

# National Plan for Official Control of the Food Chain

# 2021-2025

Version 2 - 2022



agencia  
española de  
seguridad  
alimentaria y  
nutrición



GOBIERNO  
DE ESPAÑA

MINISTERIO  
DE INDUSTRIA, COMERCIO  
Y TURISMO

MINISTERIO  
DE AGRICULTURA, PESCA  
Y ALIMENTACIÓN

MINISTERIO  
DE SANIDAD

MINISTERIO  
DE CONSUMO

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## 1. INTRODUCTION

The National Plan for Official Control of the Food Chain (PNCOCA) describes the official controls carried out in Spain by different competent authorities at state, regional and local level, in order to ensure compliance with regulation throughout the food chain, from primary production to points of sale to the final consumer.

The Plan is a tool for the improvement of all existing official control systems. The description of these activities reveals the evidence of solidity of the base upon which food safety and quality is sustained in Spain, and will also signal, through the annual reports of the Plan, those questions to be resolved, so that improvement becomes a continuous process.

The Plan has been drafted taking into account the territorial and competence organisation of the Spanish state, conceived as a framework upon the competent authorities plan and execute official controls in the field of competencies.

## 2. GUIDING PRINCIPLES

The guiding principles in the drafting of this plan are:

- The food chain, in all its phases, must be subject to the official control programmes necessary and interdependent control of dangers, taking into account their frequency and seriousness and, where applicable, their removal.
- Official quality control must be ensured, guaranteeing the remedy of any non-compliance with the requirements established, adopting corrective measures necessary and subsequent verification.
- Transparency and coordination between Administrations shall be guaranteed, and with economic operators who are to be subject to official control. On the basis of this principle, both the Plan and the reports of execution and their proposals for improvement shall be public.
- The cooperation and collaboration between the different competent authorities (state, regional and local) ensure that the Plan encompasses a design where the channels of coordination are sufficient to guarantee their efficiency, applicability and full validity of the provisions.
- The efficient use of the resources available, including the guarantee of the management of human resources.
- The guarantee of fair treatment for all citizens and economic operators, harmonising and implementing the design of the inspection methods, through the drafting of planning documents, inspection protocols and reports.

### 3. COMPETENT AUTHORITIES

#### 3.1. Territorial and sectoral organisation

##### 3.1.1 Territorial organisation

The Spanish State is organised territorially into municipalities, provinces and autonomous communities. All of these entities enjoy autonomy for the management of their respective interests (Art. 137 of the Spanish Constitution). Therefore, Spain has three levels of territorial public administrations:

- General State Administration
- Regional administration
- Local administration

Articles 148 and 149 of the Constitution establish the distribution of competencies between the State and autonomous communities, so that the State has exclusive competency for the following areas relating, directly or indirectly, to Official Control:

1. International relations
2. Administration of justice.
3. Criminal legislation, procedural legislation.
4. Legislation on intellectual and industrial property.
5. Customs and tariff regime; foreign trade.
6. Foreign health. General bases and coordination of healthcare.
7. General bases and coordination of general planning of economic activity.
8. Basis of the legal regime of the public administrations and the statutory regime of civil servants which, in all cases, shall guarantee common treatment before the administration; common administrative procedure, without prejudice to the specialities arising from the organisation of autonomous communities and the system of responsibility of all public administrations.
9. Maritime fishing, without prejudice to the competences attributed to the autonomous communities in the management of the sector.

The **autonomous communities** assume competency for the following areas directly or indirectly related to official control:

1. Organisation of self-governance of institutions.
2. Alterations of municipal terms comprised within their territory and, in general, the functions corresponding to the State Administration on local corporations and whose transfer is authorised by the legislation on the Local Regime.
3. Agriculture and livestock, in accordance with the general order of the economy.

4. Fishing in some inland waters, shellfish and aquaculture, hunting and freshwater fishing.
5. Healthcare and sanitation.
6. Defence of the interests of consumers and users.

**Local administration** is composed of provinces and municipalities. Each of the provinces that compose the autonomous communities constitute a local entity with its own legal status, determined by the grouping of municipalities and by territorial division, in order to carry out the activities of the State. With regard to the municipalities, they enjoy full legal status. Their government and administration, corresponding to their respective local authorities, composed of mayors and councillors.

Matters not expressly assigned to the State by virtue of the present Constitution may fall under the jurisdiction of the autonomous communities by virtue of their respective Statutes. Matters for which jurisdiction has not been assumed by the Statutes of Autonomy shall fall within the jurisdiction of the State, whose laws shall prevail, in case of conflict, over those of the autonomous communities regarding all matters over which exclusive jurisdiction has not been conferred upon the latter. State law is, in all cases, supplementary to that of the autonomous communities.

In this context, we must highlight the competencies developed under the statutes of the autonomous communities with regard to jurisdiction for the agri-food industry, healthcare, agriculture and livestock. And, on the contrary, the exclusive competency of the state in the area of the Protected Designations of Origin (DOP) and Protected Geographic Indications (IGP), which are of supra-regional scope, and in the matter of imports and exports.

### **3.1.2 Sectoral organisation**

In the General State Administration, the management of each of the competencies is conducted through the division into ministries.

In this regard, it is worth highlighting that Law 50/1997, of 27 November, of the Government, establishing, among other aspects, the composition, organisation and collaboration and support bodies of the Government, their functioning regulations and the delegation of competencies. Article 2 of Chapter I, "Governance, composition, organisation and functions, on the President of the Government" establishes the need to create, amend and remove, by royal decree, the ministerial departments and state secretariats, and to resolve conflicts of jurisdiction that may arise between the different ministries. Article 4, on Ministries, states that the holders of ministerial departments also have competency and responsibility in their specific sphere of action. Article 5, on the Council of Ministers, establishes the function of same as the creation, modification and removal of the governing bodies of the ministerial departments.

At the same time, the organisation and distribution of competencies between the different departments and bodies that constitute state and regional administration are the responsibility of the President of the Government of Spain and the presidents of the autonomous communities. All of this appears in the state royal decrees and regional decrees on the organisation and structuring of the public administration.

Whereas are other departments with limited responsibilities in the Plan, in general, in accordance with Royal Decree 2/2020, of 12 January, restructuring the departments and their corresponding royal decrees of organic structure, the competencies for activities included in the scope of the Plan for the following:

- Ministry of Agriculture, Fisheries and Food (MAPA):
  - Primary production of food of plant and animal origin, including hygiene, health, animal welfare and plant health
  - Food quality, organic production and differentiated quality
  - Importation of live animals, plants and products of plant origin, by-products of animal origin not for human consumption and products for animal feed.
  - Export of plants, plant products, other items and products subject to veterinary certification for third countries.
- Ministry of Consumer Affairs (MCO):
  - Food Safety at internal market level, through the Spanish Agency for Food Safety & Nutrition (AESAN)
  - Protection of consumers through the quality control of food products and unfair business practices through the General Directorate for Consumer Affairs.
- Ministry of Health (MS):
  - Importation of food, materials in contact with food and other goods for human use, through the Sub-directorate General for Foreign Health
- Ministry of Industry, Trade and Tourism (MINCOTUR), through the SOIVRE Inspection Service of the Territorial and Provincial Directorates of Trade coordinated by the Sub-directorate of Inspection, Certification and Technical Assistance for Foreign Trade:
  - Inspection and control of trade quality of products subject to foreign trade.
  - Border control of compliance with legislation applicable to organic agriculture products for importation from third countries.

In the autonomous administration, each autonomous community has its own legal framework in which to establish its composition, organisation and operating rules. In general, the management of the respective competencies is conducted through so-called Regional Ministries, which received different names depending on the autonomous community in question, and which, as a general rule, are structured in a manner similar to that of the General State Administration. Commonly, these are the Regional Ministry with competency for Health, Trade and Consumer Affairs, Agriculture and Livestock, these aspects being covered by the Directorate Generals of Public Health (DGSP), the Directorate Generals of Consumer Affairs (DGC) and the Directorate Generals of Agriculture, Livestock and/or Fisheries (DGAGP), respectively.

In the corresponding systems of official control, the legislative references and websites that provide detailed information on the structure, organisation and functions of the competent authorities.



### 3.2. Coordination bodies

The functioning of the public administration is currently based on Law 40/2015, of 2 October, of the Legal Regime of the Public Sector, which establishes as the general principles of action of the Administrations that *“the public Administrations serve with the public interest objectively and act in accordance with the principles of hierarchy, decentralisation, de-concentration and coordination, with full submission to the Constitution and the Law. They must, in their activity and relations, respect the following principles: K) Cooperation, collaboration and coordination between the public administrations.”*

To such effect, Article 145 states *“The cooperation bodies are multilateral or bilateral, of general or special scope, constituted by representatives of the General State Administration, the Administrations of the Communities or Cities of Ceuta and Melilla or, where applicable, the Local Entities, to voluntarily agree actions that improve the exercises of the competencies of each Public Administration.”*

In compliance with this law, and to achieve a uniform application of Regulation (EU) 2017/625, there are coordination bodies in which the periodic, control programmes, guides and standardise criteria for interpretation of regulation are agreed, among other matters.

The coordination bodies may have a specific or general character. At the same time, these bodies may be inter-territorial, that is, that may be comprised of ministries and autonomous communities within the same sphere of competence or, indeed, inter-territorial and inter-sectoral, in which case they also include representatives of all the bodies with competencies in the matter, from the different public administrations. There are also forums in which the business sector and consumers participate

The agreements adopted in these coordination bodies initially have no binding judicial character, although, when transposed into technical agreements and adopted by consensus, there are applied equally through the corresponding tools. If considered necessary, or if mandatory for legal certainty for citizens, these are passed to the corresponding superior body for approval, or the specific state or regional regulation is approved.

The coordination bodies of the General State Administration and the autonomous communities of the different spheres of competence included in this Plan are detailed in the part of the Plan on *“Official Control of the Food Chain in Spain”*.

In the case of official controls that are the responsibility of the General State Administration, the coordination work if the Inspection Services is carried out by the Sub-directorates General mentioned in the section *Coordination*.

### 3.3. Obligations of personnel at the service of the public administrations

The persons who work in the Spanish public administrations and civil servants, and their rights and duties and codes of conduct are found in Royal Legislative Decree 5/2015, approving the recast text of the Civil Service Basic Statute.

There are civil servants at all levels of the administration: in the General State Administration, in the autonomous communities and in local authorities. The number of civil servants involved in official control, in management positions, as inspectors, auxiliary personnel and laboratory staff, is detailed each year in the Annual Report of the Results of the PNCOCA.

### 3.3.1 Code of conduct. Independence and absence of conflicts of interest

The personnel who carry out official controls shall not incur any conflict of interest in accordance with Regulation (EU) 2017/625. Said personnel belong to the public Administration and, therefore is subject to compliance with Royal Legislative Decree 5/2015, of 30 October, approving the recast text of the Civil Service Basic Statute.

Article 52 of the Civil Service Basic Statute, establishes that *“civil servants must perform their assigned work diligently and ensure the general interest subject to, and in accordance with, the Constitution and the rest of the legal system, and must act in accordance with the following principles: objectivity, integrity, neutrality, responsibility, impartiality, confidentiality, dedication to public service, transparency, exemplariness, austerity, accessibility, efficiency, honour, promotion of the cultural and environmental sphere and respect for equality between women and men, which inspire the Code of Conduct of Civil Servants, configured by the ethical principles and conduct regulated in the following articles.”*

The actions of public employees must seek to satisfy the public interest of citizens and are based on objective considerations geared towards impartiality and the common interest, aside from any other factor expressing personal, family, corporate, client or other positions that may collide with this principle.

Thus, in all actions, they adhere to the principles of loyalty and good faith to the Administration in which they provide their services, their superior officers, colleagues, subordinates and the citizens. Their conduct is based on respect for fundamental rights and public freedoms, avoiding any action that may lead to discrimination on grounds of racial or ethnic origin, gender, sex, sexual orientation, religion or convictions, opinion, disability, age or any other personal or social condition or circumstance.

Furthermore, they must abstain from any matters in which they have a personal interest or in another whose resolution may influence such matters; in all matters in which they are administrators of the company or entity in question, or have outstanding legal issues with an interested party, if they have links through marriage or similar partnership situation or blood relation within four degrees or affinity within the second degree, with any interest parties, with the administrators or the entities or companies involved and also the advisers, legal representatives or agents involved in the procedure, and if they share a professional office or are associated with such persons for advisory, representation or agent services; if they have an intimate friendship or manifest enmity with any of the persons mentioned above; if they have intervened as an expert or witness in the procedure; or if they have had a service relationship with the a natural person or legal entity directly involved in the matter, or if they have provided professional services of any kind and under any circumstances and in any place in the last two years. All of the above is in accordance with Article 23 of Law 40/2015, of 1 October.

They may not accept any favour or situation that implies unjustified privilege or advantage for natural persons or private entities. Nor may they influence on the streamlining or resolution of any process or administrative procedure without due cause and under no circumstances where such would lead to privilege or benefit for the holders of public office or their immediate family or social circle, or where it constitutes an undermining of the interests of third parties.

### 3.3.2 Transparency and confidentiality

The competent authorities who carry out official control activities shall maintain a high level of transparency, in accordance with Article 11 of Regulation (EU) 2017/625. For this purpose, relevant information will be made available on the organisation and the completion of official controls.

In order to maintain a level of transparency in Spanish public administrations, Law 19/2013, of 9 December, on transparency, access to public information and good governance, which aims to extend and reinforce the transparency of the public activity, regulate and guarantee the right of access to information relating to the activity and establish the obligations of good governance with which public decision-makers must comply and the consequences of non-compliance.

The personnel who carry out official control tasks must act transparently, without undermining the principle of confidentiality, professional secrecy and personal data protection standards.

To carry out this compliance, the information of interest for the general public shall be published on the websites of the competent authorities and regional authorities.

With respect to confidentiality, Royal Legislative Decree 5/2015 establishes that the personnel who carry out control activities shall maintain secrecy of the matters classified and others whose disclosure is legally protected, and shall maintain due discretion around any matters of which they have knowledge due to their position, without making use of the information obtained for their own benefit or that of third parties, or to the detriment of the public interest.

On this matter, Royal Decree 1945/1983 and Law 28/2015 also regulate that the inspectors are strictly obliged to comply with professional secrecy. Failure to comply with this duty shall be sanctioned in accordance with the provisions of the Regulation of the Disciplinary Regime of the public administrations where they provide their services and, additionally, that of the State Civil Servants.

## 4. POINT OF CONTACT IN SPAIN

The regulation of the European Union establishes that all Member States shall designate one or several link bodies who shall duly establish contact with the link bodies of other Member States. The function of the link bodies shall be to facilitate and coordinate communication between competent authorities and, in particular, the transfer and receipt of requests for assistance.

In Spain, the point of contact for the PNCOCA is:

### **SUB-DIRECTORATE GENERAL OF ALERTS AND OFFICIAL CONTROL PROGRAMMING**

Spanish Agency for Food Safety & Nutrition (AESAN) Ministry of Consumer Affairs

C/ Alcalá 56 (Madrid)

sgcaa@aesan.gob.es. Tel.: +34.91.338.07.15

## 5. HIGH-LEVEL OBJECTIVES

The National Plan for Official Control of the Food Chain is governed by the following high-level objectives:

- **OBJECTIVE 1.** Reduce the risks to the health of people, animals or plants through compliance on the part of operators involved in primary production with the regulation in force applicable to food safety, animal and plant health and animal welfare.
- **OBJECTIVE 2.** Reduce the risks to people's health present in food, ensuring the welfare of animals for slaughter for human consumption, through the organisation of official controls in food establishments and verify compliance on the part of the operators of the regulation applicable in food safety, nutrition and animal welfare.
- **OBJECTIVE 3.** Guarantee the achievement of a high level of food quality, including Differentiated Quality and Organic Production of agri-food products and intensifying the fight against food fraud throughout the food chain to achieve the sustainability of the agri-food system, increasing consumer trust, guaranteeing their rights to information and the protection of their economic interests against unfair business practices.
- **OBJECTIVE 4.** Reduce the risks to people's health and their interests for the health of animals or plants through compliance of operators with the regulation in force on food safety, animal health, plant health, animal welfare, business quality, organic production, guaranteeing the achievement of a high level of food safety as well as fight against fraudulent or deceptive practices in animals, plants and food introduced or imported across Spanish borders.

And to offer health and phytosanitary guarantees for plant and animal products for export.



Table of areas of Article 1 (2) of Regulation (EC) No. 2017/625, high-level and strategic objectives, official control programmes and competent authorities responsible for coordination.

Areas of control Art 1 (2) Regulation (EU) 2017/625	High-level objective	Strategic objective	Control programmes
Article 1 (2) a). Foods and food safety, integrity and health in any phase of production, processing and distribution of foods, including rules to guarantee fair business practices and protect the interests and information of consumers, and the manufacturing and use of materials and articles intended to be in contact with foods;	Obj. 1	1.1.	1.1.1 PNCO for hygiene in primary agriculture production and the use of phytosanitary products
			1.1.2 PNCO for hygiene in primary livestock production
			1.1.3 PNCO for hygiene in primary extractive fishery production
			1.1.4 PNCO for hygiene in primary aquaculture production
	Obj. 2	2.1.	2.1. Inspection of food establishments
			2.2. Audits of in-house control systems
			2.3. Slaughterhouses, game handling establishments and meat processing establishments
			2.4. Labelling of food and materials in contact with food.
		2.2.	2.5. Allergens and substances that cause intolerance
			2.6. Release of Genetically Modified Organisms (GMOs)
			2.7. Notification, labelling and composition of food supplements
		2.3.	2.8. Biological hazards in food
			2.9. Anisakis
			2.10. Monitoring of antimicrobial resistance of zoonotic food agents
			2.11. Contaminants in foods
			2.12. Additives and other technological ingredients in food
	2.13. Materials in contact with foods		
	2.14. Pesticide residue in foods		
	Obj. 3	3.1. 3.1.1 PNCO for food quality	
		3.2.1 General control of compulsory and voluntary food information with no repercussions for food safety and nutrition at point of sale to the final consumer.	
3.2.2 General control of food quality at point of sale to the final consumer. 3.2.3 Control of unfair commercial practices with consumers in the marketing of food			
Obj. 4	4.2.	4.2.1 Official control of goods for human use or consumption from third countries.	
		4.2.2 Official control of shipments with no commercial character from third countries	
		4.2.3 Control of kitchen waste from international transport	
		4.2.4 Designation and supervision of border control and medical storage of goods.	
	4.3.	4.3.1 Official control of compliance with marketing standards applicable to food products trades externally with third countries.	
	4.4.	4.4.1 PNCO for exports of products subject to veterinary certification	

Areas of control Art 1 (2) Regulation (EU) 2017/625	High-level objective	Strategic objective	Control programmes
Art 1 (2) b) the intentional release into the environment of genetically modified organisms GMOs for the purpose of producing food and feed;	Obj. 1	1.2.	1.2.1. PNCO for the voluntary release of genetically modified organisms (GMOs) for the production of food and feed.
Art 1 (2) c) Feed and feed safety in any phase of production, transformation and distribution and use of said feeds, including regulations to guarantee fair business practices and to protect the health, interests and information consumer;	Obj. 1	1.1.	1.1.2. PNCO for hygiene in primary livestock production
		1.3.	1.3.1. PNCO for animal feed
	Obj 4	4.1.	4.1.1. PNCO for importation of animals, products of animal origin not for human consumption, products for animal feed and importation of plants, products of plant origin and other objects.
		4.4.	4.4.1. PNCO for exports of products subject to veterinary certification
Art 1 (2) d) requirements relating to animal health;	Obj.1	1.1.	1.1.2. PNCO for hygiene in primary livestock production
Art 1 (2) d) requirements relating to animal health;	Obj. 1		1.4.1. PNCO for verification of compliance with the regulation on animal health and aquaculture products
			1.4.2. PNCO for identification and registration of bovine, ovine and caprine species.
			1.4.3. PNCO of containment establishments
			1.4.4. PNCO of residues of veterinary medicinal products and other substances (PNIR) in primary production
			1.4.5. PNCO of control posts Delegated Regulation EU 2019/2035
		1.4.	1.4.6. PNCO of hatcheries and establishments for the selection, multiplication and rearing of poultry from which birds or hatching eggs are moved to another Member State
			1.4.7. PNCO of quarantine establishments for kept terrestrial animals other than primates from which the animals are moved within a Member State or another Member State
			1.4.8. PNCO of bumble bee production establishments isolated from their environment.
			1.4.9. PNCO for authorised establishments of reproduction products of bovine, equine, ovine, caprine and porcine species
	Obj. 4	4.1.	4.1.1. PNCO for importation of animals, products of animal origin not for human consumption, products for animal feed and importation of plants, products of plant origin and other objects.
		4.4.	4.4.1. PNCO for exports of products subject to veterinary certification.

Areas of control Art 1 (2) Regulation (EU) 2017/625	High-level objective	Strategic objective	Control programmes	
Art 1 (2) e) the prevention and reduction to a minimum of risks to human and animal health of by-products of animal origin and derivative products;	Obj. 1	1.5.	1.5.1. PNCO for by-products of animal origin not for human consumption in SANDACH establishments and transport	
	Obj. 2	2.1.	2.1.1. Inspection of food establishments	
			2.1.2. Audits of in-house control systems	
			2.1.3. Slaughterhouses, game handling establishments and meat processing establishments	
	Obj. 4	4.1.	4.1.1. PNCO for importation of animals, products of animal origin not for human consumption, products for animal feed and importation of plants, products of plant origin and other objects.	
			4.2.	4.2.1 PNCO for exports of products subject to veterinary certification.
			4.3.1 Official control of goods for human use or consumption from third countries.	
			4.3.	4.3.2 Official control of shipments with no commercial character from third countries.
			4.3.3 Control of kitchen waste from international transport.	
	(f) animal welfare requirements;	Obj. 1	1.6.	1.6.1 PNCO for animal welfare on livestock holdings and during transport of animals
Obj. 2		2.1.	2.1.1. Slaughterhouses, game handling establishments and meat processing establishments	
Obj.4		4.1.	4.1.1. PNCO for importation of animals, products of animal origin not for human consumption, products for animal feed and importation of plants, products of plant origin and other objects.	
			4.4.	4.4.1 PNCO for exports of products subject to veterinary certification.
(g) protection measures against plant pests;	Obj. 1	1.1.	1.1.1 PNCO for hygiene in primary agriculture production and the use of phytosanitary products	
		1.7.	1.7.1. PNCO for plant health	
	Obj. 4	4.1.	4.1.1. PNCO for importation of animals, products of animal origin not for human consumption, products for animal feed and importation of plants, products of plant origin and other objects.	
			4.4.	4.4.2 PNCO for exports of products subject to phytosanitary certification
(h) requirements relating to the marketing and use of phytosanitary products and sustainable use of pesticides, with the exception of the pesticide application;	Obj. 1	1.1.	1.1.1. PNCO for hygiene in primary agriculture production and the use of phytosanitary products.	
		1.8.	1.8.1. PNCO for marketing of phytosanitary products.	

