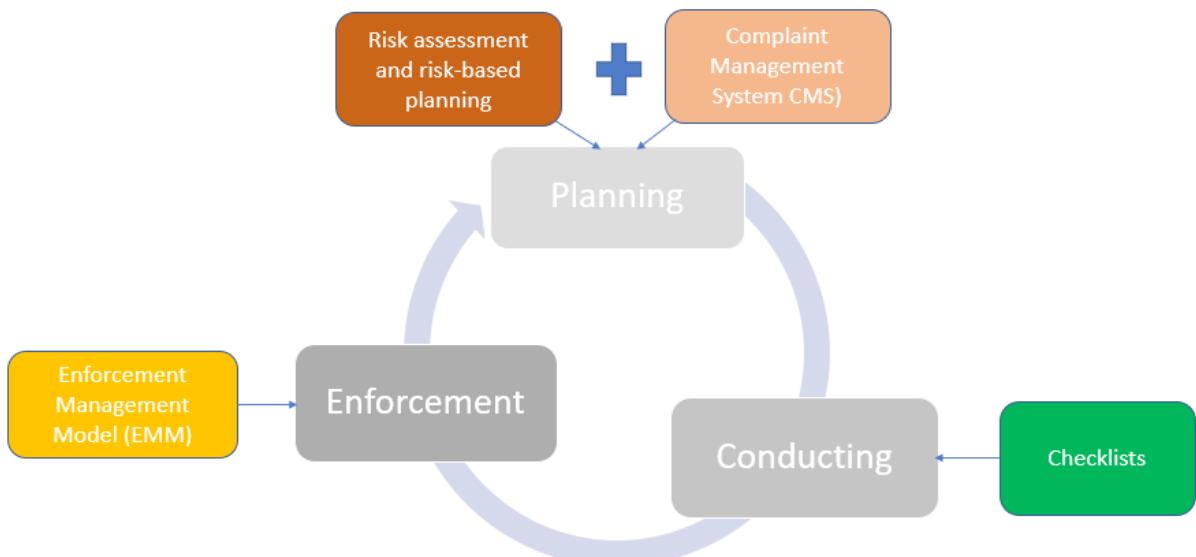


Figure 1: Supervision cycle

2. The Enforcement Management Model

2.1. What is the EMM?

According to Law 4512/2018, the EMM is the tool that guides inspectors in making decisions on providing guidance and information and on imposing measures and sanctions in cases where violations are identified during an inspection. The EMM sets out the criteria and parameters that inspectors should take into account when taking enforcement actions in response to infringements that involve risks to the public interest. These actions should be reasonable and proportionate to the threatened damage to the public interest.

The EMM:

- promotes enforcement consistency by setting out a structured and logical pathway for decision making on enforcement;
- promotes proportionality and targeting by setting out the criteria against which decisions are made;
- provides a transparent and accountable process by setting out the approach that inspectors will use when arriving at enforcement decisions;
- provides a framework for making enforcement decisions transparent, and for ensuring that those who make decisions are accountable for them;
- helps inspectors assess their decisions in complex cases;
- guides less experienced and trainee inspectors in making enforcement decisions; and
- allows for peer review of enforcement actions.

The EMM can also assist business operators in understanding the principles and procedures that inspectors follow when deciding on a particular course of action.

2.2. How is the EMM used?

To the extent possible, the goal of the EMM is to:

- reinforce legal obligations under the relevant legislation;
- achieve outcomes consistent with the relevant legislation;
- deter non-compliant behavior; and
- assertively apply consistent and proportionate enforcement actions.

Each EMM is designed to assist inspectors in making enforcement decisions to achieve consistency, efficiency, effectiveness, and transparency in the administration of the relevant legislation. These guidelines set out general principles to provide an understanding of how each supervision authority will approach enforcement.

When inspectors are carrying out their core functions, such as on-site inspections, they use the

EMM and consider the level of compliance to identify proportionate enforcement actions to secure compliance. The EMM helps to ensure that the purpose and expectations of the inspection have been met, thereby promoting consistency and fairness in enforcement. Following an inspection, inspectors link their findings to an inspection risk rating and an expected response.

3. Enforcement

Enforcement is the total set of actions and measures taken to compel the observance of or compliance with a law, rule, or obligation.

The purpose of enforcement is to:

- ensure that the regulated party manages, and controls risks effectively to prevent harm;
- bring a business, product, activity or process into compliance with the relevant laws;
- promote and achieve sustained compliance;
- prevent future non-compliance by the inspected business and other regulated parties;
- ensure that the regulated party takes action to immediately deal with serious risks; and
- ensure that the regulated party, who breaches serious requirements, creates risks, and fails in his/her responsibilities, may be held to account.

3.1 The process of enforcement

Making decisions about appropriate enforcement is fundamental to the role of a supervision authority. Inspectors use various enforcement tools and techniques to deal with risks and secure compliance with the law, ranging from the provision of guidance to license revocation, sealing of an establishment, and/or confiscation of a product. They can initiate or recommend prosecution where the circumstances warrant criminal sanctions. The appropriate use of enforcement powers, including prosecution, is important—both to secure compliance with the law and to ensure that regulated parties may be held to account for failing to safeguard security, health, safety, and welfare.

3.2 Principles of enforcement

Enforcement decisions should follow the following principles:

- Enforcement actions must be proportionate in applying the law and in securing compliance to prevent a future breach;
- Decisions about an enforcement action must be transparent, impartial, justified and procedurally correct;
- Enforcement actions must be consistent in their approach.

3.2.1. Proportionality

Proportionality means relating the enforcement action to the risks it is intending to mitigate. Enforcement actions taken by inspectors should aim to achieve compliance or bring business operators to account for non-compliance. These actions should be proportionate to the risks posed to the public interest or to the seriousness of the breach, which includes any actual or potential harm arising from a breach of the law.

In practice, the principle of proportionality means that inspectors will take into account the extent of risk caused by the business operator's non-compliance and will try to enforce actions that are proportionate to the harm (Box 1).

In its Inspection Principles, the Danish Food and Veterinary Authority describes the “reaction” as follows:

The control process should employ whatever sanctions are necessary to ensure that the regulations are observed. On the one hand, the reaction should not be more radical than necessary, while on the other hand, sanctions must have sufficient impact to ensure that the regulations are respected.

If the establishment or primary producer concerned fails to comply with the control authority’s sanctions, the sanctions should be escalated.

Source: Danish Food and Veterinary Authority, Ministry of Environment and Food of Denmark

Box 1: Danish Food and Veterinary Authority

3.2.2. Transparency

Transparency means that any enforcement decision is clear to the business operator and that the operator understands the way in which inspectors reached this decision over other options. Transparency also implies that rules governing enforcement decisions are made public.

It is important to help business operators understand what is expected of them in order to achieve compliance. Inspectors must therefore explain to business operators what to do to comply with the law and why. It is preferable to resolve all points of potential differences before the end of the inspection. In the case of prohibition, the inspector should explain why the prohibition is necessary.

3.2.3. Consistency

Consistency of approach does not mean uniformity; it means taking a similar approach in similar circumstances to achieve similar ends.

Business operators who manage similar risks expect a consistent approach to enforcement decisions from the relevant inspectors, whether this involves merely guidance or a decision to prosecute.

Consistency is not a simple matter. Inspectors are faced with many variables, such as the degree of risk, the attitude and competence of management, any history of incidents or breaches involving the business, previous enforcement actions, and the seriousness of the breach, including any potential or actual harm caused. Consequently, it is important that consistency is promoted in decisions on enforcement actions.

3.3. Types of enforcement actions

Inspectors exercise discretion to take any enforcement action they consider appropriate in the circumstances. Paragraph 4 of art. 149, Law 4512/2018 suggests that an inspection decision shall be based on the conclusions of the inspection, the documents reviewed, the results of the checklist, and the analysis that took place during the course of or following the inspection. It is therefore important that inspectors apply the right enforcement action after taking into account the risks identified during an inspection and the establishment's overall compliance level. The level of risk derives directly from the outcome of the checklist, as described in Guide 2. The goal of some enforcement actions may be considered punitive, whereas others may aim to preventing the potential harmful impact of offenses.

Art. 151, Law 4512/2018 introduces the rules that inspectors can use in dealing with the identified infringements, according to the severity of the risk caused. Most specifically, the law provides inspectors the option of not imposing measures and sanctions on economic operators in cases where there is a minor lack of compliance and instead provide verbal instructions, guidance, and information on how to address non-compliance issues. However, where there is the potential for serious risks to occur as a result of non-compliance, the inspectors shall impose a measure or sanction that increases gradually if non-compliance continues.

Paragraph 5, art. 151, Law 4512/2016 describes the following common measures and sanctions that could be adopted by supervision authorities as the basis for a future sanctions system in Greece:

- a) Guidance;
- b) Written recommendation for compliance within a deadline, reinspection within a deadline, and warning of enforcement of sanctions, where appropriate;
- c) Imposition of a fine;
- d) Temporary or permanent banning of operations;
- e) Seizure, freezing, sealing, withdrawal, revocation, restriction of circulation and availability on the market, or destruction of products that pose a risk to human health, safety, and the environment, or of products that are sold without meeting the requirements set out in legislation relevant to each case;
- f) Reporting to the Public Prosecutor's office, provided that the provisions stipulate criminal punishment for the specific violation; and
- g) Administrative measures and sanctions stipulated by specific legislation.

The choice of specific enforcement action will be determined with reference to the seriousness of the breach of legislation and the desired outcome at the conclusion of the action.

As a guide, the provision of guidance and written recommendations are generally reserved for low-risk or minor breaches; administrative penalties and fines should be imposed in cases of moderate to serious breaches; temporary or permanent banning of operations and seizure, freezing, sealing, withdrawal of products, license suspension or revocation, and prosecution referrals are generally reserved for major or serious breaches of legislation (Table 1).

| Compliance Level (checklist's outcome) | Types of Enforcement | | | | | | |
|--|--|------------------------|----------------------|--|---------------------|---|--|
| | Guidance and provision of instructions | Written recommendation | Imposition of a fine | Temporary or permanent banning of operations | Banning of products | Reporting to the Public Prosecutor's office | Administrative measures and sanctions stipulated by specific legislation |
| High Risk (Severe / Major Breach) | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Medium Risk (Moderate Breach) | ✓ | ✓ | ✓ | — | — | — | ✓ |
| Low Risk (Minor / Insignificant Breach) | ✓ | ✓ | — | — | — | — | — |

Table 1: Application of types of enforcement

3.3.1. Guidance and provision of instructions

According to paragraph 2, art. 151, Law 4512/2018, if minor compliance issues have been identified that do not pose a risk to human health and safety, the environment, or any other aspect of the public interest, the inspector may provide the economic operator with guidelines, instructions, and information on compliance. The provision of guidance and directions is important, especially when it comes to small businesses. Small businesses are more limited in their capacity to address complex regulations compared to larger businesses. It is therefore important to provide guidance in cases where **insignificant breaches** are found.

3.3.2. Written recommendations

Written recommendations ordering a business operator to take specified action within a specific period of time—or face the imposition of sanctions (as per paragraph 5a, art. 151, Law 4512/2018)—can be issued by inspectors where there have been **minor breaches** of legislation, where the immediate imposition of a financial penalty is not considered appropriate, and where a warning that the business operator's conduct is in breach of the legislation is considered a sufficient response. Failure to comply, however, should lead to the imposition of stricter enforcement measures.

3.3.3. Imposition of a fine

The imposition of fines, as provided for in paragraph 5d, art. 151, Law 4512/2018, is generally a stricter mechanism for securing compliance in cases where a more moderate breach has been recorded or in combination with a license suspension or revocation and/or prosecution in case of more severe breaches.

In general, fines should not be used as an enforcement measure in cases of insignificant or minor breaches, but they should be imposed if the operator fails to comply with prior written recommendations. The imposition of a fine should follow the principle of proportionality, under which inspectors follow a predetermined model to calculate the level of the fine according to the

severity of the breach and taking into account factors such as:

- The level of risk;
- The size of the business (using criteria such as revenue, number of employees, number of beds in accommodations, and so on);
- The compliance history of the business; and
- The number of times the same breach has occurred.

This model should be included in the reviewed sanction systems to achieve clarity in decision making.

The following table contains the calculation method applied by EFET before imposing a fine. EFET takes into account the level of risk, the size of business, the compliance history and the multiple violations.

| ΠΙΝΑΚΑΣ 1 | | ΠΙΝΑΚΑΣ 2 | | ΠΙΝΑΚΑΣ 3 | |
|--|-----------|----------------|---|--|---------------------|
| ΒΑΘΜΟΙ ΕΠΙΧΩΝΤΗΤΑΣ | | ΕΥΡΟΣ ΕΠΙΧΩΝΤΗ | | ΕΥΡΟΣ ΧΡΗΜΑΤΙΚΟΥ ΥΨΟΥΣ ΔΙΟΙΚΗΤΙΚΗΣ ΚΥΡΩΣΗΣ | |
| ΙΩΔΑΡΩΤΗ | ΒΑΘΜΟΣ | A | 0 | ΕΛΑΧΙΣΤΟ | 0 |
| ΧΑΜΗΛΗ | 1 | B=(A+Γ)/2 | 0 | ΜΕΓΑΛΟ | 0 |
| ΜΕΣΑΙΑ | 2 ή 3 | Γ | 0 | | |
| ΥΨΗΛΗ | 4 ή 5 | x=(Γ-A)/2 | 0 | | |
| ΙΔΙΑΙΤΕΡΑ ΥΨΗΛΗ | 6 ή 7 ή 8 | | | | |
| ΠΟΛΛΑΠΛΟΤΗΤΑ ΜΗ ΣΥΜΜΟΡΦΩΣΩΝ | | ΠΙΝΑΚΑΣ 2 | | ΠΙΝΑΚΑΣ 3 | |
| ΑΡΙΘΜΟΣ | ΒΑΘΜΟΣ | A | 0 | ΚΑΤΗΓΟΡΙΑ ΧΡΗΜΑΤΙΚΟΥ ΥΨΟΥΣ ΔΙΟΙΚΗΤΙΚΗΣ ΚΥΡΩΣΗΣ | ΣΥΝΟΛΙΚΗ ΒΑΘΜΟΛΟΓΙΑ |
| ΜΙΑ | 0 | B | 0 | 1η | 2 |
| ΔΥΟ | 1 | C | 0 | | 3 |
| ΤΡΕΙΣ ΚΑΙ ΛΑΝΟ | 2 | D | 0 | | 4 |
| ΜΕΓΕΘΟΣ ΕΠΙΧΕΙΡΗΣΗΣ | | E | 0 | | 5 |
| ΜΕΓΕΘΟΣ | ΒΑΘΜΟΣ | F | 0 | | 6 |
| ΠΟΛΥ ΜΙΚΡΗ < 500.000€ | 1 | G | 0 | | 7 |
| 500.000€ < ΜΙΚΡΗ < 1.500.000€ | 2 | H | 0 | | 8 |
| 1.500.000€ < ΜΕΣΑΙΑ < 5.000.000€ | 3 | I | 0 | | 9 |
| ΜΕΓΑΛΗ > 5.000.000€ | 4 | J | 0 | | 10 |
| ΥΠΟΤΡΟΦΗ | | K | 0 | | 11 |
| ΑΡΙΘΜΟΣ | ΒΑΘΜΟΣ | L | 0 | | 12 |
| ΜΗ ΥΠΟΤΡΟΦΗ | 0 | M | 0 | | 13 |
| ΜΙΑ | 1 | N | 0 | | 14 |
| ΔΥΟ ΚΑΙ ΛΑΝΟ | 2 | O | 0 | | 15 |
| ΣΥΝΟΛΙΚΗ ΒΑΘΜΟΛΟΓΙΑ | | P | 0 | | 16 |
| ΟΛΗΣΙΣ ΧΡΗΣΕΩΣ ΤΟΥ ΠΙΝΑΚΑ ΥΠΟΛΟΓΙΣΜΟΥ | | | | | |
| 1. Στον ΠΙΝΑΚΑ 1 η Τριμελής Επιφυλή Βαθμολογία το βαθμό κλικενσύνωσης, τη πολλαπλότητα, το μέγεθος της καταδίκησης και την υπερτροφή καταχωρίνεται ο βαθμός που απλώνεται στο αντίστοιχο "πράσινο" λαδίο. | | | | | |
| Από τη καταχώρηση της βαθμολογίας προσκύπτει αυτόματα η ΣΥΝΟΛΙΚΗ ΒΑΘΜΟΛΟΓΙΑ για την εξισιάζουμε με συμπλήρωση. | | | | | |
| 2. Στον ΠΙΝΑΚΑ 2 Τριμελής Επιφυλή καταχωρίζεται η πλάστιτη τιμή προσίτου (Α) και την μάρκητη τιμή προσίτου (Γ) που προβλέπεται στο άρθρο 23 του Ν. 4235/2014 για τη κατηγορία της εξισιάζουμε με συμπλήρωση. | | | | | |
| Με τη καταχώρηση της πλάστιτης τιμής (Α) και της μάρκητης τιμής (Β) στον ΠΙΝΑΚΑ 3 στο "πράσινα λαδία" το πρόγραμμα υπολογίζει και αριθμεί τα αυτόματα στον ΠΙΝΑΚΑ 2 την πιτι Β και την στον ΠΙΝΑΚΑ 3 το προβλεπόμενο κύρος του χρηματικού προσίτου (αλλάσσεται και το μάρκετ) για κάθε κατηγορία χρηματικού ύψους διοικητικής κύρωσης. | | | | | |
| 3. Η Τριμελής Επιφυλή μαζί με τη συνολική βαθμολογία αντιστοιχίζει την εξισιάζουμε με συμπλήρωση στην κατηγορία του ΠΙΝΑΚΑ 3 και προσδιορίζει απριβώς το πρόστιμο αντίς, του κύρους, που αριθμείται για αυτή τη κατηγορία. | | | | | |

Box 2: Calculation method applied by the Hellenic Food Authority (EFET) before imposing a fine

3.3.4. Temporary or permanent banning of operations

Temporary banning of operations (as per paragraph 5b and 6, art. 151, Law 4512/2018) is usually imposed by suspending a license to operate or by temporarily banning (all or part of) operations. This type of enforcement could be accompanied by a fine, and possible prosecution can also be applied. Temporary prohibition of operations should be used in case major breaches are detected that pose immediate risk to public health, safety, and the environment. In such cases, inspectors should order a business operator to take specified actions within a specific period of time. When the operator complies, this prohibition should be lifted.

