



Thematic Study

Athens, October 2015

Market inspections and surveillance

Executive Summary



This study was prepared by the House of the Greek Manufacturing Industry ("Stegi tis Ellinikis Viomixanias") and with the support of the Hellenic Federation of Enterprises (SEV), within the scope of the project "Creation of an intervention mechanism for identifying, processing and assessing the administrative obstacles faced by enterprises. It is implemented under the Operational Programme "Public Administration Reform", 2007 - 2013.



Με τη συγχρηματοδότηση της Ελλάδας και της Ευρωπαϊκής Ένωσης

Message by the President of SEV

Ensuring the proper functioning of the economy and the society requires a clear framework of principles and rules as well as an effective system constituting the prevention of violations and controlling conformity. . It is based on a functional relationship between auditor and auditee and the recognition of the need for inspections and the confidence in the integrity of the auditors.

Ensuring a current, preventative and above all effective monitoring and inspections system over products being produced and handled in the Greek market is the State's commitment not only towards Greek consumers and businesses but to our European partners in the single market.

Although the legal framework on monitoring results from European regulations and commitments, the national monitoring and inspections system is still fragmented, lacks targets and scope, allows the development of anti-competitive practices and corruption ultimately partially fulfilling the surveillance function of the Greek State.

The multiple overlapping of inspections that businesses are obliged to endure, the lack of a centralized and structured system of inspections and surveillance and the inability to manage the risk factors, render the monitoring authorities' inability to protect the public interest, to conquer anti-competitive practices and to guarantee the smooth operation of the market.

Despite the encouraging initiatives and the efforts undertaken by various inspection bodies during the previous period, the lack of human and financial resources in the recent period have led to the reduction in the number of inspections taking place, especially the preventive inspections, and during a period when the need for inspections has remained the same or has increased (for certain product categories the decrease reached 41%).

This study documents, in a systematic way, the problems regarding the existing product inspection and surveillance system and the initiatives that have taken place for the improvements that have been more or less successful during the last years.

The study also proposes the implementation of a modern strategy adapted to the particularities of the country, as an entry point for products coming in from third countries into the EU. Furthermore, the implementation of more than 20 interventions (22 horizontal and 9 specialized by product category) concerning the reformation of the inspection and surveillance system focusing on the parallel development of detection and preventative mechanisms.

The proposed combination of interventions that become the foundation of the operation of a Single Surveillance and Coordination Entity of inspections encourages the following:

- the self-regulation of businesses
- the upgrading of existing inspection mechanisms through the use of IT tools and communication, and
- the development of a single audit system

It also aims at creating an inspection and surveillance system which will ensure the protection of the public interest, the protection of businesses from unfair competition and the maintenance of the proper functioning of the market and the business environment.

It is appropriate and feasible to establish a new relationship of trust between businesses, consumers and inspection mechanisms to unleash the potential growth of the free market economy. The proposed reform of the inspection and surveillance system of consumer and industrial products can be a significant step towards the aforementioned goal. I hope that this study will be used as a useful guide for practical interventions that will benefit the public interest.

Theodoros Flessas
President of SEV

Business Environment Observatory

vision

establishing institutions and rules that support the competitiveness between enterprises and the country's development

mission

indicating radical policies and reforms of business environment, through the partnership of creative business forces and public administration

The establishment of the Observatory is **the legal extension of SEV's initiative: "Entrepreneurship without obstacles: opening the way to growth"**. SEV has undertaken this initiative in order to contribute to the improvement of the business environment and the removal of any obstacles standing in the way of entrepreneurship.

Within the scope of its legal role in the promotion of policies for the social progress and cohesion, the country's economic development and business competitiveness, SEV has proceeded to the organisation and operation of the **Business Environment Observatory**, the goals of which include the following:

Through the **Business Environment Observatory**, the objectives pursued are:

- **systematically identify** limitations, obstacles and problems that hinder business development, have a significant negative economic effect and often overturn the expected benefits of the business venture itself.
- **evaluate** the friendliness of the business environment and the consistency of the regulatory framework which forms it.
- formulate **documented policy recommendations** aiming to promote the necessary changes and reforms as well as to establish an effective business environment.
- systematically monitor and **assess the effectiveness** and efficiency of reforms and changes which are implemented in order to improve the business environment.
- develop a new **change and reform implementation** methodology, supported by the partnership of creative business forces and public administration to achieve more effective regulation of matters of public interest.
- conduct **consultation**, with constant and meaningful cooperation between competent officers from both enterprises and public administration, an activity that ensures the completeness of the process of identifying obstacles from original sources and the joint effort to produce solutions.

The **activities** undertaken by the Observatory are, in summary, the following:

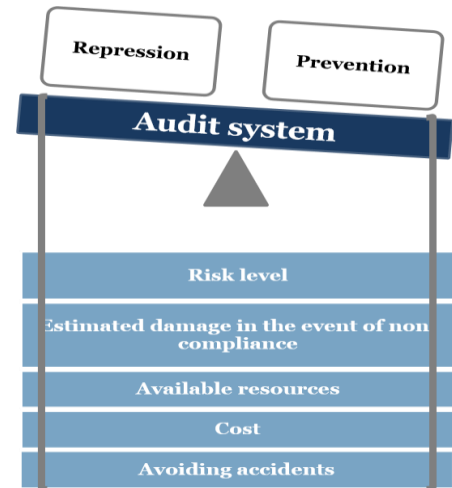
- Thematic studies for significant areas of obstacles.
- Specialised studies on obstacles and reports on methods to address them.
- Opinion research/Public services quality barometer.
- Detailed recording of procedures and obstacles in the business environment.
- Consultation workshops.
- Planning of policy recommendations.
- Cooperation with the public administration authorities and the scientific and business community.

For further information regarding the actions and the operation of the Observatory, you can visit www.observatory.org.gr

Key directions for the improvement of the inspections and surveillance system

An orderly and effective inspection and surveillance system should be based on **the balanced development of mechanisms** aimed both at preventing crisis situations and at the immediate implementation of risk management plans and incidents within the limits set by the available resources, and the risk level.

Indeed, the complete avoidance of adverse incidents and accidents is preferable, especially in cases where the impact is expected to be non-reversible. The emphasis on prevention and detection is paramount. A precondition for the effectiveness of such a system entails risk-based targets and stages in the audit process to be proportional. This will limit the burden of compliance in businesses, as much as possible, safeguarding the public interest.



The strategy for the improvement of the inspection and surveillance system is based on an Integrated Action Plan, comprising three strategic pillars and based on the synchronous development of prevention and detection mechanisms:

- I.** to enhance market **self-compliance**
- II.** **to upgrade** the inspection and surveillance system, and
- III.** to develop a single audit system («**Integration**»)

Specifically, regarding the preventive character of the system, the first Strategic Pillar (“Enhancement of market self-compliance”) emphasizes on encouraging businesses to act in accordance with the regulations by self-compliance and encouraging consumers to participate in the surveillance of the market. On the other hand, regarding the detective mechanisms of the system, improvement measures are proposed within the second Strategic Pillar (“Upgrade of inspections and surveillance system”). The action plans for the two Strategic Pillars have a medium-term completion and the implementation of the changes proposed will provide the basis for the third and longer-term Strategic Pillar, which concerns the development of a single audit system.

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the 1990s, the number of people with diabetes has increased in all industrialized countries, and this increase is continuing to rise (1).

Diabetes is a chronic disease that is associated with a high risk of cardiovascular morbidity and mortality. The prevalence of cardiovascular disease is higher in people with diabetes than in people without diabetes (2).

The aim of this study was to determine the prevalence of cardiovascular disease in people with diabetes.

Methods

Study design

This study was a cross-sectional study. The study was conducted in the Netherlands in 1997.

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1 General context

The multiple overlapping inspections, which the enterprises are required to endure, continue to be a real and in several cases a growing problem. The lack of a central and structured system of inspections and surveillance, fails to protect the public interest, raises the administrative burden of the enterprises and creates a privileged area for the development of anti-competitive practices.

Thus, the truenature and goal of the surveillance procedure is altered. The consumer recognizes the lack of protection and the companies on numerous occasions are targeted unreasonably by the state and are challenged by unjust commercial practices, discouraging them.

The efficient operation of the a surveillance network constitutes one of the state’s obligations for ensuring consumer security and health, the smooth operation of the internal market, as well as competition. However, this will not constitute an extra burden to the enterprises producing and distributing products.

The Business Environment Observatory, having already assumed the initiative of promoting regulatory changes with a positive impact to the business’ environment, hosted a special thematic research **regarding the inspections and the surveillance of the industrial and consumer products throughout the distribution circle**, with purpose to formulate a complete design for the improvement of the current inspection and surveillance system of the market.

The purpose of the research was the assessment of the current inspection system and the suggestion of a new and complete inspection system regarding the production and the distribution of consumer and industrial products inside the Greek market.

The purpose was the removal of the regulatory and administrative barriers, placed on the enterprises during the inspection process, intensifying the inspection wherever necessary, and guaranteeing the efficiency of the inspection bodies through a new way of organization and operation of the system and of the inspections network.

Purposes of the research are:

- Improving the inspection and the audit procedures
- Raising the compliance rate of the produced and distributed products with European security and quality standards
- Securing the smooth operation of the market and, finally
- Reducing the administrative burden of the enterprises.

“Inspections” are the procedures of evaluating the compliance of the enterprises (products and services) with the orders of the respective existing laws and contain products’, facilities’, operations’, documents’ inspection etc. while

“Supervision” is the surveillance and adjustment that the state’s authorities apply through audit procedures for the correct and handed application of the laws and regulations and the procedures of audit authorities regarding the assurance of compliance, as opinions, guidance, information etc.

Graph 1. Scope of work



It is noted that the context of the research and for its feasibility, a methodology of reduction (extrapolation) was implemented, testing certain chosen categories of Fast-Moving Consumer Goods.(FMCGs), and products bearing the CE symbol.

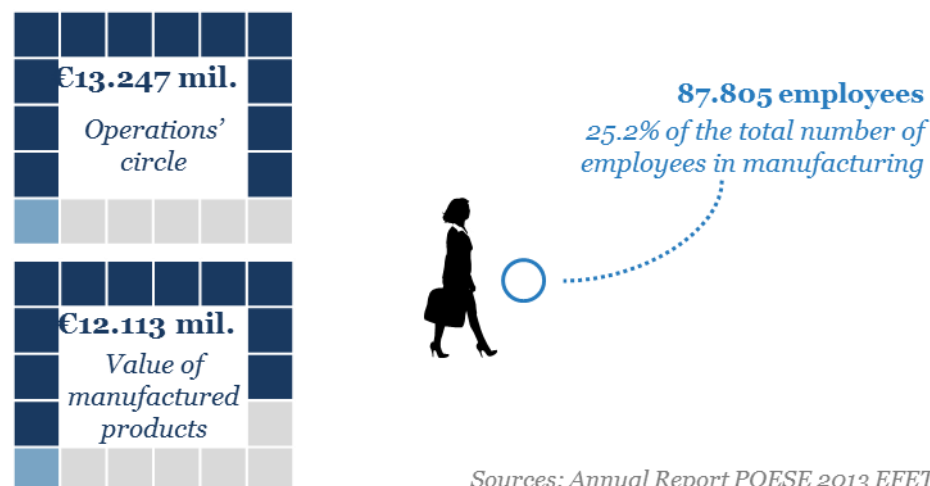
In particular, the study focused on the food and beverage market, cosmetics products as well as building materials. This choice was the result of large sizes that characterize these markets, the diversity of products, that they cover as a whole and the large number of consumers to whom they are addressed. The aim was, that the sample is as representative as possible regarding the Hellenic economy, allowing the reduction of general conclusions for the inspections and surveillance system of the markets by the analysis results.

Food and beverage

In 2013...

... **242.713 businesses trade**,
of which **14.510 processing businesses**

Food and Beverage Processing, 2012



Sources: Annual Report POESE 2013 EFET

Cosmetic products

In 2013, the **turnover** of the sector amounted to **€ 815.5 mil.**, presenting a **downward trend over the past 4 years**.