Areas of control Art 1 (2) Regulation (EU) 2017/625	High-level objective	Strategic objective	Control programmes
(i) production and labelling of organic products;	Obj 3	3.1.	3.1.2 PNCO for organic production
		3.2.	3.2.4 Monitoring of food information and the quality of organic products at point of sale to the final consumers.
		3.2.	3.2.5 General control of food quality at point of sale to the final consumer.
	Obj 4	4.3.	4.3.1 Official control of compliance with legislation applicable to organic production products for importation from third countries. (Included in the PNCO for organic production)
(j) use and labelling of protected designations of origin, protected geographic indications and guaranteed traditional specialities.	Obj 3	3.1.	3.1.3 PNCO for differentiated quality linked to geographic origin and traditional specialities guaranteed before marketing
		3.2.	3.2.5 Specific control of food information and quality linked to protected designations of origin, protected geographical indications and traditional specialities guaranteed at point of sale to the final consumer.

- Competency MS-SGSE
- Competency MAPA
- Competency MCO-AESAN
- Competency MCO-D.G. Consumer Affairs
- Competency MINCOTUR-SOIVRE

## 6. OFFICIAL CONTROL OF THE FOOD CHAIN

The official control of the food chain is organized according to the objectives of high level that are developed below:



# HIGH-LEVEL OBJECTIVE 1

Reduce the risks to the health of people, animals or plants through compliance on the part of operators involved in primary production with the regulation in force applicable to food safety, animal and plant health and animal welfare.



National Plan for Official Control  
of the Food Chain

**2021-2025**

**Version 2 - 2022**



Ministry of Agriculture, Fisheries and Food

**The competent authority responsible for the coordination for the granting of this objective is the Ministry of Agriculture, Fisheries and Food (MAPA)**

## **A. STRATEGIC OBJECTIVES**

The strategic objectives that make up high-level objective 1 and the programmed provided for to achieve the following:

- **Strategic objective 1.1.** Control the degree of compliance with the regulation and ascertain as broadly as possible the situation in terms of compliance with relevant legislation in the area of primary agricultural and livestock production to ascertain the necessary aspects of control, both inspectors and those inspected.

Ensure that food operators in areas subject to these programmes comply with European, national and regional legal provisions in force for control of hazards and the correct hygiene practices in primary production and related operations of extractive fishing and aquaculture.

- 1.1.1 National Programme for Official Control of hygiene in primary agriculture production and the use of phytosanitary products.

- 1.1.2. National Programme for Official Control of hygiene in primary livestock production

- 1.1.3. National Programme for Official Control of hygiene in primary extractive fishing process

- 1.1.4 National Programme for Official Control of hygiene in primary aquaculture production

- **Strategic objective 1.2.** Guarantee intentional release of GMOs to produce foods and feeds adheres to the requirements established in the applicable regulation.

- 1.2.1 National Programme for Official Control for the voluntary release of genetically modified organisms (GMOs) for the production of food and feed.

- **Strategic objective 1.3.** Ensure that feeds, as the first link in the chain of production of food of animal origin, complies with the general requirements of food safety established in Article 15 of Regulation (EC) 178/2002. This objectives includes the verification of compliance with the provisions relating to manufacturing, trading and use of feed, including control of labelling and remaining information for the final consumer, so that the safety of feed is guaranteed and, with it, the protection of public health, by the competent party.

- 1.3.1. National Programme of Official Control of Animal feed.

- **Strategic objective 1.4.** Control the degree of compliance with health regulation in officially authorised bodies, institutes or centres under Directive 92/65, authorised assembly centres for bovine, ovine, caprine, equine, and porcine species, authorised establishments for bovine reproduction products and all matters relating to the identification and traceability of ruminants and conduct monitoring of corrective measures applied in the event of non-compliance.
  - 1.4.1. National Programme of Official Control (PNCO) for verification of compliance with the regulation on animal health and aquaculture products
  - 1.4.2. PNCO for identification and registration of bovine, ovine and caprine species.
  - 1.4.3. PNCO of Confinement establishments.
  - 1.4.4. PNCO of residues of veterinary medicinal products and other substances (PNIR) in primary production
  - 1.4.5. PNCO of control posts Delegated Regulation EU 2019/2035
  - 1.4.6. PNCO of hatcheries and establishments for the selection, multiplication and rearing of poultry from which birds or hatching eggs are moved to another Member State
  - 1.4.7. PNCO of quarantine establishments for kept terrestrial animals other than primates from which the animals are moved within a Member State or another Member State
  - 1.4.8. PNCO of bumble bee production establishments isolated from their environment.
  - 1.4.9. National Official Control Programme for approved germinal products of bovine, equine, ovine, caprine and porcine species.
- **Strategic objective 1.5.** Control the degree of compliance with the regulation of by-products of animal origin not for human consumption and monitoring of corrective measures applied in the case of non-compliance.
  - 1.5.1 National Programme of Official Control of by-products of animal origin not for human consumption in SANDACH establishments and transport
- **Strategic objective 1.6.** Reduce the risks for the welfare of animals through the monitoring of compliance with regulation (on protection of animals on farms, during transport and at the time of slaughter outside the slaughterhouse) on the part of operators, increasing the sustainability of the agri-food system and the trust of consumers.
  - 1.6.1 National Programme of Official Control of animal welfare on livestock holdings and during transport of animals.
- **Strategic objective 1.7.** Protect plants and plant products from damage from pests, and ensure sustainability of agricultural activity and food production.
  - 1.7.1 National Programme of Official Control of plant health
- **Strategic objective 1.8.** To ascertain, as broadly as possible, the state situation, carrying out controls to verify the degree of compliance with the relevant regulation in the sphere of the use and marketing of phytosanitary products.
  - 1.8.1 National Programme of Official Control of marketing of phytosanitary products.

## **B. GENERAL ORGANISATION: COMPETENT AUTHORITIES, COORDINATION MECHANISMS AND OFFICIAL CONTROL RESOURCES**

### **1. OFFICIAL CONTROL UNDER SCOPE OF PRIMARY PRODUCTION**

The purpose of this section is to establish, within the National Programme of Official Control of the Food Chain, the planning of official controls in primary production, in the corresponding spheres regulated by the rules set out in Article 1, section 2 of Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017

The coordination for these official control corresponds to the Ministry of Agriculture, Fisheries and Food, while the execution thereof is, in most cases, the responsibility of the competent bodies of the autonomous communities.

The structure of the Ministry of Agriculture, Fisheries and Food (MAPA) was approved by Royal Decree 430/2020, of 3 March, developing the basic organic structure of the Ministry of Agriculture, Fisheries and Food and amending Royal Decree 139/2020, of 28 January, establishing the organic structure of the ministerial departments.

The units of MAPA with competence for planning and coordination with the autonomous communities for the execution of these official controls of Regulation (EU) No. 2017/625, of 17 March, are:

#### **■ General Secretariat for Agriculture and Food**

- Directorate General for Agricultural Production and Markets
  - Sub-directorate General of Livestock and Cynegetic sector (SGPGC)
  - Sub-directorate General of Livestock Production (SGMPG)
  - Sub-directorate General for Means of Agricultural Production and the Spanish Office of Plant Varieties (SGMPAOEW)
- Directorate General for the Health of Agricultural Production
  - Sub-directorate General of Animal Health and Hygiene and Traceability (SGSHAT)
  - Sub-directorate General of Health Agreements and Border Control (SGASCF)
  - Sub-directorate General of Plant and Forestry Health and Hygiene (SGSHVF)

#### **■ General Secretariat for Fisheries**

- Directorate General for Fisheries and Aquaculture Management
  - Sub-directorate General for Fisheries and Structural Actions. (SGACPAE)

At the following link you can find the organisational chart of the MAPA:

<https://www.mapa.gob.es/es/ministerio/funciones-estructura/organigrama/default.aspx>



At the following link you can access the PNCOCA through the MAPA website:

<http://www.mapa.gob.es/es/ministerio/planes-estrategias/plan-nacional-de-control-de-la-cadena-alimentaria/default.aspx>



A fundamental element for the integration of these official controls in the primary production in the National Plan for Official Control of the Food Chain is the coordination of different units of the MAPA involve, and the dialogue with the rest of the Units in other Departments responsible for the development of the Plan.

For this purpose, Royal Decree 430/2020, of 3 March, assigns this responsibility to the Sub-directorate General for Support and Coordination, of the Secretariat General for Agriculture and Food, as a strategic element for the adequate planning and coordination of official controls.

The following attached document contains the legal basis that establishes the structure of the central coordination authorities (MAPA) and the competent official control authorities in the autonomous communities.

### ORGANIC STRUCTURE: COMPETENT AUTHORITIES



## 2. ORGANISATIONAL STRUCTURE OF THE OFFICIAL CONTROLS.

The official control system is structured around the following levels:

### ■ Areas of control

The following 8 areas of control are established, in which official controls are carried out to verify compliance with the applicable regulations:

AREA OF CONTROL	REGULATIONS SUBJECT TO CONTROL
Food and food safety	The integrity of the health of foods and raw materials thereof applicable in the phases of primary production, including control of regulations to ensure fair business practices and to protect consumers' interest and information.
Release of Genetically Modified Organisms (GMOs)	The intentional release into the environment of GMOs for the purpose of producing food and feed.
Animal Feed	Feed and feed safety in any phase of production, transformation and distribution and use of said feeds, including regulations to guarantee fair business practices and to protect health, interests and consumer information.
Animal Health	Animal health and traceability requirements.
Animal by-products not for human consumption (SANDACH)	The prevention and reduction to a minimum of risks to human and animal health of by-products animal origin and derivative products, in establishments regulated by Regulation (EC) 1069/2009 and in transport.
Animal Welfare	Welfare requirements of animals on livestock holdings and in transit.
Protection against Pests	Protection measures against plant pests
Pesticide and phytosanitaries	Requirements relating to the marketing and use of phytosanitary products and sustainable use of pesticides, with the exception of the pesticide application equipment.



For each of these areas, strategic objectives are established. Their achievement is assessed at the end of the five years of the plan through the analysis of the degree of compliance with the operating objectives of the programmes applicable in that area. These strategic objectives are the following:

AREA OF CONTROL	STRATEGIC OBJECTIVE
Foods and food safety	<p><b>1.1.</b> Control the degree of compliance with the regulation and ascertain as broadly as possible the situation in terms of compliance with relevant legislation in the area of primary agricultural production to ascertain the necessary aspects of control, both inspectors and those inspected.</p> <p>Ensure that food operators in areas subject to these programmes comply with European, national and regional legal provisions in force for control of dangers and the correct hygiene practices in primary production and related operations of extractive fishing and aquaculture.</p>
Release of Genetically Modified Organisms (GMOs)	<p><b>1.2</b> Guarantee that the intentional release of GMOs to produce foods and feeds adheres to the requirements established in the applicable regulation.</p>
Animal Feed	<p><b>1.3.</b> Ensure that feeds, as the first link in the chain of production of food of animal origin, complies with the general requirements of food safety established in Article 15 of Regulation (EC) 178/2002. This objectives includes the verification of compliance with the provisions relating to manufacturing, trading and use of feed, including control of labelling and remaining information for the final consumer, so that the safety of feed is guaranteed and, with it, the protection of public health, by the competent party.</p>
Animal Health	<p><b>1.4.</b> Control the degree of compliance with health regulation in officially authorised bodies, institutes or centres under Directive 92/65, authorised assembly centres for bovine, ovine, caprine and equine species and authorised dealers of bovine, ovine, caprine and porcine species, establishments for bovine, equine, ovine, caprine and porcine reproduction products, and fish farms, and all matters relating to the identification and traceability of ruminants and to conduct monitoring of corrective measures applied in the event of non-compliance.</p>
Animal by-products not for human consumption (SANDACH)	<p><b>1.5.</b> Control the degree of compliance with the regulation of by-products of animal origin not for human consumption and monitoring of corrective measures applied in the case of non-compliance.</p>
Animal Welfare	<p><b>1.6.</b> Reduce the risks for the welfare of animals through the monitoring of compliance with regulation (on protection of animals on farms, during transport and at the time of slaughter outside the slaughterhouse) on the part of operators, increasing the sustainability of the agri-food system and the trust of consumers.</p>
Protection against Pests	<p><b>1.7.</b> Protect plants and plant products from damage from pests, and ensure sustainability of agricultural activity and food production.</p>
Pesticide and phytosanitaries	<p><b>1.8.</b> To ascertain, as broadly as possible, the state situation, carrying out controls to verify the degree of compliance with the relevant regulation in the sphere of the use and marketing of phytosanitary products.</p>



The achievement of these strategic objectives is carried out through the execution of controls planned and structured in the following national programmes of official control.

### ■ National Programmes of Official Control

The national programmes of official control are documents that describe the organisational structure on the basis of which the official controls are planned and executed to verify applicable regulation in each of the areas established in the previous section.

For reasons of efficiency in the organisation of controls, the same programme may verify compliance with the regulation applicable to more than one area of control. Similarly, official controls to verify compliance with the regulation in each area may be distributed between several programmes.

The operating objectives are established in each programme and must be assessed every year.

They establish:

- The rules that are subject to control within the framework of the programme.
- The unit of the MAPA responsible for the coordination, and the competent authorities of the autonomous communities or the General State Administration responsible for the execution of the official programmes
- The mechanisms of coordination between the different competent authorities involved.
- The organisation, general management, categorisation of risk and national and regional legal basis of the controls encompassed within the programme.
- The delegation of tasks carried out in delegate bodies and natural persons.
- Actions after the detection of non-compliance, including the legal basis for the application of sanctions.
- The supervision mechanisms of controls.
- Internal audits to be managed by each competent authority over the course of the period of duration of the Plan.
- The assessment mechanisms of the programme, including objectives and indicators for the purpose of adopting the modifications necessary for improving the efficiency of controls.

The following table displays the programmes developed in primary production for each of the areas of control established:



AREA	NATIONAL PROGRAMME OF OFFICIAL CONTROL	MAPA UNIT MANAGING THE PROGRAMME
Foodstuff and food safety	PNCO for hygiene in primary agriculture production and the use of phytosanitary products (* <sub>1</sub> )	SGSHVF
	PNCO for hygiene in primary livestock production (* <sub>2</sub> )	SGSHAT
	PNCO for hygiene in primary extractive fishery production	SGACPAE
	PNCO for hygiene in primary aquaculture production	
Release of Genetically Modified Organisms (GMOs)	PNCO for the voluntary release of genetically modified organisms (GMOs) for the production of food and feed.	SGMPAOEW
Animal Feed	PNCO for animal feed	SGMPG
	PNCO for hygiene in primary livestock production (* <sub>2</sub> )	SGSHAT
Animal Health	PNCO for verification of compliance with the regulation on animal health and aquaculture products	SGSHAT
	PNCO for identification and registration of bovine, ovine and caprine species	SGSHAT
	PNCO of containment establishments	SGSHAT
	PNCO of residues of veterinary medicinal products and other substances (PNIR) in primary production	SGSHAT
	PNCO of control posts Delegated Regulation EU 2019/2035	SGSHAT
	PNCO of hatcheries and establishments for the selection, multiplication and rearing of poultry from which birds or hatching eggs are moved to another Member State	SGSHAT
	PNCO of quarantine establishments for kept terrestrial animals other than primates from which the animals are moved within a Member State or another Member State	SGSHAT
	PNCO of bumble bee production establishments isolated from their environment.	SGSHAT
	PNCO for authorised establishments of reproduction products of bovine, equine, ovine, caprine and porcine species	SGMPG
Animal by-products not for human consumption (SANDACH)	PNCO for by-products of animal origin not for human consumption in SANDACH establishments and transport	SGSHAT
Animal Welfare	PNCO for animal welfare on livestock holdings and during transport of animals.	SGPGC
Protection against Pests	PNCO for plant health	SGSHVF
Pesticide and phytosanitarie	PNCO for hygiene in primary agriculture production and the use of phytosanitary products (* <sub>1</sub> )	SGSHVF
	PNCO for marketing of phytosanitary products	

Note: Asterisks (\*<sub>1</sub> and \*<sub>2</sub>) indicate the programmes applicable to more than one area of control.

### ■ Documented procedures.

For each programme, the competent authorities of the autonomous communities and of the MAPA responsible for the material execution of the controls shall establish procedures with the following objectives:

- Organisation of the competent authorities, including the functions and responsibilities of each of the participants and the coordination bodies between the different competent authorities involved.
- Establishment of sampling procedure, control methods and techniques.
- Detailed instructions for inspection of preparation, execution and management of official controls.
- Actions to be taken in light of the results of the controls.
- Supervision of completion of controls in accordance with the mechanisms established in the programme.
- Any other activity of information necessary for the effective functioning of official controls.

### 3. COORDINATION BODIES OF THE OFFICIAL CONTROLS

The coordination of these official controls is conducted at four levels:

- Sectoral conference.
- Coordination bodies of the National Plan
- Coordination bodies of each national programme of official control.
- Coordination bodies of the competent authorities of the autonomous communities

#### 3.1. SECTORAL CONFERENCE.

The Sectoral Conferences are multilateral cooperation bodies for a specific sector of public activity. They are made up of the holder of the Ministerial Department and all the Regional Ministers with competency in the area. Due to its composition, number and activity, it constitutes the principal pillar of inter-administrative cooperation.

Law 40/2015 on the Legal Regime of the Public Sector contains a minimal framework regulation of the Sectoral Conferences (Article 147), which determines that they are called by the corresponding Ministry and that their agreements are signed by same and by the Regional Ministers of the autonomous communities. The functioning of the Sectoral Conferences is governed by the agreement for the creation of each of these and their internal regulation.



The Sectoral Conference on Agriculture and Rural Development (whose current regulation was created on 13 December 1995 and last amended in 2009) and the Sectoral Conference on Fisheries are responsible for approving the *Official Control Plans for Primary Production and Food Quality*. Similarly, where basic changes to the plan are necessary or where the circumstances require a high-level approval, these Sectoral Conferences shall be the bodies responsible for coordination and decision making.

### 3.2. COORDINATION BODIES OF THE NATIONAL PLAN

The DG for Support and Coordination (SGAC) is the Unit within the MAPA with responsibility for the coordination of the PNCOCA. This function is carried out through the following coordination group:

Coordination group with units of MAPA

With competency for official controls included in the scope of Regulation (EC) No. 2017/625, of 15 March, and with the units responsible for control of imports and exports.

This group's objectives are the coordination of the following activities:

- Drafting of official control plans, their updating and amendment.
- Design and preparation of annual reports of the results of the control plan.
- Analysis and assessment of questions put forward relating to controls that affect the plan as a whole.

### 3.3. COORDINATION BODIES OF THE OF THE NATIONAL OFFICIAL CONTROL PROGRAMMES

Each programme establishes, where necessary, their coordination and decision-making body. The MAPA management unit of each programme is responsible for the management of the coordination body included in the programme.

In these bodies, all of the competent authorities of the autonomous communities or general state administration responsible for the execution of controls are represented, where applicable.

The coordination bodies have the following functions:

- Review of the measures for the harmonised and coherent application throughout the Spanish territory of the controls that affect the programme.
- Drafting of the programme, along with updates and amendments.
- Design and compilation of the information relating to the results of the programme for the preparation of the annual reports of the results.
- Evaluation and analysis of the results of the controls for the adoption of the measures that improve the efficiency of the programme.



The following attached document lists the national coordination bodies that are fundamental, at different working levels for the understanding and harmonisation of criteria and actions of the official controls included within the scope of Regulation (EU) No. 2017/625, of 15 March.

## ORGANIC STRUCTURE COMPETENT AUTHORITIES



### 3.4. COORDINATION BODIES OF THE COMPETENT AUTHORITIES OF THE AUTONOMOUS COMMUNITIES

At autonomous level, the execution of the official controls requires the coordination between the central and peripheral services, and the coordination between competent authorities.

The information relating to the coordination mechanisms and bodies of each autonomous community are contained in the documented procedures of each programme.

## 4. SUPPORTS FOR THE CONTROL PROGRAMME.

In addition to inspection personnel, the resources that support and collaborate on the functioning of official control are:

- Analysis laboratories, including national reference laboratories.
- The IT applications, national and regional databases, for the management of official controls.
- The bodies and personnel to whom some of the official control tasks are delegated.
- Training of personnel.

### 4.1. OFFICIAL CONTROL LABORATORIES

The laboratories that participate in official controls, including reference laboratories, must be designated by the competent authority responsible for official control, following the criteria and requirements established in Article 37 of Regulation (EU) No. 2017/625, of 15 March.

For the purpose of harmonising the process of designation, the following procedure has been established:

## PROCEDURE OF DESIGNATION OF THE LABORATORIES FOR AREAS UNDER SCOPE OF MAPA



The attached document also lists the official control laboratory designated by the MAPA for official controls in the scope of Regulation (EC) No. 2017/625, of 15 March. The plant health laboratories whose accreditation is not compulsory according to the Regulations.



#### LABORATORIES OF OFFICIAL CONTROL DESIGNATED BY MAPA

The laboratories designated by the competent authority for the execution of controls are indicated in the documented procedures of each programme.

#### 4.2. IT RESOURCES FOR OFFICIAL CONTROL

Each specific control programme, and each documented procedure of the autonomous communities, includes the information relating to IT applications or databases that serve to support official control and which may be used for one or several programmes.

#### 4.3. DELEGATION OF OFFICIAL CONTROL TASKS

Each national programme of official control includes the information relating to those tasks delegated to control bodies or natural persons. These delegations shall be executed in accordance with the provisions in Regulation (EU) No. 2017/625, of 15 March.