Given that a permanent restriction on carrying out a business activity is the strongest response to a violation, this type of enforcement action should be used only in cases of severe breaches that have caused harm or pose immediate and irreversible risk to public health, safety, and the environment, and when no other enforcement action has worked. Permanent prohibition should not be used for first-time offenders who show willingness to remedy the situation and who have cooperated with the regulator before.

3.3.5. Seizing, freezing, sealing, withdrawal, revocation, restriction of circulation and availability on the market, or destruction of products

Seizing, freezing, sealing, withdrawal, revocation, restriction of circulation and availability on the market, or destruction of products that pose a risk to human health, safety, and the environment, or of products that are sold without meeting the requirements set out in the relevant legislation for each case should be used in cases where inspectors have uncovered severe breaches of legislation that relate to the safety of products. This type of enforcement is usually accompanied by fines and possible prosecution.

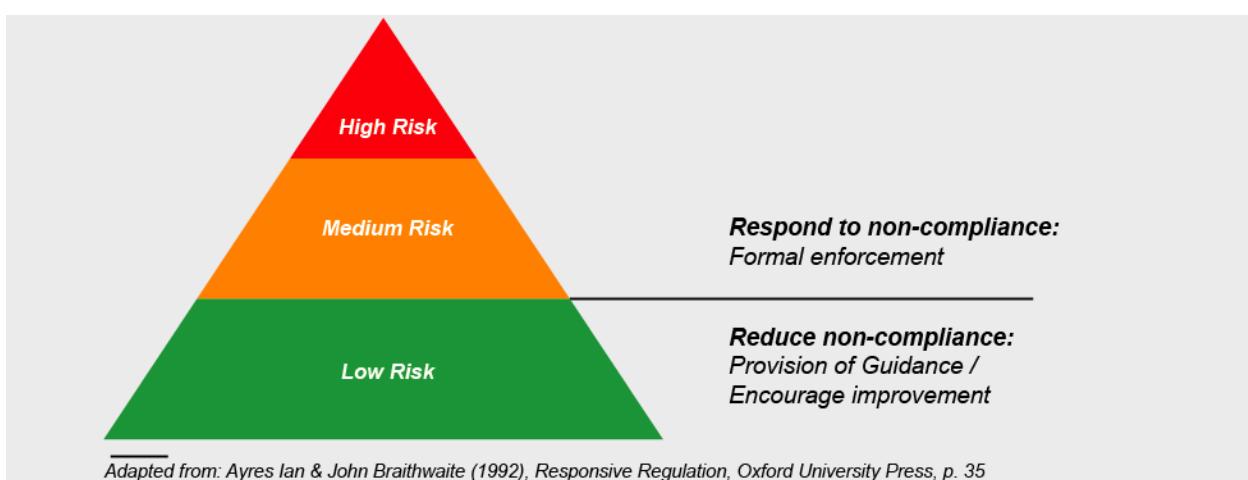


Figure 2: The enforcement pyramid (The enforcement pyramid that depicts the enforcement response)

3.4. The enforcement pyramid

This approach follows the logic of an enforcement pyramid (Ayres and Braithwaite 1992). This pyramid depicts the escalation of the enforcement response according to the significance of the violation.

The process of making enforcement decisions is complex. Each regulated party is unique, and inspectors must have a thorough understanding of the risks and control measures associated with each economic activity. It is vital that inspectors have the discretion to exercise their professional judgement and choose between a specified range of responses, according to each situation.

Different inspectorates use different enforcement approaches to achieve compliance through a proportionate system (Boxes 3–5; Annexes 1–3).

Health Canada's compliance and enforcement activities help the protection against health and safety risks.

The decision factors inform the choice of actions.

Decision factors

- *Information pertaining to non-compliance:*
- *health and safety risk factors*
- *behavior of regulated parties, e.g., including conformance with the conditions of a marketing authorization and post-authorization reporting requirements*
- *compliance history*
- *other factors*

Choice of actions

A choice of actions intended to reduce non-compliance or respond to non-compliance are presented in a pyramid. Actions at the top of the pyramid (prosecution, investigation) reinforce actions at the bottom (guidance, education) by clarifying expectations and demonstrating that those who do not comply can be held to account.

Source: Health Canada, <https://www.canada.ca/en/>

Box 3: Health Canada's enforcement approach

The Office for Nuclear Regulation's enforcement guide states that the appropriate use of enforcement powers, including prosecution, is important, both to secure compliance with the law and to ensure that those who have duties under it may be held to account for failures to safeguard security, health, safety and welfare.

Source: Office of Nuclear Regulation (UK), <http://news.onr.org.uk>

Box 4: Types of Enforcement in the United Kingdom's Office for Nuclear Regulation

Dairy Food Safety Victoria (DFSV) takes enforcement actions when deemed necessary to fulfil its statutory objective to ensure that the standards which safeguard public health are maintained in the Victorian dairy industry. Consistent with the principles of the Australian and New Zealand Food Regulation Enforcement Guideline DFSV takes actions proportionate to the seriousness of the legislative non-compliance identified and the food safety or business risk.

Source: Dairy Food Safety Victoria, Australia (DFSV), <https://www.dairysafe.vic.gov.au/>

Box 5: The Dairy Food Safety Victoria Enforcement Model in Australia

4. Overview of the EMM

As described above, the supervision cycle consists of three major steps: planning inspections, conducting inspections, and enforcing measures and sanctions (Figure 3). Inspections are conducted with the use of a checklist that identifies the level of compliance. The EMM is used at the final step of supervision to assist inspectors in considering the right factors and imposing appropriate enforcement measures.

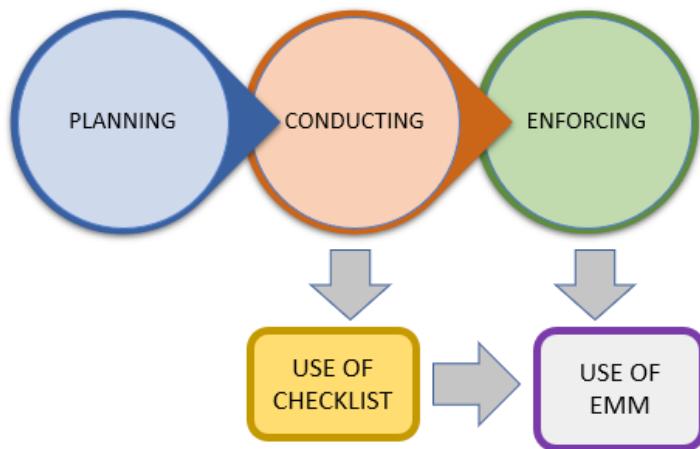


Figure 3: Tools used during the inspection process

As discussed above, the EMM includes the criteria and parameters that inspectors should take into account when deciding on enforcement actions as a response to infringements that involve risks to the public interest. To describe how the EMM is used, the following sections describe each of its components separately to build an overall view.

The process includes:

1. **The starting point of the EMM, which is the conclusion derived from the outcome of the checklist;**
2. **Separating out the immediate risks that may need to be addressed first and are not subject to review;**
3. **Identifying compliance issues that are not risk-based and were not taken into consideration during the checklist-based inspection;**
4. **Applying factors related to the business operator; and**
5. **The enforcement conclusion.**

To develop a proper methodology and tool for making enforcement actions, it is essential for inspectorates to understand the concept, set the context, and define their scope of work.

4.1. Starting point

Paragraph 4, art. 149, Law 4512/2018 suggests that the EMM shall be based on the inspection's conclusions, the documents reviewed, the results of the checklist, and the analysis that took place during the course of or following the inspection. During an inspection, inspectors use a checklist to gather information about the nature of the risks identified and the level of compliance (Guide 2). Checklists are the official documents that inspectors use during inspections to record risks and identify the level of compliance. They indicate the inspector's final conclusion, usually on the basis of a scoring system that calculates the risk level of the establishment at that moment, as per the overall assessment of risks found and the compliance level of the business operator. At the end of an inspection, the establishment is characterized as low-, medium-, or high-risk according to the compliance found and recorded by the inspectors at the time of inspection. This categorization is the starting point of the EMM.

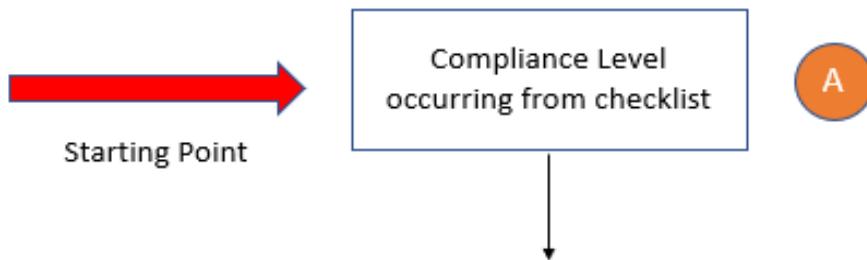


Figure 4: Starting point

4.2. Deal with serious risks first

Where an inspection identifies an immediate risk that can affect certain aspects of the public interest, such as human health, safety, or the environment, it is important that inspectors deal with this risk first. Inspectors should first address immediate safety and security risks, including risk of serious personal injury and circulation of dangerous products that can cause serious risk of permanent or long-term impact on the environment, cultural heritage, or animals—regardless of the establishment's overall risk classification or overall compliance level. Inspectors should use the most appropriate regulatory tool provided for in the relevant legislation—such as temporarily banning all or part of the activity or seizing products that are creating the risk—until the risk is addressed.

By taking immediate action, the inspector is likely to have controlled the risk effectively such that there remains negligible or no risk. However, the inspector will also need to determine:

- whether further enforcement actions are required to secure sustained compliance with the law in relation to all other risks they have identified; and
- whether to consider criminal prosecution.

Inspectors should readdress the situation, identify any remaining risks, and continue applying the EMM from the beginning. Figure 6 depicts the process to be followed in cases where an immediate risk is identified.

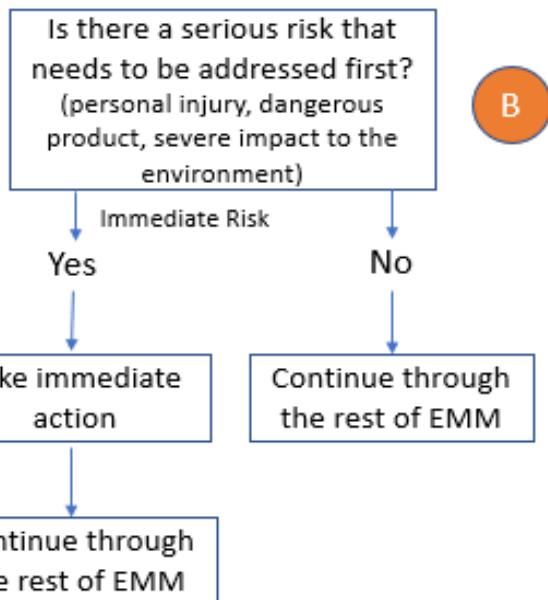


Figure 5: Dealing with serious risks

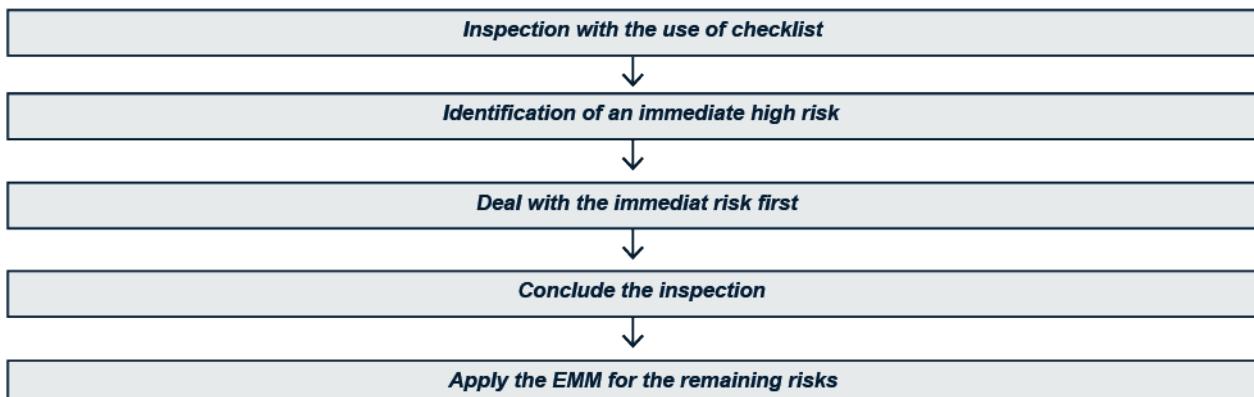


Figure 6: The inspection process when an immediate risk is identified

4.3. Determine compliance issues that are not risk-based

As presented Guide 2 on the development of checklists, checklists contain essential questions that are related to risks. Through these questions, the compliance level of the business can be derived. When applying the EMM to a particular case, it is important to ensure that all contributory risk-based issues are identified and assessed.

However, some legal duties do not directly result in control of risk but still demand some actions by the business operator, for example requirements to keep the notification file on the business premises, to maintain a safety file or log, or to report incidents. These “non-risk-based compliance” or “administrative” issues (Figure 7) refer to legal requirements that are not in themselves risk-based and are considered separately from risk-based issues in the EMM.

Where there is lack of compliance on these issues, enforcement measures are determined in the relevant legislation and should be applied separately.

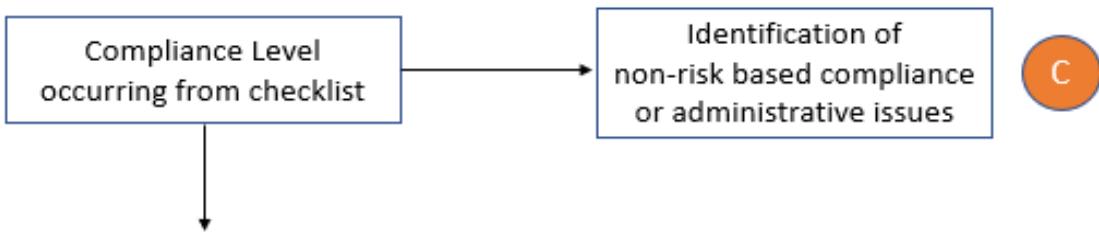


Figure 7: Identification of non-risk-based compliance issues

4.4. Apply factors relevant to the business operator

Although an enforcement action should secure compliance with the law, it should also be fair and equitable and have regard for the wider socioeconomic factors that are relevant to the local and national business environments.

Paragraph 3, art. 149, Law 4512/2018 suggests that the decision making that follows the conclusion of an inspection shall be carried out in accordance with the following criteria:

- a) the reduction of potential hazards and the prevention or reduction of infringements and irregularities or exclusion of these;
- b) the behavior and the degree of cooperation of the economic operator undergoing inspection.

The inspector's choice of enforcement action therefore has to be targeted effectively to achieve maximum impact. Consequently, after choosing the initial enforcement action, it is important to consider factors that are specific to the particular case (Figure 8). These are the factors relevant to the business operator and may influence the final enforcement action.

Examples of factors relevant to the business operator may include:

- compliance history;
- previous risk incidents recorded;
- motives for non-compliance (such as seeking economic advantage or unintentional breach);
- possible willingness to comply.

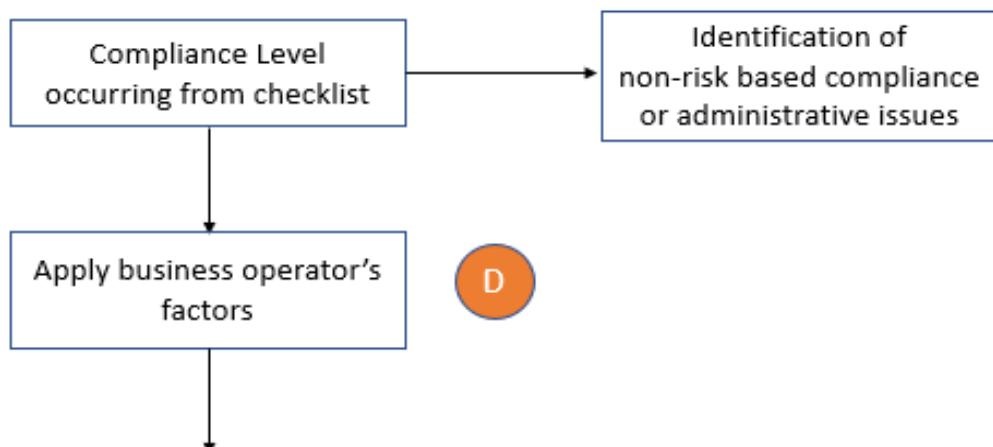


Figure 8: Application of factors relevant to the business operator

4.5. Enforcement conclusion

When the final enforcement decision is reached, it is important that the following principles be addressed (Figure 9):

- The enforcement action deals with the most serious risks in order of priority, and over an appropriate time frame;
- The cause of the risk has been addressed;
- Immediate failures to control risk or comply with the law have been dealt with; and
- Underlying problems have been addressed.