However, the choice of this market was based on the fact that the products of this category are addressed to a large number of consumers. In particular, the following table presents the categories and products, which are recognized under the mapping and classified as cosmetics.

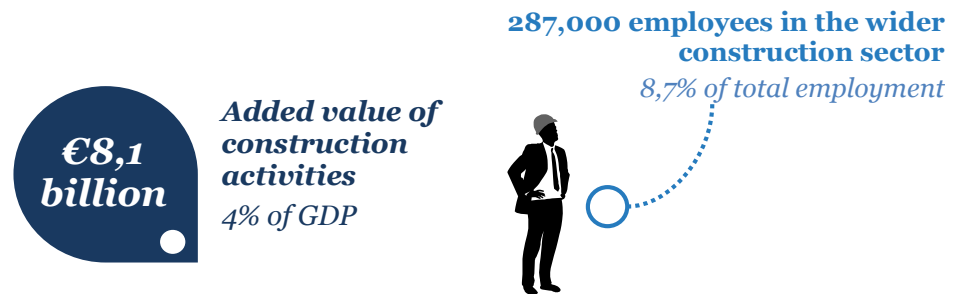
Table 1. Cosmetics Group

Group	Indicative products
<i>Hair care products</i>	- Products of hair cleansing (lotions, powders, shampoos) - Products for waving, straightening and fixing hair - Hairdressing products (lotions, lacquers, brilliantines, gels) - Hair maintenance products (lotions, creams, oils, masks)
<i>Oral and dental hygiene products</i>	- Toothpaste - Mouthwash - Bleaching teeth
<i>Skin and body care</i>	- Body cleansing products (shower gels, soaps, exfoliating products)

Group	Indicative products
<i>Products</i>	<ul style="list-style-type: none"> - Body care products (emulsions, creams, oils, lotions) - Powders for after bath use - Cleaning and care products for sensitive areas of the body, external use - Deodorants
<i>Face care products</i>	<ul style="list-style-type: none"> - Facial cleansing products (soaps, lotions, exfoliating products) - Facial care products (emulsions, creams, oils, lotions, masks) - Makeup products and cleansing
<i>Others</i>	<ul style="list-style-type: none"> - Products intended for application to the lips - Products for dyeing and nail care - Shaving products (creams, foams, lotions, razors)

Building materials

In 2013, the added value of construction activities and industry employment were as follows:



Source: IOBE, 2015. The importance of development, the barriers and future of the construction industry

Innovations of the Observatory's study, are both the method (use of sources of knowledge) and the width of the field's investigation. Specifically:

- **Utilization of the market's and public administration's knowledge and expertise:** the study was drawn up through continuous and substantive cooperation and consultation of the competent officials of both enterprises and of the public administration itself, a fact that ensures the completeness of barriers' detection from primary sources, and the design of solutions.
- **Scope of the analysis:** the analysis that takes place, is not limited to the detection of administrative barriers and the recording of the administrative burden but is also extended to the entire obstacles and charges (opportunity costs, administrative costs, financial costs, etc.), that result from the regulatory framework and the business environment, focusing on the unlocking of the enterprises' growth prospects.
- **Completeness of the intervention's suggestions:** the study is not limited to exporting ascertainment and conclusions, but to suggest complete suggestions.

In May 2015, an extensive and repeated consultation with the state begun with business representatives and other experts in the field. The first phase of consultation was about identifying problems, and the impact to the business.

Specifically, the following took place during the first phase of the consultation:

3 Focus Groups, with **38 officials**, of which:

- 12 officials from the public administration
- 17 experienced officials from enterprises
- 3 experts
- 6 associations' representatives

4 Meetings with 11 officials of the main audit authorities (H.F.C., S.G.L., N.D.A., Directorate of Institutional Regulation and Market Surveillance), where the purpose of the meetings was the search of reliable qualitative and quantitative data, as well as the recording of improvement suggestions of the inspections and supervisory system.

3 Meetings with 4 experienced officials of enterprises, where the purpose of the meeting was the search of reliable qualitative and quantitative data, as well as the recording of main problems that enterprises are dealing with during the inspections procedure.

3 Meeting with experts of the sectors, where the purpose of the meetings was the search of reliable qualitative and quantitative data, as well as the recording of improvement suggestion of the inspections and surveillance system.

The second phase concerns the formulation of suggestions, which will be concluded by hosting a special consultation meeting. The conclusions from the second phase will be integrated in the next and final version of the study.

2 Current Situation

2.1 Qualitative assessment of the existing inspection and surveillance systems

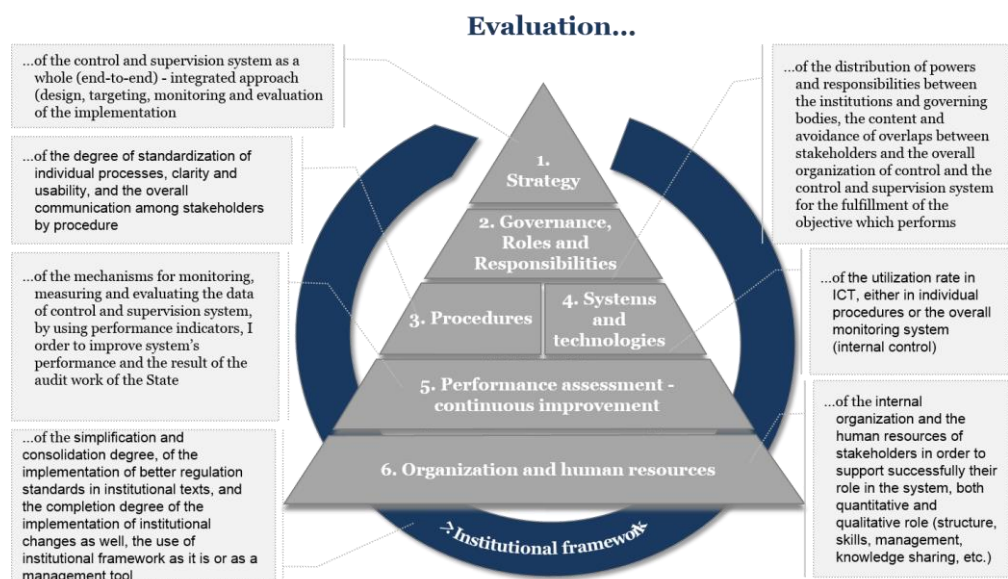
This section presents the methodology and the results of the evaluation of inspection and surveillance system in the selected business sectors (food and beverages, cosmetics and products labeled CE).

2.1.1 Methodological evaluation approach

The conclusions arising from the review of the best practices and the guidelines of the OECD were utilized to evaluate the Greek inspections and surveillance system in order to identify those points which emphasize the mature inspections and supervisory systems over less mature.

The Business Environment Observatory, in the context of the preparation of studies, has developed a specific methodology for the evaluation of the systems and their comparison of the best practices, which is presented below.

Graph 2. Methodological evaluation approach of the Business Environment Observatory



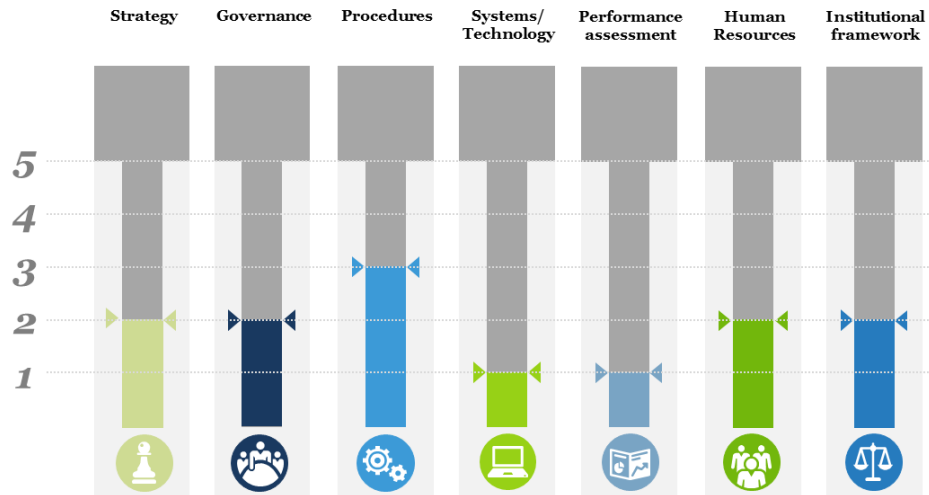
According to this methodology, the results of the evaluation which are presented below, are categorized based on specific criteria, which are grouped under these seven (7) dimensions.

For each one of the dimensions, the maturity of the national inspections and surveillance system is evaluated, taking into account the complete performance of the system regarding the improvement of the entrepreneurship and the assurance of the public interest. The rating was made on a scale from one (1) "low degree of maturity" up to five (5) "high degree of maturity."

2.1.2 Presentation of the results of evaluation

The complete assessment of the degree of maturity of the inspection and surveillance system in Greece under the seven (7) dimensions is charted in the graph, then the main findings per dimension are presented below.

Graph 3. Evaluation of the inspections and surveillance system



Strategy

The new conditions in the market as well as in Governments operations create a greater need for a more effective monitoring and inspections system, both in terms of resources spent and the results obtained.

The lack of an integrated strategy approach, which is determined on a national level, has several major effects on the inspection and surveillance system. Particularly, it is noted:

- **Fragmentary planning of the processes** making them ineffective
- **Failing to determine specific and measurable targets and indicators** for the evaluation
- **Disproportioned emphasis on the compliance inspections** on the available distribution channels and the various stages of the value chain
- **Lack of cooperation** with businesses and consumer organizations to audit work in most markets

The inspection of the market present deficiencies (mainly in the field of cosmetic products and products labeled CE), as a result security issues and unfair competition prevail towards businesses in which comply with what is expected of them.



Governance, Roles and Responsibilities

When the auditing responsibilities are shared between different services of public administration at national, regional and local levels without a coordination and organizational system, the inspections become ineffective due to overlaps and gaps in surveillance, while confusion is provoked to the enterprises.

The absence of a strong organizational structure and the lack of cooperation and information sharing between stakeholders, both in supervisory as well as in audit / executive levels prevent the effective execution of investigative work. Particularly, the following are found:

- **Weakness in the quality of guidance, inspection and surveillance** of the audit work which is performed by regional / local bodies at the surveillance level, due to absence of direct administrative links between the services involved
- **Large number of stakeholders involved** at regional level, where coordination is paramount, which is hindered by the lack of administrative relationships
- **Gaps in responsibilities and overlaps of roles** between the authorities, at an audit level

At inspections level, competencies gaps and overlaps of roles between the supervisory authorities are identified, as for example in case of EFET and the Directorate of Institutional Monitoring Regulation of Market Products and Services concerning the inspections labeling and frauds.



Procedures

The lack of information and in some cases the late transposition of EU legislation into national law create ambiguities in the inspections process. The overlaps of responsibilities, the repetition of the procedures and the misallocation of resources are some of the main consequences of a system which is consisting of many stakeholders. Thus, despite the improvement actions taken, such as the adoption of procedures that follow the EU practice and the improvement of their standards, the following are observed:

- **Differences in practices**, particularly between central and regional services, regarding the handling of audit procedures
- **Inadequate feedback to the inspected enterprises**, which does not allow a full understanding of compliance requirements, especially for small and medium-sized enterprises
- **Limited implementation of risk assessment** in all decision-making levels, from the organization and the implementation of inspections, up to the proportionality of sanctions
- **Limited use of toolboxes**, due to their insufficient development

Although some improvements concerning the inspections procedures have been noticed, there is a limited use of relevant tools, such as the risk assessment, due to lack of relevant guidelines, toolkits and checklists.



Systems and technologies

The limited implementation of information systems does not enable the interconnection of prior data (where entered) with the objectives and the strategy of inspection bodies.

As a result, there is no performance indicator mechanism to evaluate the surveillance and inspection system, both in terms of processes and surveillance bodies.