#### 4.4. TRAINING OF OFFICIAL CONTROL PERSONNEL

Each competent authority for the execution or coordination of official controls is responsible for ensuring that the personnel intervening in official controls receive training that enables them to perform their tasks adequately. This training shall include the additional updates required.

The training shall include, among other aspects, the relevant areas detailed in Annex II Chapter I of Regulation (EC) No. 2017/625, of 15 March.

The following document includes the plans, procedures and criteria for the planning of training in each autonomous community and the management bodies organisation of training.



#### COMPETENT BODIES

## C. CONTROL PROGRAMMES

### NATIONAL PROGRAMMES OF OFFICIAL CONTROL OF THE MAPA FOR THE HIGH-LEVEL OBJECTIVE 1.

- PNCO for hygiene in primary agriculture production and the use of phytosanitary products

PNCO HPPA Y USO FITOSANITARIO



- PNCO for hygiene in primary livestock production.

PNCO HIGIENE PRODUCCIÓN PRIMARIA GANADERA



- PNCO for hygiene in primary extractive fishery production.

PNCO HIGIENE PRODUCCIÓN PRIMARIA PESCA



- PNCO for hygiene in primary aquaculture production.

PNCO HIGIENE PRODUCCIÓN PRIMARIA ACUICULTURA



- PNCO for the voluntary release of genetically modified organisms (GMOs) for the production of food and feed.

PNCO LIBERACIÓN OMG



- PNCO for animal feed.

PNCO ALIMENTACIÓN ANIMAL



- PNCO for verification of compliance with the regulation on animal health and aquaculture products.

PNCO NORMATIVA SANIDAD ANIMAL



- PNCO for identification and registration of bovine, ovine and caprine species.

PNCO IDENTIFICACIÓN BOVINOS, OVINOS Y CAPRINOS



- PNCO of containment establishments

PNCO DE LOS ESTABLECIMIENTOS DE CONFINAMIENTO



- PNCO of residues of veterinary medicinal products and other substances (PNIR) in primary production

PNCO INVESTIGACIÓN DE RESIDUOS (PNIR)



- PNCO of control posts Delegated Regulation EU 2019/2035

PNCO PUESTOS DE CONTROL RGTO 2019/2035



- PNCO of hatcheries and establishments for the selection, multiplication and rearing of poultry from which birds or hatching eggs are moved to another Member State

PNCO PLANTAS DE INCUBACIÓN Y ESTABLECIMIENTOS DE SELECCIÓN, MULTIPLICACIÓN Y RECRÍA DE AVES DE CORRAL



- PNCO of quarantine establishments for kept terrestrial animals other than primates from which the animals are moved within a Member State or another Member State.

PNCO ESTABLECIMIENTOS DE CUARENTENA PARA ANIMALES TERRESTRES EN CAUTIVIDAD



- PNCO of bumble bee production establishments isolated from their environment.

PNCO ESTABLECIMIENTOS DE PRODUCCIÓN DE ABEJORROS



- PNCO of approved germinal product establishments of bovine, equine, ovine, caprine and porcine species

PNCO ESTABLECIMIENTOS PRODUCTOS REPRODUCTIVOS



- PNCO for by-products of animal origin not for human consumption in SANDACH establishments and transport.

PNCO SANDACH EN ESTBLECIMIENTOS



- PNCO for animal welfare on livestock holdings and during transport of animals.

PNCO BIENESTAR ANIMAL



- PNCO for plant health.

PNCO SANIDAD VEGETAL



- PNCO for marketing of phytosanitary products.

PNCO COMERCIALIZACIÓN





## D. VERIFICATION OF THE QUALITY OF OFFICIAL CONTROLS

The verification of the quality of controls means evaluating whether these are adequate for the achievement of the objectives pursued.

This activity is developed in the following stages:

### ■ **Planning of official controls:**

This process is conducted within each of the programmes including measures and actions carried out in the context of the execution of the programme.

Each programme details the operating objectives pursued in the execution thereof. The degree of achievement of these objectives is carried out through the indicators established in the programme.

### ■ **Assessment of the results of the national programme of official control:**

The competent authorities for the execution of the programme and the coordination body thereof assess the following aspects of the results of the programme on an annual basis:

- Execution of the controls in accordance with the procedures and criteria established in the programme and applicable documented procedures by:
  1. **The competent authority for its execution**, which shall avail, among other instruments, of the control supervision procedures, verifying that the inspectors conduct the controls in accordance with the procedures and instructions established.
  2. **Audit bodies** designated by the competent authorities, for the purpose of verifying, via internal audits, that the programme as a whole is being delivered in accordance with the applicable provisions and procedures.
- Compliance with the objectives, to review the results of the indicators established to determine the degree of achievement.
- Evaluation of the adequacy and efficiency of the control programme, which will consider the results of the assessments mentioned above, and the findings and results of internal audit.



### ▪ Adoption of corrective measures:

After the evaluation effected in the previous point, the competent authority at Autonomous Community level or General State Administration, and, where applicable, the coordinating body at national level shall carry out the modifications necessary for documented procedures and national programme.

The following document establishes criteria for the application of the verification of efficient of controls in the following points:

- The supervision of official control.
- The assessment of the objectives and use of indicators.
- The audits of the official controls.

### GUIDELINE DOCUMENT FOR ASSESSMENT OF SYSTEMS EFFECTIVENESS



The following attached document describes the structure of audits in Spain within the scope of the MAPA, both for competencies of national and regional official control.

### AUDIT STRUCTURE



## E. ANNUAL REPORT OF RESULTS

### ANNUAL REPORT: GUIDELINES AND PROCEDURE FOR DRAFTING OF ANNUAL REPORT.

This report is drafted in accordance with the standard model form established in the Commission Implementing Regulation (EU) 2019/723 of 2 May 2019. For the drafting of the report, the following procedure is followed:

- The coordinating unit of the PNCOCA in the MAPA (SGAC) indicates the annual schedule for the information of the results of controls.
- The same unit requests, from the MAPA units responsible for the different programmes, the information that must be issued to comply with Part I and section 1 “general conclusion on the level of fulfilment achieved” in section 1 of Part II of the report template.
- The coordination group of the MAPA Units establishes the structure of the information to be contained in sections 1 “section 1 “general conclusion on the level of fulfilment achieved”. The structure of the information contained in this section will be reviewed annually to introduce modifications that are deemed appropriate.
- The unites of the MAPA managers of each national control programme, in the term established by the SGAC, shall record in the SDCP-AROC (Data Collection Platform-Annual Reports on Official Controls) application of the Commission, the results of the official controls conducted the previous year, following the criteria agreed in the coordination group of the MAPA units and the guidelines contained in the Commission document on the guide to compliance with the report template approved by Regulation (EU) 2019/723, of 2 May.
- Once the terms for the recording of the results is finalised, the SGAC shall review compliance with all sections of the report in order to communicated to AESAN the validation of the annual report on primary production and food quality.

## HIGH-LEVEL OBJECTIVE 2

Reduce the risks to people's health present in food, ensuring the welfare of animals for slaughter for human consumption, through the organisation of official controls in food establishments and verify compliance on the part of the operators of the regulation applicable in food safety, nutrition and animal welfare.



National Plan for Official Control  
of the Food Chain

**2021-2025**

**Version 2 - 2022**



Ministry of Consumer Affairs,  
Spanish Agency for Food Safety  
& Nutrition (AESAN)



**The competent authority responsible for coordination for the achievement of this objective is the Spanish Agency for Food Safety & Nutrition (AESAN), Ministry of Consumer Affairs (MCO)**

## A. STRATEGIC OBJECTIVES

The strategic objectives that make up high-level objective 2 and the programmed provided for to achieve the following:

- **Strategic objective 2.1:** Improve compliance with the food hygiene regulation and animal welfare in food establishments.
  - Programme 2.1. Inspection of food establishments
  - Programme 2.2. Audits of in-house control systems
  - Programme 2.3. Slaughterhouses, game handling establishments and meat processing establishments
- **Strategic objective 2.2:** Improve compliance with the legislation so that food products to be made available to consumers contain the food safety information established in legal provisions.
  - Programme 2.4. Labelling of food and materials in contact with food.
  - Programme 2.5. Allergens and substances that cause intolerance
  - Programme 2.6. Release of Genetically Modified Organisms (GMOs)
  - Programme 2.7. Notification, labelling and composition of food supplements
- **Strategic objective 2.3:** To reduce, where possible and in all cases to acceptable levels, the exposure of consumers to biological and chemical risks present in food.
  - Programme 2.8. Biological hazards in food
  - Programme 2.9. Anisakis
  - Programme 2.10. Supervision of antimicrobial resistance of zoonotic food agents
  - Programme 2.11. Contaminants in foods
  - Programme 2.12. Control of technological ingredients
  - Programme 2.13. Materials in contact with foods
  - Programme 2.14. Pesticide residue in foods
  - Programme 2.15. Veterinary medicine and other substances in foods of animal origin
  - Programme 2.17. Control of irradiated food
- **Strategic objective 2.4:** Promote healthy and sustainable eating through the fostering of nutritional quality and control thereof in school meals and in food and drink in vending machines and cafeterias.
  - Programme 2.16. School meals, vending machines and cafeterias in schools
- **Strategic objective 2.5:** To reduce, where possible and in all cases to acceptable levels, the exposure of consumers to emerging risks or risk of special concern and difficult to control.

## **B. GENERAL ORGANISATION: COMPETENT AUTHORITIES, COORDINATION MECHANISMS AND OFFICIAL CONTROL RESOURCES**

This section sets out the development of the system through which Spain organises control on food establishments and foods produced or marketed in the intra-community market to verify compliance with regulations on food safety and resources that sustain that system to comply with the high-level objective to reduce risks to health and persons present in foods, ensuring the welfare of animals for slaughter for human consumption, through the organisation of official controls in food establishments to verify compliance on the part of the operators of the regulation applicable in food safety, nutrition and animal welfare.

### **1. COMPETENT AUTHORITIES AND COORDINATION BODIES**

In accordance with Article 4 of Regulation (EU) 2017/625, the Member States will designate the competent authorities that will be assigned the responsibility of organising official controls and other official activities to verify compliance with the applicable regulation of the whole food chain.

The State can assign the responsibility of organising and conducting official controls to more than one competent authority on a different level (national, regional or local) and may allow competent authorities to assign specific responsibilities to other public authorities, provided there is coordination and cooperation around the controls.

Articles 148 and 149 of the Spanish Constitution distribute these competencies between the General State Administration and the autonomous communities and allocate competencies in the area of health and hygiene to the autonomous communities. The Regional Ministries of Health of the autonomous communities are the competent authorities responsible for planning and executing scheduled official controls to comply with the current objective of reducing the risks present in foods through controls in food establishments and foods.

On the other hand, Article 109 of Regulation (EU) 2017/625 establishes that each Member state shall designate a single body to liaise with European bodies and the contact bodies of other Member States.

In Spain, the only body responsible for coordinating the drafting of the National Control Plan, and compiling information with a view to presenting the annual report is the Spanish Agency for Food Safety & Nutrition (AESAN), Ministry of Consumer Affairs, through the Sub-directorate General for Coordination of Alerts and Official Control Programmes (sgcaa@aesan.gob.es - Tel: +34 913380715).

#### **■ Structure and organisation of competent authorities**

AESAN primarily plays a role of coordination and dialogue with the autonomous communities, with the other Member States and with the international bodies. Furthermore, it has the power to draft national legislation in cases it considers necessary and also has a national risk assessment body through the Scientific Committee.

The coordinating role of AESAN with the autonomous communities arises from the executive competencies as they have their own systems of control, planning and methods of execution for the different controls conducts in their respective territories.

Within the Regional Ministries of Health of the Autonomous communities are the Directorates General for Public Health (DGSP), which usually hold these competencies. The structure of each of the autonomous communities is published in the Decree of Autonomy which reflects the existing bodies in each Autonomous Community and their powers.

Frequently, local entities also exercise powers in the sphere of Public Health, as reflected in Article 25 of *Law 7/1985, regulating the bases of the local regime*, establishing that the municipalities shall, in all cases, exercise their own competencies in the terms of the national and regional legislation in the following areas relating to the National Plan for Official Control of the Food Chain (PNCOCA):

- Produce fairs, markets, fish markets and street trade.
- Protection of public health.

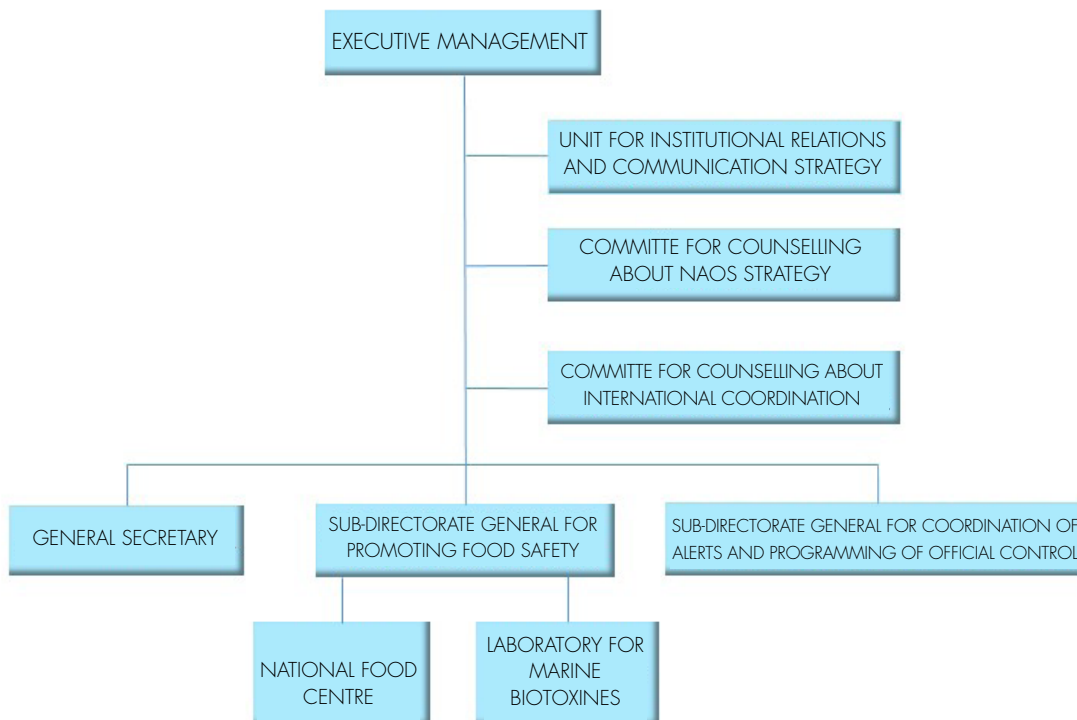
Municipal competencies are determined by Law, duly assessing the convenience of the implementation of local services in accordance with the principles of decentralisation, efficiency, stability and financial sustainability.

**Annex I** includes a list of the autonomous communities assigned these controls, their Websites and judicial rules through which they have been designated.



### ANNEX I. COMPETENT AUTHORITIES

Within AESAN, there are two units involved in the application of the different requirements included in Regulation (EU) 2017/625, the Sub-directorate General for Coordination of Alerts and Programming of Official Control, and the Sub-directorate General for Promotion of Food Safety.



In accordance with Royal Decree 19/2014, which describes the objectives and functions of the Spanish Agency for Food Safety & Nutrition, the Sub-directorate General for Promotion of Food Safety, assumes the development of functions relating to the management of food risk in production, processing, preparation, transport, distribution and sale or service to the final consumer and collectives and the Secretariat of the Interministerial Commission for Food Management (CIOA) and the following tasks:

- To propose food risk management measures, formulating, among other measures, proposals for new regulatory developments and promoting the simplification and unification of the rules, and the planning coordination and development of strategies in relation to food-borne diseases.
- Coordinate and report on the position of Spain and, where applicable, represent it in the matters of food safety, nutrition and consumer affairs at European Union level and in international bodies, especially the Joint FAO/WHO Codex Alimentarius Commission, of which the Agency is a point of contact.
- Manage the General Health Registry for Food Companies and Foods.
- Draft, promote and participate in studies research works on consumer affairs, nutrition and food safety.
- Complete analysis, testing and trial on quality and safety for foods, goods and services for use and consumption, training and advice for technical personnel, the development of analytical advice and dissemination.

This Sub-directorate General is also responsible for control and supervision of the National Reference Laboratory and the Laboratory for Marine Biotoxins.

The **Sub-directorate General for Coordination of Alerts and Programming of Official Control**, performs the following functions:

- Coordinate the actions of the public administrations in national territory, relating to official control food products to protect the health and the interests of consumers and all stakeholders in the food chain.
- Coordinate the function of existing alert networks in Spanish territory and their integration with the respective community and international systems.

To achieve a uniform application of Regulation (EU) 625/2017 and for the different systems of control to function on a homogeneous basis, there are inter-territorial and inter-sectoral coordination basis, whose purpose is to coordinate the activities AESAN and the





DGSP-autonomous communities. These bodies approve procedures, control programmes, guides and homogeneous regulatory interpretation criteria.

The principal existing coordination bodies in AESAN for the processing of issues relating to food safety are:

- **MANAGEMENT COUNCIL** The governing body of the agency, with representatives of the autonomous communities and the Ministries of Health; Consumer Affairs; Agriculture, Fisheries and Food; Environment and Economic Affairs and Digital Transformation. There are also representatives of the municipalities and the provinces, of Consumers and Users and the economic organisations representing agri-food sectors.
- **INSTITUTIONAL COMMISSION** With representatives of all autonomous communities at Directorate General level, exercise functions of inter-territorial and inter-departmental coordination. Also represented are the Ministries of Health; Consumer Affairs; Agriculture, Fisheries and Food; the Environment and Economic Affairs and the Digital Transformation, as well as local authorities.
- **ADVISORY COUNCIL.** The body for active participation of society. There are representatives of the most important economic, social and professional organisations related to food safety and nutrition.
- **PERMANENT COMMISSION FOR FOOD SAFETY AND PERMANENT COMMITTEE FOR NUTRITION.** Both of these commissions have representatives of all autonomous communities and autonomous cities. Different proposals and documents of consensus are developed at the request of the Institutional Commission and the final documents of the working groups are ratified.
- **SPECIFIC WORKING GROUPS.** Created in the Institutional Committee at its own initiative or subject to the report of the Permanent Committees. For example, the working group for the verification of efficiency or internal audits of official control.

Annex II details other coordination bodies of a general and sectoral nature, at central and regional level.

## ANNEX II. COORDINATION BODIES



## 2. LEGAL SUPPORT

The competent authorities have the statutory power necessary to conduct official controls and other official activities, and to adopt the necessary measures established in Regulation (EU) 2017/625, and said standards guarantee the access of personnel to premises and documentation of operators so that control agents can adequately fulfil their duties.

In addition to the rules governing the legal advice for conducting official controls in all scopes of application of the Regulation (EU) 625/2017, there are other national and regional legal provisions that apply in official controls of food establishments and foods.

Some of these provisions are horizontal and affect the official control system generally or a certain sector, but different hazards, and other provisions affect certain control programmes specifically.

Annex III details all of the horizontal legal provisions. The specific legal provisions are included in each of the programmes affected.

### ANNEX III. LEGAL PROVISIONS



### 3. LABORATORY RESOURCES

In compliance with the provisions of Regulation (EU) 2017/625 on sampling, analysis, testing and diagnostic methods (Chapter IV), official laboratories, European laboratories and national reference laboratories (title III, laboratories and reference centres), analytical support for official control programmes in Spain is structured around official control laboratories, national reference laboratories and EU reference laboratories.

- **Official control laboratories**, designated by competent authorities to conduct the analysis of the samples taken within the framework of official control. They comply with the obligations of the laboratories described in Article 38 of Regulation (EU) 2017/625 in relation the requirements adhering to European standards: EN ISO/IEC 17025, EN 45002 and EN 45003 and are accredited by the National Accreditation Entity (ENAC). Furthermore, the official laboratories participate in comparative inter-laboratory trials or proficiency tests organised or the analysis testing or diagnostics carried out in their capacity as official laboratories, at the request of the national reference laboratory or European Union reference laboratory.
- The list of laboratories designated for official control are available on the AESAN website, through the IT application of the Network of Food Safety Laboratories (RELSA)

<https://www.aesan.gob.es/AECOSAN/web/laboratorios/subseccion/RELSA.htm>



- **National reference laboratories**, are designated in accordance with Article 100 of *Regulation (EU) 2017/625* and fulfil the responsibilities and tasks provided for in Article 101 of mentioned Regulation. In Spain there are two National Reference Laboratories for official control of foods, under the jurisdiction of AESAN:
  - The National Food Centre (CNA) in Majadahonda, and the
  - Laboratory for Marine Biotoxins (LCRBM) in Vigo.

- **European Union reference laboratories**, designated by the European Commission as centres technical-scientific support and the official laboratories so that they have up-to-date information on the methods available, organise comparative inter-laboratory tests or participate actively in them and offer training courses for national reference laboratories or official laboratories. These laboratories have great technical capacity (infrastructure and teams) and highly qualified and trained personnel. In Spain there is also a European Union reference laboratory under the jurisdiction of AESAN:
  - The European Union Reference Laboratory for Marine Biotoxins (LCRBM) in Vigo.

### ■ Designation of laboratories

The authorities of the autonomous communities and the General State Administration are the competent authorities for the designation of the official control laboratories in accordance with Article 37 of Regulation (EU) 2017/625. This designation is carried out on the basis of the *“Procedure for the designation of official laboratories within the scope of food safety”*.

In order to be designated as an official laboratory by a Competent Authority, both public and private, must meet certain requirements regarding resources and operating capacities, described in the *“Procedure for the designation of official laboratories in the scope of food safety”*.



### PNT DESIGNACIÓN LABORATORIOS

There are no requirements in terms of their location, as they may be located in the autonomous community or another, or in another Member State or the third country party to the Agreement on the European Economic Area, in accordance with the requirements established in point 37 (2) of Regulation (EU) 2017/625.

The competent authorities and the official laboratories must coordinate and plan the tests to be carried out over the course of the year based on the annual programming of the competent authorities and analysis activities of the laboratories.

The laboratories designated laboratories for official control may be subject to audit or inspection on the part of the competent authorities for the verification of compliance with the commitments and requirements established in the procedure for the designation in accordance with Article 39 of the Regulation (EU) 2017/625. The verification activities shall be carried out on a regular basis, at the appropriate frequency, and where deemed necessary.