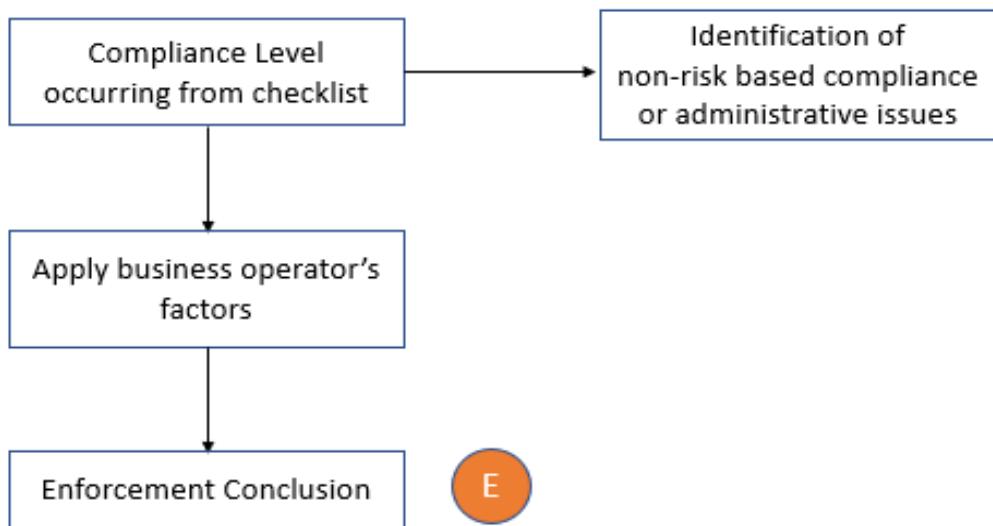


Figure 9: Enforcement conclusion

Bringing all components of the EMM together, the concept and process of the methodology can be visualized as follows:

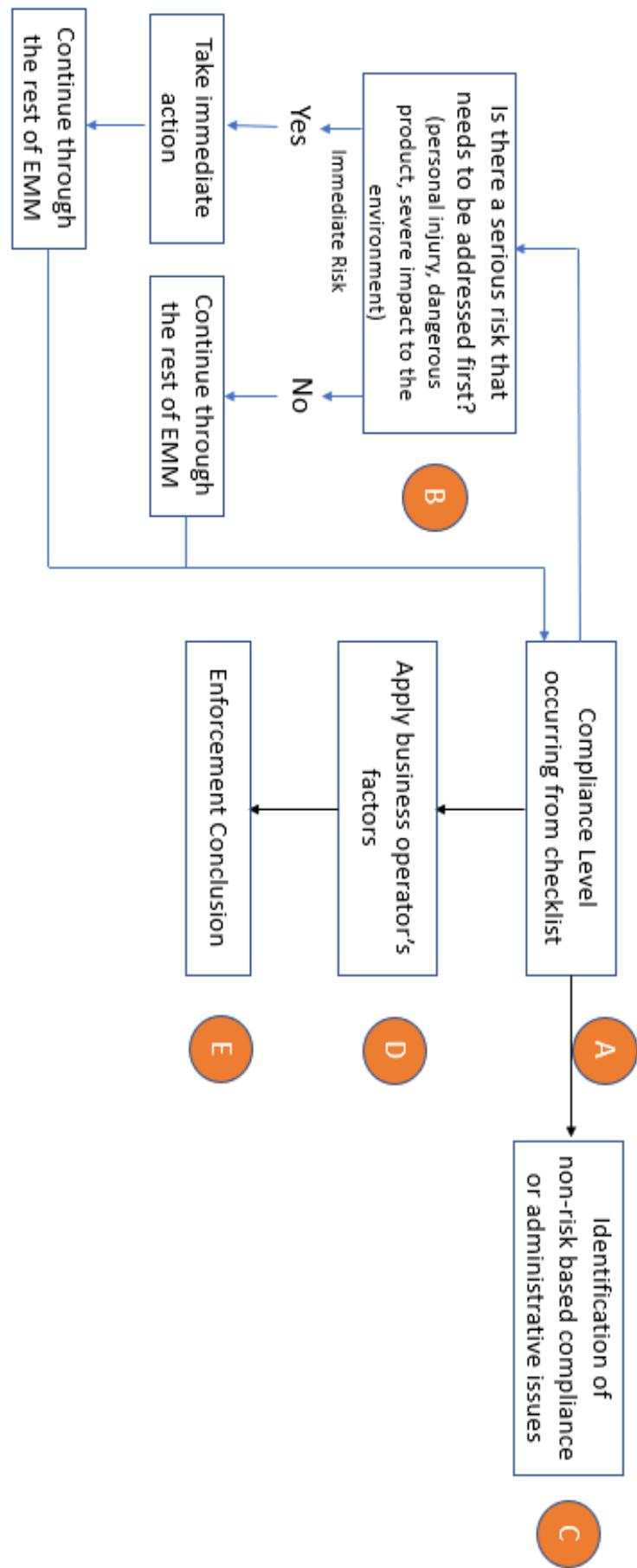


Figure 10: The Enforcement Management Model (EMM)

5. Developing the EMM step by step

To develop the EMM, each supervision authority must first complete certain steps to complete the EMM.

These are:

- **Step 1: Determine the factors relevant to the business operator;**
- **Step 2: Apply the factors relevant to the business operator in a flowchart; and**
- **Step 3: Match enforcement actions (reviewed sanctions) to risk levels.**

Step 1 – Determine the factors relevant to the business operator

As explained in Section 4.4, because each case is unique, inspectors should consider the factors relevant to the business operator before deciding on the final enforcement action. It is important that these business factors be included in the reviewed sanctions systems.

Before applying these business operator factors, each supervision authority must create a table of these factors and consider their implications for the initial enforcement action (Box 6).

The Health and Safety Executive (HSE) takes into consideration the following factors:

Is there a relevant incident history?

YES *The dutyholder has a history of related incidents, or there is evidence of related incidents, eg accidents, cases of ill health and/or dangerous occurrences.*

NO *No previous history or evidence of related accidents, ill health and/or dangerous occurrences.*

Does the dutyholder have a history of relevant enforcement being taken against them?

YES *Enforcement action has been taken against the dutyholder on the same or similar issues by verbal warning, letter requiring action, notice or prosecution.*

NO *No history of enforcement action against the dutyholder on the same or similar issues.*

Is the dutyholder deliberately seeking economic advantage?

YES *The dutyholder is deliberately avoiding minimum legal requirements for commercial gain. (For example failing to price for or provide scaffolding for high roof work).*

NO *Failure to comply is not commercially motivated.*

What is the level of actual harm?

SERIOUS *A ‘serious personal injury’ or ‘serious health effect’ has occurred as a result of the matter under consideration.*

NOT SERIOUS *There has been no actual harm, or the harm has been no greater than a ‘significant personal injury’ or a ‘significant health effect’.*

What is the inspection history of the dutyholder?

- POOR** The dutyholder has an inspection history of significant problems, copious advice and poor inspection ratings.
- REASONABLE** The dutyholder has an inspection history of nominal or piecemeal problems, where non-compliance has been related to new or obscure duties and where the rating history is in the average range.
- GOOD** The dutyholder has an inspection history of good compliance, effective response to advice, consistently high standards and a low rating.

What is the standard of general conditions?

- POOR** There is a general failure of compliance across a range of issues, including those matters related to the activity being considered through the EMM. For example failure to address risks arising from hazardous substances, machinery, transport, vibration, noise etc or inadequate welfare facilities.

- REASONABLE** The majority of issues are adequately addressed with only minor omissions.

- GOOD** Full compliance across the whole range of indicators with no notable omissions.

Does inspector's assessment of the dutyholder give confidence the dutyholder can and will comply?

- CONFIDENT** It is clear that the dutyholder is both fully capable of, and is strongly committed to, compliance with the law through the effective management of health and safety, and can be trusted to put the matter(s) right.

- SOME CONFIDENCE** The dutyholder demonstrates some capability and commitment to compliance with the law through effective management of health and safety.

- LITTLE OR NO CONFIDENCE** There is concern that the dutyholder does not have the capability, or commitment, to comply with the law and ensure the effective management of health and safety.

Source: www.hse.gov.uk

Box 6: United Kingdom Health and Safety Executive – Dutyholder Factors

Step 2 – Apply factors relevant to the business operator in a flowchart

The way that business operator factors are applied, after the compliance level has been determined by the checklist outcome, is presented in flowcharts. Each supervision authority should create a decision tree that takes into consideration each compliance level (low/medium/high risk) and the business operator factors (as explained above) that will assist inspectors in reaching their final enforcement decision. This decision tree will be used by the inspectors following the end of an inspection.

The elements in each flowchart vary because different enforcement expectations are influenced by different factors relevant to the business operator. Each supervision authority should create separate flowcharts, one for each risk that corresponds to the compliance level.

If the business is classified as low-risk (compliance level), it is unlikely that any further consideration would alter this decision. This is because the risk is generally expected to be nominal. There may be particular circumstances, however, under which writing a notice or a recommendation to the business operator may be more appropriate if the matter has been raised previously.

Each supervision authority can use its own depiction of the process (examples are depicted in Figures 11 and 12), as long as these depictions take into consideration the criteria and parameters

that inspectors should take into account when taking enforcement actions, in accordance with art. 149, Law 4512/2018.

After applying the EMM, an inspector must deliver the inspection's final conclusion to the business operator.

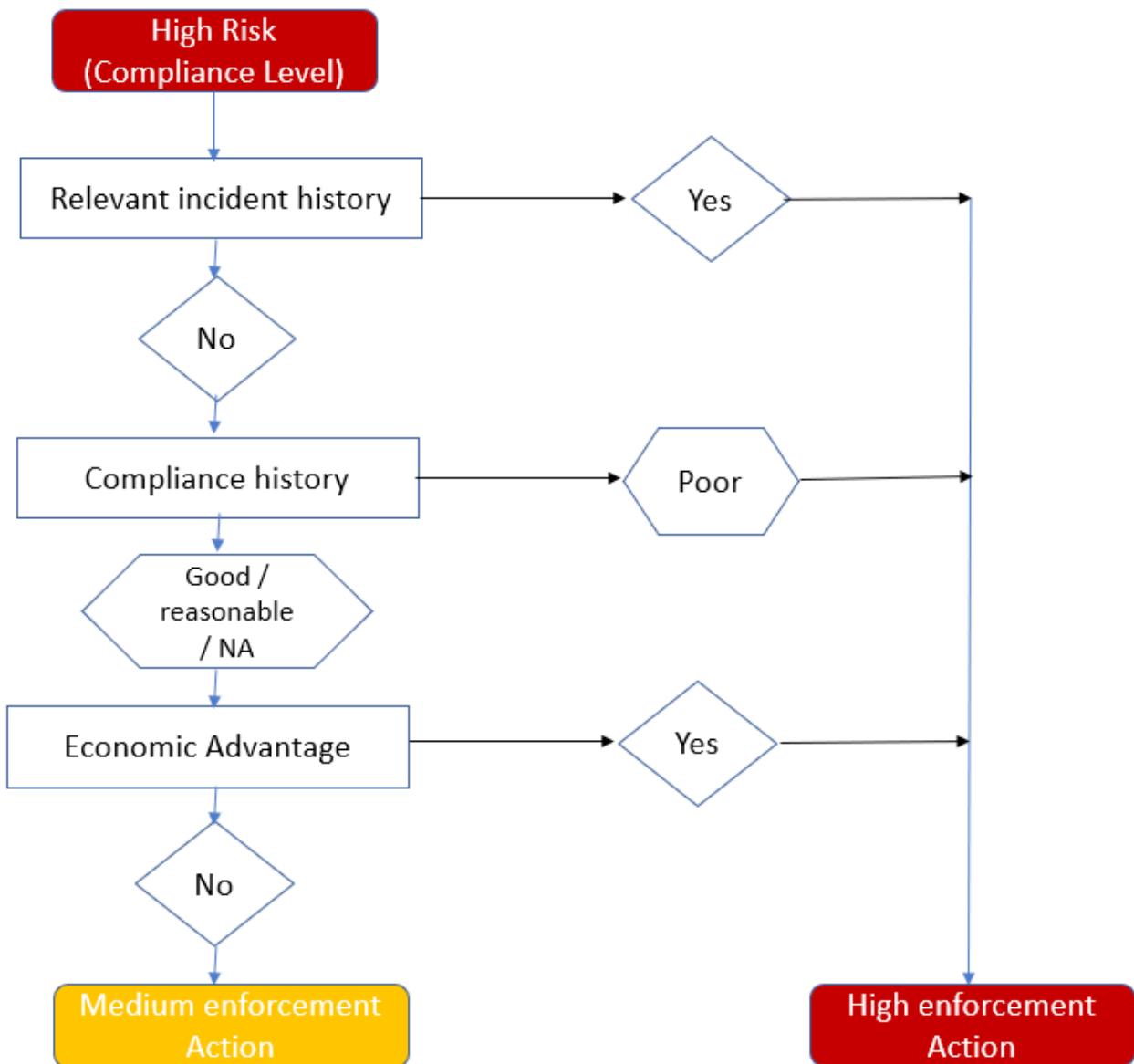


Figure 11: Example of a high-risk compliance level flowchart, after applying factors relevant to the business operator (adjusted from the HSE EMM)

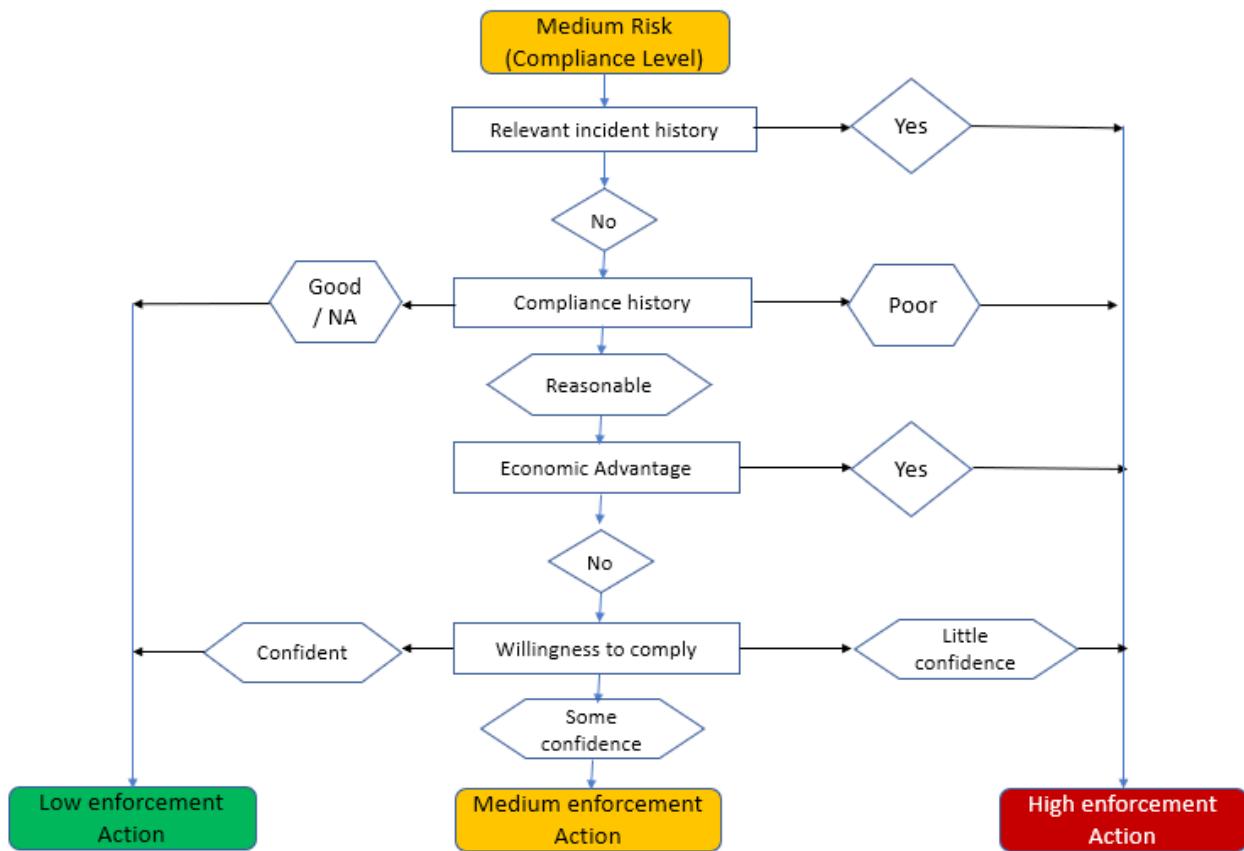


Figure 12: Example of a medium-risk compliance level flowchart, after applying factors relevant to the business operator (adjusted from the HSE EMM)

Examples from the HSE can be found in Annex 4.

Step 3 – Match enforcement actions (reviewed sanctions) to risk levels

After conducting an inspection with the use of a checklist, the inspector identifies certain risks and determines the risk level of the business based on its level of compliance. As explained above, this compliance level is the starting point of the EMM. For an inspector to deliver an enforcement conclusion after applying the EMM, it is important to have a list of the enforcement actions (measures and sanctions) that are available in the relevant legislation and correspond to the level of compliance.

Section 3.3 above provides a list of the types of enforcement actions (measures and sanctions) determined in art. 151, Law 4512/2018, as well as the circumstances under which it is proposed that they be imposed according the level of the breach. This list of possible enforcement measures should be matched with the level of compliance (Table 2).

| <i>Compliance Level (checklist's outcome)</i> | <i>Types of Enforcement</i> |
|---|-----------------------------------|
| High Risk (Severe Breach) | |
| High Risk (Medium Breach) | High Enforcement Actions |
| Medium Risk (Upper-Moderate Breach) | |
| Medium Risk (Lower-Moderate Breach) | Medium Enforcement Actions |
| Low Risk (Minor Breach) | |
| Low Risk (Insignificant Breach) | Low Enforcement Actions |

Table 2: Match the compliance level with the enforcement actions available

6. Review of the EMM

It is advised that each supervision authority review the EMM after a pilot period. This review will allow the creation of a useful tool that aligns fully with the possible enforcement actions suggested in art. 151, Law 4512/2018.

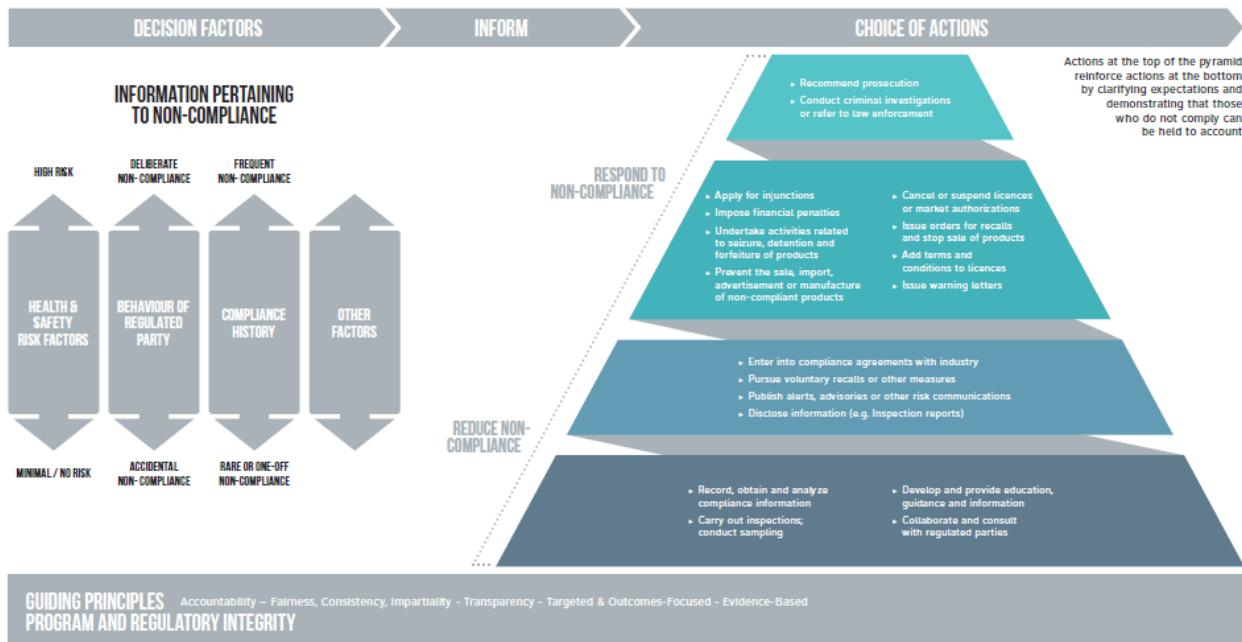
7. Dissemination of the EMM

According to paragraph 1, art. 149, Law 4512/2018, each supervision authority must issue a decision to adopt the EMM and publish the model on its website, as part of its commitment to transparency. This will help to educate the public about the authority's expectations and approach to compliance. Operators and businesses who have specific obligations under the relevant legislation are encouraged to familiarize themselves with each EMM.