Although there is an improvement concerning the disclosure of certain information (such as information of legal framework and regulatory changes, test results and products posing risks) through websites, to inform the stakeholders, there is a substantial lack of ICT use at all stages of the audit work (organization, implementation and monitoring). The main operative factors are as follows:

- **Lack of adequate infrastructure** and limited efforts to integrate IT systems, mainly due to lack of resources
- **Dissemination of information available** to different bodies of the public administration, which are not used collectively for market monitoring
- **Loss of many business entries to the register**, making it difficult to detect them

The General Directorate for Manufacturing has developed an ERP which remained at a pilot stage.



Performance assessment – continuous improvement

The absence of a mechanism evaluating the performance of the system and the audit work, as well as the absence of a system of definite scorecard, these do not permit a systematic monitoring, so that any fragmentary improvement does not become effective. Specifically, it is observed:

- **Limited performance assessment** at the level of compliance with prior data and publication of results
- **Absence of connection between the prior data** (wherever entered) **and the objectives and the strategy** of the audit work

Even in the cases where prior data are recorded, there is no established connection between the objectives and the strategy of inspections bodies, so as to assess and identify some actions that would help improve the system.



Organization and human resources

There is a lack of a team-working and collaboration culture among the administration bodies, and also between the public administration and the companies under surveillance. In conjunction with the substantial staffing limitations which exist in quantitative and qualitative terms, there are major obstacles to the audit work of the competent authorities. Specifically, the followings are observed:

- **Human resource limitations in the inspection authorities**, due to a significant number of retirements that have not been replaced, in conjunction with the increased responsibilities
- **Lack of specialized knowledge and skills** which are required for inspections and are not covered by the staff that it is currently available to Regions

- **Absence of a systematic mechanism responsible for the configuration of staffing standards** of the units involved in the inspections
- **Absence of an integrated knowledge management system, training and education** for existing and new officers
- **Absence of a systematic way of sharing information and developing common practices** among audit services

Today the human resources of EOF at the Directorate for the Cosmetology Assessment, consists of just two (2) persons, while the agency's Audit Department consists of five (5) persons who are responsible for carrying out the checks, particularly in the sector of medicines and complementary products to the cosmetics industry.



Legal framework

According to the OECD, the fragmented information concerning the operation rules (compliance requirements, national inspections bodies) leads to uncertainty and it reduces the investments in equipment and / or new initiatives

The legal framework governing the inspections and surveillance system in our country is based primarily on the EU legislation, although in some cases the national surveillance practices have not adjusted accordingly, yet. Despite the improvements that have occurred in some cases, such as the decriminalization of certain offenses in the food and beverage market, the following were observed:

- **Deviations of the national law by the Community**, in many cases
- **Stakeholders not being appropriately informed** (companies and competent inspection authorities) regarding the legal framework referring to the compliance of the products
- **Disproportionate penalties concerning risk levels and the extent of the (estimated) impacts**

Typically, in the building materials' sector, the Greek Technical Specifications (E.TE.P.) have not been revised to be harmonized with the EU legislation, so – besides the safety issues that arise - the minimum requirements for public procurement of construction products are subject to interpretation of the relevant contracting authorities.

2.2 Qualitative assessment of the existing inspections and surveillance system

2.2.1 The inspections and surveillance system in numbers

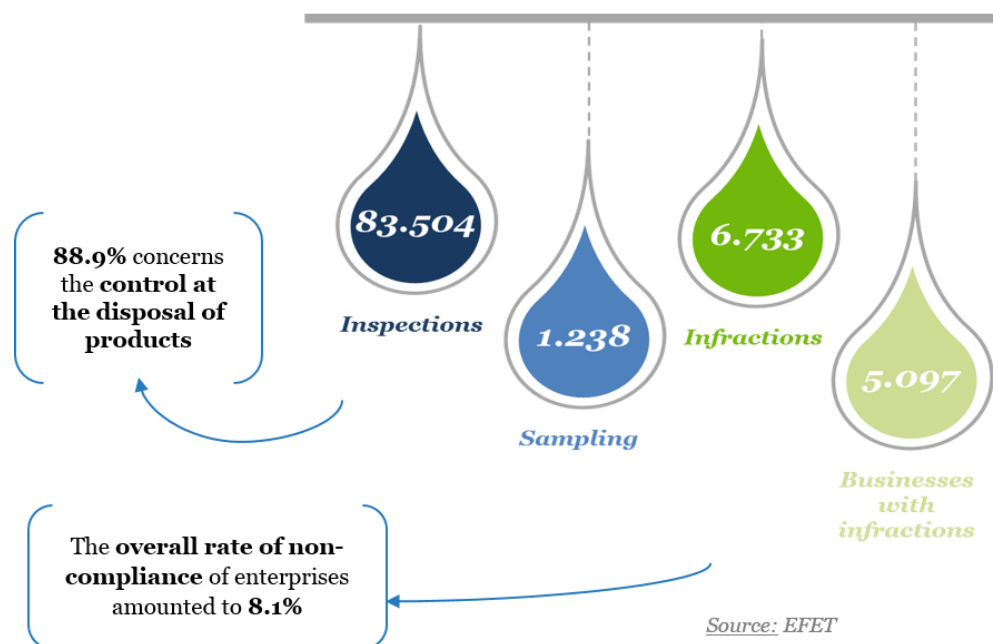
This section presents the key elements of inspections of the markets examined. However, it is noted that the collection of data which refers to the testing of cosmetic products, was not possible.

Inspections on food

They relate to all the stages of the value chain, particularly in hygiene and they are focused on:

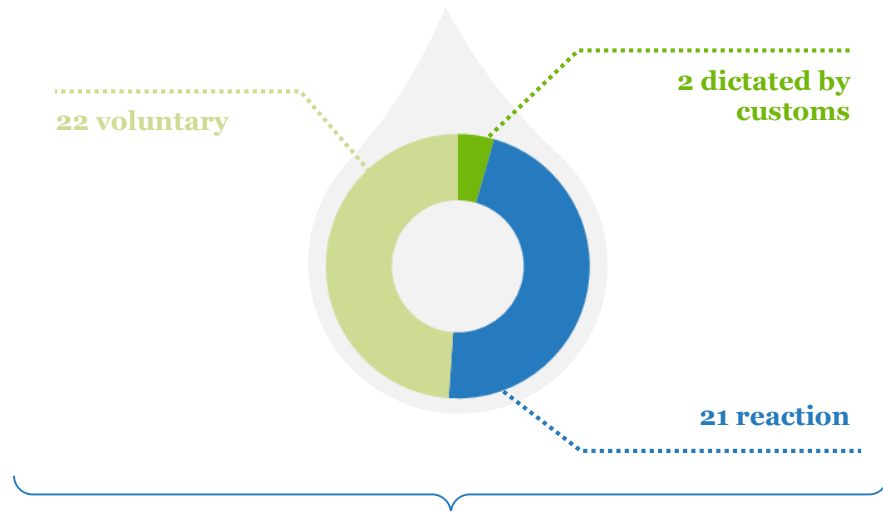
- | | | |
|---------------|---|--|
| EFET | { | <ul style="list-style-type: none"> ▪ Food hygiene ▪ Food of animal origin |
| YIAIEN | { | <ul style="list-style-type: none"> ▪ Organic agricultural products ▪ Protected designation products ▪ Food Marketing standards of animal origin |

Ex-post data 2013



Inspections in building materials

Prior data 2013
Inspections were reduced by 41%, from 76 to 45 inspections, since 2012, due to lack of funding



- **43** resulted in a finding of **non-compliance (96%)**
- Only in **1** case **penalties** were imposed

Source: FB inspections program assessment for building materials (2010 – 2013)

2.2.2 Methodological approach of assessment of the burden

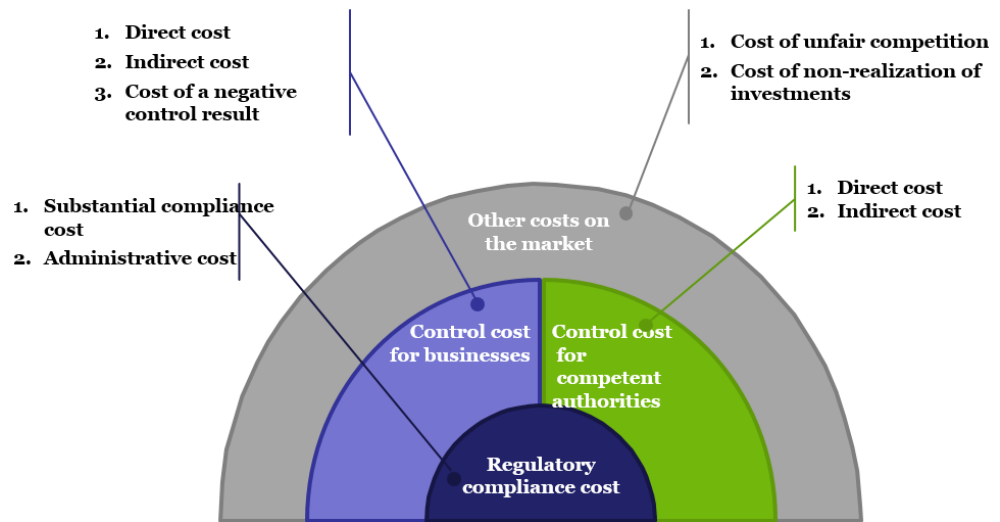
Then they present the methodology and the results of the quantification - evaluation in monetary terms - the burden on businesses, allowing the assessment of the current situation on measurable data and a more substantial (comparative) evaluation.

For the collection of data an entrytable was designed, and it was adapted to the requirements of each test market. Additional entry tables were formed, with the necessary elements for measuring the costs of regulation and the instructions for filling them.

For the purposes of this analysis, data from various sources are collected and tested. Particular emphasis placed on the collecting of empirical data (qualitative and quantitative) by executives of competent inspection authorities and the private sector through visits and telephone interviews.

The cost analysis of the overall burden resulting from the surveillance and monitoring and inspections system depicted in the following graph.

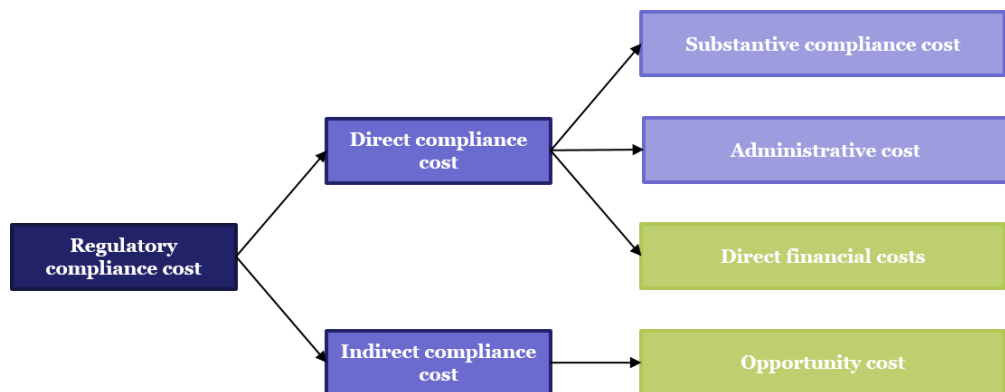
Graph 4. Analysis of the overall burden of inspections and surveillance system



Regulatory cost

The estimation of the regulatory cost shall be based on the extended Standard Cost Model:

Graph 5. Analysis of the regulatory compliance cost



- The essential compliance cost issue from the need for spending on equipment tests and measurements and for the training of scientific and technical personnel so they can correspond to the requirements of EU and national legislation. Specifically, this cost is calculated by taking into account the following factors:
 - *Implementation cost of standards and procedures*
 - *Fees of the inspection and certification enterprises*
 - *Cost of tests / labs*
 - *Cost of equipment / laboratory required*
 - *Staff training cost*
- The administrative cost incurred by the companies includes the administrative monitoring cost, the concentration cost, the cost for collection and update of technical files, as well as the cost of human resources needed annually to monitor the changes in statutory requirements.