The competent authorities may remove the designation of an official laboratory, in part or in full, in the event that the laboratory does not does not fulfil the verification activities or does not comply with the commitments agreed for the maintenance of the designation of official laboratory.



#### 4. INFORMATION TECHNOLOGIES (IT) RESOURCES FOR OFFICIAL CONTROL

In the exercise of official controls, IT applications and databases are often used for the purpose of simplifying management, cutting down on administrative procedures, times and, ultimately, improving the quality and efficiency in the execution of official controls.

Databases managed by AESAN:

- General Health Registry for Food Companies and Foods (RGSEAA). This is a support tool for official control with national and public scope whose creation and management are regulated by Royal Decree 191/2011, on the General Health Register of Food Companies and Food. The RGSEAA must register each of the food establishments or, in the event that they do not have establishments, the companies themselves, provided they meet the following requirements:
  - a) That the establishment or the headquarters or registered address of the company that has no establishment is in Spanish territory.
  - b) The purpose of its activity is:
    1. Foods or food products for human consumption.
    2. Materials or objects in contact with foods.
    3. Technological adjuvants used in production of foods.
  - c) That their activity can be classified in one of the following categories:
    1. Production, processing, drafting and/or packaging.
    2. Storage and/or distribution and/or transport.
    3. Importation of products from countries that do not belong to the European Union.

The industries and establishments located in any other EU Member State can also be registered on the RGSEAA. The registered establishments can be consulted on the AESAN website through the following link:

[https://rgsa-web-aesan.mscbs.es/rgsa/formulario\\_principal\\_js.jsp](https://rgsa-web-aesan.mscbs.es/rgsa/formulario_principal_js.jsp)



- **IT application for the Management of Food Alerts and Official Controls (ALCON).** This application constitutes an essential tool for the management and coordination of the official controls at national level. It has two different applications:
  - Management of the network of food alerts through the website, both national (SCIRI) and European (RASFF).

- Compilation of the official control data submitted by the autonomous communities for the update of the annexes of the PNCOCA for the drafting of the reports on the results of official control.

The autonomous communities have different tools, the most common of these the application for the regional registration of food establishments located in their territory, tools for the classification of the establishments based on risk and the programming of the controls and applications for the official control actions.

Annex IV details the IT tools that support official control, both national and regional.

#### ANNEX IV. INFORMATIC SUPPORTS 2020



### 5. STANDARDISED PROCEDURES

The competent authorities establish procedures and mechanisms to guarantee the impartiality, efficiency, suitability, quality and coherence of official controls and other official activities at all levels, as established in Article 5 of Regulation (EU) 2017/625.

According to the scope and sphere of application of these procedures, they can be differentiated in:

- **Internal procedures** approved by the unit itself, in accordance with the structure and system of management and geared towards the organisation and operation of each unit. The autonomous communities and AESAN have access to these types of procedures.
- **Specific working procedures of the autonomous communities**, applied internally by the competent authorities under the regional body that has approved them. These are usually technical in nature, aimed at unifying and describing in detail the performance of the tasks of the stakeholders responsible for official control, in most cases related to the different control programmes.
- **Specific working procedures agreed between AESAN and the autonomous communities**, applicable throughout the national territory for the competent authorities of the autonomous communities and AESAN, depending on the responsibilities described therein. They are drafted based on the need to standardise mechanisms of action in some areas of official control. These procedures are usually worked on in specific working groups or directly in the Permanent Food Safety Committee (CPSA) and approved in the Institutional Committee (CI) for direct implementation.
- **Specific working procedures in the inter-territorial sphere**, applicable throughout the national territory, as they are adopted on a consensus basis between various ministries and regional ministries for the purpose of clarifying competencies in the case of related activities or those activities in which it a high level of coordination and cooperation is required to correctly exercise the function established in the legislation.

Guidance documents and guidelines are also developed to harmonise certain issues directly related to the implementation of official control. These documents are incorporated into each of the control programmes concerned.

In this line, the “**Guidance Document on Fees on Official Controls**” has been developed, harmonising at national level the requirements set out in Regulation (EU) 2017/625 regarding the calculation, costs and deductions of the fees applied to official controls and approved in the IC of 17 December 2021.



Annex V shows the procedures and other documents relating to the organisation and functioning of AESAN and the autonomous communities. The specific procedures are linked with each of the programmes affected.

## ANNEX V. DOCUMENTED PROCEDURES



### 6. EMERGENCY PLANS

Under Article 55, section 1 of Regulation (EC) 178/2002, relating to the General Plans for the management of the crisis, all Member States must draft these types of contingency plans for crisis management.

The objective of these plans is to foresee the systems and actions to be implemented in the event of food incidents that may constitute a serious risk to the health of consumers or food emergency situations.

In Spain, there are different tools for the development of these plans.

#### ■ Coordinated system for Rapid Exchange of Information (SCIRI)

The fundamental objective of this systems is to guarantee consumers that the products they find on the market are safe and do not pose a threat to health. To achieve this objective, this system is structured in the form of a network, whose primary basis is the rapid exchange of information between different competent Authorities, thus facilitating the appropriate actions regarding those food products might pose a direct or indirect risk to the health of consumers, the ultimate purpose of which is the removal of the products in question from the market and their subsequent destruction, reshipment or use for other purposes.

At the same time, this system is integrated with the other Food Alert Systems, both European, through the “Rapid Alert System for Food and Feed” (RASFF), established at EU level in Article 50.1 of Regulation (EC) No. 178/2002, and in which includes the incidents linked to feed and food for human consumption, and international, through the WHO’s Department of Food Safety, Zoonoses and Foodborne Diseases (INFOSAN).

The procedure is described in the “Action Procedure of the SCIRI-ACA Network”, included as members of the competent authorities of the autonomous communities and AESAN.





## ■ Food crisis management system

Commission *Implementing Decision (EU) 2019/300* of 19 February 2019, establishing a general plan for crisis management in the field of the safety of food and feed, specifies, in Annex I, the tasks of the coordinators of the crisis in accordance with Article 5.

At national level, there is a specific procedure for the management of the emergency called “Management procedure for serious incidents and food emergency situations” establishing the procedure of basic actions to follow in the event of serious incidents and food emergency situations, for the purpose of optimising the management of incidents, facilitating the appropriate information for the consumer and minimising, insofar as possible, the health and economic impact.

## 7. TRAINING OF PERSONNEL

In accordance with Article 5 of Regulation (EU) 2017/625, the competent authority shall guarantee that all personnel responsible for implementing official controls have adequate training that enables them to fulfil their function competently and effect the official controls in a coherent manner.

Article 28 of Law 17/2011 establishes that the public administrations shall guarantee that all personnel responsible for conducting the official controls received adequate continuous training in their sphere of activity, which enables them to fulfil their function in a competent and coherent manner in line with the criteria established in the guidelines in the area of training provided by European bodies.

In Spain, the public employees access public administration positions after selection process and the training required for each position. This selection process requires a level of general knowledge of national, European and international regulation and specific knowledge of food, laboratory and animal health knowledge, among others.

From there, the competent authorities organise the training plans:

- a) Identification of training needs.** The competent authorities plan, on an annual or multiannual basis, the training plans of public employees. Among other factors, this programming takes into account the following:
- the priorities established by services or management units
  - the priorities demanded by control agents
  - the training needs identified in accordance with new regulation, new internal organisation objectives, unsatisfactory results in supervision, unsatisfactory results in internal audits.
  - newly hired personnel.



- b) Implementation of training plans.** For each training activity the adequate measures to guarantee maximum fulfilment on the part of attendees, taking into account the theoretical and practical content of each activity and with suitable speakers. The documentation of each training activity shall include detailed course content, the timetable, the materials, the speakers and the scheduled number of participants.
- c) Registration and training assessment.** The entire training plan is reflected in the document, from programming, contents and evaluation. At the end of each training activity, participants are given a document accrediting that they have completed the activity and they will complete an individual assessment. The competent authority responsible for the training plan completes a summary reports of the activities programmed and completed and an assessment that will serve as a recommendation for the following training cycle.

Depending on the body that organises and promotes the training activity, public employees can participate in:

- **International training**, organised by the European Commission within the framework of Better Training for Safer Food (BTSF). The offering of courses is distributed between the central and/or regional competent authorities from the point of contact for BTSF in AESAN.
- **Training at state level**, organised by AESAN or through another central administration body. Internal training for own personnel, directly or indirectly related to official control activities, or geared towards the competent Authorities and inspection personnel of the autonomous communities or other administrations, sector representatives, specialists or the general public.
- **Training at regional level**, organised at regional level by regional ministries of health or equivalent autonomous community bodies. Training geared towards personnel participating in official control in the autonomous community itself, relating to organisation, management and other skills needed depending on the position and the specific areas of official control.

## C. CONTROL PROGRAMMES

The control programmes are designed to comply with the objectives established below:

- **Programme 1.** Inspection of food establishments

### P1. INSPECCIÓN



- **Programme 2.** Audits of HACCP-based procedures

### P2. AUDITORIA AUTOCONTROL



- **Programme 3.** Slaughterhouses, game handling rooms and fighting cattle treatment rooms

### P3. MATADERO





- **Programme 4.** Labelling of food and materials in contact with food

#### P4. ETIQUETADO



- **Programme 5.** Allergens and substances that cause intolerance

#### P5. ALÉRGENOS



- **Programme 6.** Release of Genetically Modified Organisms (GMOs)

#### P6. OMG



- **Programme 7.** Notification, labelling and composition of food supplements.

#### P7. COMPLEMENTOS



- **Programme 8.** Biological hazards in food

#### P8. PELIGROS BIOLÓGICOS



- **Programme 9.** Anisakis

#### P9. ANISAKIS



- **Programme 10.** Monitoring of antimicrobial resistance of zoonotic food agents

#### P10. RAM



- **Programme 11.** Contaminants in foods

#### P11. CONTAMINANTES



- **Programme 12.** Additives and other technological ingredients in food

#### P12. ADITIVOS



- **Programme 13.** Materials in contact with foods

#### P13. MECA



- **Programme 14.** Pesticide residue in foods

#### P14. PLAGUICIDAS



- **Programme 15.** Veterinary medicine and other substances in foods of animal origin  
P15. PNIR
- **Programme 16.** School meals, vending machines and cafeterias in schools  
P16. MENÚS
- **Programme 17.** Control of irradiated food  
P17 IRRADIADOS



## COORDINATED STUDIES AND CONTROL PLANS

The general objective of the coordinated control plans is coordinated at national level for certain risks or sectors for the purpose of conducting a specific coordinated official control activity. At national level, the “Procedure for Nationally Coordinated Studies and Control Plans” developing the management, design, presentation of results and conclusions.

The organisation of coordinated studies and control plans responds to compliance with:

Strategic objective 2.5: To reduce consumer exposure to emerging risks or risks of particular concern and difficulty of control as far as possible and to acceptable levels.

The reasons for the completion of a of a coordinated control plan may include:

- Increase of incidence of some danger considered in the official control programmes.
- Requirement of the European Commission, in accordance with Article 112 of Regulation 2017/625, for a recommendation of improvement or request for intensification of controls.
- Lack of sufficient personnel to carry out any specific control
- Establish future priorities in official controls at national level
- Lack of accredited laboratories for any technique or matrix or high cost of certain analyses.
- Emerging risks not considered in official control programmes.
- Among others, the reasons for the organising a coordinated study may include:
  - Assessing the existing risk at national level of a specific threat
  - Prospective studies of the implementation of an analysis technique in the laboratory
  - Promotion of legislative changes
  - Suggestions or reports of the AESAN Scientific Committee indicate same
  - Emerging risks not considered in official control programmes.

Both AESAN and the autonomous communities may propose the organisation of a coordinated activity to the CPSA which shall be approved, where applicable, in the CI. Each coordinated study or control plan shall be subject to a specific procedure describing the models for the submission of results and the indicators for the assessment, and issuing a detailed report of each coordinated activity that will be made available to the public on the AESAN website.



- **Procedure for Nationally Coordinated Studies and Control Plans**  
PNT-AP-07\_Planes de control y Estudios coordinados



## D. VERIFICATION OF THE QUALITY OF OFFICIAL CONTROLS

### ■ REVIEW OF THE SYSTEM

The principal objective of Regulation 625/2017 is to guarantee the quality of official controls carried out to ensure the correct and efficient application of food legislation. To do this, it establishes that the competent Authorities shall guarantee the efficiency and adequacy of official controls of food and feed, animal health and welfare, plant health and phytosanitary products in all phases of production, processing, transformation and distribution.

A review of the control system should therefore be carried out to verify the compliance and efficiency thereof. As part of these verifications, the following activities are carried out:

- **Supervision of official controls**, the set of actions carried out at senior levels of the hierarchy on official control agents to assess the correct and efficient fulfilment of their functions and the implementation of European and national food safety regulations.

It shall be carried out in accordance with the "Orientation document for supervision of official control" agreed between AESAN and the autonomous communities.



### GUIDELINE DOCUMENT FOR SUPERVISION

- **Internal audits of official control**, activities conducted as part of audits assess the efficiency of the system established by the competent authorities to execute official controls at structural and organisation levels and the resources available such as planning and specific execution of control programmes. This activity is carried out by a team with guaranteed independence with respect to the organisation or programme to be audited.

It is carried out in accordance with the "Framework Document of Official Control Audit Systems" agreed between AESAN and the autonomous communities.

- **Verification of official control programmes**, activity that fundamentally assesses the execution and the results of the control programmes through the assessment of the tailored indicators of the general and operational objectives of each programme.

It is carried out in accordance with the "Guidance paper for verification of the effectiveness of official control" agreed between AESAN and the autonomous communities.



### GUIDANCE PAPER FOR VERIFICATION OF THE EFFECTIVENESS OF OFFICIAL CONTROL

Listed below, in summary form, are some characteristics of the official control system review techniques:

	SUPERVISION	VERIFICATION	AUDIT
<b>Purpose</b>	Verification of compliance and individual effectiveness	Verification of compliance and effectiveness of the official control system	Verification of compliance, effectiveness and adequacy of the system
<b>Programming cycle</b>	Annual	5-Year cycles with annual targets	5-Year cycles
<b>Personnel responsible</b>	Senior Official	Team responsible for system	Audit team
<b>Element to study</b>	Actions of official control agents/Services	Effectiveness of official control system	Overall effectiveness of plans and programmes of the official control system
<b>Coverage</b>	All official control agents	All official control plans and programmes	Sampling of plans and programmes through prioritisation based on risk
<b>Method</b>	Supervision procedure	Verification procedure	Audit procedure
<b>Results</b>	Supervisions satisfactory/unsatisfactory	Indicators of compliance and effectiveness of the official control system	Instances of non-compliance Audit satisfactory/unsatisfactory
<b>Conclusions</b>	Specific conclusions regarding official control agents	Specific and general conclusions of control plans and programmes	General conclusions regarding control plans and programmes
<b>Measures to adopt</b>	Corrections at individual and collective level Review of the system Dissemination of good practices	Adjustment of plans, programmes, organisation and resources	Improvement of plans, programmes, organisation and resources

The results obtained through the different system review techniques reveal possible areas of improvement, which allow for the reformulation of strategies, modification of objectives and assignment of resources and the fostering of participation, commitment and motivation and all levels of the system.

Those actions developed by competent authorities that might contribute to the improvement of official control systems may also be considered “good practices”. For the purpose of disseminating best practice between the competent authorities may be communicated in accordance with the dissemination mechanism provided for in “Best practices and their dissemination” included in the “Framework document for audit systems of official control of autonomous communities-SP”.



## FRAMEWORK DOCUMENT FOR AUDITS

### ■ ADAPTATION OF PLAN

The National Plan is subject to annual adaptation as a result of amendments in the legislation arising from the annual report, structural changes, etc.

Furthermore, the overall analysis of the results obtained through the System Review will lead to the adoption of the measures considered appropriate and necessary for the continued improvement of the efficiency of the National Plan for Official Control of the Food Chain, which may include:

- Adapting the control programmes
- Complete a new coordinated control plan and design new programmes

- Amend the content of a section of the Plan
- Design the new PNCOCA or a strategic plan
- Legislative proposals: establish the position in European legislative proposals and develop national regulation.
- Modify the organic structure or the distribution of competencies, create coordination bodies, etc.
- Develop the new working procedures coordinated with the autonomous communities
- Training initiatives

## E. ANNUAL REPORT OF RESULTS

The control system for food establishments and foods is assessed through an annual report on the results of official control. The purpose of this report is to assess compliance with the strategic and general high-level objectives through the indicators designed for that purpose.

To complete the report of results, the competent authorities and autonomous communities responsible for the design and execution of the different control programmes shall submit the result obtained in the process to AESAN through the system established for same. The AESAN is responsible for gathering the data and compiling the report of the results and analysis of same.

In accordance with Article 18 of Law 17/2011 on food safety and nutrition, the annual report on the execution of the National Plan for Official Control of the Food Chain is submitted to Parliament for information and control, and made available to the public through the AESAN website.

Based on the specific requirements in the Commission Implementing regulation (EU) 2019/723 of 2 May 2019, laying down rules for the application of Regulation (EU) 2017/625 as regards the standard model form to be used in the annual reports submitted by Member States, the report on the execution of the PNCOCA is drafted and submitted to the European Commission by 31 August of the year following the execution of the controls.

The terms and definitions used in a Glossary of terms and definitions used in this part of the PNCOCA applicable to the control programmes and the drafting of the annual report of results.

### GLOSSARY OF TERMS





## HIGH-LEVEL OBJECTIVE 3

Guarantee the achievement of a high level of food quality, including Differentiated Quality and Organic Production of food products and intensifying the fight against food fraud throughout the food chain to achieve the sustainability of the agri-food system, increasing consumer trust, guaranteeing their rights to information and the protection of their economic interests against unfair business practices.



National Plan for Official Control of the Food Chain

**2021-2025**  
**Version 2 - 2022**



GOBIERNO DE ESPAÑA

MINISTERIO DE AGRICULTURA, PESCA Y ALIMENTACIÓN

MINISTERIO DE CONSUMO

Ministry of Agriculture, Fisheries and Food;  
Ministry of Consumer Affairs

The competent authorities responsible for the coordination for achieving this objective are:

- **General Secretariat for Agriculture and Food of the Ministry of Agriculture, Fisheries and Food (MAPA)**
- **Sub-directorate General for Coordination, Quality and Cooperation in Consumer Affairs, Directorate General for Consumer Affairs, Ministry of Consumer Affairs (MCO)**

The strategic objectives that make up high-level objective 3 and the programmed provided for to achieve the following:

- **Strategic objective 3.1.** Strengthen food safety control, Differentiated Quality and Organic Production to reduce non-compliance and guarantee the achievement of a high level of food safety, and intensify the fight against food fraud throughout the food chain, except for final sale to the consumer, to achieve the sustainability of the food system and increase consumer trust; and protection against unfair business practices.
  - 3.1.1** National Programme of Official Control of the Food quality
  - 3.1.2** National Programme of Official Control of Organic Production
  - 3.1.3** National Programme of Official Control for differentiated quality linked to geographic origin and traditional specialities guaranteed before marketing
- **Strategic objective 3.2.** Guarantee the achievement of a high level of food quality, including Differentiated Quality and Organic Production, of agri-food products available to the consumer. Intensify the fight against food fraud and ensure fair business practices, and the protection of consumers' interests and their right to receive accurate information on the label and in advertising of agri-food products.
  - 3.2.1** General control of compulsory and voluntary food information with no repercussions for food safety and nutrition at point of sale to the final consumer.
  - 3.2.2** General control of food quality at point of sale to the final consumer.
  - 3.2.3** Control of unfair business practice with the consumer.
  - 3.2.4** Specific control of food information and quality of organic products at point of sale to the final consumer.
  - 3.2.5** Specific monitoring of food information and quality linked to protected designations of origin, protected geographical indications and traditional specialities guaranteed at point of sale to the final consumer.

## A. STRATEGIC OBJECTIVE

**Strategic objective 3.1.** Strengthen food safety control, Differentiated Quality and Organic Production to reduce non-compliance and guarantee the achievement of a high level of food safety, and intensify the fight against food fraud throughout the food chain, except for final sale to the consumer, to achieve the sustainability of the food system and increase consumer trust; and protection against unfair business practices.

The competent authority responsible for the coordination for the achievement of strategic objective 3.1. is the General **Secretariat for Agriculture and Food of the Ministry of Agriculture, Fisheries and Food (MAPA)**:

## B. GENERAL ORGANISATION: COMPETENT AUTHORITIES, COORDINATION MECHANISMS AND OFFICIAL CONTROL RESOURCES

### 1. OFFICIAL CONTROL IN THE AREA OF FOOD QUALITY

The **purpose** of this document is to establish, within the National Programme of Official Control of the Food Chain, the planning of official controls in food quality, in the corresponding spheres regulated by the rules set out in Article 1, section 2 of Regulation (EU) 2017/625 of the European Parliament and of the Council, of 15 March 2017.

The coordination of these official control corresponds to the Ministry of Agriculture, Fisheries and Food, while the execution thereof is, in most cases, the responsibility of the competent bodies of the autonomous communities.

The structure of the Ministry of Agriculture, Fisheries and Food (MAPA) was approved by **Royal Decree 430/2020, of 3 March**, developing the basic organic structure of the Ministry of Agriculture, Fisheries and Food and amending Royal Decree 139/2020, of 28 January, establishing the organic structure of the ministerial departments.

The MAPA unit with competency for the execution of official controls of the of supra-regional quality marks, and the planning and coordination with autonomous communities of the execution of other official controls of Regulation (EU) No. 2017/625, of 17 March, is:

- General Secretariat for Agriculture and Food
  - Directorate General for the Food Industry
    - Sub-directorate General for Control of Food Quality and Agri-food Laboratories. (SGCCALA)

At the following link you can find the organisational chart of the MAPA:

<https://www.mapa.gob.es/es/ministerio/funciones-estructura/organigrama/default.aspx>





At the following link you can access the PNCOCA through the MAPA website:

<http://www.mapa.gob.es/es/ministerio/planes-estrategias/plan-nacional-de-control-de-la-cadena-alimentaria/default.aspx>



A fundamental element for the integration of these official controls into the National Plan for Official Control of the Food Chain is the coordination of different units of the MAPA involved and the dialogue with the rest of the Units in other Departments responsible for the development of the Plan.