References

- Ayres, Ian, and John Braithwaite. 1992.** Responsive Regulation: Transcending the Deregulation Debate. Oxford University Press. Available at: <http://johnbraithwaite.com/wp-content/uploads/2016/06/Responsive-Regulation-Transce.pdf>
- Government of Canada. 2018.** “Compliance and enforcement policy framework,” available at: <https://www.canada.ca/en/health-canada/corporate/mandate/regulatory-role/what-health-canada-does-as-regulator/compliance-enforcement-framework.html#enforcement>
- Dairy Food Safety Victoria (DFSV). 2018.** “Enforcement Model Guidelines,” available at: <https://www.dairysafe.vic.gov.au/publications-media/regulations-and-resources/guidelines/231-enforcement-model-guidelines-1>
- Department of Environment and Heritage Protection, State of Queensland, Government of Australia. 2016.** Enforcement Guidelines, available at: <https://environment.des.qld.gov.au/management/pdf/enforcement-guidelines.pdf>
- Food Standards Agency (United Kingdom). 2008.** “Food Law Code of Practice,” available at: <https://www.food.gov.uk/enforcement/codes-of-practice/food-law-code-of-practice>
- Health and Safety Executive (HSE) (United Kingdom). 2013.** “Enforcement Management Model,” available at: <http://www.hse.gov.uk/enforce/enforcement-management-model.htm>
- Health and Safety Inspectorate, States of Jersey. n.d.** “Enforcement policy statement: health and safety at work,” available at: <https://www.gov.je/Industry/HealthSafetyWork/HSI/Inspectorate/Pages/EnforcementPolicyStatement.aspx>
- Ministry of Environment and Food of Denmark, Danish Veterinary and Food Administration. 2015.** “Inspection Principles, available at: https://www.foedevarestyrelsen.dk/english/Inspection/Inspection_principles/Pages/default.aspx
- Office of Nuclear Regulation (United Kingdom). 2018.** “ONR Enforcement Guide,” available at: <http://news.onr.org.uk/2018/04/new-onr-enforcement-management-model/>
- World Bank Group. 2018.** Poland Catching-Up Regions: Safer Food, Better Business in Podkarpackie and Lubelskie, available at: <http://documents.worldbank.org/curated/en/289891529314549019/pdf/127296-WP-P165726-Activity-9-Inspections-Report.pdf>

Annex



Health Canada Santé Canada Canada

Figure 13: Health Canada's Enforcement Approach (source: Health Canada, <https://www.canada.ca/en/>)

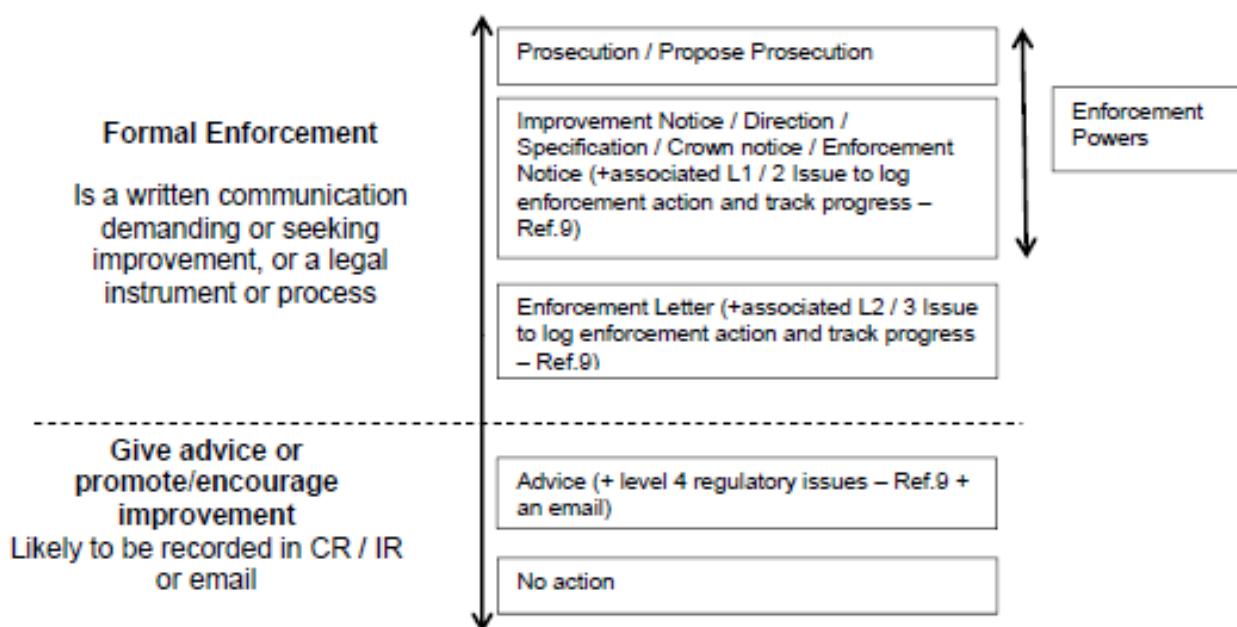


Figure 14: Office of Nuclear Regulation - types of enforcement (source: Office of Nuclear Regulation (UK), <http://news.onr.org.uk>)

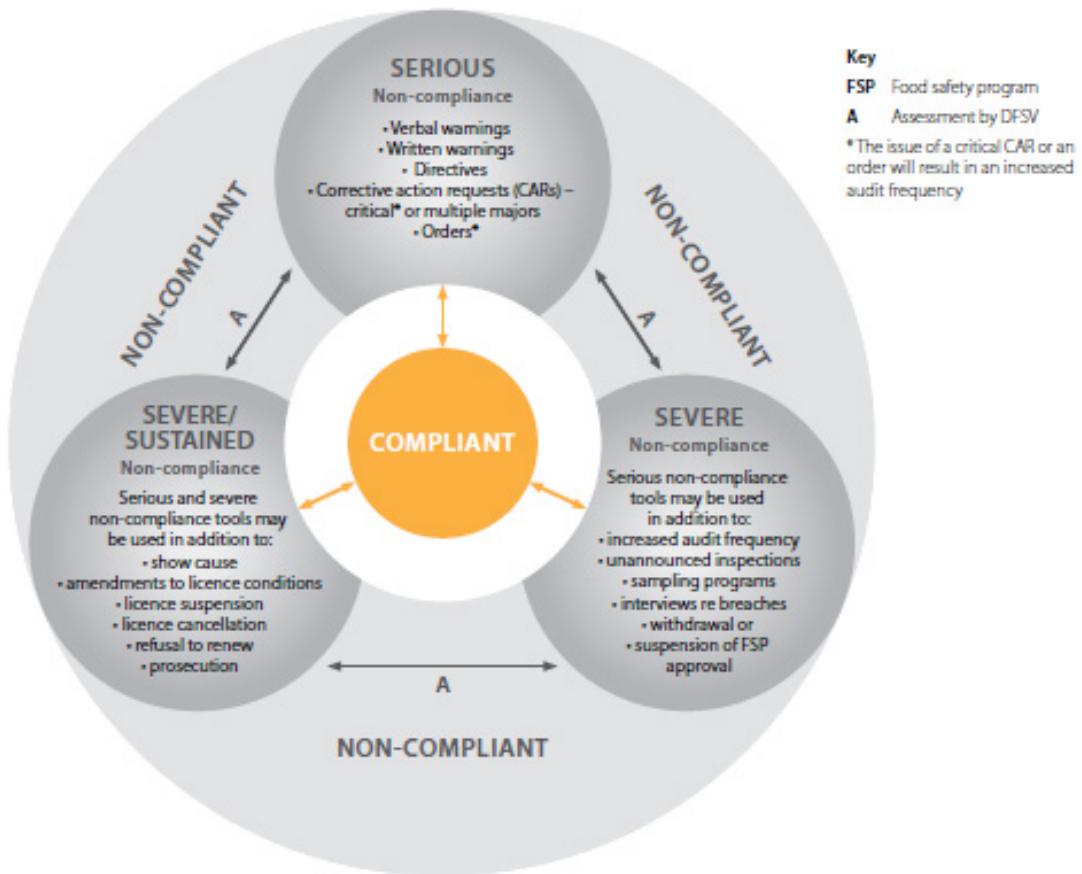


Figure 15: Dairy Food Safety Victoria (DFSV) Enforcement Model (source: Dairy Food Safety Victoria, Australia (DFSV), <https://www.dairysafe.vic.gov.au/>)

In the United Kingdom's HSE model, when considering what enforcement action is appropriate, the dutyholder factors are applied, where relevant, to the initial enforcement expectation. The way that dutyholder factors are applied is represented in flowcharts. The elements included in each flowchart vary because different enforcement expectations are influenced by different dutyholder factors.

Figure 16 shows the flowchart used when the initial enforcement expectation is a “prohibition notice.” Several dutyholder factors are being taken into consideration to determine whether prosecution is also necessary.

Similarly, Figures 17 and 18 show the relevant factors taken into consideration in deciding whether to impose a higher sanction than that foreseen in the initial enforcement expectation or to consider a lower measure.

Figure 19 shows the factors considered in cases where a verbal warning is first considered. The flowchart shows how dutyholder factors can influence this initial expectation in favor of instead producing a written letter.