The administrative cost was calculated by using the following formula:

Graph 6. Assessment of administrative compliance cost



Opportunity cost

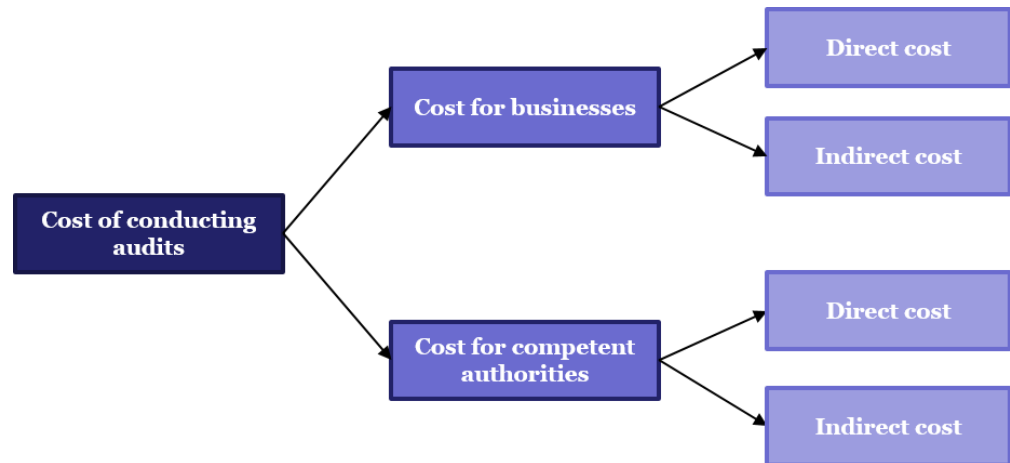
The opportunity cost refers to the cost of non-implementation of investment due to obstacles arising from the existing inspection and surveillance system. This cost proceeds from the complexity of the institutional framework, the uncertainty of the inspections, the lack of information and / or the guidance provided to businesses, the possible inability to connect inspections and the level of risk and the excessive stringency and / or compliance to the words and not to the overall intention of the law, from the side of the auditors.

The calculation of this cost requires specialized study to identify the part of the investments that are not realized as a result of problems in the current inspections and supervisory system. However, it is estimated that the difference in the regulatory costs has no meaning due to the unstable economic environment prevailing in the country at this moment and it increases the cost of capital.

Cost of conducting audits

As it is reflected in the following graph, the cost incurred by both the company and the inspection authorities are taken into account to estimate the costs of conducting audits.

Graph 5. Analysis of cost of conducting audits



Cost of conducting audits for businesses

The cost of conducting audits for companies is divided up into direct cost and indirect cost and it concerns:

- Direct cost
 - *Cost of preparation: Cost of man-hours work required for the recovery / collection of the necessary documents, after the communication from the competent authorities to conduct an audit*
 - *Inspection Cost: Cost of man-hours work required and spent by the staff and the management of the company during the audit*
 - *Cost of complementary actions (if it is required): Cost of man-hours work required for the additional actions to be done by the company, under the inspections*

The direct cost of conducting the audit was calculated using the following formula:

Graph 6. Estimation of the direct cost of conducting the audit

$$\text{Direct cost} = \text{Man-hours work} \times \text{Labor cost}$$

- Indirect cost
 - Missing revenue/ profits of business : Days of work lost as a result of a delay or an interruption of the operation of the company during the audit

Graph 7. Estimation of the direct cost of conducting the audit

$$\text{Indirect cost} = \text{Days of work lost} \times \text{Average daily production} \times \text{Average unit contribution}$$

Cost of conducting audits for competent authorities

The cost of conducting audits for competent authorities is divided into direct cost and indirect cost, and it concerns:

- Direct cost: The cost of the supervisory authorities to carry out the physical (inspection) and the laboratory testing of products. The factors taken into account are these below:
 - *Man-hours work needed and dedicated to the on-the-spot checks and the laboratory testing*
 - *Transport costs/ travel expenses*
 - *Workshop Operating expenses*
- Indirect cost: The cost borne by the competent authorities for the back-office functions, regarding the preparation and the organization of the inspections. These expenses relate to:
 - *Third party costs (e.g. updating costs/review cost of M.I.S.)*
 - *Man-hours work needed and dedicated to the expansion of the market and to the organization of targeted checks*

Other costs on the market

Other costs revolve around administrative burdens that the businesses are confronted with due to an inadequate surveillance system of the market and the ambiguities created by the authorities when managing problems.

- Cost unfair competition: It refers to the burden carried by compliant businesses due to their non-compliance competitors, who are not inspected.
- Damage to the brand name: It refers to the costs incurred to firms who comply, by inspecting authorities who solve problems in a way which may distort the image of a product or a company, with consequent reduction of the revenues, the loss of market share and in particular cases entire market share.

It is noted that, similarly to the case of opportunity costs, the charges concerning the cost of unjust competition and the damage to the brand name of a product or of one business, were not examined in this study.

Acceptances and constraints analysis

All the elements of cost and time, have determined by the relevant executives of the parties involved in the sample based on experience, and they used without changes.

Sample

The sample was collected from companies and experts and it refers to the cost borne by firms in the conduct of the audit and the annual compliance cost with the requirements of national and Community legislation. The sample consists of 7 cases, and three (3) of them concern food and beverage. It is noted that it was not possible to obtain information on the cost for conducting audits from the audit authorities.

2.2.3 Results - Burden analysis

Quantification of regulatory cost

According to the methodology for the estimation of the regulatory cost discussed above, the tables with the costs per sector examined (food and beverages, cosmetics and building materials marked CE) are presented below. The cost is divided into direct and indirect compliance cost.

It should be noted that the calculation of the regulatory compliance cost is based on the following assumptions:

- Due to the small size of the sample, the estimation of the regulatory cost is presented in ranges rather than absolute numbers.
- For the calculation of administrative cost, the average price per working hour was set at € 15 / hour. However, it should be taken into account that this value is indicative as it depends largely on the size of the company, the range of the products produced, the hierarchical level of the employee in the compliance requirements of the products, as well as the remuneration policy of the company.
- The substantive compliance costs relates to costs of laboratory testing, third-party costs, inspection fees organisms and / or certification cost and implementation of standards

For food and beverage businesses, the regulatory cost is the highest during the production stage and increases significantly when the companies follow stringent quality inspections and quality assurance procedures in order to meet the trust and the preference of consumers.

Regulatory cost for food and beverage businesses

Compliance costs vary by the size of the enterprise, while the number of products produced, imported or featured/ distributed by the company in the market has an important role.

Table 1. Estimation of the regulatory cost for food and beverage businesses

Size of Business	Substantial compliance cost (€)	Administrative compliance cost (€)	Total (€)
Very Small	3.000 – 4.000	500 – 1.500	3.500 – 5.500
Small	5.000 – 6.000	500 – 1.500	5.500 – 7.500
Medium	7.000 – 9.000	1.000 – 2.000	8.000 – 11.000
Big	> 20.000*	2.000 – 4.000	> 22.000

* Note that the compliance cost may surpass the €200.000 mark for big businesses that produce a wide range of products. The abovementioned costs refer mainly to 3rd party expenses and product testing.

Regulatory cost for building materials companies

According to the New Approach directives, the manufacturer is mainly responsible for ensuring that the products labeled CE are compliant and the importer or the distributor are simply obliged to have the necessary documents proving that the product has been produced in accordance with the provisions of the legislation. Based on the above and in order to present the actual compliance costs, the calculation exercise on building materials is focused on the production.

Another feature of compliance costs for companies which produce building materials is that each product has a different compliance cost, which is formed by the type of conformity in accordance with the law. Also, compliance costs are within the cost of acquisition of CE marking and the annual average cost of maintaining the CE marking.

Based on the above and in order to better represent the regulatory compliance costs, the table below reflects the average administrative cost and the essential cost per construction product during the production phase.

Table 2. Estimation of the regulatory cost in the production per product in building materials businesses

	Administrative cost (€)	Substantial compliance cost (€)	Total (€)
Obtaining CE marking	400 – 500	1.000 – 6.000	1.400 – 6.500
Maintaining CE marking*	400 – 500	500 – 4.000	900 – 4.500

* It is noted that the cost of maintaining the CE marking is annual.

Regulatory cost for building cosmetics' companies

The amount of the substantial compliance cost vary according to the value chain stage and the size of the business. However, another feature of this product category is that the substantial compliance cost advances to higher levels in production in relation to the import and the distribution cost and it refers mainly to laboratory testing of cosmetic products and in fees to certification organizations.

In cases of large cosmetics companies which apply more stringent compliance requirements, the substantial compliance cost can overrun the amount of € 100.000.

Table 3. Estimation of the regulatory cost per value chain stage in cosmetics' companies

	Administrative cost (€)	Substantial compliance cost (€)	Total (€)
<i>Production</i>	9.000	5.000 – 15.000	14.000 – 24.000
<i>Import</i>	9.000 – 48.000	–	9.000 – 48.000
<i>Distribution</i>	9.000 – 48.000	–	9.000 – 48.000

The administrative cost varies on the same level in all the three stages of the value chain, but it can be increased significantly, mainly, in large companies that manage a wide range of products and the compliance requirements procedure employs one or more employees.

Audits cost estimation

The cost that charges the enterprise for the audits, was evaluated based on the actions required by the company during and after the inspection. The following table shows the inspection cost for the companies of the examined sectors per stage of the value chain.

Table 4. Estimation of the cost for conducting audits for the companies of the examined sectors per stage of the value chain

	Food and Beverage (€)	Building materials (€)	Cosmetics (€)
<i>Production*</i>	500 – 800	400 – 600	500 – 2.000
<i>Import</i>	Data not available	Data not available	500 – 1.000
<i>Distribution</i>	500 – 800	Data not available	400 – 800

* It is noted that data relating to the inspection / audit conduction in the production illustrate the cost per industry.

The cost for conducting audits relates to:

- **Preparation Cost**, cost of man-hours work required for the recovery / collection of the necessary documents, after the communication from the competent authorities to conduct an audit
- **Inspection Cost**, Cost of man-hours work required and spent by the staff and the management of the company (inspected) during the audit
- **Cost of complementary actions** (if it is required): Cost of man-hours work required for the additional actions to be done by the company, under the inspections

It is characteristic that in any case of the sample, the existence of missing revenue as a result of a delay or an interruption of the operation of the company during the audit was not reported.

The analysis of the data shows that the cost for conducting audit / inspection, the cost of man-hours work per day or during the days of inspection, as a burden on businesses is probably very limited. So, this leads to the conclusion that the compliant businesses are not burdened by the audit, as in most cases they have

The compliant businesses are not burdened by the audit, as in most cases they have already incorporated the strict self-inspections and quality assurance into their operating procedures. However the damage suffered by the businesses focuses on the lack of inspections to the competitors and generally to the market.

Non-compliance entails the reduction of the cost for production / product import. Particularly, it implies a "cost savings" which may be either moved to the consumer by increasing the company's share in the market (and thus the turnover) or it may be retained by the company increasing its net profit through the largest profit margin.

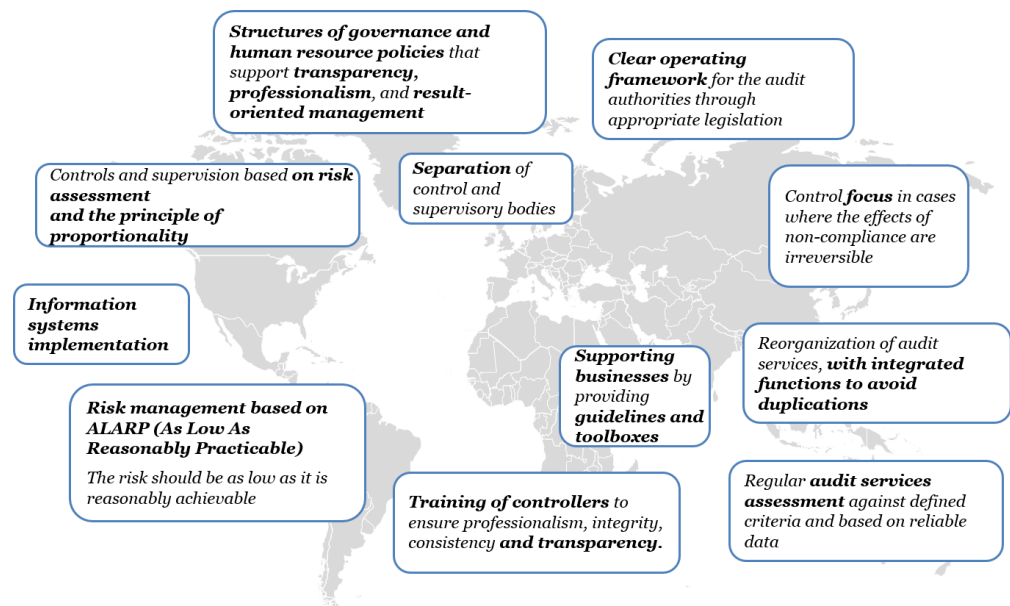
already incorporated the strict self-inspections and quality assurance into their operation procedures. However the damage suffered by the businesses focuses on the lack of inspections to the competitors and generally to the market.