For this purpose, Royal Decree 430/2020, of 3 March, assigns this responsibility to the **Sub-directorate General for Support and Coordination**, of the Secretariat General for Agriculture and Food, as a strategic element for the adequate planning and coordination of official controls.

The following attached document contains the legal basis that establishes the structure of the central coordination authorities (MAPA) and the competent official control authorities in the autonomous communities.



## ORGANIC STRUCTURE COMPETENT AUTHORITIES

### 2. ORGANISATIONAL STRUCTURE OF OFFICIAL CONTROLS.

The official control system is structured around the following levels:

#### ■ Areas of control

The following 3 areas of control are established, in which official controls are carried out to verify compliance with the applicable regulations:

AREA OF CONTROL	REGULATIONS SUBJECT TO CONTROL
Foods	The integrity of foods and raw materials thereof in the food industry, including control of regulations to ensure fair business practices and to protect consumers' interest and information.
Organic production	Production and labelling of organic products
Differentiated quality	Use and labelling of protected designations of origin, protected geographic indications and guaranteed traditional specialities.

A strategic objectives is established for each of these areas. Their achievement is assessed at the end of the five years of the plan through the analysis of the degree of compliance with the operating objectives of the programmes applicable in that area. These strategic objectives are the following:

AREA OF CONTROL	STRATEGIC OBJECTIVE
Foods	3.1 Strengthen food safety control, Differentiated Quality and Organic Production to reduce non-compliance and guarantee the achievement of a high level of food safety, and intensify the fight against food fraud throughout the food chain, except for final sale to the consumer, to achieve the sustainability of the food system and increase consumer trust; and protection against unfair business practices.
Organic production	
Differentiated quality	

The achievement of these strategic objectives is carried out through the execution of controls planned and structured in the following national programmes of official control.

### ■ National Programmes of Official Control

The national programmes of official control are documents that describe the organisational structure on the basis of which the official controls are planned and executed to verify applicable regulation in each of the areas established in the previous section.

The operating objectives are established in each programme and must be assessed every year.

They establish:

- The rules that are subject to control within the framework of the programme.
- The unit of the MAPA responsible for the coordination, and the competent authorities of the autonomous communities or the General State Administration responsible for the execution of the official programmes.
- The mechanisms of coordination between the different competent authorities involved.
- The organisation, general management, categorisation of risk and national and regional legal basis of the controls encompassed within the programme.
- The delegation of tasks carried out in delegate bodies and natural persons.
- Actions after the detection of non-compliance, including the legal basis for the application of sanctions.
- The supervision mechanisms of controls.
- Internal audits to be managed by each competent authority over the course of the period of duration of the Plan.
- The assessment mechanisms of the programme, including objectives and indicators for the purpose of adopting the modifications necessary for improving the efficiency of controls.

The following table displays the programmes developed in primary production for each of the areas of control established:

AREA	NATIONAL PROGRAMME OF OFFICIAL CONTROL	APA UNIT MANAGING THE PROGRAMME
Foods	PNCO for food quality	SGCCALA
Organic producti	PNCO for organic production	SGCCALA
Differentiated quality	National Programme of Official Control for differentiated quality linked to geographic origin and traditional specialities guaranteed before marketing	SGCCALA

### ■ Documented procedures.

For each programme, the competent authorities of the autonomous communities and of the MAPA responsible for the material execution of the controls shall establish procedures with the following objectives:

- Organisation of the competent authorities, including the functions and responsibilities of each of the participants and the coordination bodies between the different competent authorities involved.
- Establishment of sampling procedure, control methods and techniques.
- Detailed instructions for inspection of preparation, execution and management of official controls.
- Actions to be taken in light of the results of the controls.
- Supervision of completion of controls in accordance with the mechanisms established in the programme.
- Any other activity of information necessary for the effective functioning of official controls.

### 3. OFFICIAL CONTROL COORDINATION BODIES

The coordination of these official controls is conducted at four levels:

- Sectoral conference.
- Coordination bodies of the National Plan
- Coordination bodies of each national programme of official control.
- Coordination bodies of the competent authorities of the autonomous communities

#### 3.1. SECTORAL CONFERENCE.

The Sectoral Conferences are multilateral cooperation bodies for a specific sector of public activity. They are made up of the holder of the Ministerial Department and all the Regional Ministers with competency in the area. Due to its composition, number and activity, it constitutes the principal pillar of inter-administrative cooperation.

Law 40/2015 on the Legal Regime of the Public Sector contains a minimal framework regulation of the Sectoral Conferences (Article 147), which determines that they are called by the corresponding Ministry and that their agreements are signed by same and by the Regional Ministers of the autonomous communities. The functioning of the Sectoral Conferences is governed by the agreement for the creation of each of these and their internal regulation.



The Sectoral Conference on Agriculture and Rural Development (whose current regulation was created on 13 December 1995 and last amended in 2009) and the Sectoral Conference on Fisheries are responsible for approving the *Official Control Plans for Primary Production and Food Quality*. Similarly, where basic changes to the plan are necessary or where the circumstances require a high-level approval, this Sectoral Conference shall be the body responsible for coordination and decision making.

### 3.2. COORDINATION BODIES OF THE NATIONAL PLAN

The DG for Support and Coordination (SGAC) is the Unit within the MAPA with responsibility for the coordination of the PNCOCA. This function is carried out through the following coordination group:

#### ■ Coordination group with units of MAPA.

With competency for official controls included in the scope of Regulation (EC) No. 2017/625, of 15 March, and with the units responsible for control of imports and exports.

This group's objectives are the coordination of the following activities:

- Drafting of official control plans, their updating and amendment.
- Design and preparation of annual reports of the results of the control plan.
- Analysis and assessment of questions put forward relating to controls that affect the plan as a whole.

### 3.3. COORDINATION BODIES OF THE OF THE NATIONAL OFFICIAL CONTROL PROGRAMMES

Each programme establishes, where necessary, their coordination and decision-making body. The MAPA management unit of each programme is responsible for the management of the coordination body included in the programme.

In these bodies, all of the competent authorities of the autonomous communities or general state administration responsible for the execution of controls, where applicable.

The coordination bodies have the following functions:

- Review of the measures for the harmonised and coherent application throughout the Spanish territory of the controls that affect the programme.



- Drafting of the programme, along with updates and amendments.
- Design and compilation of the information relating to the results of the programme for the preparation of the annual reports of the results.
- Evaluation and analysis of the results of the controls for the adoption of the measures that improve the efficiency of the programme.

The following attached document lists the national coordination bodies that are fundamental, at different working levels for the understanding and harmonisation of criteria and actions of the official controls included within the scope of Regulation (EU) No. 2017/625, of 15 March.



## NATIONAL COORDINATION BODIES

### 3.4. COORDINATION BODIES OF THE COMPETENT AUTHORITIES OF THE AUTONOMOUS COMMUNITIES.

At autonomous level, the execution of the official controls requires the coordination between the central and peripheral services, and the coordination between competent authorities.

The information relating to the coordination mechanisms and bodies of each autonomous community are contained in the documented procedures of each programme.

## 4. SUPPORTS FOR THE CONTROL PROGRAMME.

In addition to inspection personnel, the resources that support and collaborate on the functioning of official control are:

- Analysis laboratories, including national reference laboratories.
- The IT applications and national and regional databases for the management of official controls.
- The bodies and personnel to whom some of the official control tasks are delegated.
- Training of personnel.

### 4.1. OFFICIAL CONTROL LABORATORIES

The laboratories that participate in official controls, including reference laboratories, must be designated by the competent authority responsible for official control, following the criteria and requirements established in Article 37 of Regulation (EU) No. 2017/625, of 15 March.

For the purpose of harmonising the process of designation, the following procedure has been established:



## PROCEDURE FOR LABORATORIES DESIGNATION

The attached document also lists the official control laboratory designated by the MAPA for official controls in the scope of Regulation (EC) No. 2017/625, of 15 March.



#### LABORATORIES OF OFFICIAL CONTROL DESIGNATED BY MAPA

The laboratories designated by the competent authority for the execution of controls are indicated in the documented procedures of each programme.

#### 4.2. IT RESOURCES FOR OFFICIAL CONTROL

Each specific control programme, and each documented procedure of the autonomous communities, includes the information relating to IT applications or databases that serve to support official control and which may be used for one or several programmes.

#### 4.3. DELEGATION OF OFFICIAL CONTROL TASKS

Each national programme of official control includes the information relating to those tasks delegated to control bodies or natural persons. These delegations shall be executed in accordance with the provisions in Regulation (EU) No. 2017/625, of 15 March.

#### 4.4. TRAINING OF OFFICIAL CONTROL PERSONNEL

Each competent authority for the execution or coordination of official controls is responsible for ensuring that the personnel intervening in official controls receive training that enables them to perform their tasks adequately. This training shall include the additional updates required.

The training shall include, among other aspects, the relevant areas detailed in Annex II Chapter I of Regulation (EC) No. 2017/625, of 15 March.

The following document includes the plans, procedures and criteria for the planning of training in each autonomous community and the management bodies organisation of training.

#### TRAINING



### C. NATIONAL PROGRAMMES OF OFFICIAL CONTROL

- PNCO for food quality.

#### PNCO CALIDAD ALIMENTARIA



- PNCO for organic production.



#### PNCO PRODUCCIÓN ECOLÓGICA

- PNCO for differentiated quality linked to geographic origin and traditional specialities guaranteed before marketing.



#### PNCO CALIDAD DIFERENCIADA

### D. VERIFICATION OF THE QUALITY OF OFFICIAL CONTROLS

The verification of the quality of controls means evaluating whether these are adequate for the achievement of the objectives pursued.

This activity is developed in the following stages:

#### ■ Planning of official controls:

- This process is conducted within each programme, therefore the information regarding activities and measures in the context of the programme execution is collected.
- Operational objectives are established for each programme. The degree of achievement of these objectives is evaluated through appropriate indicators.

#### ■ Assessment of the results of the national official control programme:

- The competent authorities responsible for the programme execution, as well as the coordinating body annually assess the following aspects about the results of the programme:
  - Execution of the controls in accordance with criteria and documented procedures established in the programme by:
    - **The competent authority**, by using among others, procedures for control supervision, will assess whether the inspectors conduct the controls in accordance with the procedures and instructions established.
    - **Audit bodies** designated by the competent authority, will assess through internal audits whether the programme as a whole is carried out in accordance with the provisions and application procedures.
  - **Compliance with the objectives**, to review the results of the indicators established to determine the degree of achievement.
  - **Evaluation of the adequacy and efficiency of the control programme**, which will consider the results of the assessments mentioned above, and the findings and results of internal audit.

#### ■ Adoption of corrective measures:

After the assessment described in the previous section, either the competent authority at the level of the Autonomous Community or at the central level, and when applicable the National coordinating body, will carry out the modifications in the documented procedures and in the national programme.



The following document establishes criteria for the application of the verification of the effectiveness of the controls in the following points:

- Official control supervision.
- The assessment of objectives and use of indicators.
- The audits of official controls.



## GUIDE FOR VERIFICATION OF EFFECTIVENESS

The document enclosed describes how the audits structure works in Spain, under the scope of the Ministry of Agriculture (MAPA), both for competencies of national and regional official control.



## AUDITS

### E. ANNUAL REPORT: PROVISIONS AND PROCEDURE TO DRAFT ANNUAL REPORT

The annual report is drafted in accordance with the standard form established in the Commission Implementing Regulation (EU) 2019/723, of 2 May 2019, following the following stages:

- The coordinating unit for the PNCOCA in the MAPA (SGAC) informs about the annual schedule for collecting the results of the controls.
- This unit (SGAC) also requests to the MAPA units responsible of the different programmes, the information that must be issued to comply with Part I and section 1 of the Plan "general conclusion on the level of fulfilment achieved" in section 1 within Part II of the report template.
- The coordinating unit of the MAPA Units establishes the structure of the information to be contained in section 1 "general conclusion on the level of fulfilment achieved". The structure of the information contained in this section will be reviewed annually to introduce modifications that are deemed appropriate.
- The units of the MAPA managers of each national control programme, in the term established by the SGAC, shall record in the SDCP-AROC (Data Collection Platform-Annual Reports on Official Controls) application of the Commission, the results of the official controls conducted the previous year, following the criteria agreed in the coordination group of the MAPA units and the guidelines contained in the Communication from the Commission on a guidance document on how to fill in the standard form model contained in the annex to Commission Implementing Regulation (EU) 2019/723.
- Once the terms for the recording of the results is finalised, the SGAC shall review compliance with all sections of the report and will communicate to AESAN the validation of the annual report on primary production chain and food quality.





## A. STRATEGIC OBJECTIVE

**Strategic objective 3.2.** Guarantee the achievement of a high level of food quality, including Differentiated Quality and Organic Production, of agrifood products available to the consumer. Intensify the fight against food fraud and ensure fair business practices, and the protection of consumers' interests and their right to receive accurate information on the label and in advertising of food products.

The competent authority responsible for the coordination for achieving strategic objective 3.2 is the Sub-directorate General of Coordination, Quality and Cooperation in Consumer Affairs of the Directorate General for Consumer Affairs, Ministry of Consumer Affairs (MCO)

## B. GENERAL ORGANISATION: COMPETENT AUTHORITIES, COORDINATION MECHANISMS AND OFFICIAL CONTROL RESOURCES

### 1. GENERAL PART

#### 1.1. INTRODUCTION

In the General Part of this Plan, it is described how **high-level objective 3 (FOOD QUALITY):** *Guarantees the achievement of a high level of food quality, including Differentiated Quality and Organic Production of agro-food products and intensifying the fight against food fraud throughout the food chain to achieve the sustainability of the agro-food system, increasing consumer trust, guaranteeing their rights to information and the protection of their economic interests against unfair business practices.*

This document refers to the development **strategic objective 3.2:** *Guarantee the achievement of a high level of food quality, including Geographic Indications and Organic Production, of agri-food products available to the consumer. Intensify the fight against fraud and ensure fair business practices, and the protection of consumers' interests and their right to receive accurate information on the label and in advertising of food products.*

To comply with the above, in the defence of the rights of consumers and users to receive fair information, including fair business practices, official controls are established that must be conducted by Consumer Affairs administrative bodies to verify compliance with legislation regulating the duty to provide correct and accurate information to consumers so that they have adequate knowledge of the characteristics of food products offered and the duty not to prejudice



their legitimate economic interests, that is control of labelling and advertising of products made available to consumers and control of unfair business practices with consumers and users, in those aspects that have no repercussion of food safety or nutrition.

Therefore, the controls conducted by the health authorities for the purpose of preventing risks to human health and authorities with competencies for the defence of fraud at origin are excluded from these official controls. Nevertheless, where Consumer Affairs Inspection is necessary, in accordance with the regulation of different autonomous communities, controls could be carried out at establishments of origin of products.

The above does not, in itself, prevent the Quality Control and anti-fraud services from acting at points of sale to the final consumer when a line of inspection is followed.

Finally, it must be underlined that autonomous communities will participate in those programmes included in strategic objective 3.2 of the National Plan for Official Control of the Food Chain in accordance with their competencies attributed.

## **1.2. REGULATORY LEGISLATION**

### **1.2.1 EU legislation**

- Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
- Regulation (EU) 2017/625 of the European Parliament, of 15 March 2017, relating to controls and other official activities conducted to guarantee the application of food and feed legislation, and regulations on animal health and welfare, plant health and phytosanitary products.
- Commission Implementing Regulation (EU) 2019/723 of 2 May 2019 laying down rules for the application of Regulation (EU) 2017/625 of the European Parliament and of the Council as regards the standard model form to be used in the annual reports submitted by Member States.
- Communication from the European Commission on a guidance document on how to complete the model standard form set out in the Annex to the European Commission Implementing Regulation (EU) 2019/723 laying down detailed rules for the implementation of Regulation (EU) 2017/625 of the European Parliament and of the Council as regards the model standard form to be used in the annual reports submitted by Member States. (2021/C 71/01).
- European regulation of different aspects relating to food products.

### **1.2.2 National legislation**

- Royal Legislative Decree 1/2007, of 16 November, approving the consolidated text of the General Law on the Defence of Consumers and Users and other complementary laws.

- Law 39/2015, of 1 October, on the Common Administration Procedure of public administrations.
- Law 40/2015, of 1 November, on the Public Sector Legal Regime.
- Royal Decree 1945/1983, of 22 June, regulating infractions and sanctions in the sphere of defence of the consumer and agri-food production.
- Royal Decree 2/2020, of 12 January, restructuring the ministerial departments.
- Royal Decree 139/2020, of 28 January, establishing the basic organic structure of the ministerial department.
- Royal Decree 495/2020, of 28 July, developing the basic organic structure of the Ministry of Consumer Affairs and amending Royal Decree 139/2020, of 28 January, establishing the organic structure of the ministerial departments.
- Decrees of transfers to the autonomous communities of the functions and services in the defence of consumer rights.

### 1.2.3 Autonomous community legislation

- ANDALUCÍA. - Law 13/2003, of 17 December, on Defence and Protection of Consumers and Users in Andalucía.
- ARAGÓN. - Law 16/2006, of 28 December, on the Protection and Defence of Consumers and Users in Aragón.
- ASTURIAS. - Law 11/2002, of 2 November, on Consumers and Users of Asturias.
- ISLAS BALEARES. - Law 7/2014, of 23 July, on the Protection and Defence of Consumers and Users in the Islas Baleares.
- ISLAS CANARIAS. - Law 3/2003, of 12 December, on Defence and Protection of Consumers and Users in the Islas Canarias.
- CANTABRIA. - Law 1/2006, of 7 March, on the Protection and Defence of Consumers and Users.
- CASTILLA LA MANCHA. - Law 3/2019, of 22 March, of the Consumers Statute in Castilla la Mancha.
- CASTILLA Y LEÓN. - Law 2/2015, of 4 March, approving the Consumers Statute of Castilla y León.
- CATALUÑA. - Law 22/2010, of 20 July, on the Consumer Code of Cataluña.
- EXTREMADURA. - Law 6/2019, of 20 February, Consumer Statute of Extremadura.
- GALICIA. - Law 2/2012, of 28 July, on the Protection and Defence of Consumers and Users.
- LA RIOJA. - Law 5/2013, of 12 December, on the Protection and Defence of Consumers and Users.

- MADRID. - Law 11/1998, of 9 December, on the Protection of Consumers in the Autonomous Community of Madrid.
- MURCIA. - Law 4/1996, of 14 June, the Consumers and Users Statute in the Region of Murcia.
- NAVARRA. - Law 7/2006, of 20 June, on Protection and Defence of Consumers and Users.
- PAÍS VASCO. - Law 6/2003, of 22 December, the Consumer and User País Vaco.
- VALENCIA. - Legislative Decree 1/2019, of 13 December, of the Regional Council, on approval of the consolidated text of the Consumers and Users Statute of Valencia.

### 1.3. AREAS AND CONTROL PROGRAMMES

#### 1.3.1 Areas of control

The following areas of control are established for verification of compliance with the applicable regulations.

Area of control	Applicable regulation
Food products: food information, commercial quality and protection of consumers' rights	Legislation on labelling of foods, legislation pertaining to commercial quality of foods and regulation referring to the protection of consumers' rights.
Organic food products: food information and quality. (commercial quality laid down in product-specific quality regulations)	Legislation relating to labelling and quality of organic products.
Differentiated quality food products: food information and commercial quality. (commercial quality laid down in product-specific quality regulations)	Legislation relating to labelling and quality of products under the differentiated quality marks: protected designations of origin, protected geographic indications and guaranteed traditional specialities.
Retail food operators: unfair commercial practices, documentary control and control of the conditions of sale	Legislation on unfair commercial practices, conditions of sale, advertising and prices.

#### 1.3.2 National Programmes of Official Control

The national programmes of official control are documents that describe the organisational structure on the basis of which the official controls are planned and executed to verify applicable regulation in each of the areas established in the previous section.

For reasons of efficiency in the organisation of controls, the same programme may verify compliance with the regulation applicable to more than one area of control. Similarly, official controls to verify compliance with the regulation in each area may be distributed between several programmes.

The operating objectives are established in each programme and must be assessed every year.

Each programme establishes:

- The purpose and scope of application
- Regulatory legislation
- The operating objectives
- The methods of control
- The nature of control
- The rules that are subject to control within the framework of the programme.
- The measures to be adopted after detection of instances of non-compliance.
- The evaluation indicators of the programme
- The assessment mechanisms of the programme for the purpose of adopting the modifications necessary for improving the efficiency of controls.

Within strategic objective 3.2, 5 official control programmes are developed, reflecting the general objectives of food information, including both labelling and advertising and other aspects relating to food information in accordance with the provisions of Regulation (EU) No. 1169/2011, of 25 October 2011, of the European Parliament and of the Council, on the food information provided to the consumer. The general control of food quality at point of sale to the consumer is also developed, controlling certain elements of quality relating to the veracity of labelling of food quality.

Another programmes developed is the protection of consumers in relation to business practices, such as the presentation of the products, the price information, containers and materials and the effective content.

With regard to the production and labelling of organic products, the programme for the specific control of food information and the quality of organic products is developed at point of sale to the final consumer.

The use and labelling of protected designations of singular origin, of the protected geographic origin and guaranteed traditional specialities reflected the specific control programme of food information and food quality linked to protected designations of origin, protected geographic indications or guaranteed traditional specialisations at point of sale to the final consumer.

Finally, the development of previous programmes will reflect the objectives of verifying compliance with those documentary requirements that the competent authorities deem necessary in relation to control activities, along with achieving the good functioning of the market.



## 1.4. COMPETENT AUTHORITIES

Article 51 of the Spanish Constitution establishes that the public authorities shall guarantee the protection of consumers and users and shall, by means of effective measures, safeguard their safety, health and legitimate financial interests.

### 1.4.1 General State Administration

– **Directorate General of Consumer Affairs. General Secretariat for Consumer Affairs and Gambling.** Ministry of Consumer Affairs.

Unit of reference:

**Sub-directorate General of Coordination, Quality and Cooperation in Consumer Affairs**

(Calle/ Príncipe de Vergara, 54 – 28006 Madrid).