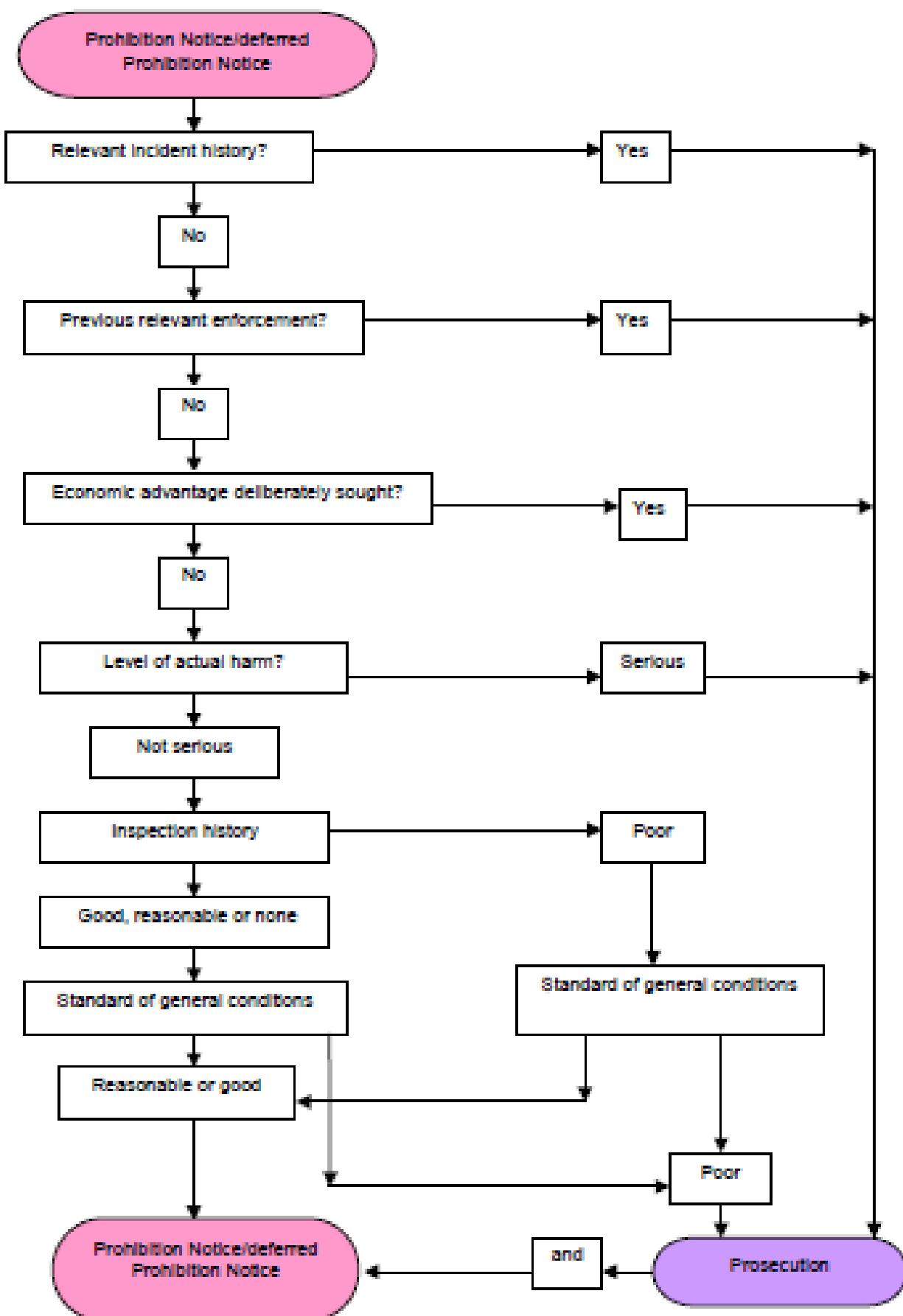


Figure 16: Prohibition Notice

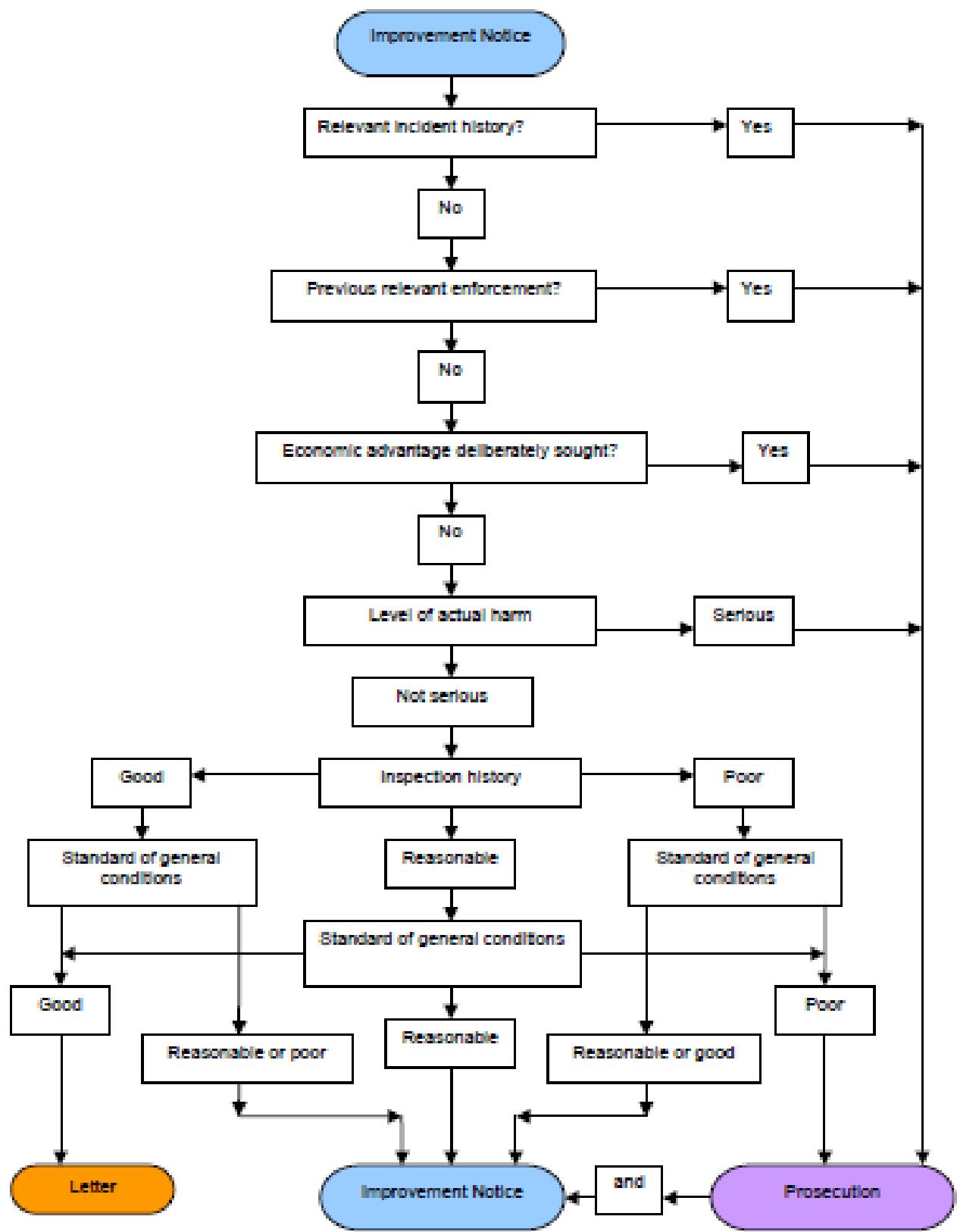


Figure 17: Improvement notice

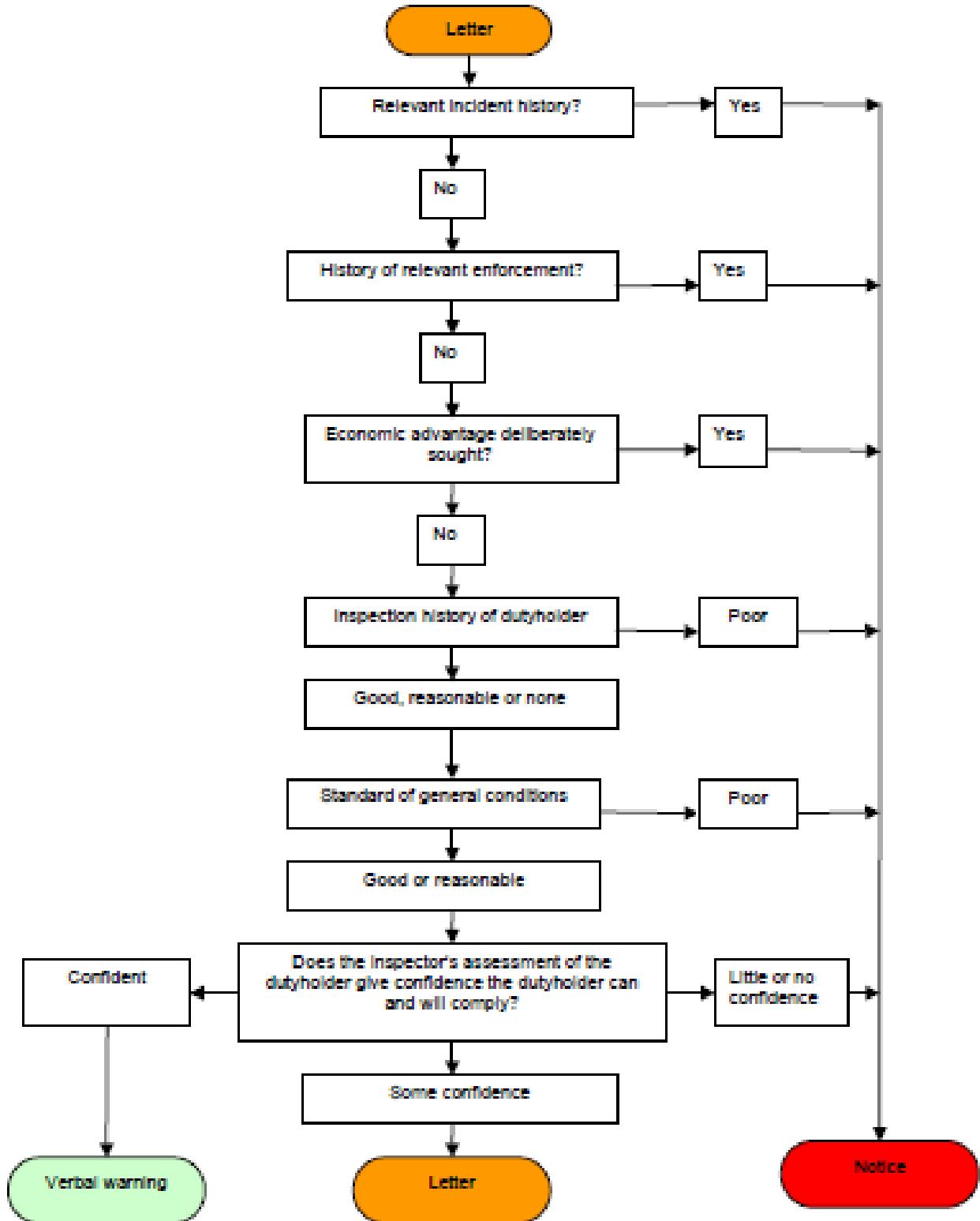


Figure 18: Letter

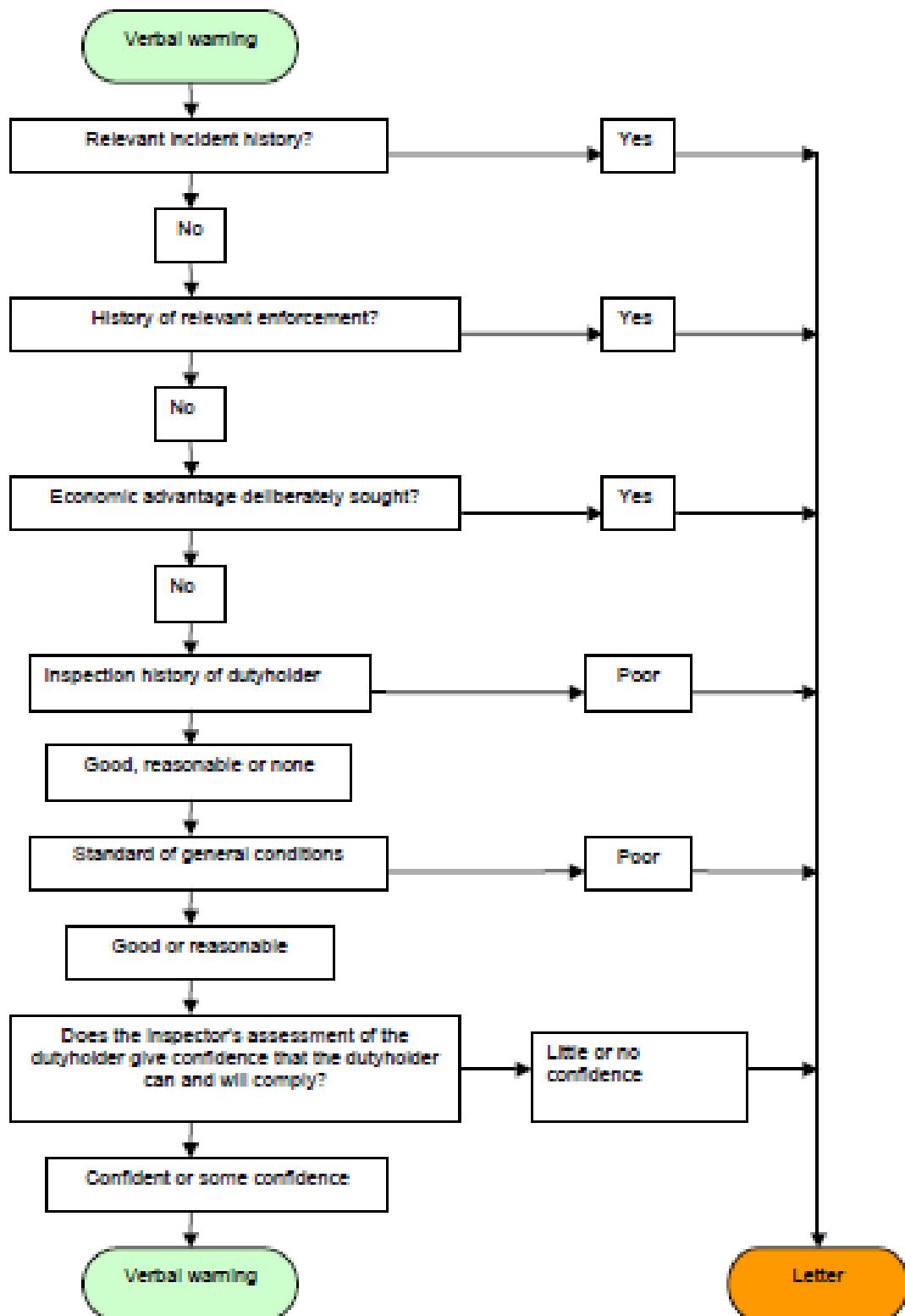


Figure 19: Verbal warning

GUIDE 4

Development of a Risk-Based Complaint Management System

Contents

- pg. 85 1. Purpose and scope of the guide**
- pg. 85 2. The benefits of a risk-based complaint management system**
- pg. 86 3. The strategic relevance of complaints in a risk-based inspection system**
- pg. 86 4. Developing a risk-based complaint management system – institutional and policy aspects**
- pg. 89 5. Developing a risk-based complaint management system – operational aspects**
- pg. 94 Annex**

1. Purpose and scope of the guide

Art. 140 of Law 4512/2018 requires inspectorates to adopt a complaint management framework to better align their responses to complaints with the law's proactive, risk-based planning. The objective of this framework is to allow inspectorates to concentrate their resources and deal with serious risks in a timely manner and thereby reduce the time spent on low-risk or trivial issues, investigation of which does not contribute to the accomplishment of the inspectorates' objectives and the attainment of better regulatory outcomes.

The purpose of this guide is to help inspectorates develop a risk-based complaint management system by introducing objective, priority-based selection criteria for managing complaints. Additionally, the purpose of this guide is to help inspectorates develop alternative responses to complaints, instead of reactive inspections.

The guide is designed for practical use. It presents, in brief, the steps necessary to develop a risk-based complaint management system from both organizational and technical (content) perspectives. Consideration should be made to tailor the complaint management system to the specific characteristics, methods, and tools that are relevant to each regulatory area.

2. The benefits of a risk-based complaint management system

In a risk-based system of supervision, inspections should be planned primarily on the basis of risk assessments. Complaints should be used as a source of information to improve risk targeting and inspection planning and should only in few cases lead to impromptu inspections. A risk-based complaint management system is thus indispensable in ensuring coherence between proactive inspections that take place after careful risk-based planning and reactive inspections that are unplanned and occur in an ad hoc manner in response to serious complaints. A risk-based selection of complaints:

- i. contributes to the development of an intelligence-led, risk-based, and outcome-focused regulatory approach;
- ii. ensures consistency with the broader risk-based strategy;
- iii. filters out complaints at the low-risk end, which may be trivial or ill-informed and should not divert the inspectorates' resources away from high-risk complaints;
- iv. prioritizes high-risk cases that jeopardize the regulator's objectives and, in doing so, contributes to better regulatory outcomes by redirecting resources to frontline activities that have a higher impact;
- v. develops a proportionate and consistent response to issues raised by the public; and
- vi. leverages third-party complaints⁹ effectively as a source of high-quality data to enhance risk assessments.

⁹ While such complaints should never be taken as the primary driver for targeting inspections, they are an important, complementary source of information. For example, repeated, well-founded complaints about the same product or business should be a factor that markedly raises its risk level, which will in turn cause inspections to become more likely and/or frequent.

3. The strategic relevance of complaints in a risk-based inspection system

Complaints received by inspections agencies are an important source of information that can be leveraged jointly with other data sources to inform the inspectorates' risk assessments. The primary use of complaints in a risk-based inspection system is as a source of risk analysis, rather than as a key driver of inspection planning.

As discussed in Guide 1 on risk assessment and risk planning methodology, risk assessments should be developed based on risk factors for targeting. Similarly, when receiving complaints or other information, risk-based criteria should be employed to determine whether to conduct reactive inspections, including the reliability or credibility of the information, the seriousness of the risk outlined in the complaint, and the past track record of the establishment or product (previous complaints), among others.

A systematic response (one complaint, one inspection) should not be pursued as a strategy, and reactive measures such as investigations¹⁰ or inspections should remain in the minority compared to proactive inspections. Reactive on-site inspections should be maintained for exceptional cases where there is sufficient reason to believe that an imminent danger may be present and an immediate reaction may therefore be warranted. Other types of measures should instead be deployed to replace reactive inspections, manage these complaints with more proportional responses, and maintain the inspectorates' credibility as supervisory and enforcement authorities.

4. Developing a risk-based complaint management system – institutional and policy aspects

The following steps and activities are recommended to initiate and organize the process of developing a risk-based complaint management system.

4.1. Define a complaint

It is necessary to define what constitutes a complaint by providing a description of the source, content, and substance. Inspectorates should aim to establish a harmonized definition to the extent possible. This will help frontline staff to decide whether a concern reported by a complainant is within the inspectorate's mandate or should be rerouted to a more competent authority. For example, each competent authority could adopt a definition of a complaint as follows:

“A complaint is a statement that something is wrong or unsatisfactory in relation to an economic activity, that is sufficiently specific to enable identification of the issue, and that has caused or has the potential to cause significant harm to the public interest, and/or appears to constitute a significant breach of a law for which the enforcing authority to impose compliance.”

¹⁰ An investigation does not necessarily include an on-site inspection. This is consistent with the Law 4512/2018 which provides the option of an on-site inspection or not in Article 140, paragraph 3(c).

4.2. Design a policy on investigating complaints

At the outset, inspectorates need to devise a policy on how to respond to complaints based on the risks they pose to the inspectorate's objectives. This should consist of a policy statement that is made publicly available, ideally through an online resource, to communicate the new overall policy change (from random or systematic inspection based on complaints to a risk-based inspection and complaint management strategy). The policy should make clear that the inspectorate will not investigate each complaint filed by the public through a brief and easily understood, non-technical message on the change of strategy. It should clarify that decisions on whether to investigate will be based on:

- the complaint's relevance to the inspectorate's objectives;
- the complainant's profile (for example, complaints filed by anonymous or serial complainants should be treated as less credible and therefore receive lower priority);
- the substance of the complaint;
- the perceived risks to the inspectorate's regulatory objectives; and
- the availability of resources.

This can be supported by a one-page colored guidance sheet for the public on when and how to submit a good complaint.

The policy should also clarify any potential secondary usage of complaints, which may include research, compilation of statistical data, and reports.

4.3. Identify all possible complaint sources

Given that complaints are a source of intelligence, the inspectorates should cast a wide net to enable everyone to access the complaint mechanism as needed. Every natural and legal person shall have the right to file a complaint with the inspectorates, be it a consumer, a current or former employee, another industry, or any member of the public. This right extends to all entities in public administration, including central and local authorities, legal entities of public law, and legal entities of private law.

Complaints can be signed or anonymous and filed in a variety of forms, including electronically (by email or through a dedicated complaint platform), in writing (by mail, by filing a report in hard copy, or via fax), over the phone through a dedicated service number, or in person. The authorities must encourage the electronic submission of complaints in order to manage them more effectively and quickly.

Finally, information on violations that may pose risks to the inspectorate's regulatory objectives may come to the inspectorate's attention through channels other than the traditional channels of complaint management. For example, information in the media (paper, internet, social networks) or information from other government institutions may come to the inspectorate's attention without being submitted as a complaint. In some cases, this information may not even be communicated as a violation per se, but a skilled professional inspector may be able to recognize the risks involved. To that end, inspectorates should treat any information that comes to their attention from

any source according to the same process applied to complaints received through the regular, formal channels. It is important to note that not every piece of information in the media can be treated with the same importance as a complaint, and inspectorates should not be expected to proactively track every piece of news. At the same time, inspectorates should incorporate a proactive approach to complaint management, whereby staff is expected to acknowledge and act on publicly available information that may pose risks to their regulatory objectives, even if this information is not provided as a formal complaint.

4.4. Assign roles and responsibilities

Depending on the regulatory area and the department's location, handling complaints can be a time-consuming and labor-intensive task. Additionally, there is an opportunity cost to assigning expert inspectors to the frontlines of complaint management, since these inspectors will have to shift their time from regular control activities, thus leaving high-risk facilities with a suboptimal level of control. Consideration must therefore be given to how to allocate human resources to better manage this task. For example, the United Kingdom's Health and Safety Executive (HSE) has delegated this task to designated complaints officers who are tasked with recording and investigating complaints. Inspectors are involved only when a complaint requires investigation.

Consistent with good risk management practices, inspectorates in Greece should consider delegating this task to designated "Tier 1" and "Tier 2" staff who will be acting as complaints officers in this area. By compartmentalizing this task, designated complaints officers can filter complaints and only escalate those that are deemed to be high-risk and require an immediate follow-up investigation. This could be facilitated either by introducing a dedicated central unit to receive all complaints for each field/inspection domain (such as public health, environmental protection, technical safety, occupational health and safety, and so on), or by introducing this function separately for each inspectorate.

Moreover, clear protocols must be established regarding the hierarchy of decision making. Recording of the complaint and less complex decisions, such as archiving a complaint if it is not substantiated, should be delegated to less senior staff (Tier 1), while more complex decisions should be handled by more senior staff (Tier 2). Tier 2 staff would, for example, decide whether to investigate a complaint based on objective pre-set criteria or to make further inquiries about the complaint, even if the complaint meets the criteria for investigation based on the risk analysis, essentially triggering a follow-up with the complainant or other data collection before deciding to allocate resources for investigation. Moreover, some matters may not fall clearly within the purview of a single inspectorate, and joint action may be required among multiple inspectorates. The decision on whether to redirect the complaint to another department within the inspectorate, or to another inspectorate, should be taken by Tier 2 staff.

5. Developing a risk-based complaint management system – operational aspects

5.1. Design Standard Operating Procedures for complaint management

A robust complaint management system requires implementation of Standard Operating Procedures (SOPs) to ensure a coherent approach to handling complaints. This activity can be supported by developing process maps with decision trees to guide staff on how to manage complaints. These can be illustrated through procedural charts to guide staff in the inspectorates on the separate stages of the complaint management procedure—starting from submission, recording, and initial review by a Tier 1 officer; then moving to the decision taken by a Tier 2 officer, the action taken, and the enforcement decision.

For example, the complaints officer must decide whether the claim satisfies the description/definition of a complaint, as defined in 4.1 above, and whether it falls within the mandate and jurisdiction of his or her inspectorate. If not, the complaints officer must be provided with clear guidance on how to respond. At a minimum, complaints officers should obtain the full details of the complaint and, if possible, details about the complainant. See Annexes 3 and 4 for two examples on SOPs for complaint recording.

Moreover, following receipt of the complaint, the complaints officer should be required, at a minimum, to provide confirmation of receipt and a ticket number and indicate that the complaint was received, that it will be taken into account in the planning of inspections, and that all other legally foreseen actions will be followed as applicable. It is proposed that the authorities adopt a common standardized text in response to the submission of complaints.

If the matter satisfies the definition for a complaint but falls within the mandate of another department/division within the inspectorate, or within the mandate of a different inspectorate, complaints officers shall pass the complaint to the competent authority and inform the complainant accordingly.

A performance standard must be set for this decision. When the complainant reports an issue and there is a patent risk that inaction will result in serious injury, the complaints officer must be required to decide immediately and route the complaint to the competent authority with no delay. If the reported issue does not imply a risk of serious injury, the complaints officer must be required to decide as soon as possible from the moment of receiving the complaint.

5.2. Draft the complaint record form

If the claim satisfies the definition of a complaint and falls within the scope of the inspectorate's mandate, clear instructions must be established on how to properly document it. Complaints officers must be required to fill out a standardized complaint recording form to document all complaints. The form must capture information about:

- a) the complainant (where possible);
- b) the dutyholder for whom the complaint is filed; and
- c) the substance of the complaint (Box 1).

- Registration record number and name of frontline staff member recording the case;
- Date and time of filing the complaint;
- Mode of filing the complaint (such as phone, email, mail, fax, dedicated website, in person/face-to-face);
- Information about the complainant (to the extent possible);
 - o Anonymous or
 - o Full name;
 - o Identification number;
 - o Address;
 - o Contact information (telephone number(s), email);
 - o Status (i.e. current/former employee, customer, member of general public, economic operator, other government agency);
- Information on whether this is a first-time or repeat complainant;
- Date and time of the alleged violation (for example, the date and time that a product was consumed);
- Nature of/reason for the complaint (including symptoms of illness/injuries, if relevant)
- Supporting evidence, if available (such as photographs capturing the alleged violation, documentation proving hospital treatment due to alleged violation, or remainder of product sample);
- Relevant information about the specific product or service, including whether it is an imported or domestic product and the point of sale (such as a retailer, manufacturer, importer, distributor, or other);
- Relevant information about the economic operator;
 - o Trade name;
 - o Address;
- Relevant information about the establishment/facility, if applicable;
 - o Company name;
 - o Address.