For manufacturing companies, the compliance cost, i.e. the cost of adjusting the production process in the terms and conditions of the legal framework is important but is fully justified, as it ensures the safety of the products. However, the compliance cost combined with the lack of inspections may encourage the companies (especially those who operate only in the Greek market and therefore they are not inspected by surveillance authorities of other countries) to choose the practice of non-compliance. So an environment of unfair competition is established at the expense of compliant businesses as non-compliance entails the reduction of the cost of production / product import cost, which may be passed on to consumer in order to increase market share or it may be retained by the business through greater margin.

3 International and European practices and guidance

Within the scope of the market inspection and surveillance system study, systems from other countries were researched, the European trends of recent years were examined, as well as the guidance from European and international organizations were investigated. The main points documented are illustrated on the following graph presented below.

Graph 8. International and European practices and guidance



Separation of inspections and surveillance bodies

The surveillance and monitoring and inspections system of the market is formed largely into two (2) levels: the supervisory / audit and audit / executive level.

At the first level the stakeholders vary according to the European Directive for which they have responsibility for implementing. Supervisory body may be either a public institution (eg Ministry) or a specialized organization. In any case, the body involved is responsible for implementing one or more Directives and he has taken the overall market surveillance, which concerns the Directive. At the second level (surveillance / executive) the role of the stakeholders is less regulatory and organizational, but it's mainly executive.

The distinction between surveillance and inspections bodies is not absolute, however it is quite distinct and it is adapted according to the country's needs and its individual markets.

So, the surveillers sometimes carry out audits and the executive bodies have a certain degree of freedom in the formulation of the inspections programs, while they participate in policy formulation and national strategy.

The inspections and the checks should be based firstly on risk assessments, i.e. to examine factors relating to the significance of the impact of an adverse event and the probability of it happening and secondly on the principle of proportionality (selection of the sample of inspected enterprises, formulation of sanctions, etc.) based on factors such as materiality - risk findings, business history, etc)

The case of United Kingdom

In UK, the Department for Business, Innovation and Skills (BIS) constitutes the supervisory body for the purchase of consumer goods for health and insurance,. It coordinates and directs the local authorities who are responsible for planning and carrying out audits. While, for the purchase of medicines and medical devices, the inspections and surveillance functions are concentrated in Medicine and Health care Products Regulatory Agency of the Ministry of Health.

Focus on risk and proportionality

It is important to consider the risk and the risk level in all decision-making levels - from the strategic allocation of resources to the organization of audits and the proportionality of sanctions.

Furthermore, it should be taken into account **all the stages of the supervisory process**- in the planning, implementation and evaluation stage. The implementation stage is particularly important, because it is not only virtually impossible for supervisors to inspect all businesses, but also it would create a huge and unnecessary administrative burden.

The case of Germany

The Federal Institute for Risk Assessment (BfR) was created in November 2002 to enhance the protection of consumer health, following the crisis of Bovine spongiform encephalopathy (BSE).

The institute operates at the federal level and it is responsible for independent risk analysis studies, using scientific methods, without being influenced by any economic, political or social interest.

The frequency of the inspections and the resources used should reflect the level of risk and the inspection activities should be aimed to reduce the actual risk posed by offenders.

The case of United Kingdom

The United Kingdom takes the law into account regarding precautionary measures. But risk assessment is regarded the utmost important basis for action. Regarding risk management, the principle of ALARP (As Low As Reasonably Practicable) is applied, under which, the residual risk should be as low as reasonably achievable. The Cost Benefit Analysis is realizing in accordance with the above principle.

Particularly, businesses that violate the rules systematically, a higher risk level should be assigned and therefore they will be checked frequently.

By contrast, **businesses which have a history of consistent compliance with the legislation, the frequency of the inspections should gradually be reduced.**

OECD Direction

Inspection mechanisms cannot cover the whole market. Therefore, alternative ways of monitoring the markets must be developed. So, the aim should be to involve the private sector and the civil society, where feasible and effective, in the market monitoring.

Coordination and integrated organization

Reducing duplication between the relevant audit authorities contributes to better use of available public resources, reduces the administrative burden for businesses

Reducing duplication contributes to better use of available public resources, reduces the administrative burden for businesses and increases efficiency.

The processes of risk assessment should be transparent in order to be able to make investment decisions, which are based on a correct understanding of the enterprise's future obligations

and increases the efficiency. For this reason, the operation of surveillance and inspection authorities should be coordinated and, where appropriate, consolidated.

The case of The Netherlands

The Netherlands demonstrates a case where the gradual consolidation of state inspection agencies contributed to a reduction of more than 50% of the number of operators, from 26 in the year 2000 to twelve (12) in the year 2012, and an estimation to reach ten (10) by the end of the year.

The consolidation procedure carries a short-term cost, but the long-term cost savings yield significant benefits.

OECD Direction

The reorganization of audit services is one of the most important institutional reforms that can improve the effectiveness of inspections and reduce costs and administrative burdens, so that their functions will be consolidated without partial or complete overlaps.

Transparency and collaborative approach

The legal framework should provide a clear operational framework for the inspection authorities, because the ineffective conveyance of information and the absence of clear regulations create uncertainty, which is one of the key factors that may adversely affect compliance and inspections.

A key feature of such a legal framework is the **clarification of inspection responsibilities, types of inspections that are performed and the economic bodies who have the responsibility to supervise**, so that the above is clear both for audit authorities and businesses.

It is important for businesses to know what will be the impact of a regulation, so that they can determine the way to ensure compliance at the lowest possible cost.

Transparency and compliance should be supported by the use of appropriate instruments such as guidelines, toolkits and inspections lists, as **for more enterprises (especially the very small ones), it is difficult to understand what exactly they should do in order to comply with the applicable rules.**

OECD Direction

The supervisory and inspections authorities should share the information concerning the regulatory framework of inspections compliance and inspections through all available means and channels. Particularly, they should develop and publish notices or toolbars that allow the businesses to understand the requirements and the manner in which compliance is achieved in the most common situations and sectors.

The importance of these tools falls on the fact that **the enterprises acquire an official reference point, which ensures that the requirements with which they seek to comply, form in line with the requirements of auditors.**

The case of United Kingdom

For smaller businesses, the EU regulations for certain markets, such as food, is quite complicated rendering it difficult to understand.

According to the National Audit Code (business compliance) of Local Authorities (National Local Authority Enforcement Code) which is developed and it is adopted by the HSE, the role of the auditors is to support, encourage and advise businesses,

and where necessary to conform to the code, so they will be able to effectively handle the health and safety risks.

OECD Direction

Governance structures and human resources policie of audit authorities should support transparency, professionalism and be results-oriented.

The supervisory authorities should cooperate with the enterprises and strive where possible in establishing a collaborative approach, because only such operators can ensure the consistent and continuous compliance of their functions.

The case of United Kingdom

According to the national supervisory program of the country which filed in the European Commission, the United Kingdom considers that most companies are or are seeking to comply with the law, with a very small percentage not to comply with the law deliberately. Therefore, it is considered that most part of the non-compliance businesses is due to either lack of access to relevant information, or lack of understanding the requirements.

According to the National Audit Code (business compliance) of Local Authorities (National Local Authority Enforcement Code) which is developed and it is adopted by the HSE, the role of the auditors is to support, encourage and advise businesses, and where necessary to conform to the code, so they will be able to effectively handle the health and safety risks.

At this point it should be noted that the disclosure of information may be a powerful tool to encourage self-compliance and press businesses to comply with the specifications. However, care should be taken to ensure how and in what circumstances the surveilling authorities may disclose information, in order to prevent abuse on behalf of inspection authorities.

Professionalism and training

Professionalism should be the basis of the inspection authorities and the inspection services should be independent of political influence and the efforts of business compliance should be rewarded.

It is important to be ensured that auditors are able to create and follow the priorities of their work (for example which companies to inspect), based on their experience and expertise. The political decision should be limited to a level of overall strategy and resource allocation, without interfering in the daily official activities.

Additionally, auditors and inspectors should be trained to ensure professionalism, integrity, consistency and transparency.

Educational material should not be limited to the expertise and the object of the enterprise. Instead, it should include the general inspection skills related to inspections, ethics, risk management and interdepartmental cooperation.

OECD Direction

Adopting a common approach for the training of human resources in various audit services could possibly develop and improve the professional skills of auditors and inspectors. Moreover, the use of a suitable tool for the evaluation of their abilities or their shortcoming will contribute positively.

Ensuring the objectivity and independence of audit and supervisory bodies may include the identification of appropriate structures, the actions necessary for their development, as well as the composition of "cooperation protocol" between audit bodies providing the independent risk assessment and the consistency of their opinions.

Utilisation of data and information systems

The inspections should be based on data and quantifiable data. **The decision concerning what / who will be inspected and how will be the process, should depend on data and quantifiable data, and these results should be regularly evaluated. The operations and activities of audit authorities should also be frequently evaluated against the defined criteria and they should be subject to reliable data.** The performance of the staff should reflect the general objectives of the enforcement activities, the specific objectives of each organization and particularly the service performance indicators.

The case of United Kingdom

In UK Food Standards Agency (FSA) performs inspections on the audit plan and compliance procedures of local authorities and it provides a report describing the stages for improvement in which Authority will enable to focus its efforts and the recognition of common practices.

The authorities are controlled by the Framework Agreement on Official Feed and Food Inspections which sets the minimum requirements that have to be covered by the local authorities regarding the supervisory and audit activities. This program is implemented at a national level and the FSA of every country organizes and coordinates its own inspections program.

However, studies have shown that **the evaluation of the effectiveness of the supervisory authorities encounter some difficulties.** Indicatively, a low number of inspections or sanctions may possibly be a result of the high rate of compliance, but it can also be a result of reduced resources. Despite this, monitoring of such data is particularly important to assess the contribution that an inspectorate has on market regulation.

OECD Direction

Businesses' participation in the evaluation of supervisory authorities can assist in the identification of overlapping functions.

Information systems form an indispensable basis for the effective coordination of inspections and the planning of the audit plan based on risk. Information systems that are structured to support audits and inspections based on risk, are also an essential tool for complaints management, that Inspectorates often receive complaints. Although the initial assessment of complaints should be made by qualified personnel, complaints management is a part of risk management.

OECD Direction

Complaints that pass from various inspections filters should not lead to inspections, but these should be recorded in the information system, except the emergency cases, where there is need for immediate response. Repeated complaints concerning the same product or company will increase the risk level, which will lead to more inspections periodically.