The aforementioned unit performs, in the scope of its activity, the following functions:

- a)** Provide citizens with the public administrations and the stakeholders involved, information, training and education on the rights of consumers, in particular the most vulnerable, promoting responsible consumption.
- b)** The completion of the analysis and tests through the Centre of Investigation and Quality Control (CICC) to the different products, both food and industrial, present in the market that can be made available to consumers with the aim of verifying quality, safety and accuracy of the information presented on the label and that said products adhere to the different regulations and standards that apply. Furthermore, the development of the training and advice of technical personnel for research, updating and validation of efficient of methods trials of analysis.
- c)** The support for existing cooperation bodies with autonomous communities and the Sectoral Conference on Consumer Affairs.
- d)** The cooperation and technical support for the consumer services of the autonomous communities and other public administrations, in relation to official control or supervision in the goods and services market, to combat fraud, protect health and safety and the economic interests of the consumers.
- e)** The promotion and completion of studies or surveys in relation to consumer affairs, and fostering and participating in the monitoring of self-regulation codes agreed in relation to advertising, especially advertising aimed at minors, and which are adopted for the improvement of the goods and services provided to consumers and users.
- f)** Other functions corresponding to the objectives of the Directorate General of Consumer Affairs.

### 1.4.2 Autonomous communities

By virtue of their Statutes of Autonomy, the autonomous communities have attributes configured as a defence of consumers and users. On that basis, the administrative bodies of Consumption shall proceed with their activity in conducting controls of food products and the adoption of measures necessary to prevent the adoption of the measures necessary to prevent any damage to the interests of consumers, including the imposition of sanctions.

Finally, it must be underlined that autonomous communities will participate in those programmes included in strategic objective 3.2 of the National Plan for Official Control of the Food Chain in accordance with the competencies attributed.

The structure and functions of the competent administrative bodies in the defence of consumers and users is regulated through decrees and orders in each autonomous community. This information is collated in the specific files provided in each autonomous community.

<https://consumo.gob.es/es/consumo/organismos-auton-micos-de-consumo>



### 1.4.3 Cooperation bodies.

In the sphere of actions of the consumer authorities, the list of inter-territorial cooperation bodies is included below:

- Sectoral Conference on Consumer Affairs
- Sectoral Committee on Consumer Affairs.
- Market Control Section.
- Information, Training and Education Section.

Royal Legislative Decree 1/2007, of 16 November, approving the consolidated text for the General Law for the Defence of Consumers and Users and other complementary laws, dedicated to Title III of the first book to institutional cooperation. Specifically, Article 40 regulates the composition of the Sectoral Conference on Consumer Affairs, presided by the holder of the Ministry of Consumer Affairs and composed of the Minister and the Regional Ministers with competency for this area, as the most senior cooperation body of the State with the autonomous Communities. Among the functions assigned to the Conference in accordance with the requirements of Article 4 of Regulation (EC) No. 2017/625, of the European Parliament and of the Council, of 15 March, the following must be highlighted:

- Serve as a source of collaboration, communication and information between autonomous communities and the General State Administration in consumer affairs.
- Approve the common criteria for action and coordination, and proposals in relation to the policy of the sector.
- Approve the joint plans, projects and programmes.
- Ensure effective participation of the autonomous communities in European matters in the area.



- Facilitate reciprocal information in consumer affairs, design common statistics and provide citizens with the national statistical data obtained.
- Cooperate in and foster the national inspection and control campaigns.
- Promote the enactment of the relevant legislation on consumer affairs and reform and, where applicable, provide information on the regulatory provisions of same.
- Establish criteria for action where the several autonomous communities have competency.
- Programme the rational use of material resources that may be commonly used.
- Design a training and development system for personnel with specific tasks in the sphere of consumer affairs.
- Any other functions attributed in legislation.

## 1.5. SUPPORTS FOR THE OFFICIAL CONTROL PROGRAMME.

### 1.5.1 Human resources

#### ■ DIRECTORATE GENERAL OF CONSUMER AFFAIRS:

The human resources are available in the Sub-directorate General of Coordination, Quality and Cooperation in Consumer Affairs and in the Centre of Investigation and Quality Control (CICC)

#### ■ ADMINISTRATIVE BODIES OF THE AUTONOMOUS COMMUNITIES

The human resources are available in the Regional Ministries of the autonomous communities who hold the competencies for official control, with no repercussion on food safety and nutrition, of the foods made available to consumers and users.

The competent authorities of the autonomous communities, in accordance with the provisions of Article 5 of the RCO, shall guarantee:

- That the procedures and and/or mechanisms are established to guarantee the efficiency and adequacy of the official controls and other official activities
- That the procedures and and/or mechanisms are established to guarantee the impartiality, quality and coherence of official controls and other official activities at all levels;
- That the procedures and and/or mechanisms are established to guarantee that the personnel carrying out official controls and other official activities have no conflicts of interest;
- That they have suitable teams in place or accessible for laboratory analysis, testing and diagnostics
- That they have sufficient personnel, with the adequate qualifications and experience to efficiently and effectively conduct the official controls and other official activities, or shall have access to said personnel;

- That they have suitable facilities and equipment in place and in the conditions for personnel to conduct official controls and other official activities efficiently and effectively;
- That they have the legal powers necessary to conduct official controls and other official activities and to adopt the measures established in this present Regulation and in the standards referred to in Article 1, section 2;
- That they avail of the legal procedures that guarantee access of personnel to premises and documentation of the operators so that it adequately fulfils the assigned task;
- That contingency plans are in place and prepared, to be implemented in case of emergency, in accordance with the standards referred to in Article 1, section 2.

### 1.5.2 Laboratory resources

Article 37, section 1 of Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017, states that the competent authority shall designate official laboratories for the completion of the laboratory analysis, testing and diagnostics of samples taken during official controls and other control activities in the Member State in whose territory said competent authorities operate, or in another Member State or in a third country party to the Agreement on the European Economic Area.

The laboratory resources available are the following:

#### ■ DIRECTORATE GENERAL OF CONSUMER AFFAIRS:

The Centre of Investigation and Quality Control (CICC) of the Directorate General of Consumer Affairs is a set of laboratories that conducts analysis and testing on products on the market in order to assess their compliance with the applicable regulations. The verification of products is carried out exclusively at the request of administrative bodies and the bodies of the public administrations.

The CICC holds the ENAC accreditation under the framework of the Standard UNE-EN-ISO 17025, on an extensive scope of physical-chemical and sensorial or organoleptic test methods. It also has a List of Tests Under Accreditation (LEBA) for chemical elements by atomic spectrometry, as established in ENAC. document NT-18.

Centre of Investigation and Quality Control (CICC)

Avda. Cantabria s/n - 28042 Madrid



## ■ ADMINISTRATIVE BODIES OF THE AUTONOMOUS COMMUNITIES

In some cases, consumer authorities have laboratories that provide services as part of market control activities.

### 1.5.3 IT resources

#### ■ DIRECTORATE GENERAL OF CONSUMER AFFAIRS:

The Directorate General of Consumer Affairs has the comprehensive “COLABORA” application for the exchange of information between this Body and the autonomous communities with competency in the area of control of the market of products and services made available to consumers and users, which allow for the efficiency of raw and human materials.

The “GESCAN” IT application was also developed for the exchange of information between the control authorities of the autonomous communities with competencies in the area of consumer protection for national inspection and market control campaigns.

Moreover, in this application and for the purpose of processing the results of these campaigns, the IT application “GENDACO” is used, integrated within “GESCAN”.

Finally, in 2021, the web application “Official Control Autonomous Communities” was put into operation with the aim of facilitating and automating the transmission of this statistical information between the Autonomous Communities and the DGC. Since implementation, the Autonomous Communities can send information on inspection activities, actions resulting from official control, resolved files and resources derived from official control.

## ■ ADMINISTRATIVE BODIES OF THE AUTONOMOUS COMMUNITIES

The consumer administrative bodies of the autonomous communities have the IT resources for the management of market control activities.

### 1.5.4 Standardised procedures established in documentation.

The Working Group for the Implementation of the Quality System, created by the Sectoral Committee on Consumer Affairs and ratified by the 11th Sectoral Conference on Consumer, as a result of the publication of Regulation (EC) No. 882/2004 of the European Parliament and of the Council, of 29 April 2004, resumed its activities in order to boost quality procedures in relation to different areas and the guidelines published by the Commission and geared towards helping Member States comply with the obligations provided for in the aforementioned Regulation.

For this reason, from 2006, works were undertaken that led to the procedures that make up the Quality Manual of Official Control of food products by administrative bodies for consumer affairs, which was approved and the 26th Sectoral Conference on Consumer Affairs in the year 2009:

- Selection Procedure of National Inspection and Market Control Campaigns.



- Procedure for the Drafting of National Campaign Planning Documents.
- General Consumer Affairs Inspection Procedure.
- General Food Product Sampling Procedure.
- Procedure for the Processing of Inspection Records.
- Procedure for Communication of Results.

The procedures and the content of the manual shall be reviewed to update for compliance with the PN- COCA 2021-2025 (Annex 1 a).

The following working procedures have also been drafted, approved by the Sectoral Committee on Consumer Affairs (Annex 1 b):

- Standardised Working Procedure to check the legibility of food information on the label for the consumer.
- Standardised Working Procedure on Official Control of olive oils.
- Sampling Procedure for Tuna for determination of histamine
- General Procedure for Control of Food Information for Packaged Foods.
- General Procedure for control of the correct use on the market of the names registered as protected designation of origin, protected geographic indications and guaranteed traditional specialties.
- Working Procedure for supervision of the eCommerce market for goods and services.
- Precautionary procedure to prevent the distribution to consumers of products in breach of regulatory requirements (SCC/AP/I.116.05/F).
- Mechanism relating to the actions to follow in the event of the detection of suspected fraud in the analysis of samples at the Centre of Investigation and Quality Control (SCC/AP/I.117.05/F).
- General procedure for the use of the web application "Official Control Autonomous Communities" SCC/AP/D.2.21/F.
- General procedure for the control of food information for unpackaged foods and those packaged at the place of sale at the buyer's request. SCC/AP/D.2.21/F.
- General procedure for the control of food information for organic products and operators benefiting from the exemptions referred to in Article 34(2) and 35(8) of Regulation (EU) 2018/848. SCC/AP/D.4.22/F.

The following procedures are in the process of being approved by the Consumer Sectoral Commission:

- Procedure for the performance of official controls under strategic objective 3.2 of the PNCOCA 2021-2025. SCC/AP/D.39.21/R1.
- Procedure for the risk assessment of the food information provided to the consumer in the strategic objective 3.2 framework of the PNCOCA 2021-2025. SCC/AP/D.38.21/R1.

### 1.5.5 Training of personnel

The Directorate General for Consumer Affairs, in collaboration with the consumer affair authorities of the autonomous communities, every year prepares an Inter-administrative Continuous Training Plan (PFCI), aimed at employees of public administrations with competency in consumer affairs. This Plan includes the hosting of various courses, some of which are focussed on food products.

This training for the consumer affairs professionals of the public administrations has been carried for years with the assistance of the National Institute of Public Administration (INAP).

The autonomous communities may also develop training activities relating to official control of food products for consumer affairs inspection personnel within the scope of their competencies.

## 1.6. STRUCTURE OF OFFICIAL CONTROL

### 1.6.1 Planning of official controls: Prioritisation of controls.

In accordance with Regulation (EU) 2017/625, the competent Authorities may carry out official controls of all operators on a regular basis, based on the risk and with the suitable frequency.

For this purpose, for the programmes developed to respond to strategic objective 3.2: the consumer affairs authorities of the autonomous communities organise controls, primarily based on the risk associated with the type of food, considering the risk of non-compliance due to the economic value of the product, a history of fraud in the product and complaints and queries submitted in relation to it.

In addition to these controls programmed on the basis of risk, unscheduled controls are carried out where there is a reason for the competent authority to suspect a breach, such as based on a complaint, report or after an unsatisfactory analytical result or check in a sample.

The official controls of food products shall respond to the following criteria of action:

- They shall be conducted without prior notification, except in the cases in which such notification is necessary and duly justified for official control to be conducted. The competent Authorities shall guarantee their impartiality, quality and coherence at all levels.
- In general, they shall be carried under a criterion of consistency:
  1. They shall be executed within the term of the PLAN (2021-2025) especially in the categories of foods (1-22) established in Commission Implementing Regulation (EU) 2019/723 of 2 May 2019 laying down rules for the application of Regulation (EU) 2017/625, part II, point 1.4. according to competencies conferred by each Autonomous Community in this field.
  2. They are primarily carried out through the systematic control of the market to verify compliance with the applicable regulation.
  3. They are also fulfilled, through National Inspection and Market Control Campaigns to be fulfilled the following year by the consumer affairs administrative bodies of the autonomous communities in collaboration with the Directorate General of Consumer Affairs, in response to non-compliances detected in the official control performed in point 2 based on the indicators established in each programme.
  4. They shall be carried out through Regional Inspection and Control Campaigns to be developed in the territory of the consumer affairs administrative bodies of the autonomous communities, in accordance with their needs.



On the other hand, where controls come under their competencies, the consumer affairs authorities may participate in the actions adopted by the Committee in accordance with the provisions of Article 112 of the RCO:

- a) The application of coordinated control programmes (European control plans) of limited duration in one of the area regulated by the legislation considered in Article 1, section 2;
- b) The ad hoc organisation of the collection of data and information with the application of a specific set of regulations mentioned in Article 1, section 2 or in relation to the prevalence of certain dangers.

### 1.6.2 Control points

- Official controls on food available to the final consumer shall be carried out in retail shops and the definition of 'retail trade' in Article 3 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 applies.

Official controls shall be carried out at two points:

- Face-to-face retail, official control in face-to-face retail will be carried out by visiting the establishment.
- Distance selling, which includes e-commerce, official control will be carried out through a visit to the operator's website or through the means of purchase made available to the consumer.
- In cases where it is necessary to check certain aspects of a food, The Consumer Affairs Inspection may act in other phases of the food chain, provided it is assigned the competency in accordance with the regional regulations.

### 1.6.3 Nature of control

The consumer affairs administrations with competency for market control shall carry out, among others, the following tasks:

## 1. Product control:

### 1.1. Visual inspection:

- **Monitoring of food information provided to consumers by labelling.** Food information must be accurate, clear and easy to understand for the consumer. Such information must comply with both general and specific labelling regulations in terms of content and provision. Furthermore, the information shall not mislead the characteristics of the food and, in particular, its nature, identity, qualities, composition, quantity, duration, country of origin or place of provenance, and mode of manufacture or production.
- **Control of the presentation of food:** the shape, appearance and materials of the packaging used.

### 1.2. Inspection with sampling

- Checking the veracity of what is stated on the labelling. Any information declared on the label should be tested analytically to ensure that the actual content, nutrition and health claims, list of ingredients and nutritional content are in line with the declared requirements.
- Quality control in terms of composition, purity and, where appropriate, standardisation of quality standards in an analytical manner, so that the conditions corresponding to the true nature of the product are met.

## 2. Control of unfair trading practices:

- 2.1. **Control of offers, promotions and advertising,** false or misleading in those aspects that do not have an impact on human health, as well as the control of price information. This includes controls on how food is disposed of for sale and where it is displayed.



**2.2. Control of the conditions of sale**, commercial transactions, technical conditions of sale or supply, rules relating to registration, standardisation or typification and documentation.

### 3. Food fraud control:

Due to the complexity and extent of food fraud its control should not be limited to a type of control depending on its nature, it should be considered in all types of control. Any breach of agri-food regulations can be a potential food fraud whenever it involves, deceives the consumer by concealing the true quality of a product, direct or indirect economic benefit for the controller and an intention (solid grounds to believe that the breach is not a coincidence). The most common fraudulent practices are based on incorrect labelling, falsification of documentation and lack of traceability, replacement, dilution, subtraction or addition of ingredients, the use of unapproved treatments, and infringements of intellectual property rights.

#### 1.6.4. Methods and techniques of control

The fundamental methods and techniques of the Administration of Consumer Affairs are based on the following activities:

- Visit the retail establishment of the food products.
- Official control of eCommerce and other distance sale techniques of food made available to consumers.

These activities shall be described in the programmes established, and the applicable regulation and the indicators of compliance with the objectives established in each programme.

##### 1.6.4.1 Sampling

**Samples shall be taken by means of** a report drawn up, at least in triplicate, before the owner of the undertaking or establishment subject to inspection, or before his legal representative or responsible person, and in the absence thereof, before any dependent, as provided for in Article 15 of Royal Decree 1945/1983 of 22 June 1983 regulating infringements and penalties in the field of consumer protection and agri-food production, pending the development of new legislation in force reflecting the provisions of Chapter IV on sampling, analysis, testing and diagnosis of Regulation (EU) 2017/625.

The figure of “mysteryshopper”, also known in Spanish as the “cliente misterioso”, is usually used for sampling on distance selling, so that AA. CC. can obtain the products anonymously.

#### 1.6.5 Measures to be adopted for the detection of non-compliances

##### ▪ Monitoring and management of non-compliant products

Regulation (EU) 2017/625, of the European Parliament and of the Council, of 15 March 2017, in Article 138, section 1, states that where the non-compliance is established, the competent authorities shall take:

- a) the measures necessary to determine the origin and extent of the non-compliance and to establish the operator’s responsibilities; and
- b) appropriate measures to ensure that the operator concerned remedies the non-compliance and prevents further occurrences of such non-compliance. With respect to the measures to take, they are listed in section 2 of said Article.

When deciding on the measures to adopt, they should take into account different factors that may, among others, include the nature of the non-compliance itself; the damage caused to consumers; the vulnerability of those affected; the degree of knowledge, information and training of operators; the size of the company responsible; the number of consumers or user who





may have been affected and the history of the operator in terms of compliance with consumer affairs legislation.

They may be of three types:

- Non-sanction administrative measures requiring the remedy of the non-compliances detected
- Provisional or precautionary measures preventing the marketing of products or the removal of advertising
- Sanctions

The competent authorities who have adopted any measures on the marketing of foods shall perform monitoring, verifying that non-compliances detected have been remedied and that the operator responsible guarantees that there will be not further occurrences.

### ■ Sanction regime

Title VII of Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 obliges Member States to take measures if they detect non-compliances, establishing the applicable sanction regime, in the case of non-compliance with the provisions of the Regulation and adopting all necessary measures to guarantee execution. Such sanction must be effective, proportionate and dissuasive. Members States are obliged to notify the Commission of the provisions applicable to food infractions and any subsequent amendment of said provisions.

The administrative infractions and sanctions in consumer protection are found in Title IV of Royal Legislative Decree 1/2007, of 16 November, approving the consolidated text of the General Law on the Defence of Consumers and Users and other complementary laws, in the regional legislation and development regulations that order food products and their distribution to consumers.



## C. CONTROL PROGRAMMES

### NATIONAL PROGRAMMES OF OFFICIAL CONTROL OF THE MINISTRY OF CONSUMER AFFAIRS FOR THE HIGH-LEVEL OBJECTIVE 3, STRATEGIC OBJECTIVE 3.2

- **Programme 3.2.1.** General control of compulsory and voluntary food information without repercussions for food safety and nutrition at point of sale to the final consumer.

#### PROGRAMA DE INFORMACIÓN



- **Programme 3.2.2.** General control of food quality at point of sale to the final consumer.

#### PROGRAMA DE CALIDAD



- **Programme 3.2.3.** Control of unfair business practice with the consumer.

#### PROGRAMA PRÁCTICAS COMERCIALES



- **Programme 3.2.4.** Specific control of food information and quality of organic products at point of sale to the final consumer.

#### PROGRAMA DE INFORMACIÓN Y CALIDAD DE PRODUCTOS ECOLÓGICOS



- **Programme 3.2.5.** Specific monitoring of food information and quality linked to protected designations of origin, protected geographical indications and traditional specialities guaranteed at point of sale to the final consumer.

#### PROGRAMA DE INFORMACIÓN Y CALIDAD DE DENOMINACIÓN



## **D. VERIFICATION OF THE QUALITY OF OFFICIAL CONTROLS**

### **Assessment of control programmes and annual reports Supervision, verification of the efficiency of controls and updating of system Audits**

#### **1. SUPERVISION, VERIFICATION OF THE EFFECTIVENESS OF CONTROLS AND UPDATING OF SYSTEM**

The initiative to conduct supervision of official control, verification of the efficiency of the controls and the updating of the system as part of the public administrations involved that define the elements and the guidelines considered appropriate to reach the objectives. Under the auspices of the international cooperation bodies, the proposals shall be prepared and the mechanisms necessary for approval shall be applied.

#### **2. AUDITS**

Regulation (EU) 2017/625, of the European Parliament and of the Council, of 15 March 2017, establishes, in Article 6, section 1, that the competent authorities shall carry out internal audits, subject to independent examination and carried out transparently.

The purpose of the audit systems is to verify if official controls relating to food legislation are applied effectively and are appropriate to reach the objectives of the relevant legislation, including compliance with the national control plan.

The audits carried out on the form, procedures and means of conducting control functions by competent authorities in the defence of consumers' rights.

The independent examination is executed on audits carried out to assess the control services, for the purpose of verifying if they have been carried out in accordance with the guidelines and criteria established, checking the audit process is reaching its objectives and to achieve the equivalence of the different existing audit systems.

## **E. ANNUAL REPORT OF RESULTS**

#### **1. ASSESSMENT AND ANNUAL REPORTS**

The National Plan shall be assessed through an Annual Report on the results of official controls, which shall be submitted to the European Commission by 31 August of the following year, as established in Article 113 of Regulation (EU) 2017/625.

To draft the report, all public administrations involved in this control system shall submit to the designated AESAN unit, before 31 May of the following year, the data relating to the controls scheduled and completed and their results, including the results of the programmed actions. These data shall be compiled with the data provided by the rest of the authorities involved in the Plan, in order to draft an analysis report of same.

In relation to the official controls carried out in compliance with strategic objective 3.2, the consumer affairs administrative bodies of the autonomous communities, in accordance with the established procedure, shall issue that data obtained to the Directorate General of Consumer Affairs before 30 April of the following year.