Box 1: Required information in complaint recording form

Annex 1 includes an example of a complaint recording form for food safety. Similar complaint recording forms must be developed for each inspectorate, depending on the relevant risk-related factors for each regulatory area.

As soon as this information is filled out, and until a full transition to an electronic complaint reporting system materializes, the complaints officer should file the complaint recording form in a complaints log. The complaints officer will now be in a position to aggregate the answers into a risk score. The aggregate risk score will help to determine the risk categorization on the risk matrix (Section 5.3).

Complaints officers will not be required to respond individually to each complainant unless otherwise specified in specialized legislation governing the specific supervision domain.

5.3. Develop and assign risk scores to the information submitted and classify complaints using a risk matrix

The information submitted by the complainant constitutes a raw version of the incident/alleged violation and should be reviewed under the lens of the criteria stipulated in paragraph 2, art. 140, Law 4512/2018:

- a) compatibility with the scope of the supervisory authority's competence;
- b) their presumably unfounded or unsubstantiated content;
- c) submission of the necessary data to allow for an on-site inspection or survey to be carried out;
- d) the principal assessment that the report constitutes a violation of legislation;
- e) the extent to which the incident is repeated;
- f) the time that has elapsed since discovery of the problem;
- g) assessment of the degree of risk regarding the direct or indirect effects on the public, or another aspect of the public interest;
- h) the group of consumers who are exposed to danger, and possible use by vulnerable groups;
- i) taking into account the results of the testing of a sample supplied; and
- j) their credibility when they arise from repeated submission by the same complainant without having demonstrated their accuracy during previous inspections.

The risk assessment and classification of the complaint should take place as follows:

- a) The complaints officer (Tier 1) initially determines whether the complaint falls within the remit of the inspectorate. If not, the complaint shall be referred to a Tier 2 complaints officer and then be redirected to the competent supervisory authority. If the complaint is relevant, the Tier 1 officer shall decide whether to refer the complaint to a Tier 2 complaints officer or archive the complaint. Archiving by Tier 1 officers should apply only when:
 - i) the complaint does not qualify as such based on the definition, and
 - ii) the complaint is manifestly unsubstantiated based on the above criteria.
- b) If the complaint is escalated, a Tier 2 complaints officer should evaluate the significance of the submitted information vis-à-vis the criteria above and exercise discretion and professional judgment to classify the complaint into the appropriate risk category. To facilitate the complaints officer's work, specific fields/answers should be assigned a score. A low score (such as 0 or 1) can be assigned to answers that indicate low risk to the achievement of the inspectorate's objectives. A higher score (such as 2 or 3) can be assigned to answers that indicate a medium or high risk to the realization of the inspectorate's objectives. Given that the risk assessment that is initially performed to plan inspections will have teased out the most significant risk factors in each regulatory area, these can be leveraged for this exercise as well.

In cases where the inspectorate allows complainants to file their complaints online through a dedicated website, the risk score allocation could be embedded in the online form. Annex 2 provides an example of an electronic consumer complaint form used by the United States Department of Agriculture (Food Safety and Inspection Service).

The total score of the complaint will classify the complaint into the appropriate risk category. Consistent with the risk matrices developed for proactive inspection planning and targeting, the risk matrix for the initial risk categorization of complaints must refer to both the likelihood of the adverse event and the expected severity of harm if the event materializes. The intersection of

these variables will determine the total risk score for each recorded complaint. Each category of the risk matrix can correspond to an initial decision regarding the complaint.

The risk matrix below, developed by the HSE, is an example of how the degree of harm (which, in this context, reflects injury risk in the workplace), the expected impact (multiple or single/low), and the likelihood of the event can be reflected on a risk matrix.

k Based Approach - Risk Model (initial Decision Matrix)

| | | | | |
|--|----------|----------|--------|----------------|
| Multiple | Red | Red | Red | Amber |
| Single or low | Red | Red | Amber | Amber |
| Multiple | Red | Amber | Amber | Green |
| Single or low | Amber | Amber | Green | Green |
| Multiple | Amber | Green | Green | Green |
| Single or low | Green | Green | Green | Green |
| Number of possible casualties at one time | Probable | Possible | Remote | Nil/negligible |

Possible injury risk/ possible health risk

Serious Personal Injury (fatal or major) or Serious Health Effect (permanent, progressive or permanently disabling)

Significant Injury (RIDDOR reportable) or Significant Health Effect (non-permanent, reversible or non-progressive condition, or temporary disability)

Minor injury (non-RIDDOR, first-aid only) or Minor Health Effect (conditions not included above)

Colour key

Red = follow up complaint as a priority

Amber = follow up complaint

Green= do not follow up complaint

Box 2: United Kingdom's HSE risk matrix to categorize complaints and potential follow-up actions

5.4. Use existing information to strengthen the initial decision-making process

The initial decision risk matrix is a valuable tool that helps the complaints officer make an initial assessment based on the information received by the complainant. This information can be combined with the inspectorate's own intelligence regarding, for example, the compliance history of the specific economic operator/establishment or additional complaints about the same operator/establishment and, if possible, with the intelligence of other inspectorates as well. By leveraging the inspectorates' own intelligence, complaints officers can make a more informed assessment of the complaint and decide on the most appropriate follow-up action.

If the complaint is considered to be an isolated case and the decision on the follow-up action is made exclusively based on the initial decision risk matrix, the complaints officer would miss an important perspective. The lens of the inspectorate is therefore a valuable resource when classifying a complaint. Annex 5 contains an example of a flowchart used by HSE in the United Kingdom to combine the information resulting from the complaint with existing information within the inspectorate as a final step before determining the most appropriate follow-up action.

5.5. Develop SOPs to define follow-up actions based on the initial decision matrix and filters

The final risk classification assigned to the complaint, following application of the initial decision risk matrix and the filters, will determine the appropriate follow-up action, as stipulated in paragraph 3, art. 140, Law 4512/2018. The options provided by the law must be clearly linked to each risk class:

- Pursuant to art. 140(3)(a), low-risk (green channel) complaints should be archived, rerouted to the appropriate inspectorate, or recorded and incorporated in regular inspections planning activities following confirmation by a Tier 2 officer.
- Pursuant to art. 140(3)(b), medium-risk complaints (orange channel) should be recorded and incorporated in inspection planning activities or trigger an investigation with low priority.
- Pursuant to art. 140(3)(c), high-risk complaints (red channel) should be recorded and incorporated in inspection planning activities and trigger an urgent investigation, which may include an on-site inspection. It is recommended to set a time limit for follow-up, to ensure that these complaints are consistently managed within a mandated time frame. The high-risk class could be further split into two brackets, and this would need to be reflected in the SOP. One bracket would include complaints that must be treated with the highest priority and require an immediate investigation within 24 hours of receipt. A second bracket would trigger an investigation but without being prioritized, which could take place, for example, in 10 days or even more.

In cases where an inspection is conducted as a result of a complaint, the appropriate enforcement response will be selected depending on the inspection outcome (see Guide 4 on the Enforcement Management Model).

5.6. Review the Complaint Management System

Complaint management can be further strengthened by introducing and publishing a periodic and systematic analysis of received complaints. This could consist of an annual review whereby complaints are disaggregated by indicator, such as complaint type, industry, product, sources/credibility, positive/negative outcomes, actual harm related to a complaint, date and time of reported violations, and others. This analysis would allow for summary statistics on the complaints submitted in each year to enhance the transparency of the system. The analysis could also help senior management at the inspectorates and line ministries gain perspective by offering a bird's eye view of the complaint management system. In aggregating key indicators, this type of analysis could reveal patterns that point to the need for a calibration in the inspectorate's strategy, either in inspection planning or complaint management. For example, analysis may reveal a systemic problem in a subsector or product that would not have been easy to identify based on a case-by-case complaint review. Finally, this analytical exercise could help to address regional variation in inspection strategies and implementation by improving coherence across regional units.

Annex

Annex 1: Example of a complaint form in the food safety domain, including an assigned risk rating for each data point collected

| Jurisdiction on the complaint | YES | NO |
|--|-------------------------------------|---------------|
| Applicant | | |
| Anonymous | YES / 0 | NO / 1 |
| Repeat Applicant | YES / 0 | NO / 1 |
| Earlier complaint from the same complainant has been confirmed | YES / 1 | NO / 0 |
| Subject of the complaint | | |
| Product requires special storage | YES / 1 | NO / 0 |
| Product in its original packaging | YES / 0 | NO / 1 |
| Perishable product with a 48-hour life | YES / 0 | NO / 1 |
| Product with damage in its original packaging | YES / 0 | NO / 1 |
| There is likelihood that several people will be contaminated | YES / 1 | NO / 0 |
| Reason for the complaint | | |
| Microbiological contamination/poisoning | <i>Alert inspectors immediately</i> | |
| Microbiological contamination/mold | YES / 2 | NO / 0 |
| Physical/chemical contamination | YES / 2 | NO / 0 |
| Product with damage in its original packaging | YES / 1 | NO / 0 |
| Labeling | YES / 1 | NO / 0 |
| Expired product | YES / 1 | NO / 0 |
| Damaged packaging | YES / 1 | NO / 0 |
| Facility linked with the complaint | | |
| Poor hygiene conditions | YES / 4 | NO / 0 |
| Rude personnel | YES / 1 | NO / 0 |
| Any type of damage in the facility can have an adverse impact on the food (the food will go bad) | YES / 2 | NO / 0 |
| Jeopardizing the environment with noise pollution or poor hygiene | YES / 1 | NO / 0 |
| History of the facility | YES / 2 | NO / 0 |
| Scope | | |
| General application for more objects/facilities | YES / 1 | NO / 0 |
| Likelihood that irregularity will occur with more than one product | YES / 2 | NO / 0 |
| This product will be distributed locally | YES / 1 | NO / 0 |
| Measures | | Rating |
| Urgent Treatment | More than 16 | Critical |
| Priority Treatment | From 11 to 15 | High |
| Include into the short-term plan | From 9 to 10 | Medium |
| Plan the control within the regular monitoring period | From 6 to 8 | Low |
| No control/inform the party | From 1 to 5 | Unknown |

Annex 2: The Electronic Consumer Complaint Reporting Form of the United States Department of Agriculture (Food Safety and Inspection Service)

The website¹¹ has skip logic¹² features to filter out requests that are not relevant to the Food Safety and Inspection Service. For example, complainants are prompted to answer two pre-qualifying questions before they can file their complaint. If the complaint relates to a food safety issue that is not linked to specific product categories, for example, complainants are not allowed to file their complaint. Instead they are prompted to contact the appropriate agency. For instance, if the complaint relates to food safety in a food establishment (such as a restaurant) complainants are prompted to call the Health Department in their city, county, or state.

Welcome to the FSIS Electronic Consumer Complaint Reporting Form. FSIS identifies a complaint as an incident that involves reports of illness, injury, foreign objects, contamination (including chemical contamination), allergic reactions, and improper labeling which is believed to be associated with or caused by consumption of meat, poultry or processed egg products. The information you are able to provide in this form will help to support FSIS analysts in their ability to identify and respond to consumer food safety issues.

Disclaimers and notices:

- If you are a minor (under 18 years of age) please seek the advice of an adult before submitting any complaint.
- Personal information, although optional, may be captured on the following form. Please be aware of our [Privacy Policy](#) before proceeding.
- To speak with someone directly, call the USDA Meat and Poultry Hotline at 1-888-MPHotline (1-888-674-6854). The Hotline is staffed by food safety experts weekdays from 10 a.m. to 4 p.m. Eastern time.

Please answer these pre-qualifying questions:

Is your complaint related to food safety? yes no

Does your complaint relate to meat, poultry or processed egg products? yes no

[Next](#)

If the complaint falls under the mandate and jurisdiction of the Food Safety and Inspection Service, the complainant is prompted to fill out the following six forms.

Step 1 of 6 Nature Of Complaint

Nature of complaint*:
(check all that apply)

- Allergic Reaction
 Illness
 Foreign Object
 Misbranding / Mislabeled
 Injury
 Off Taste/Off Color/Off Appear
 Other (Please Specify)

Please indicate the type(s) of complaint

[Next](#)

¹¹ Available at: <https://ccms.fsis.usda.gov/ECCF/Index.aspx>

¹² Skip logic is a feature that changes what question or page a respondent sees next, based on how they answer the current question. Also known as "conditional branching" or "branch logic," skip logic creates a custom path through the survey that varies based on a respondent's answers.

Step 2 of 6
Identification Of Product

| | | |
|---------------------------------------|----------------------|---|
| Product Name*: (e.g., ground beef) | <input type="text"/> | Please enter the product name |
| Brand Name: | <input type="text"/> | Please enter the product brand name |
| Size And Package Type: | <input type="text"/> | Please enter a description of the packaging |
| Can/Package Codes: | <input type="text"/> | Please enter any codes or numbers on the packaging |
| Sell/Use By Date: | <input type="text"/> | Please enter the sell by or use by dates on the packaging |
| Establishment Number: | <input type="text"/> | Please enter an establishment (EST) number if known. |

[Previous](#) [Next](#)

Step 3 of 6
Name And Location Of Store Where Purchased

| | | |
|--------------------------|---|---------------------------------|
| Purchase Store Name: | <input type="text"/> | Please enter the store name |
| Purchase Store Address: | <input type="text"/> | Please enter the store address |
| Purchase Store City: | <input type="text"/> | Please enter the store city |
| Purchase Store State: | <input type="text" value="Select State"/> | Please enter the store state |
| Purchase Store ZIP Code: | <input type="text"/> | Please enter the store ZIP Code |

Example: 20024

[Previous](#) [Next](#)

Step 4 of 6
Product Usage

| | | |
|------------------------------------|--|---|
| Date Purchased: | <input type="text"/> | Please enter date purchased |
| Product Used: | <input type="radio"/> Yes <input type="radio"/> No | Please indicate if the product has been used |
| Incident Date*: | <input type="text"/> | The date when problem was discovered or experienced (i.e. date when illness started or the date a foreign object was found) |
| Do you have any product remaining: | <input type="radio"/> Yes <input type="radio"/> No | Please indicate if any product remaining |

[Previous](#) [Next](#)

Step 5 of 6
Illness/Injury Details

Injury or
Illness Resulted:

Yes No

Please indicate if any
illness or injury
resulted

Type of
Injury or Illness:

Please describe any
injury

Did you visit
your regular doctor:

Yes No

Please indicate if you
visited your doctor

Hospitalization Required:

Yes No

Please indicate if
hospitalization was
required

Doctor:

Please enter the
doctor's name

Hospital:

Please enter hospital
name

City:

Please enter
the hospital city

Symptom Types:

| Symptom | Onset | Comments |
|------------------------------|---------------|----------|
| Pain - Abdominal | 0-3 Hours ▼ | |
| Blistering | 3-8 Hours ▼ | |
| Sputum - Blood In | 8-24 Hours ▼ | |
| Stool - Blood In | 24-72 Hours ▼ | |
| Blue Lips | 72+ Hours ▼ | |
| Broken tooth | Unknown ▼ | |
| Choking | ▼ | |
| Constipation | ▼ | |
| Diarrhea | ▼ | |
| Diarrhea - Watery | ▼ | |
| Diarrhea - Blood In | ▼ | |
| Diarrhea - Mucus | ▼ | |
| Difficulty breathing | ▼ | |
| Dizzy/fainting | ▼ | |
| Fever | ▼ | |
| Headache | ▼ | |
| Laceration | ▼ | |
| Pain - Muscle | ▼ | |
| Muscle weakness | ▼ | |
| Nausea | ▼ | |
| Numbness | ▼ | |
| Rash | ▼ | |
| Swelling | ▼ | |
| Taste - Salty | ▼ | |
| Taste - Metallic | ▼ | |
| Vision - Impaired or Blurred | ▼ | |
| Vomiting | ▼ | |
| Vomiting - Blue or Green | ▼ | |
| Vomiting - Blood In | ▼ | |
| Other | ▼ | |

Please select any
applicable symptoms,
the amount of time it
took for symptoms to
start after eating
product, and any
additional comments.