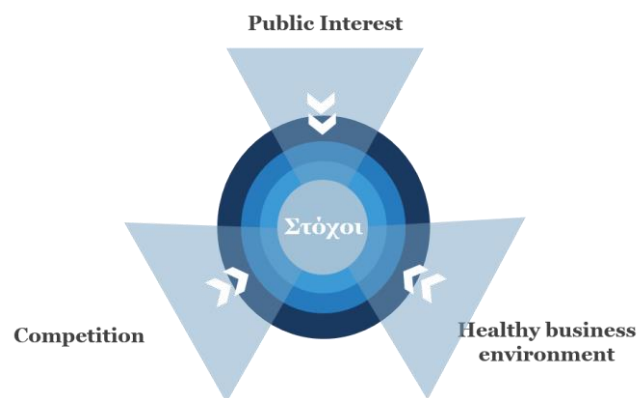
4 Strategy and recommendations for the improvement of the market's inspections and surveillance system

The strategy recommended below, aims to create an inspections and surveillance system which achieves at the same time:

the protection of the public interest

the promotion of a healthy business environment and

its protection in cases of unfair competition



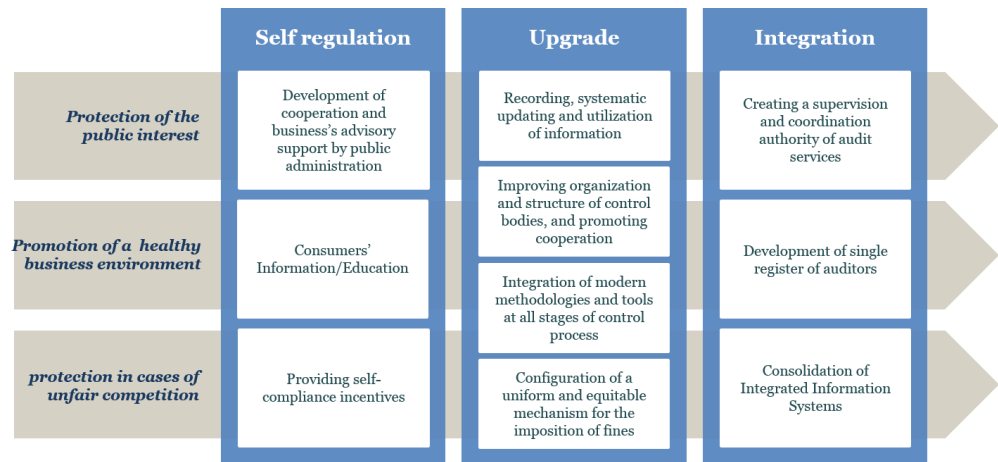
Particularly, the strategy for the improvement of the market's inspections and surveillance system depends on an **Integrated Action Plan**, which:

- It lays the foundations for **the long-term development of a comprehensive and dynamic model** for the inspections and surveillance that corresponds to the techno-economic and productive changes, with clear vision and a long-term roadmap.
- It is oriented **to the specific characteristics** and weaknesses of the **Hellenic market**.
- **It responds to the product's risk level**, while it develops a fair inspection and surveillance system.
- **It promotes effective cooperation** among stakeholders for planning, identifying opportunities for creating economies of scale and knowledge transfer.
- **It ensures the conduction of effective audits**, by clarifying the roles and responsibilities and capturing clear audit procedures.
- **It utilizes all means, technological tools and systems** for the strategic use of information, organization, planning and management of the audit process.
- **It lays the foundations for developing a clear goal setting system**, with performance indicators (KPIs) directly linked to the strategy, which covers the entire range of inspections and surveillance activities, providing incentives for the dynamic implementation of the strategy.
- **It ensures auditors' competence**, through organized and periodic training programs, based on international experience.
- **It promotes actions for the systemic simplification of the legal framework** and the elimination of obsolete regulations.

4.1 Strategic pillars and action's shafts

The **Integrated Action Plan** is directed at three strategic pillars, with individual action plans, and it is aggregated in the graph below.

Graph11. Action per strategic pillar with the goals promoted



4.2 Recommended measures

The measures that compose the Integrated Action Plan, are presented below per strategic pillar and action.

Strategic pillar 1. Enhancement of market self-compliance

Action 1.1. *Development of cooperation and business's advisory support by public administration*

Recommendation 1. *Provision of instructions and guidance on the implementation of the legal framework and information about modifications and application requirements*

The systematic documenting and updating of directives, with a clear reference to the relevant legal framework in which they relate is necessary. The design and the distribution of relevant toolboxes are proposed in order to achieve better information and support to the businesses.

The guidelines and toolboxes should be available through the authorities' official websites and they should be available in hardcopy at the authority premises. It is also proposed, sending emails to businesses (which have declared an interest) relating to changes in context.

Recommendation 2. *Exchange of expertise and information on safety and product labeling and other issues relating to inspections*

Within the context of developing a collaborative approach and culture, the exchange of information and sharing expertise is important.

This information may relate to changes in the sector and the market inspected, and it may relate to safety issues and labeling products concerning both businesses and inspections authorities. In this framework, it is proposed:

- Participation in inspectors' training sessions by businesses
- Institutional participation of public administration with business associations to establish joint working groups for the exchange of information and expertise
- Organization of workshops to highlight problems resulting from the legal framework and to plan their management methods

Recommendation 3. *Definition of specific supervisory bodies, by geographical area (e.g. at Regional level), under which every business located in the area, will report for the market monitoring, within the logic of the account manager*

Particularly, each business will be subject to an auditor ("responsible authority"). The responsible authority will observe their business records in its area of competence, it will monitor the market, it will provide instructions and guidance on the implementation of the legal framework and it will exchange information and expertise on safety issues and labeling products.

On this logic, the other audit bodies will be required to communicate with the responsible authority and take into account the advice and suggestions, before they carry out audits or they take legal action against one firm. On the other hand, the responsible authority will provide expert advices to the businesses of its responsibility regarding the regulatory framework, the good practice and the actions required in order to ensure their compliance.

Action 1.2. *Consumers' Information/Education*

Recommendation 4. *Drafting of products' recognition directives (eg authentication features, quality etc.) and communication via internet, TV etc.*

It is suggested that supervisory authorities draw up guidelines to consumers, so that the consumers can easily verify the product's authenticity, its quality or its alteration, etc., and generally these guidelines will enable the consumers to properly evaluate the products that they consume and to reduce the probability of their being misled.

All available communication channels (e.g. internet, official inspections authorities' websites, leaflets in supermarkets etc.) should be exploited, for the best possible dissemination of the information.

Additionally, it is proposed businesses' institutional involvement through their links in the process of drafting directives. While for the dissemination of information, it is recommended the exploitation of businesses' links for the industrial products and of consumers' associations for consumer goods.

Recommendation 5. *Conducting informational events and workshops on safety and health issues, which may require further substance*

The purpose of the action is to inform stakeholders - consumers and businesses - on health and safety issues and issues related to risk identification and dealing operations. This action is suitable for companies, particularly for small and very small companies.

For optimal management of resources and responsiveness and public participation in information events and workshops, the cooperation and, especially, the joint organization of events with consumers' and businesses' associations are required. Furthermore, the targeted information to consumers and businesses is very important, in cooperation with consumers' associations and businesses.

Action Plan 1.3. *Providing self-compliance incentives*

Recommendation 6. *Correlation of businesses' certifications with the frequency of checks*

It is suggested the correlation of certifications available to businesses with the frequency of inspections and, particularly, their inclusion in the criteria on which the planning of checks is released, and in the complaints management criteria. So, it will achieve the connection of certifications and good practices of companies based on internationally recognized standards, with the risk assessment and the frequency of checks carried out by the inspections authorities.

For companies who dispose the relevant qualifications, it could be delegated lower risk level, which should lead to fewer inspections, thus reducing the administrative burden. While, with regard to the supervisory authorities, a better sharing of available resources can be achieved, as the audit work focuses on activities that have the greatest risk or to activities in which the risks are less inspectionsled.

Recommendation 7. *Cooperation between public administration and business to jointly deal with crisis and emergency*

Another factor that may contribute to the strengthening of self-compliance is the institutional "consolidation" of cooperation between inspectionslers and inspectionsled bodies. The supervisory authorities should, whenever it is possible and appropriate, to establish a collaborative approach, as only such operators can ensure the consistent and continuous compliance of their functions. The aim is to develop a climate of trust, where companies would seek to resolve potential risks in cooperation with the competent authorities while supporting their work providing information.

The cooperation concerns to jointly responding to crises and emergencies, effective treatment and prevention of risks, with a view to strengthening consumer protection.

Strategic Pillar 2. Upgrade of monitoring and inspections system

Action 2.1. *Recording, systematic updating and utilization of information*

Recommendation 8. *Integration / Installation of Integrated Information Systems to support all stages of the audit, from planning up to the annual account*

It is recommended the installation and the integration (where it started and it has remained at a pilot stage) of Integrated Information Systems (IIS) to support the work of the supervisory authorities and the optimal management of information and data.

Specifically, via IIS, the inspections authorities:

- They will record all the information in a single point, where everyone will have access according to their competence
- They will feature methodologies, guidelines and tools to inspectors to perform their audit work (legislation, inspections cards, penalties per violation and calculation of fines, risks and dealing operations etc.)
- They will derive statistics in order to monitor the market and to draw conclusions and develop guidance to auditors

- They will form the inspections program based on updated market data and needs and risks arising

Recommendation 9. Interoperability of Integrated Information Systems (IIS)

The integration of available information provides a more complete picture of the market supervisory / auditor sector and it enables the improved coordination and sharing of the work of the competent bodies. Interoperability of IIS will contribute to the best possible use of information and to improve the coordination of the supervisory authorities.

In this context, the provision for interoperability of IIS is proposed, with access rights, to achieve the combined management and use of data held in fragments of individual inspections bodies.

Action's shaft 2.2. Improving organization and structure of inspections bodies, and promoting cooperation

Recommendation 10. Clarifying roles and responsibilities with an emphasis on avoiding duplications

For the best coordination of resources of the monitoring and inspections system and the avoidance of duplications, clarification of the roles and responsibilities of individual agencies is needed. Particularly, the followings are proposed:

- Study of the legal framework governing the organization and operation of market inspections services
- Mapping of all relevant audit authorities and their responsibilities
- Identification of overlaps and ambiguities
- Clarifying audit responsibilities and inspections types by authority
- Improving the distribution of responsibilities and eliminating duplication where necessary, based on the best use of resources
- Updating businesses for the above through official websites and through their institutional representatives

Recommendation 11. Conclusion of a cooperation protocol between institutions

The purpose of the conclusion of cooperation protocols between inspection bodies is the audit assignment within a predetermined and agreed framework, which sets out the award conditions and obligations of the institution undertaking the project.

With the cooperation protocols, the relationship between public administration bodies is consolidated and the followings are achieved:

- Clarification of the obligations and the expected project
- Addressing constraints on resources such as laboratory facilities and human resources
- Ensuring the coverage of Greek territory
- Achieving consistency in audit work throughout
- Improving compliance degree of businesses

Recommendation 12. Development of training courses for the improvement of technical and interpersonal skills of auditors

The training of auditors will address technical issues and industry developments affecting the market, but it will not be limited only to the expertise and inspection

object. Instead, it should include the general inspection skills related to inspections, ethics, risk management and inter-agency cooperation in order to guarantee professionalism, consistency and transparency of the auditors.

Adopting a common approach for the training of human resources in various audit services, this could possibly support the uniform development and improvement of professional skills of auditors and inspectors. Moreover, in the same direction it will contribute positively the use of a suitable tool which will be used to identify necessary skills and diagnosis of their needs.

Recommendation 13. *Development of benchmarking mechanism for audit bodies*

The mechanism relates to the periodic and consistent evaluation of the temporal performance of each Audit body, and the performance in relation to other bodies. The purpose of this proposal is to highlight areas requiring improvement and recognition of good practices by operators.

Particularly, the mechanism should assess the results achieved through performance indicators, taking into account the qualitative and quantitative adequacy of the supervisory authorities in human resources, the available financial resources and instruments available (infrastructure and equipment).

In this context, the following should be studied and defined, for the development of such a mechanism:

- Objectively and widely applicable **evaluation criteria**
- **Assessment procedures** to be followed
- **Body responsible for the evaluation** of supervisory authorities
- **Definition of incentives for the proper and continuous monitoring** of audit work by the same audit bodies (self-evaluation)

Action Plan 2.3. *Integration of modern methodologies and tools at all stages of inspections process (from planning to the conduct and the annual report)*

Recommendation 14. *Adoption of risk assessment tools, both during the planning and selection of contractors to be audited, and in carrying out inspections and imposing sanctions*

It is proposed to include the risk assessment in all decision-making levels - from the strategic allocation of resources to the organization of checks and the proportionality of sanctions. It should also be taken into account at all stages of the surveillance process - during the planning, implementation and evaluation.