## ANNEX 1 a)

## PROCEDURES APPROVED BY THE SECTORAL CONFERENCE ON CONSUMER AFFAIRS

Reference No.	Name of procedure	Programmes affected
Date 7/11/2007 Rev. 1_30/12/2015	Selection Procedure of National Inspection and Market Control Campaigns	Programas 3.2.1, 3.2.2, 3.2.3, 3.2.4 and 3.2.5
Date 13/11/2007 Rev. 1_30/12/2015	Procedure for the Drafting of National Campaign Planning Documents	Programas 3.2.1, 3.2.2, 3.2.3, 3.2.4 and 3.2.5
Date 11/12/2007 Rev. 1_30/12/2015	General Consumer Affairs Inspection Procedure	Programas 3.2.1, 3.2.2, 3.2.3, 3.2.4 and 3.2.5
Date 03/06/2008 Rev. 1_30/12/2015	General Food Product Sampling Procedure	Programas 3.2.1, 3.2.2, 3.2.3, 3.2.4 and 3.2.5
Date 02/06/2008 Rev. 1_30/12/2015	Procedure for the Processing of Inspection Records	Programas 3.2.1, 3.2.2, 3.2.3, 3.2.4 and 3.2.5
Date 05/04/2008 Rev. 1_30/12/2015	Procedure for Communication of Results	Programas 3.2.1, 3.2.2, 3.2.3, 3.2.4 and 3.2.5



## ANNEX 1 b)

## PROCEDURES APPROVED BY THE SECTORAL CONFERENCE ON CONSUMER AFFAIRS

Reference No.	Name of procedure	Programmes affected
SCC/AP/ D.26.17/F Date 12/04/2017	Standardised Working Procedure to check the legibility of food information on the label for the consumer.	Programas 3.2.1, 3.2.2, 3.2.3, 3.2.4 and 3.2.5
SCC/AP/ D.38.17/F Date: 21/09/2017	Standardised Working Procedure on Official Control of olive oils	Programas 3.2.1, 3.2.2, 3.2.3, 3.2.4 and 3.2.5
SCC/AP/ D.46.17/F Date: 22/02/2018	Sampling procedure for tuna for determination of histamine	Programas 3.2.1, 3.2.2, 3.2.3, 3.2.4 and 3.2.5
SCC/AP/ D.50.17/F Date 22/02/2018	General procedure for control of food information for packaged foods	Programas 3.2.1, 3.2.2, 3.2.3, 3.2.4 and 3.2.5
SCC/AP/ D.1.18/F Date: 22/02/2018	General procedure for control of the correct use on the market of the names registered as protected designation of origin, protected geographic indications and guaranteed traditional	Programas 3.2.1, 3.2.2, 3.2.3, 3.2.4 and 3.2.5
SCC/AP/ D.29.18/F Date 26/02/2019	Working Procedure for supervision of the eCommerce market for goods and services	Programas 3.2.1, 3.2.2, 3.2.3, 3.2.4 and 3.2.5
SCC/AP/ D.2.21/F Date: 28/10/2021	General procedure for the use of the web application "official control of autonomous communities"	Programas 3.2.1, 3.2.2, 3.2.3, 3.2.4 and 3.2.5
SCC/AP/ D.2.21/F Date: 30/06/2021	General procedure for the control of food information for unpackaged foods and those packaged at the place of sale at the buyer's request.	Programas 3.2.1, 3.2.2, 3.2.3, 3.2.4 and 3.2.5
SCC/AP/ D.4.22/F Date: 25/02/2022	General procedure for the control of food information for organic products and operators benefiting from the exemptions referred to in Article 34(2) and 35(8) of Regulation (EU) 2018/848.	Programas 3.2.1, 3.2.2, 3.2.3, 3.2.4 and 3.2.5
SCC/AP/ D.39.21/F. Date: under approval	Procedure for the performance of official controls under strategic objective 3.2 of the PNCOCA 2021-2025.	Programas 3.2.1, 3.2.2, 3.2.3, 3.2.4 and 3.2.5
SCC/AP/ D.38.21/F. Date: under approval	Risk assessment procedure for the provision of food information to consumers under strategic objective 3.2 of the PNCOCA 2021-2025.	Programas 3.2.1, 3.2.2, 3.2.3, 3.2.4 and 3.2.5
SCC/AP/ D.2.21/F Date: 28/10/2021	General procedure for the use of the web application "official control of autonomous communities"	Programas 3.2.1, 3.2.2, 3.2.3, 3.2.4 and 3.2.5



## HIGH-LEVEL OBJECTIVE 4

Reduce the risks to people's health and their interests for the health of animals or plants through compliance of operators with the regulation in force on food safety, animal health, plant health, animal welfare, business quality, organic production, guaranteeing the achievement of a high level of food safety as well as fight against fraudulent or deceptive practices in animals, plants and food introduced or imported across Spanish borders.

Offer health and phytosanitary guarantees for plant and animal products for export.



National Plan for Official Control  
of the Food Chain

**2021-2025**

**Version 2 - 2022**



GOBIERNO  
DE ESPAÑA

MINISTERIO  
DE INDUSTRIA, COMERCIO  
Y TURISMO

MINISTERIO  
DE AGRICULTURA, PESCA  
Y ALIMENTACIÓN

MINISTERIO  
DE SANIDAD

Ministry for Industry, Trade and Tourism  
Ministry of Agriculture, Fisheries and Food  
Ministry of Health

The competent authorities responsible for the coordination for achieving this objective are:

- **General Secretariat for Agriculture and Food of the Ministry of Agriculture, Fisheries and Food (MAPA)**
- **Sub-directorate for Inspection, Certification and Technical Assistance of Foreign Health, Ministry for Industry, Trade and Tourism (MINCOTUR)**
- **Subdirectorato General for Foreign Health, Directorate General for Public Health, Ministry of Health**

The strategic objectives that make up high-level objective 3 and the programmed provided for to achieve the following:

- **STRATEGIC OBJECTIVE 4.1.** Reduce the risks to people's health, animals or plants through compliance on the part of operators involved in primary production, with the regulation in force to food safety, animal and plant health and animal welfare from third countries or territories, introduced or imported across Spanish borders.
  - 4.1.** PNCO for importation of animals, products of animal origin not for human consumption, products for animal feed and importation of plants, products of plant origin and other objects.
- **STRATEGIC OBJECTIVE 4.2.** Reduce the risks to health of the people and animals, and fraudulent or deceptive business practices linked to the introduction or importation of food, materials in contact with food and other goods for human use originating in third countries or territories.
  - 4.2.1** Official control of goods for human use or consumption from third countries.
  - 4.2.2** Official control of shipments with no commercial character from third countries
  - 4.2.3** Control of kitchen waste from international transport
  - 4.2.4** Designation and supervision of border control and goods storage facilities.
- **STRATEGIC OBJECTIVE 4.3.** Guarantee the achievement of a high level of food quality through:
  - Border control of compliance with the legislation applicable to ecological production of imported third party products across Spanish borders.
  - The identification of potential fraudulent or deceptive practices in relation to marketing standards applicable in certain agri-food products for overseas trade with third countries through border control.
    - 4.3.1** Official control of compliance with marketing standards applicable to food products trades externally with third countries.
- **STRATEGIC OBJECTIVE 4.4.** Guarantee compliance with the requirements established in the applicable regulation in Article 1.2 of Regulation (EU) 2017/625, when said requirements are applicable to animals and goods to be exported from the European Union.
  - 4.4.1** PNCO for exports of products subject to veterinary certification.
  - 4.4.2.** PNCO for exports of products subject to phytosanitary certification



## A. STRATEGIC OBJECTIVE

**Strategic objective 4.1.** Reduce the risks to people's health, animals or plants through compliance on the part of operators involved in primary production, with the regulation in force to food safety, animal and plant health and animal welfare from third countries or territories, introduced or imported across Spanish borders.

The competent authority responsible for the coordination for the achievement of strategic objective 4.1 is the General Secretariat for Agriculture and Food of the Ministry of Agriculture, Fisheries and Food (MAPA)

## B. GENERAL ORGANISATION: COMPETENT AUTHORITIES, COORDINATION MECHANISMS AND OFFICIAL CONTROL RESOURCES

### 1. OFFICIAL CONTROL IN THE SCOPE OF BORDER CONTROLS.

The purpose of this document is to establish, within the National Plan for Official Control of the Food Chain, the planning of the controls of imports and exports that affected feed, animals and animal and plant products not for human consumption.

The coordination and execution of these official controls corresponds to the Ministry of Agriculture, Fisheries and Food.

The structure of the Ministry of Agriculture, Fisheries and Food (MAPA) was approved by Royal Decree 430/2020, of 3 March, developing the basic organic structure of the Ministry of Agriculture, Fisheries and Food and amending Royal Decree 139/2020, of 28 January, establishing the organic structure of the ministerial departments.

The MAPA unit responsible for the planning and execution of these controls is:

#### ■ General Secretariat for Agriculture and Food

- Directorate General for the Health of Agricultural Production
- Sub-directorate General of Health Agreements and Border Control. (SGASCF)

At the following link you can find the organisational chart of the MAPA:

<https://www.mapa.gob.es/es/ministerio/funciones-estructura/organigrama/default.aspx>



At the following link you can access the PNCOCA through the MAPA website:

<http://www.mapa.gob.es/es/ministerio/planes-estrategias/plan-nacional-de-control-de-la-cadena-alimentaria/default.aspx>



A fundamental element for the integration of these controls into the National Plan for Official Control of the Food Chain is the coordination of different units of the MAPA involved and the dialogue with the rest of the Units in other Departments responsible for the development of the Plan.

For this purpose, Royal Decree 430/2020, of 3 March, assigns this responsibility to the Sub-directorate General for Support and Coordination, of the Secretariat General for Agriculture and Food, as a strategic element for the adequate planning and coordination of official controls.

The following attached document contains the legal basis that establishes the structure of the central coordination authorities (MAPA) and the competent official control authorities in the autonomous communities.

## ORGANIC STRUCTURE



## 2. ORGANISATIONAL STRUCTURE OF THE OFFICIAL CONTROLS.

The official control system is structured around the following levels:

### ■ Areas of control

The following 2 areas of control are established, in which official controls are carried out to verify compliance with the applicable regulations:

AREA OF CONTROL	REGULATIONS SUBJECT TO CONTROL
Imports	PNCO for importation of animals, products of animal origin not for human consumption, animal feed, products for animal feed and products of plant origin.
Exports	Requirements corresponding to the certification of export shipments affected by the health and phytosanitary regulations of destination countries.

For each of these areas, strategic objectives are established. Their achievement is assessed at the end of the five years of the plan through the analysis of the degree of compliance with the operating objectives of the programmes applicable in that area. These strategic objectives are the following:

AREA OF CONTROL	STRATEGIC OBJECTIVE
Imports	4.1 Reduce the risks to the health of people, animals or plants through compliance on the part of operators involved in primary production with the regulation in force applicable to food safety, animal and plant health and animal welfare from third countries or territories, introduced or imported across Spanish borders.
Exports	4.4 Guarantee compliance with the requirements established in the applicable regulation in Article 1.2 of Regulation (EU) 2017/625, when said requirements are applicable to animals and goods to be exported from the European Union.

The achievement of these strategic objectives is carried out through the execution of controls planned and structured in the following national programmes of official control.

## ■ National Programmes of Official Control

The national programmes of official control are documents that describe the organisational structure on the basis of which the official controls are planned and executed to verify applicable regulation in each of the areas established in the previous section.

The operating objectives are established in each programme and must be assessed every year.

They establish:

- The rules that are subject to control within the framework of the programme.
- The units responsible for the execution of official controls considered in the programmes
- The organisation, general management, categorisation of risk and legal basis of the controls encompassed within the programme.
- The delegation of tasks carried out in delegate bodies and natural persons.
- Actions after the detection of non-compliance, including the legal basis for the application of sanctions.
- The supervision mechanisms of controls.
- Internal audits to be managed by each competent authority over the course of the period of duration of the Plan.
- The assessment mechanisms of the programme, including objectives and indicators for the purpose of adopting the modifications necessary for improving the efficiency of controls.

The following table displays the programmes developed for each of the areas of control established:

AREA	NATIONAL PROGRAMME OF OFFICIAL CONTROL	APA UNIT MANAGING THE PROGRAMME
Imports	PNCO for animal imports, products of animal origin not for human consumption, products for animal feed and imports of plants, products of plant origins and other objects.	SGASCF
Exports	PNCO for exports of products subject to veterinary certification PNCO for exports of products subject to phytosanitary certification	SGASCF

## ■ Documented procedures.

For each programme, the competent authorities responsible for the material execution of the controls shall establish procedures with the following objectives:

- Organisation of the competent authorities, including the functions and responsibilities of each of the participants and the coordination bodies between the different competent authorities involved.

- Establishment of sampling procedure, control methods and techniques.
- Detailed instructions for inspection of preparation, execution and management of official controls.
- Actions to be taken in light of the results of the controls.
- Supervision of completion of controls in accordance with the mechanisms established in the programme.
- Any other activity of information necessary for the effective functioning of official controls.

### 3. COORDINATION BODIES OF THE OFFICIAL CONTROLS.

The coordination of these official controls is conducted at four levels:

- Sectoral conference.
- Coordination bodies of the National Plan
- Coordination bodies of each national programme of official control.
- Coordination bodies of the competent authorities of the autonomous communities

#### 3.1. SECTORAL CONFERENCE.

The Sectoral Conferences are multilateral cooperation bodies for a specific sector of public activity. They are made up of the holder of the Ministerial Department and all the Regional Ministers with competency in the area. Due to its composition, number and activity, it constitutes the principal pillar of inter-administrative cooperation.

Law 40/2015 on the Legal Regime of the Public Sector contains a minimal framework regulation of the Sectoral Conferences (Article 147), which determines that they are called by the corresponding Ministry and that their agreements are signed by same and by the Regional Ministers of the autonomous communities. The functioning of the Sectoral Conferences is governed by the agreement for the creation of each of these and their internal regulation.

The Sectoral Conference on Agriculture and Rural Development (whose current regulation was created on 13 December 1995 and last amended in 2009) is responsible for approving the *Official Control Plans for Primary Production and Food Quality*. Similarly, where basic changes to the plan are necessary or where the circumstances require a high-level approval, this Sectoral Conference shall be the body responsible for coordination and decision making.



### 3.2. COORDINATION BODIES OF THIS NATIONAL PLAN

The DG for Support and Coordination (SGAC) is the Unit within the MAPA with responsibility for the coordination of the PNCOCA. This function is carried out through the following coordination group:

Coordination group with units of MAPA

With competency for official controls included in the scope of Regulation (EC) No. 2017/625, of 15 March, and with the units responsible for control of imports and exports.

This group's objectives are the coordination of the following activities:

- Drafting of official control plans, their updating and amendment.
- Design and preparation of annual reports of the results of the control plan.
- Analysis and assessment of questions put forward relating to controls that affect the plan as a whole.

### 3.3. COORDINATION BODIES OF THE OF THE NATIONAL OFFICIAL CONTROL PROGRAMMES

Each programme establishes, where necessary, their coordination and decision-making body. The MAPA management unit of each programme is responsible for the management of the coordination body included in the programme.

In these bodies, all of the competent authorities responsible for the execution of controls are represented, where applicable.

The coordination bodies have the following functions:

- Review of the measures for the harmonised and coherent application throughout the Spanish territory of the controls that affect the programme.
- Drafting of the programme, along with updates and amendments.
- Design and compilation of the information relating to the results of the programme for the preparation of the annual reports of the results.
- Evaluation and analysis of the results of the controls for the adoption of the measures that improve the efficiency of the programme.

The following attached document lists the national coordination bodies that are fundamental, at different working levels for the understanding and harmonisation of criteria and actions of the official controls included within the scope of Regulation (EU) No. 2017/625, of 15 March.

#### NATIONAL COORDINATION BODIES



## 4. SUPPORTS FOR THE CONTROL PROGRAMME.

In addition to inspection personnel, the resources that support and collaborate on the functioning of official control are:

- Analysis laboratories, including national reference laboratories.
- The IT applications and national and regional databases for the management of official controls.
- The bodies and personnel to whom some of the official control tasks are delegated.
- Training of personnel.

### 4.1. OFFICIAL CONTROL LABORATORIES

The laboratories that participate in official controls, including reference laboratories, must be designated by the competent authority responsible for official control, following the criteria and requirements established in Article 37 of Regulation (EU) No. 2017/625, of 15 March.

For the purpose of harmonising the process of designation, the following procedure has been established:

#### PROCEDURE FOR LABORATORIES DESIGNATION



The attached document also lists the official control laboratory designated by the MAPA for official controls in the scope of Regulation (EC) No. 2017/625, of 15 March. The plant health laboratories whose accreditation is not compulsory according to the Regulations.

#### LABORATORIES OF OFFICIAL CONTROL



The laboratories designated by the competent authority for the execution of controls are indicated in the documented procedures of each programme.

### 4.2. IT RESOURCES FOR OFFICIAL CONTROL

Each specific control programme, and each documented procedure of the autonomous communities, includes the information relating to IT applications or databases that serve to support official control and which may be used for one or several programmes.

### 4.3. DELEGATION OF OFFICIAL CONTROL TASKS

Each national programme of official control includes the information relating to those tasks delegated to control bodies or natural persons. These delegations shall be executed in accordance with the provisions in Regulation (EU) No. 2017/625, of 15 March.

#### 4.4. TRAINING OF OFFICIAL CONTROL PERSONNEL

Each competent authority for the execution or coordination of official controls is responsible for ensuring that the personnel intervening in official controls receive training that enables them to perform their tasks adequately. This training shall include the additional updates required.

The training shall include, among other aspects, the relevant areas detailed in Annex II Chapter I of Regulation (EC) No. 2017/625, of 15 March.

### C. OFFICIAL CONTROL PROGRAMMES

#### NATIONAL PROGRAMMES OF OFFICIAL CONTROL OF THE MAPA FOR THE HIGH-LEVEL OBJECTIVE 4.

- PNCO for animal imports, products of animal origin not for human consumption, products for animal feed and imports of plants, products of plant origins and other objects.

#### PNCO IMPORTACIONES



### D. VERIFICATION OF THE QUALITY OF OFFICIAL CONTROLS

The verification of the quality of controls means evaluating whether these are adequate for the achievement of the objectives pursued.

This activity is developed in the following stages:

- Planning of official controls:
  - This process is conducted within each programme, therefore the information regarding activities and measures in the context of the programme execution is collected.
  - Operational objectives are established for each programme. The degree of achievement of these objectives is evaluated through appropriate indicators.
- Assessment of the results of the national official control programme:
  - The competent authorities responsible for the programme execution, as well as the coordinating body annually assess the following aspects about the results of the programme:
    - Execution of the controls in accordance with criteria and documented procedures established in the programme by:
      - i. **The competent authority, by using among others,** procedures for control supervision, will assess whether the inspectors conduct the controls in accordance with the procedures and instructions established.





ii. **Audit bodies designated by the competent authority**, will assess through internal audits whether the programme as a whole is carried out in accordance with the provisions and application procedures.

- Compliance with the objectives, to review the results of the indicators established to determine the degree of achievement.
- Evaluation of the adequacy and efficiency of the control programme, which will consider the results of the assessments mentioned above, and the findings and results of internal audit.

▪ Adoption of corrective measures:

After the assessment described in the previous section, either the competent authority at the level of the Autonomous Community or at the central level, and when applicable the National coordinating body, will carry out the modifications in the documented procedures and in the national programme.

The following document establishes criteria for the application of the verification of the effectiveness of the controls in the following points:

- Official control supervision.
- The assessment of objectives and use of indicators.
- The audits of official controls.

#### GUIDE FOR VERIFICATION OF EFFECTIVENESS



The document enclosed describes how the audits structure works in Spain, under the scope of the Ministry of Agriculture (MAPA), both for competencies of national and regional official control.

#### AUDITS

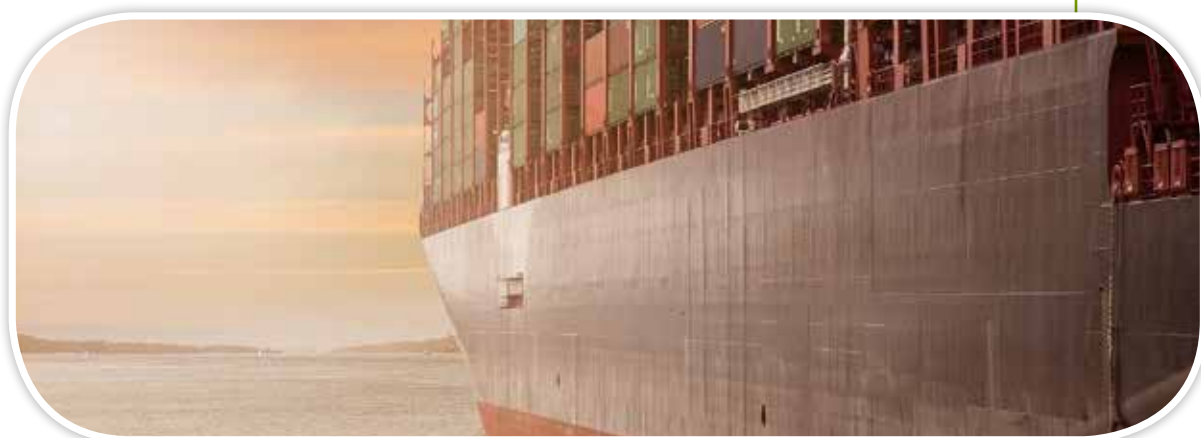


## E. ANNUAL RESULTS REPORT

### ANNUAL REPORT: GUIDELINES AND PROCEDURE FOR DRAFTING OF ANNUAL REPORT.

The annual report is drafted in accordance with the standard form established in the Commission Implementing Regulation (EU) 2019/723, of 2 May 2019, following the following stages:

- The coordinating unit for the PNCOCA in the MAPA (SGAC) informs about the annual schedule for collecting the results of the controls.
- This unit (SGAC) also requests to the MAPA units responsible of the different programmes, the information that must be issued to comply with Part I and section 1 of the Plan "general conclusion on the level of fulfilment achieved" in section 1 within Part II of the report template.
- The coordinating unit of the MAPA Units establishes the structure of the information to be contained in section 1 "general conclusion on the level of fulfilment achieved". The structure of the information contained in this section will be reviewed annually to introduce modifications that are deemed appropriate.
- The units of the MAPA managers of each national control programme, in the term established by the SGAC, shall record in the SDCP-AROC (Data Collection Platform-Annual Reports on Official Controls) application of the Commission, the results of the official controls conducted the previous year, following the criteria agreed in the coordination group of the MAPA units and the guidelines contained in the Communication from the Commission on a guidance document on how to fill in the standard form model contained in the annex to Commission Implementing Regulation (EU) 2019/723.
- Once the terms for the recording of the results is finalised, the SGAC shall review compliance with all sections of the report and will communicate to AESAN the validation of the annual report on primary production chain and food quality.