Additional
Comments:

Please enter any
additional comments

Step 6 of 6**Personal Information** See [Privacy Policy](#)

| | | |
|--|---|---|
| First Name: | <input type="text"/> | Please enter your first name |
| Last Name: | <input type="text"/> | Please enter your last name |
| Telephone Number (Home): <i>Example: 408-555-1212</i> | <input type="text"/> | Please enter your home telephone number |
| Telephone Number (Work): <i>Example: 408-555-1212</i> | <input type="text"/> | Please enter your work phone number |
| Address: <i>(Street, P.O. Box, etc.)</i> | <input type="text"/> | Please enter your street address |
| City: | <input type="text"/> | Please enter your city |
| State*: | <input type="text" value="Select State"/> ▾ | Please enter your state |
| ZIP Code: <i>Example: 20024</i> | <input type="text"/> | Please enter your ZIP Code |
| E-mail address: | <input type="text"/> | Please enter your e-mail address |

[Previous](#) [Finish](#)

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0583-0133. The time required to complete this information collection is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

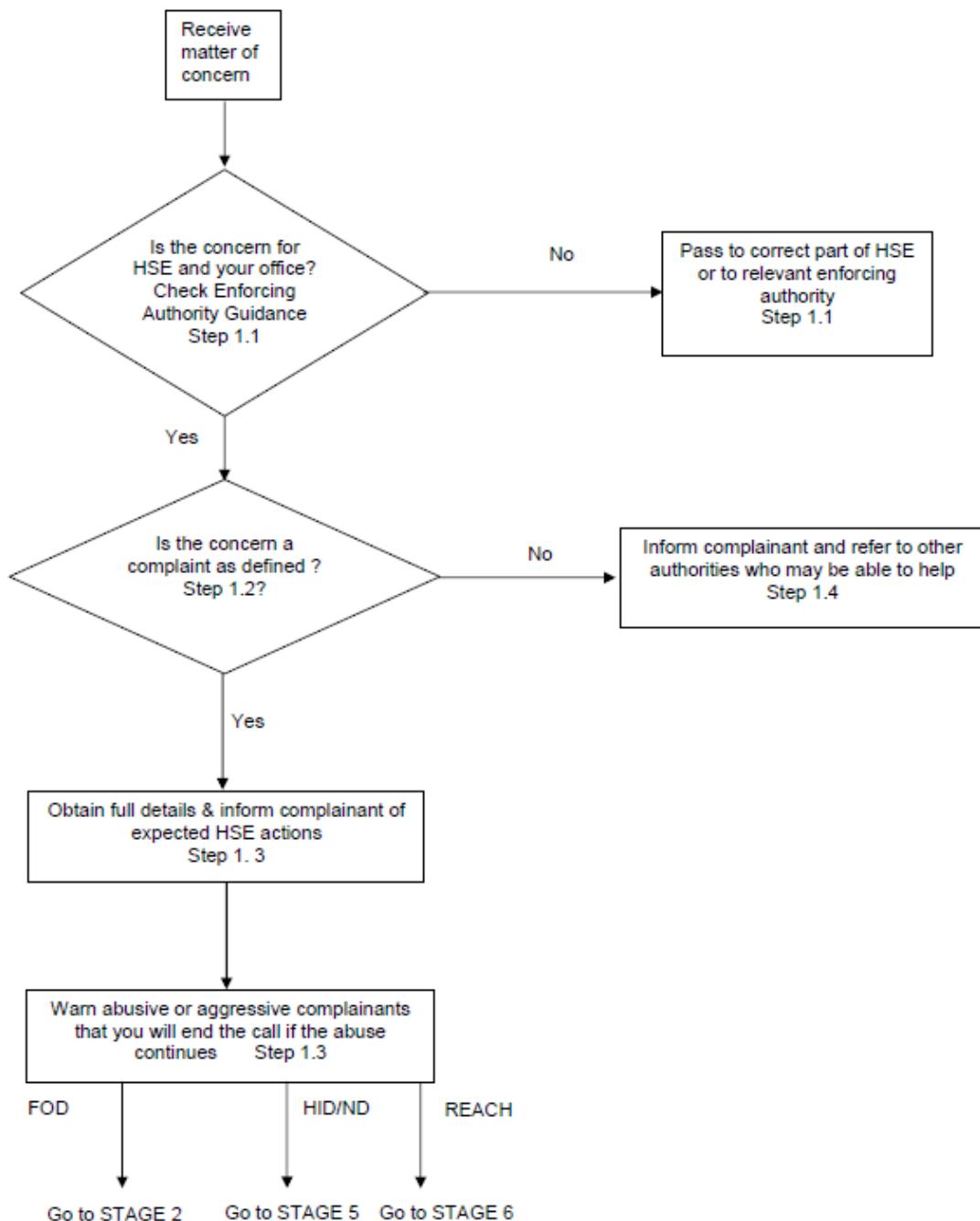
Annex 3: Example of a decision tree upon receipt of the complaint



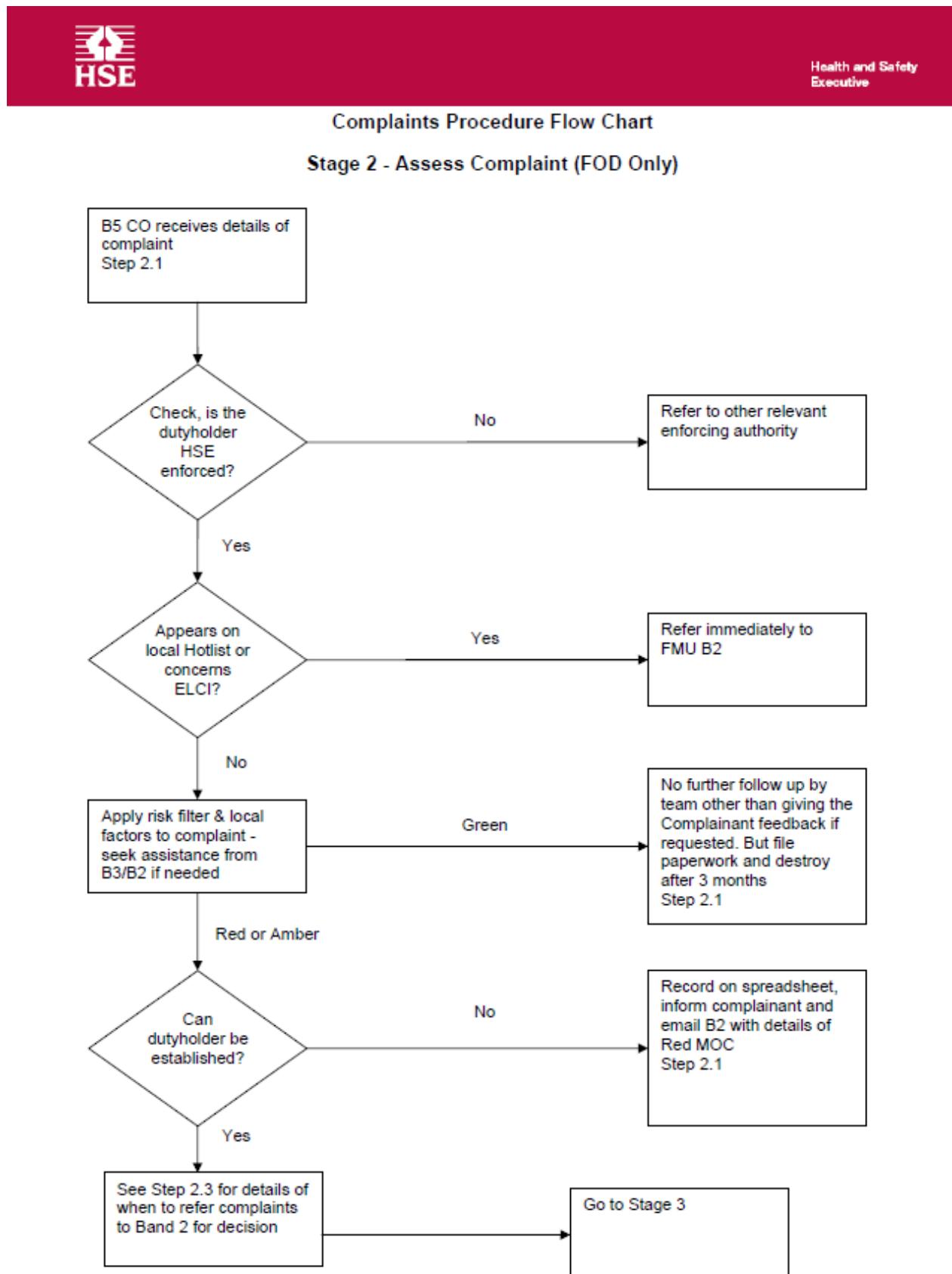
Health and Safety
Executive

Complaints procedure flow chart

Stage 1 - Receive a concern

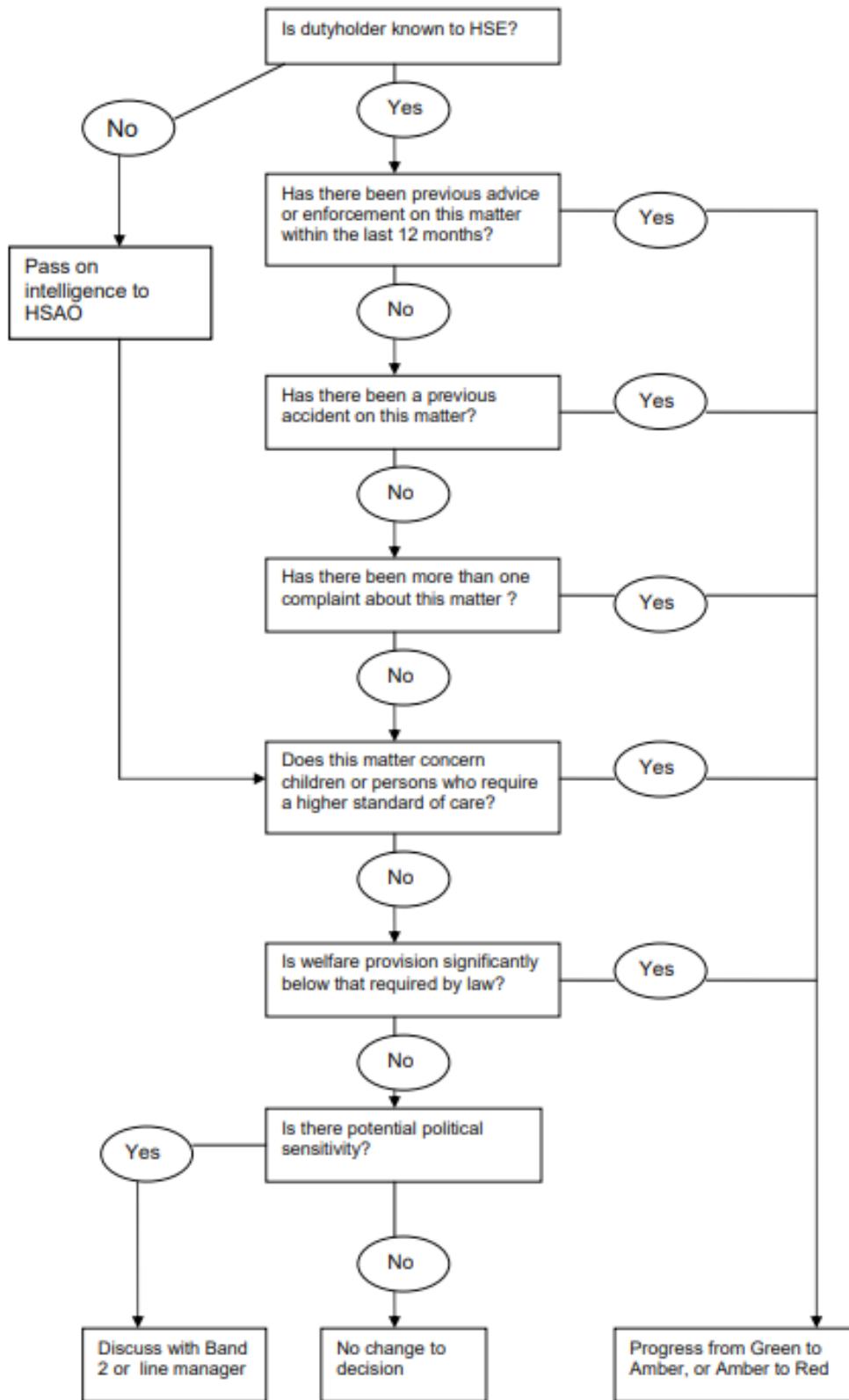


Annex 4: Example on a complaints procedure flow chart



Annex 5: Example of a flowchart that draws on existing information of the inspectorate

Risk Based approach - Local factors



If the answer to any of the questions is “yes,” except for the first question, then the risk rating is escalated, for example from green to amber/orange or amber/orange to red. In this context, welfare complaints, which are not assessed using the risk matrix, should be considered under this filter, which asks whether welfare provision significantly below that required by law. Complaints officers are required to whether if there is a denial of basic employee welfare facilities.

For complaints where there may be political sensitivity, the case should be discussed with a Tier 2 officer. Examples include all conventional health and safety issues at nuclear sites, or issues raised by elected members of local or central government.

GUIDE 5

Development of Guidance to Businesses

Contents

- pg. 107 1. Purpose and scope of the guide**
- pg. 108 2. How to decide on the content of the guide**
- pg. 111 3. Governing principles for the content of the guide**
- pg. 112 4. How to organize the development of the guide**
- pg. 113 5. The “secrets” of good guidance**
- pg. 114 6. Good practice in guidance**
- pg. 117 7. Conclusions**
- pg. 118 References**

1. Purpose and scope of the guide

This guide for development of guidance to businesses is completing the new supervisory tools prepared in accordance with the new institutional framework (art. 136 of Law 4512/2018). The new supervision and inspection model, through the tools presented—risk assessment, checklists, the Enforcement Management Model, the complaint management system, and guidance to businesses—creates an innovative framework with aim to achieve mutual benefits for supervisory authorities and businesses.

The existing institutional; framework of Inspection mechanisms is changing and requires a smooth transition and mutual adjustment on the part of concerned parties (supervisory authorities and businesses). The main changes concerned new principles, a set of operations and actions that constitute the supervision process (Table 1), strengthening the compliance.

The supervisory bodies (art. 142) acquire a new role, enabling them to provide necessary information and advice to businesses on various issues, as laid out in Table 1:

| | | |
|--|--|--|
| Legal requirements for compliance and how to interpret them | The compliance and risk assesment procedures, including information and guidelines for compliance relating to legal obligations | Means and communication procedures with the authorities |
| Provide information and guidelines for compliance | Conducting inspections, inclouding the programs of audit items, checklists and process | Action in the event of infringements |
| Complaints procedure | | Remedies that the subject of inspections may act on |
| | | |

Table 1: The supervision proces

The main purpose of this guide is to:

- transmit to the supervisory authorities the basic principles to be followed when provide guidance to businesses, with the aim of achieving effective implementation of the new supervisory framework;
- form a unified and standardized process used by inspectors for mentoring businesses based on defined principles and methodology;
- develop an the appropriate information among the relevant parties on the need for supporting guidance to businesses;
- contribute to the dissemination and diffusion of best practices.

- serve as a key tool for communication between supervision authorities and businesses, with the aim of better implementing legislative requirements and enhancing business compliance.

The guide provides broad outlines of conformity in the new framework, with a dual purpose: (a) to inform businesses about new oversight arrangements; and (b) to mediate between supervisory authorities and businesses by establishing an information and learning process in which businesses acquire the necessary information and skills to meet compliance in their daily practice.

To build this channel of communication between supervisors and businesses, it is appropriate to understand the basic types of non-compliance: unintentional non-compliance, escalating non-compliance due to complexity, and intentional non-compliance.



Figure 1: The dual purpose of guidance to businesses and three types of non-compliance

The supervisory authorities, through proper guidance and information, will play a key role in consolidating trust between businesses and the state. With clearly defined rights and obligations, the two sides will be able to work together to build a modern governance model that will support consistency, legality, compliance, and, ultimately, the proper functioning of the market.

2. How to decide on the content of the guide

Before starting to develop the guidance to businesses, a key question is how to decide its content and the scope of information to be covered. Businesses will have different compliance requirements depending on the type of economic activity carried out and the sector to which they belong. As a result, they will need different guidance.

As supervisory authorities inspect more than one object or different areas of oversight, it is important to be able to prioritize information by taking into account certain parameters.

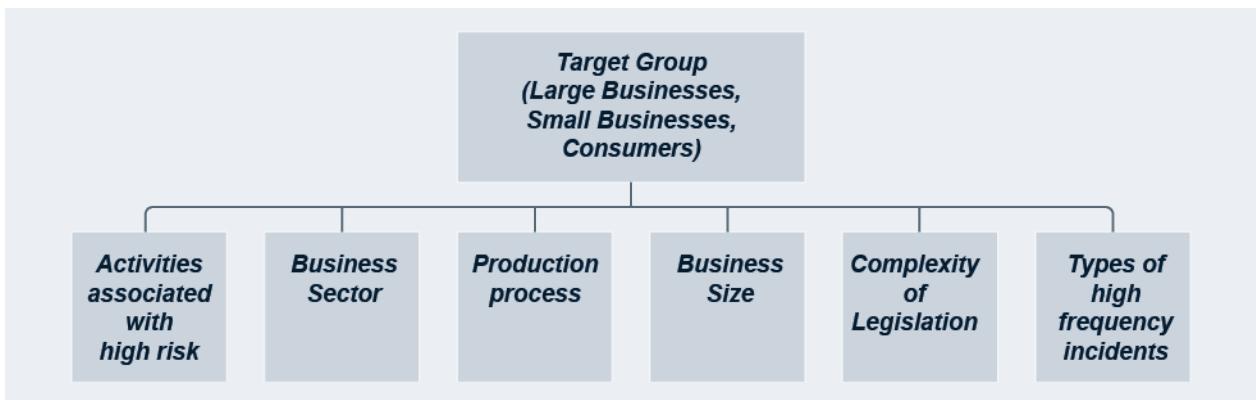


Figure 2: Key parameters in prioritizing guidance to businesses

In determining the content of the guide, the authority should first decide which compliance needs and individual objectives should be strengthened. The first step is to define the target group to which the guide is addressed (for example, large enterprises, small businesses, or consumers).

Key criteria that can guide the supervisory authorities in better targeting the appropriate information to the right businesses can be summarized as follows:

- a) High risk:** activities that pose high risks for important aspects of public interest, such as health, safety, and the environment; and those that could potentially endanger important groups of the population (employees, for example).
- b) Business sector approach:** specific business sectors are often required to comply with requirements that address high risks (for example, the chemical industry).
- c) Production process:** the production process following specific business categories (such as food enterprises) is recommended at individual stages, each of which have different compliance requirements (including the receipt and storage of raw materials, production, packing/repacking, and storage).
- d) Legislation:** Legislation often specifies compliance requirements, but may be characterized either by complexity or a lack of clarity.
- e) Business size:** Business size is inevitably associated with the range of consumers with whom the business interacts and the infrastructure/resources upon which it can draw to meet compliance requirements.
- f) High frequency of specific infringements:** The most frequent infringements detected by the supervision authority are set in priority in order to achieve prevention and enforce compliance towards them.

Following the above, the supervisory authority should take into account the cognitive understanding and professional status of the specific reader, as guidelines would be written differently if they are supposed to be read by a manager for a plant security manager, a worker, a business owner, and so on.

The example followed by the Ohio Environmental Protection Agency's oversight authority reflects the structure of the relevant guidance content to help small businesses understand and comply with environmental requirements.