The inspections and the inspections should be based on the assessment of the potential risk and the principle of proportionality. The inspections' frequency and the resources used should reflect the risk level and the inspections activities should be aimed at reducing the actual risk posed by offenders. So, audit authorities' work will focus on activities that have the greatest risk or where the risks are less monitored.

Recommendation 15. *Creation of management system and prioritization of complaints, in which the risk will be taken into account*

In the same context, the investigation of complaints is an important part of detection inspections, whereas effective management of malicious and unfounded complaints

can significantly lighten the administrative burden of both the audit body and businesses. Therefore, it is necessary the creation of a management system and the prioritization of complaints in which the risk will be taken into account.

The complaint management system should support both the evaluation and the prioritization / classification of complaints, based on specific criteria. Thus, the complaints go through various inspections filters should not lead to inspections, but they should be recorded in the information system.

Action Plan 2.4. Configuration of a uniform and equitable mechanism for the imposition of fines

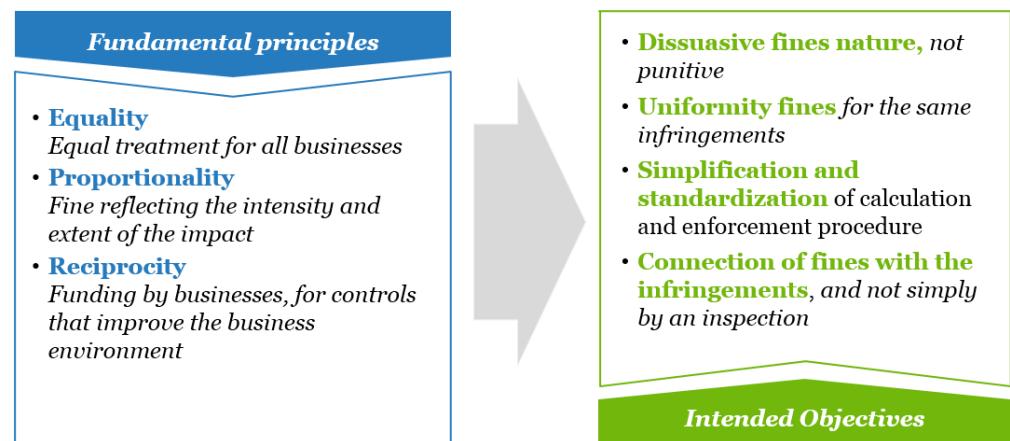
Recommendation 16. Designing a common methodological approach for calculating the fines and provision of guidance and support to the supervisory authorities and auditors

The aim of the new methodological approach should be **the prevention of delinquency** from the business perspective and the objective judgment by the supervisory authorities.

For this purpose it is important to review the nature of sanctions towards the prevention and dissuasion and the fundamental revision and particularisation of the way of calculating the fines.

Particularly, the graph below reflects the fundamental principles on which basis it is proposed to develop the methodological approach and it also reflects the purposes that it serves:

Graph 9. Designing a common methodological approach



Following the above, the calculation of fines is proposed and it is based on the following:

- Risk level
- Contravention’s frequency
- Negligence or contravention knowingly by the business
- Intensity and extent of impact to the consumer, business environment / market
- Historical conduct of the business

Furthermore, it is important to provide, systematically, guidance and support to the competent authorities and auditors (instruction manuals, quantifying consumer loss tools, etc.).

The aim of the above is that the strictness imposed as fine, not to depend on the auditor that will conduct the inspection, but on an objective evaluation of the findings, ensuring that operators comply with the requirements for the protection of consumers.

Recommendation 17. *Update business for the fines' calculation methodology*

To date, the amount of the fine that may be imposed by the type of the infringement will depend primarily on the auditor that will conduct the test rather than an objective assessment of the infringement. Thus, despite the fact that companies comply with the requirements of auditors, this does not mean, automatically, compliance with the spirit of the law.

This fact reflects from one side the companies which feel exposed to inspections and the auditor's judgment and from the other side the protection of the consumer cannot be ensured.

Therefore, the need of renovation business for the calculation and imposition of fines is necessary in order to support the transparency of audit work, to protect business from power abuses and to achieve the protection of consumers from the real dangers.

Strategic Pillar 3. Development of a single audit system

Action Plan 3.1. *Creating a surveillance and coordination authority of audit services*

Recommendation 18. *Development of a Single Supervisory Body, responsible for the supervision of control bodies (EFET, GCSL, EOF, etc.), development of a strategy, programs' approval, budget allocation, monitoring and coordination of audits*

The Unified Supervisory Body will be responsible for approving individual supervisory programs, and for evaluating their performance in order to avoid overlaps between audit authorities and to ensure the proper allocation of resources. Also, this body will be responsible for monitoring of their implementation, in order to intervene directly and taking corrective action in case of deviation or emergency occurrence.

In addition it is important that the new body will manage the financial resources which are available for the inspections process and it will allocate them to individual supervisors based on documented needs, including the estimated risk of products and businesses.

Recommendation 19. *Study to investigate the form of the Single Supervisory Body, its role and responsibilities*

The Single Supervisory Body may be established either by upgrading an existing supervisory body in which will be given additional powers or by creating a new one. The form of the body, the detailed responsibilities, the reference lines, the functions, staffing and other resources are objects, which their determination requires a specific study.

The aim is to develop a new supervisory unit without cause any further barriers and obstacles to the investigation, but this development will act positively in planning, coordination and optimum resource management.

Action Plan 3.2. Development of single register of auditors

Recommendation 20. Development of single register of auditors under the Single Supervisory Body with the participation of existing inspectors and potential use of external auditors upon certification

The registry will be used for the full registration of auditors (at central and regional level), by specialty and geographic region and it has as purpose channeling them to the checks, based on the ordinary and extraordinary needs. Single Supervisory Body will be responsible for the register and it will act as a pool of auditors from where supervisors will be able to find auditors who are required by their characteristics and the audit work that they have to do. They will be responsible for providing guidance, methodologies, market information and tools (logistics) to the inspectors.

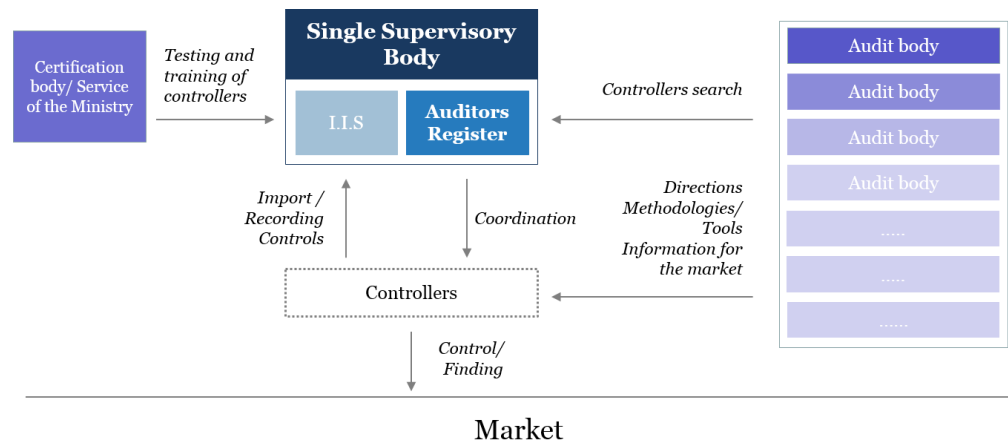
In this action the possibility and the modalities of individuals' participation (natural and legal persons) and workshops will be studied. For all those who will participate in the registry a certificate of their proficiency in specific fields will be provided, while all these persons will be bounded to the relevant Code of Conduct.

The auditors will undertake the audit work separately, by the type of inspections (as it is practiced today) or as a single audit, to develop synergies, to reduce duplications and drafting integrated finding.

The auditors will report to the Single Supervisory Body and they will be responsible for the continuous updating of IIS by introducing and recording information, both for inspections carried out, and for the companies themselves.

Specifically, the way of auditors' exploitation and conduct of audits is depicted in the following graph:

Graph 10. New organizational structure of inspections and surveillance system



Action Plan 3.3. Consolidation of Integrated Information Systems

Recommendation 21. Development and use of common tools and methodologies from all authorities

In order to homogenization, simplification and standardization of the audit work, it is proposed to develop common tools and methodologies for all aspects of audit activity and for all stakeholders, to be integrated into a common Integrated Information System (see. Next action).

Graph 11. Inspections dimensions



To this end, it is suggested the creation of a group of specialized auditors of all auditing bodies, which will take the action, from the required specifications and registration of existing toolbars to the review of international practice and the formation of the mixture of tools and methodologies that will be used .

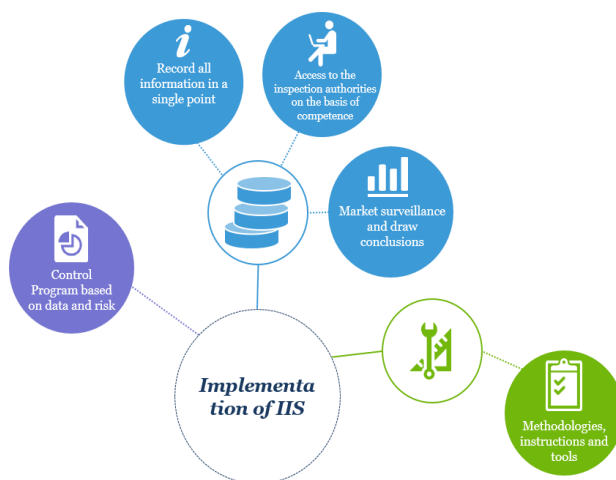
The methodologies and tools would be diversified, depending on the needs and characteristics of the inspections object, however they would be common to all, to the greatest possible extent.

Recommendation 22. Consolidation of Integrated Information Systems (IIS)

The proposal relates to the full consolidation of all IIS of the individual supervisors, under the responsibility of Single Supervisory Body, with a view to more effective coordination, management and monitoring of the audit and the development of synergies.

The aim of this action is to create a common reference point, for all inspections mechanisms of public administration, from which they would obtain the information, organize and coordinate their actions. At the same time it would support them by providing guidelines and toolboxes for the implementation and management of the project, based on specific and common methodological approach and utilizing combinatorial information.

Graph 12. Implementation of IIS



In this context, setting up a scientific group is proposed, by involving members of all stakeholders, which will undertake the identification and registration of technical requirements and the major factors affecting the audit work for each audit authority in order to identify common reference points which could initially be the field of interest of the group.

Special proposals

Products labeled CE

- I. Utilisation – Updating the information system of the General Secretariat of Manufacturing
- II. Continuous updating of businesses and those involved in audit regarding amendments / changes / additions of New Approach Directives by the General Secretariat of Manufacturing

Food and Beverage

- III. Creation of a management and prioritization complaints system, to the Directorate of Institutional Settings and Monitoring Product Market, which will be considered the risk level
- IV. Preparation, organization and implementation of an annual audit program by the Department of Institutional Settings and the Product Market Monitoring in collaboration with other audit institutions, which will emphasize on avoiding duplication
- V. Extension of cooperation's protocols and introduction of new protocols between the FSA and other bodies, in order to carry out inspections at regional level
- VI. Clarifying the role and responsibilities of the FSA, with emphasis on avoiding duplication and the overall surveillance and inspections of the food market

Cosmetics

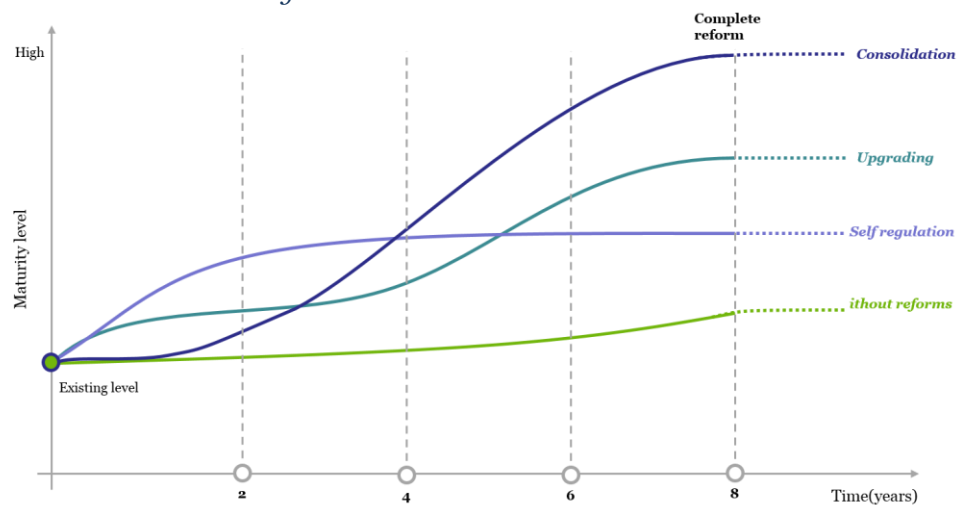
- VII. Focusing the inspections at regional distribution channels, where higher delinquency occurs (eg. TV, internet)
- VIII. Exclusive use of all cosmetics businesses' assistance to inspections this market
- IX. Adoption of a law JMD for the incorporation of the regulation 1223/2009 regarding cosmetics, which would include the mandatory language on the label, the amount of penalties and information concerning the possible effects of the products

5 Implementation of proposed measures

5.1 Impact of the strategic pillars in the maturity level of the control and surveillance system

The expected impact of the measures per strategic pillar, in the level of maturity of the Greek inspections and surveillance system is reflected in the following graph.

Graph 13. Impact of the strategic pillars in the maturity level of the control and surveillance system



The inspections and surveillance system ...

- ... will marginally improve over the next few years, if no measures are adopted.*
- ... will be upgraded fairly quickly (~ 2 years) and will remain stable with the implementation of the actions of the strategic pillar one ("Self-compliance").*
- ... will be limited improved in the short term, while in the second year the implementation of all actions will lead to significant improvement.*
- ... will be able to effectively protect the public interest and contribute positively to the operation of the market in the long term, by the application of the actions of the strategic pillar 3, on the basis of previous improvements.*

Note that in the above figure, each line reflects the influence of the respective pillar in the system, without taking into account the benefit of the other two.

5.2 Quick wins & Big bets

Based on the time frame for the implementation, the degree of importance and the degree of their feasibility (easiness), the following measures' categories have been recognised:

- Quick wins
- Big bets
- Nice to have

Graph 14. Prioritisation of proposed measures

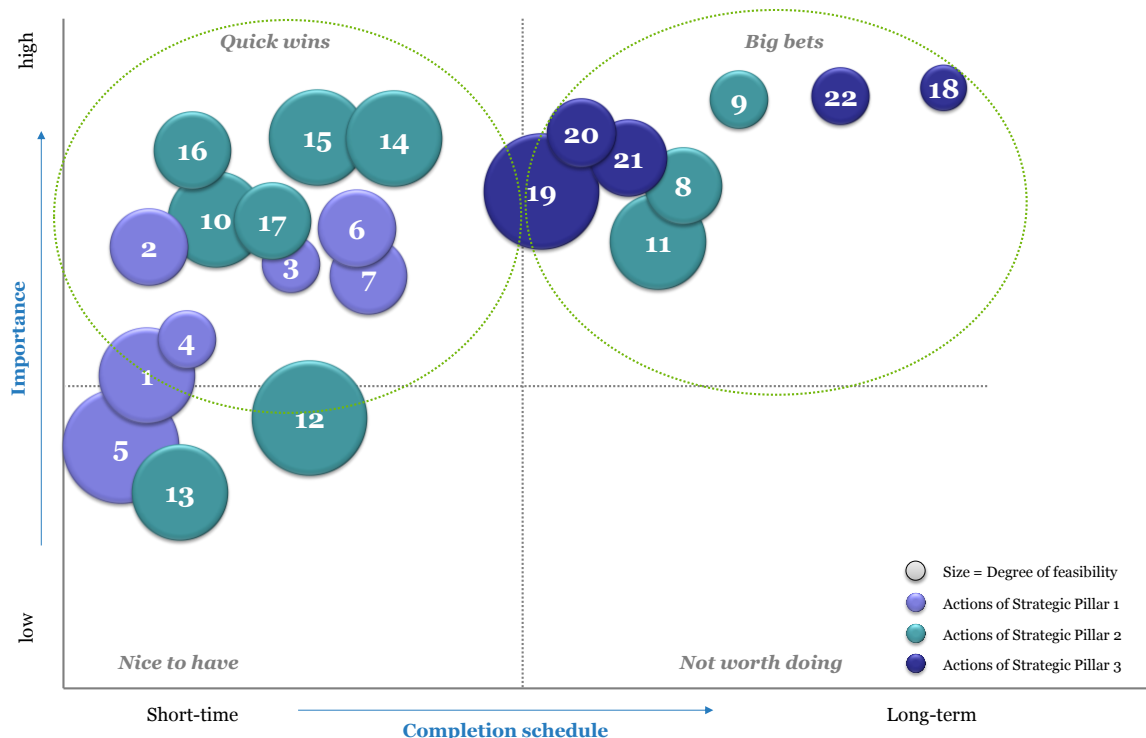


Table 5. Quick wins

#	Measure	Significance	Easiness	Completion schedule
Strategic Pillar 1				
1.	Provision of instructions and guidance on the implementation of the legal framework and information about modifications and application requirements	4	3	Short-term
2.	Exchange of expertise and information on safety and product labeling and other issues relating to inspections	3	4	Short-term
3.	Definition of specific supervisory bodies, by geographical area (e.g. at Regional level), under which every business located in the area, will report for the market monitoring, within the logic of the account manager	2	4	Short-term
4.	Drafting of products' recognition directives (eg authentication features, quality etc.) and communication via internet, TV etc.	4	3	Short-term
6.	Correlation of businesses' certifications with the frequency of checks	3	4	Short-term
7.	Cooperation between public administration and business to jointly deal with crisis and emergency	3	4	Short-term
Strategic Pillar 2				
10.	Clarification of roles and responsibilities with an emphasis on avoiding duplication	4	4	Short-term
14.	Adoption of risk assessment tools, both during the planning and selection of contractors to be audited, and in carrying out inspections and imposing sanctions	4	5	Short-term

#	Measure	Significance	Easiness	Completion schedule
15.	<i>Creation of management system and prioritization of complaints, in which the risk will be taken into account</i>	4	4	Short-term
16.	<i>Designing a common methodological approach for calculating the fines and provision of guidance and support to the supervisory authorities and auditors</i>	3	5	Short-term
17.	<i>Update business for the fines' calculation methodology</i>	3	4	Short-term

Table 6. Big bets

#	Measure	Significance	Easiness	Competition schedule
Strategic Pillar 2				
8.	<i>Integration / Installation of Integrated Information Systems to support all stages of the audit, from planning up to the annual account</i>	5	3	Long-term
9.	<i>Interoperability of Integrated Information Systems (IIS)</i>	5	2	Long-term
11.	<i>Conclusion of a cooperation protocol between institutions</i>	4	4	Long-term
Strategic Pillar 3				
18.	<i>Development of a Single Supervisory Body, responsible for the supervision of control bodies (EFET, GCSL, EOF, etc.), development of a strategy, programs' approval, budget allocation, monitoring and coordination of audits</i>	5	1	Short-term
19.	<i>Study to investigate the form of the Single Supervisory Body, its role and responsibilities</i>	5	5	Medium term
20.	<i>Development of single register of auditors under the Single Supervisory Body with the participation of existing inspectors and potential use of external auditors upon certification</i>	5	3	Medium term
21.	<i>Development and use of common tools and methodologies from all authorities</i>	5	3	Medium term
22.	<i>Consolidation of Integrated Information Systems (IIS)</i>	5	2	Long-term

Table 7. Nice to have

#	Measure	Significance	Easiness	Competition schedule
Strategic Pillar 2				
5.	<i>Conducting informational events and workshops on safety and health issues, which may require further substance</i>	3	5	Short-term
12.	<i>Development of training courses for the improvement of technical and interpersonal skills of auditors</i>	3	5	Short-term
13.	<i>Development of benchmarking mechanism for audit bodies</i>	3	4	Short-term

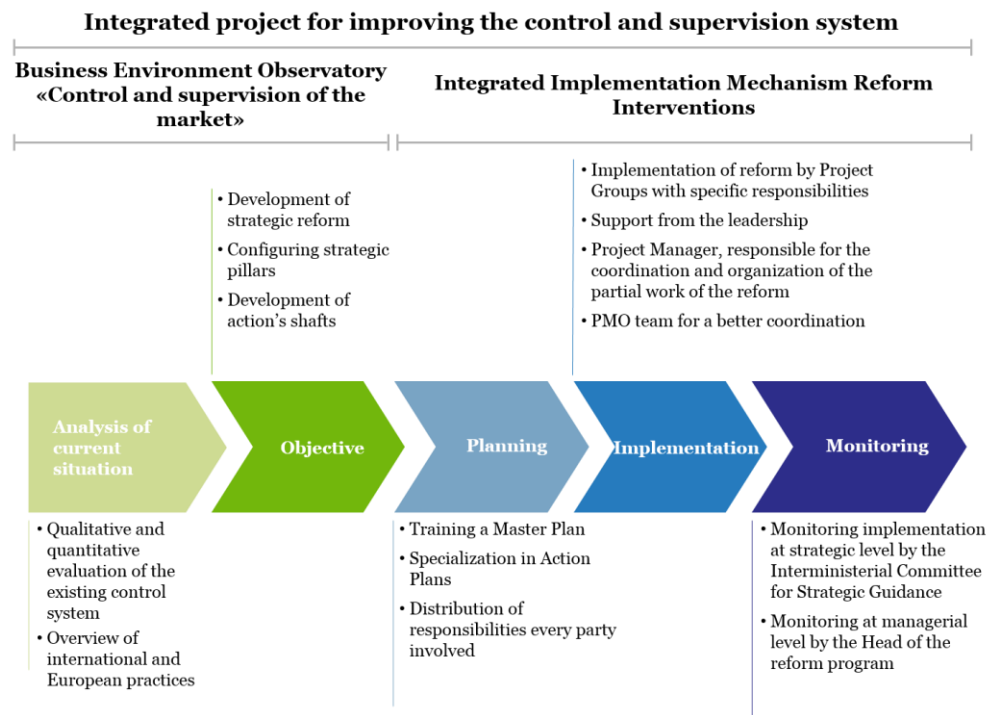
5.3 Integrated mechanism for the reform implementation

The integrated implementation mechanism presented below, is the last part of a comprehensive plan to improve the existing monitoring and inspections system and market surveillance activities proposed in the relevant study.

According to OECD, reforms of inspections systems are difficult to implement successfully, mainly because they threaten customs and practices of times.

Therefore, one of the most crucial elements for ensuring a successful reform is the existence of a specialized team that will implement the project, which will have the support of leadership of the reform.

Graph 15. Integrated project for improving the inspections and surveillance system



In particular, for the successful and rapid implementation of proposed interventions of inspections and surveillance system, will require the establishment of a comprehensive central Implementation of Mechanism Reform interventions, which will take:

- on a *strategic* level, the design of the reform program, providing guidance and monitoring of results
- at *management* level, the management of program implementation and
- at the *executive* level, technical and legal support for the implementation of individual projects

The Hellenic Federation of Enterprises and the Business Environment Observatory, through studies and research undertaken and the monitoring and measuring instruments available, can support the Mechanism for the documentation of actions for optimal monitoring of the implementation and technical support in program implementation.

Graph 16. Suggested structure of Implementation of Reform Interventions Mechanism



Critical success factors for the effective functioning of the proposed mechanism is as follows:

- **Political Commitment**
- **Clear structure** and organization of the mechanism that runs vertically and horizontally the public administration structures
- Full **clarification of roles** and responsibilities
- Ensuring adequate funding and **appropriate human resources**
- **Effective communication** with stakeholders
- Creating a **framework for the engagement** of third parties
- **Realistic scheduling** of individual operations
- Determination of **performance measurement indicators** to allow monitoring of the achievement of objectives at program level and individual projects and results / impact to the ultimate objective of reducing congestion pending cases and restoration of the smooth flow of settling administrative disputes.