Ohio EPA Self-Assessment Guide

Table of Contents

| | |
|---|----|
| General Information and Instructions | 2 |
| General Facility Information | 4 |
| Water Pollution Control and Drinking Water | 5 |
| Air Pollution Control..... | 9 |
| Solid, Hazardous and Infectious Waste | 11 |
| Spill Prevention Control and Countermeasure Plans | 16 |
| Emergency Planning and Community Right-To-Know..... | 18 |
| PCBs and Other Toxic Substances..... | 21 |
| Appendix A — Industries That Require an NPDES Permit for Storm Water Discharges..... | 23 |
| Appendix B — Common Small Business Air Emission Sources/Activities..... | 24 |
| Appendix C — De Minimis Air Contaminant Source Exemption Ohio Administrative Code 3745-15-05..... | 25 |
| Appendix D — Air Permit Exemptions Ohio Administrative Code 3745-31-03..... | 26 |
| Appendix E — Common Hazardous Wastes Generated by Small Businesses..... | 30 |
| Appendix F — List of Extremely Hazardous Substances Ohio Administrative Code 3750-20-30..... | 32 |
| Appendix G — Identifying PCBs..... | 41 |
| Appendix H — Environmental Resources for Businesses..... | 42 |
| Appendix I — Common Environmental Terms..... | 43 |

Ohio EPA Self-Assessment Guide



Air Pollution Control

Division of Environmental and Financial Assistance

| General Requirements | | | (If you answer a box highlighted in gray, this indicates that a potential problem exists.) | | |
|---|--------------------------|--------------------------|--|-----|----|
| 1) Has your business identified its air emission sources? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Yes | No |
| <i>Note: Units or activities that discharge air pollutants (for example, fumes, dust and gases) to the atmosphere are called air emission sources. Common air emission sources/activities are identified in Appendix B.</i> | | | | | |
| 2) Do any of your business's air emission sources fit within any of the exemptions from Ohio EPA's air permit requirements? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Yes | No |
| <i>Note: See information in Appendices C and D for air permit exemptions.</i> | | | | | |
| 3) For air emission units/activities that do not meet the exemptions described in question 2, has your business obtained a permit-to-install and operate (PTIO) from Ohio EPA's Division of Air Pollution Control? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Yes | No |
| 4) Are your business's air permits up-to-date? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Yes | No |
| (a) If your business has an up-to-date permit or permit-by-rule , do you monitor compliance with the conditions of these permits? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Yes | No |
| <i>Note: Under your permit, you may be required to keep or submit certain records to Ohio EPA. It is very important that you read and understand your permit conditions. If you cannot find your permit, contact your Ohio EPA District Office or local air agency.</i> | | | | | |
| 5) Is your business planning any construction activity that will result in an increase in the amount of air pollution that might be discharged? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Yes | No |
| (a) If yes, has your business discussed the proposed activities and possible permitting requirements with Ohio EPA before beginning construction? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Yes | No |
| <i>Note: You need to contact your Ohio EPA district office or local air agency about your proposed activities to determine if you need to have a new PTIO, or need to modify your existing permit.</i> | | | | | |
| 6) Does your business have any sources of fugitive air emissions (examples: unpaved roads, storage piles, material handling areas)? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Yes | No |
| (a) If yes, has your business taken measures to either control or obtain an EPA air permit for these emissions? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Yes | No |
| 7) Is your facility undergoing any renovation activities that involves the removal or disturbance of asbestos-containing materials (e.g., insulating material around pipes or equipment, ceiling tiles, floor tiles, plaster) or undergoing demolition of a structure? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Yes | No |
| (a) If yes, is your business aware of the specific EPA air pollution control regulations that apply to asbestos removal/abatement activities? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Yes | No |
| <i>Note: Depending on the nature of the demolition or renovation project, Ohio rules may require an asbestos survey, proper notification, specific work practices and proper disposal of asbestos-containing material. All demolitions at a facility require notification, even if no asbestos is present. The notification requirement is different for facility renovation activities and is dependent upon the amount of regulated asbestos-containing material at the site.</i> | | | | | |
| 8) Does your business burn waste outside in burn barrels, piles, etc.? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Yes | No |
| <i>Note: Ohio's open burning regulations strictly prohibit open burning in most situations. You need to check with your Ohio EPA district office or local air agency to see whether your activities are allowed.</i> | | | | | |

Box 1: Sample guidance table of contents

The supervisory authority, in addition to providing more general information and guidance on the environmental compliance of small businesses, has chosen to include self-compliance checklists on significant environmental topics (such as air pollution control and cleanliness of drinking water). The self-compliance checklists emphasize the critical points and the most important compliance requirements that small businesses have to meet.

Box 2: Sample self-compliance checklist

3. Governing principles for the content of the guide

It is commonly accepted that all businesses benefited when they implement and maintain effective compliance programs. Especially for large companies, such programs make it easier to comply with legal requirements and adapt quickly to changes in the regulatory environment. For this reason, guidance and information focuses mainly on small and medium enterprises, as they are more likely to fail to comply successfully with legal requirements due to structural characteristics, fewer resources, lack of experience, and information deficits. Compliance requirements are often costly (in terms of time and money) for such businesses, as they are forced to hire external experts (such as consultants, engineers, and accountants).

The guidance, through appropriate communication should aim to convince micro, small, and medium enterprises (SMEs) that compliance serves their business interest and can be an advantage. In summarizing the benefits, it becomes clear that compliant businesses avoid legal problems and long term judicial processes, help maintain their reputation, and greatly reduce potential risks and costs. Businesses with a high compliance profile are more attractive to prospective economic partnerships and cooperation opportunities.



Figure 3: Benefits of compliance for SMEs

Particularly important is In this sense, guidance on required compliance activities should focus on ensuring the best possible result.

The guidance provided to businesses should focus on the risks that the specific supervisory authority is trying to limit. Inspectors, as specialists, can focus on the main and most important risks and prioritize the most critical points among all the legal requirements that exist.

The guidance should select, through this classification, companies will be able to know and assess the severity of the infringements in order to deter them.

The effectiveness of the guideline depends on whether it helps businesses understand how to comply with the above requirements. The guidance should give businesses confidence that the advice and information it offers are complete, accurate, and in line with current requirements.

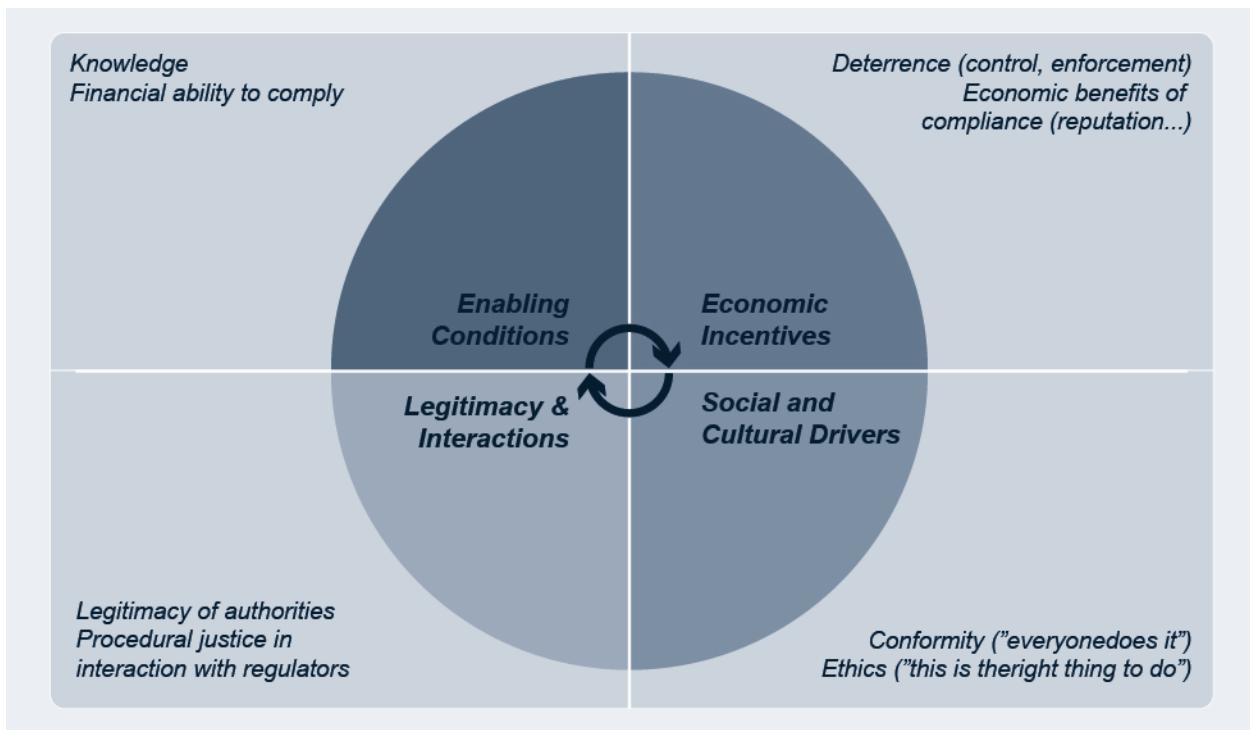


Figure 4: Factors enabling compliance

4. How to organize the development of the guide

Step 1: Set up a working group

A small working group of three to six people must first be set up, with the main task of developing the content of the guide according to the criteria discussed in Section 2. It is important for the working group to include experienced inspectors in the field in order to have an in-depth theoretical and practical background on the process and on failures in business compliance.

Step 2: Prepare the schedule of the working group for writing the contents of the guide

The working group should prepare a schedule that reflects the key points and deadlines associated with the preparation of chapters/sections of the guide.

Step 3: Collection, composition, and configuration of the material

The working group will proceed with the composition of the material that has been collected and will determine the format and size of the guide according to the target group and information needed to meet defined objectives.

Step 4: Consultation with the private sector and business associations

Consultation with the private sector is deemed necessary as the businesses consist the main recipient of the information provided. Feedback is essential for possible amendments and improvements of the content.

Step 5: Regular review of the content of the guide

The working group defines the period during which it is necessary to review and update the content of the guide.

5. The “secrets” of good guidance

The practical application and usability of the guide can be ensured when the guide includes clear principles and instructions.

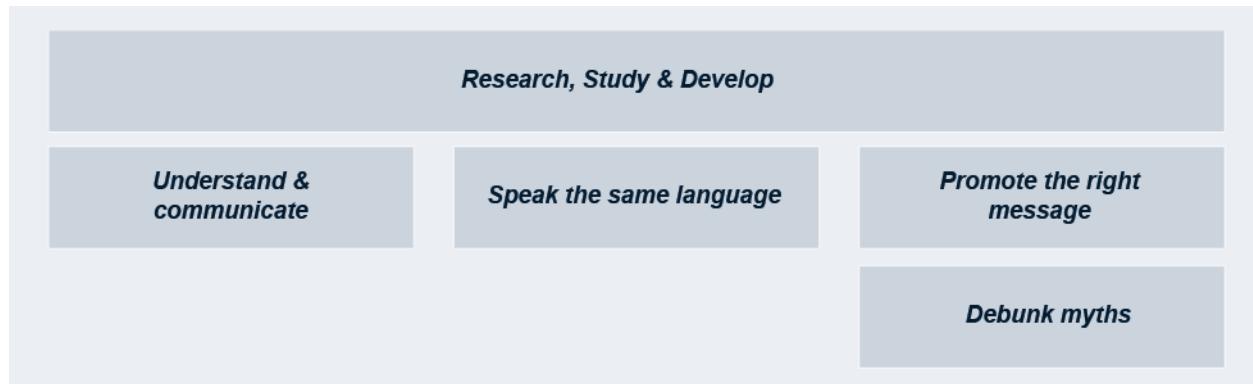


Figure 5: The secrets of good guidance

5.1. Research, study, and plan

Research aims to collect and evaluate input from different sources (auditors, businesses, SMEs, trend analysis, experience). The research supports achievement of the overall goal, which is to strengthen business compliance. The objective and systematic gathering of information helps to focus on the right audience, selecting the right message and focusing on the right actions and compliance decisions.

The results that emerge from the research need to be presented in a manner that is easily understood if it is to influence the businesses to which it is addressed; to change opinions, attitudes, and stereotypes; and to elicit useful feedback.

Only through proper planning will the guidance answer the specific questions of businesses, resolve their problems in a responsive manner, and improve businesses' opportunities to meet daily compliance difficulties.

5.2. Promote the right message

The selected information will need to be presented in a way that meets the needs of the target audience (business community) and, above all, that provides an attractive indicator of the regulator's interest in the company's "interest." The message gains better traction when it is positive, simple, clear, recognizable, unique, and memorable. Excessive use of technical terms and bureaucratic language creates noise in communication and prevents good understanding of recipients.

5.3. Create two-way understanding and communication

Understanding of values, goals, and business culture is a prerequisite for providing the right guidance and tips for resolving problems related to compliance.

5.4. Speak the same language

The chosen communication code creates a common framework that covers all levels of a business's employees who are required to comply (from high and middle management to average workers). If a large number of staff are found to be foreigners, care should be taken to address the language gap. Persuasive communication will highlight the benefits of compliance, aiming both to promote consistent and positive behavior on the part of firms and to develop mutual understanding between regulators and industry.

5.5. Breaking the Myths

Compliance is not a matter for "specialists," but a day-to-day practice of the company that involves all staff, from lower to higher levels.

6. Good practice in guidance

Good-practice guidance works to increase usability for the recipient to ensure compliance with legal requirements (Figure 6).



Figure 6: Good-practice guidance

6.1. Good understanding of the target audience

Effective guidance requires an in-depth understanding of the specific characteristics and needs of the business group being targeted by the guidance. Depending on the type of economic activity being carried out and the sector in which they operate, businesses will have different compliance requirements and need different guidance.

6.2. Business data and data design

The best way to understand the needs of business recipients is to search for data in the primary source, ie. businesses and their official representative bodies (eg. Chambers, Unions). At the same time, the experience of supervisors and their findings on compliance problems act as a feedback to focus on the most demanding issues.

6.3. Compatibility of the guide with a business mentality

Providing advice to businesses on compliance issues should not be performed by listing or reproducing legal regulations and requirements. The complexity of the modern business environment and growing financial demands have made the operation of businesses more challenging, leading businesses to focus more on complying with their internal procedures than with legal requirements.

In many cases, there is a failure on the part of businesses to connect their business processes to legislative requirements. Confusion also arises when there are compliance requirements from different regulatory aspects that need to be fulfilled at the same time. Advisory guidance should be designed to describe the compliance requirements for each business stage.

6.4. Easily understandable content for the user

The more easily understandable the guide, the more easily it will be followed. The guide should be written using clear and informal language that is adapted to the audience—that is, the businesses it is targeting.

The guide should avoid the use of specific phrases and acronyms with which the end user (for example, the employees of the business) is not familiar. As communication is not limited to text only, the use of appropriate flowcharts and other illustrations will help in understanding.

Guides should be as short as possible so that users do not have to spend too much time reading. The user should be able to recognize which compliance requirements are in line with the company's procedures so as to be motivated to continue reading the guide. Advisory guidance should be concise, allowing businesses to apply it quickly.

6.4.1. Quick-start guide

A quick-start guide can be an effective way to introduce businesses to compliance measures. The aim is for these guides to act as an entry point to compliance issues, especially for users with limited understanding of the subject or for more complex issues.

The format and details of the guide may vary depending on user requirements. Quick-start guides will include a brief summary of the guidance and could include key steps or a checklist with the basic compliance requirements. The quick-start guide may be part of the overall guide, but should not occupy more than 10 percent of the total guide.

6.4.2. Boosting business confidence regarding compliance

The effectiveness of guidance is judged by how much it helps businesses understand how to comply with the requirements. The guidance should create a firm belief that the advice and instructions are complete, accurate, and in line with current requirements and that they ensure compliance.

To further strengthen the firm's belief in "good compliance," advisory guidance should be focused mainly on positive statements about users' expectations, scope, and possible constraints.

Appropriate information should be provided on who businesses can contact (for example, at the offices of the competent supervisor) if they need further advice or clarifications.

6.5. Issuing the Guide at a Good time

Issuing the guide at a good time is important, as it can reduce business compliance costs. Businesses should be informed at the appropriate time of changes in the supervisory regulatory framework in order to properly prepare their systems and procedures. Otherwise, delayed guidance may cause excessive compliance due to a sense of insecurity and uncertainty over the regulatory environment, with higher associated costs.

6.5.1. Easy access

The guide should be easily available to the user. Access by electronic means (on the website of the supervisory authority or through relevant links) is deemed necessary. Other forms of communication, including providing the guide directly to businesses or other business information structures (such as chambers of commerce and industry links), are also useful.

The main goal is for the guide to be read by businesses. To disseminate the guide in the appropriate way, it can be helpful to consult the business itself at the planning/development stage or the relevant business community on preferred methods. The supervision authority should make sure to check that the guide is available through the preferred channel.

To ensure widespread dissemination of the guide to businesses, a number of complementary actions can be taken at the same time. Examples include organizing meetings with the business community, publishing press releases, creating slides, producing short video simulations of compliance actions for businesses, and creating summary posters of compliance guidelines for employees.

A good practice in promoting the guide is to have businessmen and workers (opinion leaders) serve as mentors, discussing their positive experiences and describing the benefits they have gained in their everyday work by using the guide.

6.5.2. Evaluation and improvement

The evaluation, review, and feedback process is an integral part of the quality of the guidance. Users will play an important role in this process, as their participation through comments and observations should become active through specific channels of communication with the supervision authority.

Even if the guide has been designed and tested well before publishing, it may not have the desired results in practice. Improvements should then be set as a priority, especially when users point out misunderstandings or practical problems that need to be evaluated and improved. It should be stated clearly in the text of the guide that it will be reviewed formally within a specific time frame. This way, users can be sure they are using the most up-to-date version. Each version of the guide will be withdrawn or archived when a newer version is available.

By setting up the appropriate mechanism (for example, an online contact form or a link), the supervision authority will allow users to participate in the review of the guide and to submit the points they consider to be problematic or in need of correction.

7. Conclusion

Based on European best practices, guidance to businesses is useful tool for enhancing compliance by providing information in a way that is not restrictive or binding for the supervisory authorities.

The supervisory authorities should take all appropriate steps and measures to ensure the availability of timely and accurate information on business issues relating to compliance with legal requirements, including through:

- Electronic messaging (email) or individual undertakings or associations of undertakings;
- Replies through social media applications, in case supervisory authorities are involved;
- Press releases or circulars on specific issues that require additional guidance; and
- Organization of educational activities (such as seminars, workshops)

The supervisory authorities, through proper guidance and information, will play a key role in consolidating trust between businesses and the state. With clearly defined rights and obligations, the two sides will be able to work together to build a modern governance model that will support consistency, legality, compliance, and, ultimately, the proper functioning of the market.

References

Department for Business Innovation and Skills (United Kingdom). 2009. Code of Practice on Guidance on Regulation, available at: http://www.fwr.org/WQreg/Appendices/CoP_on_Guidance_on_Regulation.pdf

Government Communication Service (United Kingdom). 2014. Writing a Communication Strategy, available at:

<https://gcs.civilservice.gov.uk/wpcontent/uploads/2016/06/Writing-a-comms-strategy.pdf>

Ohio Environmental Protection Agency, Office of Compliance Assistance and Pollution Prevention (United States). 2017. Small Business Environmental Compliance Self-Assessment Guide, available at: <https://www.epa.ohio.gov/portals/41/sb/publications/selfgde.pdf>

Organisation for Economic Co-operation and Development (OECD). 2014. Good Practices in Development Communication. Paris: OECD Publishing, available at:

<http://www.oecd.org/dev/DevCom%20Publication%20Good%20Practices%20in%20Development%20Communication.pdf>

Ryerson University. 2011. Change Management Leadership Guide, available at:

<https://www.ryerson.ca/content/dam/hr/managerresources/docs/change-management-leadership-guide.pdf>