## A. STRATEGIC OBJECTIVE

**Strategic objective 4.2.** Reduce the risks to health of the people and animals, and fraudulent or deceptive business practices linked to the introduction or importation of food, materials in contact with food and other goods for human use originating in third countries or territories.

The competent authority responsible for the coordination for achieving strategic objective 4.2 is the **Sub-directorate General for Foreign Health, Directorate General for Public Health, Ministry of Health**

## B. GENERAL ORGANISATION: COMPETENT AUTHORITIES, COORDINATION MECHANISMS AND OFFICIAL CONTROL RESOURCES

### OFFICIAL CONTROL OF GOODS FOR HUMAN USE OR CONSUMPTION FROM THIRD COUNTRIES.

The need for rigorous control of international cargo traffic is evident in light of the food crises of recent decades, such that the official border control for goods for human use or consumption from third countries constitutes a key element of protecting the health of consumers.

On the other hand, the growing importation of these types of products originating or proceeding from countries located outside the European Union requires, on the part of the competent health authorities, with sufficient resources and efficient and flexible coordinated supervision systems that prevent critical situations and provide, in such situations, for the necessary mechanisms to safeguard public health.

All this justifies the need to establish uniform procedures for the control of different goods for human use or consumption consigned from third countries, thus ensuring strict compliance with requirements for introduction or importation in the Union.

## 1. HUMAN, TECHNICAL AND MATERIAL RESOURCES

### 1.1. Competent authorities

At central level, the Sub-directorate General for Foreign Health (SGSE), a body under the jurisdiction of the Directorate General for Public Health (DGSP) itself under the Ministry of Health, is the body responsible for:

- the technical coordination of border inspection services
- the drafting of control programmes and their review and updating
- the drafting and review of the Annual Foreign Health Supervision Plan
- supervision of the application of the programmes and supervision and control plans

- the proposal of the designation of official control laboratories for foods and materials in contact with foods consigned from third countries
- the designation, suspension, revoking or amendment of the scope of designation of facilities for border control and goods storage
- the instruction of the sanction file for actions or omissions constituting health infractions
- the training of personnel responsible for executing controls, and
- coordination with other competent authorities of official control.

At peripheral level, the competent bodies for official border control, and for the verification and supervision of hygiene conditions of the border control facilities or health storage of goods, are the Foreign Health Inspection Services (hereinafter the Foreign Health Services). The inspection personnel of the Foreign Health Services, while it is a functional body under the jurisdiction of the Ministry of Health, are organically ascribed to the Ministry of Territorial Policy and Public Function, through the Areas and Dependent Bodies of Health and Social Policy of the Delegations and Sub-delegations of Government.

## 1.2. POINTS OF CONTACT

The point of contact in the sphere of official controls on goods for human use and consumption imported from third countries or territories is the Sub-directorate General of Foreign Health of the Ministry of Health:

### SUBDIRECTORATE GENERAL FOR FOREIGN HEALTH

Directorate General of Public Health

Ministry of Health

Paseo del Prado 18-20, 28071 Madrid (España)

saniext@sanidad.gob.es / areacim@sanidad.gob.es

Tel.: +34915962040

## 1.3. Legal support

In addition to the standards already listed in the general part of the PNCOCA which constitutes the legal support to implement the official controls of all areas of application of Regulation (EU) 2017/6251, there are other legal provisions, both national and European, that result in the application in the sphere of official controls carried out by the Foreign Health Services on different goods for human use or consumption consigned from third countries.

<sup>1</sup> Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation).

Thus, the following table contains some of the provisions applicable in this sphere:

EU Regulation	Subject
Commission Implementing Regulation (EU) 2021/632 of 13 April 2021	laying down rules for the application of Regulation (EU) 2017/625 of the European Parliament and of the Council as regards the lists of animals, products of animal origin, germinal products, animal by-products and derived products, composite products, and hay and straw subject to official controls at border control posts, and repealing Commission Implementing Regulation (EU) 2019/2007 and Commission Decision 2007/275/EC
Commission Delegated Regulation (EU) 2021/630 of 16 February 2021	supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards certain categories of goods exempted from official controls at border control posts and amending Commission Decision 2007/275/EC
Commission Implementing Regulation (EU) 2019/1793 of 22 October 2019	on the temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from certain third countries implementing Regulations (EU) 2017/625 and (EC) No 178/2002 of the European Parliament and of the Council and repealing Commission Regulations (EC) No 669/2009, (EU) No 884/2014, (EU) 2015/175, (EU) 2017/186 and (EU) 2018/1660.
Commission Implementing Regulation (EU) 2019/1715 of 30 September 2019	laying down rules for the functioning of the information management system for official controls and its system components ('the IMSOC Regulation').
Commission Delegated Regulation (EU) 2019/625 of 4 March 2019	supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements for the entry into the Union of consignments of certain animals and goods intended for human consumption.
Commission Implementing Regulation (EU) 2019/627 of 15 March 2019	laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls.
Commission Implementing Regulation (EU) 2020/2235 of 16 December 2020	laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates, model official certificates and model animal health/official certificates, for the entry into the Union and movements within the Union of consignments of certain categories of animals and goods, official certification regarding such certificates and repealing Regulation (EC) No 599/2004, Implementing Regulations (EU) No 636/2014 and (EU) 2019/628, Directive 98/68/EC and Decisions 2000/572/EC, 2003/779/EC and 2007/240/EC
Commission Implementing Regulation (EU) 2021/404 of 24 March 2021	laying down the lists of third countries, territories or zones thereof from which the entry into the Union of animals, germinal products and products of animal origin is permitted in accordance with Regulation (EU) 2016/429 of the European Parliament and the Council.
Commission Implementing Regulation (EU) 2019/1012 of 12 March 2019	supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council by derogating from the rules on the designation of control points and from the minimum requirements for border control posts.
Commission Implementing Regulation (EU) 2019/1013 of 16 April 2019	on prior notification of consignments of certain categories of animals and goods entering the Union.
Commission Implementing Regulation (EU) 2019/1014 of 12 June 2019	to lay down detailed rules on minimum requirements for border control posts, including inspection centres, and for the format, categories and abbreviations to use for listing border control posts and control points.
Commission Implementing Regulation (EU) 2019/1081 of 8 March 2019	establishing rules on specific training requirements for staff for performing certain physical checks at border control posts.
Commission Implementing Regulation (EU) 2019/1602 of 23 April 2019	supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council concerning the Common Health Entry Document accompanying consignments of animals and goods to their destination.
Commission Implementing Regulation (EU) 2019/1666 of 24 June 2019	supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards conditions for monitoring the transport and arrival of consignments of certain goods from the border control post of arrival to the establishment at the place of destination in the Union.
Commission Implementing Regulation (EU) 2019/1873 of 07 November 2019	on the procedures at border control posts for a coordinated performance by competent authorities of intensified official controls on products of animal origin, germinal products, animal by-products and composite products.
Commission Delegated Regulation (EU) 2019/2074 of 23 September 2019	supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards rules on specific official controls on consignments of certain animals and goods originating from, and returning to the Union following a refusal of entry by a third country.
Commission Implementing Decision (EU) 2019/2098 of 28 November 2019	on temporary animal health requirements for consignments of products of animal origin for human consumption originating in and returning to the Union following a refusal of entry by a third country.
Commission Implementing Regulation (EU) 2019/2122 of 10 October 2019	supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards certain categories of animals and goods exempted from official controls at border control posts, specific controls on passengers' personal luggage and on small consignments of goods sent to natural persons which are not intended to be placed on the market and amending Commission Regulation (EU) No 142/2011.

EU Regulation	Subject
Commission Delegated Regulation (EU) 2019/2123 of 10 October 2019	supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards rules for the cases where and the conditions under which identity checks and physical checks on certain goods may be performed at control points and documentary checks may be performed at distance from border control posts.
Commission Implementing Regulation (EU) 2019/2124 of 10 October 2019	supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards rules for official controls of consignments of animals and goods in transit, transshipment and onward transportation through the Union, and amending Commission Regulations (EC) No 798/2008, (EC) No 1251/2008, (EC) No 119/2009, (EU) No 206/2010, (EU) No 605/2010, (EU) No 142/2011, (EU) No 28/2012, Commission Implementing Regulation (EU) 2016/759 and Commission Decision 2007/777/EC.
Commission Delegated Regulation (EU) 2019/2126 of 10 October 2019	supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards rules for specific official controls for certain categories of animals and goods, measures to be taken following the performance of such controls and certain categories of animals and goods exempted from official controls at border control posts.
Commission Delegated Regulation (EU) 2019/2127 of 10 October 2019	amending Regulation (EU) 2017/625 of the European Parliament and of the Council as regards the date of application of certain provisions of Council Directives 91/496/EEC, 97/78/EC and 2000/29/EC.
Commission Implementing Regulation (EU) 2019/2128 of 12 November 2019	establishing the model official certificate and rules for issuing official certificates for goods which are delivered to vessels leaving the Union and intended for ship supply or consumption by the crew and passengers, or to NATO or a United States' military base.
Commission Implementing Regulation (EU) 2019/2129 of 25 November 2019	establishing rules for the uniform application of frequency rates for identity checks and physical checks on certain consignments of animals and goods entering the Union.
Commission Implementing Regulation (EU) 2019/2130 of 25 November 2019	establishing detailed rules on the operations to be carried out during and after documentary checks, identity checks and physical checks on animals and goods subject to official controls at border control posts.
Regulation (EU) 2016/429 of the European Parliament and of the Council Of 9 March 2016	on transmissible animal diseases and amending and repealing certain acts in the area of animal health.
Commission Delegated Regulation (EU) 2020/692 of 30 January 2020	supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin.
Regulation (EU) 1069/2009 of the European Parliament and of the Council of 21 October 2009	laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation).
Commission Regulation (EU) No 142/2011 of 25 February 2011	implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (Text with EEA relevance)

National legislation	Subject
Order of 20 January 1994	Establishing the forms of health control on foreign trade products intended for human consumption and customs facilities allocated to such purpose.
Royal Decree 1528/2012, of 8 November	laying down the rules applicable to animal by-products and derived products not intended for human consumption.
Royal Decree 65/2006, of 30 January	establishing the requirements for the import and export of biological samples
Order SAS/3166/2009, of 16 November	replacing the annexes to Royal Decree 65/2006, laying down the requirements for the import and export of biological samples.

## 1.4. LABORATORY RESOURCES

The analytical tests carried out on official samples of food products and materials in contact with foods collected by the Foreign Health Services may only be performed at public or private laboratories specifically designated by the Directorate General of Public Health, using officially approved methods of analysis or, in the absence thereof, those recommended nationally or internationally.

The list of laboratories designated by the Directorate General of Public Health for the official control of food products and materials in contact with foods coming from third countries shall be published and periodically updated on the website of the Ministry of Health, available at the following link:

Laboratories for Official Control designated by DGSP



This information can also be found through the search engine of the [Network of Food Safety Laboratories](#) (RELSA).

## 1.5. IT RESOURCES FOR OFFICIAL CONTROL

### ■ Official control information management system (SGICO)

The SHICO, developed in Commission Implementing Regulation (EU) 2019/1715, represents a tool for the integrated functioning of all the IT applications through which data and documents relating to official control and other official activities are managed and exchanged.

This system does not constitute an application in itself, but an umbrella encompassing the following IT applications managed by the European Commission:

- iRASFF System, through which the procedures of the following systems are executed:
  - [Rapid Alert System for Food and Feed](#) (RASFF).
  - [Administrative Assistance and Cooperation System](#) (ACA).
  - [Integrated Veterinary Information System](#): (TRACES NT).
  - [Animal Disease Notification System](#) (ADIS).
  - [European Union Notification System for Plant Health Interceptions](#) (EUROPHYT).





## ■ Integrated Veterinary Information System: Trade Control and Expert System - New Technology (TRACES NT)

The TRACES system, in its new version (TRACES New Technology), is used to record the information corresponding to official controls carried out by Foreign Health Services on shipments of products for human use and consumption from third countries. Furthermore, this system allows for consultations of data linked with each item, constituting a tool of the first order when it comes to conducting analysis of the risk sustaining official controls.

## ■ Foreign Health IT System (SISAEX)

Similar to TRACES, the [Foreign Health IT System](#) (SISAEX) allows for the electronic management of certain procedures and processes relating to controls carried out by Foreign Health on goods from third countries.

### 1.6. DOCUMENTED OFFICIAL CONTROL PROCEDURES

In accordance with the provisions of Article 12 of Regulation (EU) 2017/625, the Foreign Health Services must conduct official controls in accordance with the documented procedures. With this aim, the SGSE maintains a constant production of Protocols, Instructions and Communications, dictating specific instructions for inspection personnel, taking into account the methodology and control techniques established by the current legislation and the needs detected from the risk analysis.

Through the following link, you can consult some of the guides and protocols drafted by the Sub-directorate General for Foreign Health in the scope of the official controls on imports:

- [Guides, documents and protocols drafted by the Ministry of Health or by DG SANTE \(European Commission\)](#)

For their part, each Foreign Health Service must document the official control activities carried out at each point of entry and maintain written records of same, in accordance with the provisions of Article 13 of Regulation (EU) 2017/625.



## 1.7. CONTINGENCY PLANS

In order to guarantee the right and obligation to relate to the liaise with the public administrations electronically, in accordance with Article 14 of Law 39/2015<sup>2</sup>, and for the purpose of preventing possible de-lays in the health clearance of imported goods, the SGSE has drafted a Contingency Plan for procedures developed by electronic means, whose objectives is to establish a protocol of action for cases in which the IT systems used in official control activities might not be operational.

- [Contingency Plans for procedures developed by electronic means](#)



## 1.8. TRAINING OF PERSONNEL

Within the *Annual Training Programme of the Ministry of Territorial Policy and Public Function*, the following courses, organised by the SGSE, are periodically held:

- Course on controls on food imports aimed at inspectors and technical inspection personnel responsible for official controls on goods for use and consumption from third countries.
- Course on hygiene and health conditions at facilities for border control and health storage of goods.
- Courses aimed at Foreign Health laboratories.

The SGSE, meanwhile, is responsible for the selection of the personnel of the Foreign Health Services who attend the different courses delivered as part of the European Commission's Better Training for Safer Food programme.

## 2. GENERAL ASPECTS OF PLANNING

### 2.1. STRATEGIC OBJECTIVE OF THE OFFICIAL CONTROL SYSTEM

**Strategic objective 4.4:** Reduce the risks to health of the people and animals, and fraudulent or deceptive business practices linked to the introduction or importation of food, materials in contact with food and other goods for human use from third countries or territories.

2

Law 39/2015, of 1 October, on the Common Administrative Procedure of the public administrations.

## 2.2. LIST OF OFFICIAL CONTROL PROGRAMMES

This section is structured on the following programmes:

- Programme 1. Official control of cargo for human use or consumption from third parties
- Programme 2. Official control of shipments with no commercial character from third countries
- Programme 3. Control of kitchen waste from international transport
- Programme 4. Designation and supervision of border control and medical storage of goods

## 2.3. PLANNING OF OFFICIAL CONTROLS: CATEGORISATION BASED ON RISK

No shipment for human use or consumption from a third country should enter or, where applicable, be imported to Spanish territory without being subject to the official controls legally established in order to guarantee the high level of security and protection of public health and to identify possible infractions perpetrated through fraudulent or deceitful practices.

To do that, the Foreign Health Services plan health controls of goods depending on the risk and appropriate frequency, taking into account, among other factors, the following aspects contained in Article 9 of Regulation (EU) 2017/625:

- The risks identified in relation to:
  - i) animals and goods;
  - i) the activities carried out under the control of operators;
  - i) the location of the activities or operations of the operators;
  - i) The location of products, processes, materials or substances that might affect the security, integrity and health of the feed, animal health or welfare, plant health or, with respect to NGOs and phytosanitary products, that may also have negative repercussions on the environment;
- Any information that indicates the likelihood of misleading consumers, especially in relation to the nature, identity, qualities, composition, quantity, duration, country or place of origin and form of manufacture or procurement of the foods;
- The history of the operators in terms of the results of official control subject to compliance with the applicable regulation;
- The reliability of the results of the controls carried out by operators or one third upon their request;
- The information relating to possible infractions shared through the administrative support mechanisms such as the RASFF, SCIRI and ACA;
- All information that might indicate non-compliance with the applicable regulation.

Similarly, and specifically, they must take into account the reference criteria to determine the frequency indices of the identification and physical controls established for certain shipments of goods in Commission Implementing Regulation (EU) 2019/1715 and in the rest of the measures mentioned in the Article 47.1, d), e) and f) of Regulation (EU) 2017/625.

These criteria for the calculation of the frequencies of official controls can be found in the procedure [Guidelines on type of control to be carried out \(calculation of identification and physical control frequencies\) on a certain shipment](#), drafted by the SGSE.

## 2.4. ANNUAL FOREIGN HEALTH SURVEILLANCE PLAN

In application of the provisions of Article 4.5 and in point 5, of Annex II, of Commission Implementing Regulation (EU) 2019/2130, the SGSE organises an Annual Surveillance Plan which aims to take random samples and analytical tests on shipments imported in order to verify compliance with the EU legislation or, where applicable, the corresponding national regulations, especially in relation to those factors that constitute a risk to human health.

Thus, the Annual Foreign Health Surveillance Plan consists of the periodic programming of a series of samples and their analysis, in accordance with the frequencies based on the nature of the products and the inherent risk thereof, taking into account all the relevant supervision parameters, and the frequency and number of shipments imported and results of the prior controls.

This Annual Plan is comprised of the random border analyses within the framework of the national plans for the control of pesticides, waste and pollutants, as well as those controls conducted for supervision of other established or emerging risk factors, as well as those analyses performed for prospective purposes.

The Plan is drafted, therefore, as a useful tool for both the determination and management of risk, constituting an elements of assistance for decision making within the framework of the official control system for goods for human use or consumption from third countries.



## 2.5. FOOD FRAUD

One important aspect of the competency framework of the SGSE is the reduction of the risk to health of persons linked to fraudulent or deceitful practices in the introduction or importation of goods for human use or consumption from third parties.

Frequently, fraudulent practices in food constitute a risk to public health, as the inherently deceitful nature thereof conceals the real properties of the products or mask the replacement of ingredients with other less healthy one or considered harmful to health.

The following table lists some of the fraudulent practices subject to supervision in the sphere of official control conducted by the SGSE, due to the fact that it constitutes some type of risk to public health:

FRAUDULENT PRACTICES		RISKS TO FOOD SAFETY
Replacement, adulteration, dilution, addition or removal of components.	Substitution of species.	Loss of traceability.
		Presence of medical waste and pathogens in products of animal origin.
	Adulteration of unauthorised ingredients.	Presence of histamine-producing species, ciguatoxines, marine biotoxins in fishery products.
		Contamination from pesticides, presence of toxic species in product of non-animal origin.
Unauthorised processing or processing methods.	Presence of pesticides in organic products.	Loss of traceability.
		Presence of allergens or ingredients harmful to health.
Certified or falsified documentation.	Falsification of geographic origin or health attestations.	Presence of pharmacologically active substances in food supplements.
		Migration of substances harmful to human health from materials in contact with foods.
Deceitful labelling	Most fraudulent practices involve the display of false or deceitful information of the labelling of food products.	Masking of organoleptic signs of deterioration in fishery products.
		Possible provenance from third establishments or countries not authorised for exports to the European Union, and absence of guarantees of compliance of the food products.
		Possible presence of allergens or dangerous ingredients, especially for vulnerable groups.

## CONTROL PROGRAMMES

- **Programme 1.** Official control of goods for human use or consumption from third parties

PROGRAMA 1 SANEX



- **Programme 2.** Official control of shipments with no commercial character from third countries

PROGRAMA 2 SANEX



- **Programme 3.** Control of kitchen waste from international transport

PROGRAMA 3 SANEX



- **Programme 4.** Designation and supervision of border control and medical storage of goods

PROGRAMA 4 SANEX



## D. REVIEW OF OFFICIAL CONTROL SYSTEM

Article 6 of Regulation (EU) 2017/625 states that *“the competent authorities shall carry out internal audits or have audits carried out on themselves and shall take appropriate measures in the light of the results of those audits”* to ensure that the objectives of the Regulation are reached.

With regard to the audits, Commission Decision

2006/677/EC<sup>3</sup> with the aim of setting out the guidelines laying down criteria for the conduct of these audits, indicating that *“the purpose of audit systems is to verify whether official controls (...) effectively implemented and are suitable to achieve the objectives of the relevant legislation, including compliance with national control plans.”*

Article 12 (2 and 3) of Regulation (EU) 2017/625 states that *the competent authorities shall establish examination procedures of official controls, and to adopt corrective measures in all which all the procedures (...) detect deficiencies in the control system.*

Furthermore, according to Commission Decision 363/2007<sup>4</sup>, *the verification of the efficiency of official controls should guarantee the quality, impartiality, consistency, coherence and effectiveness of same at all levels, in the competent authorities and between them, with the inclusion of regional and local authorities.*

<sup>3</sup> 2006/677/EC: Commission Decision of 29 September 2006 setting out the guidelines laying down criteria for the conduct of audits under Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls to verify compliance with feed and food law, animal health and animal welfare rules.

<sup>4</sup> 2007/363/EC: Commission Decision of 21 May 2007 on guidelines to assist Member States in preparing the single integrated multi-annual national control plan provided for in Regulation (EC) No 882/2004 of the European Parliament and of the Council.

## 1. SUPERVISION OF OFFICIAL CONTROLS

### 1.1. CONCEPT

The supervision of official controls is defined as the set of actions carried out at senior levels of the hierarchy on official control agents (inspectors of the Foreign Health Services) in order to assess the correct and efficient fulfilment of their functions and the implementation of European and national public health and food safety regulations. That is, the supervision of a technique that allows for the verification of compliance and efficiency of not only the system as a whole but the official control agents.

### 1.2. PROGRAMMING AND EXECUTION OF SUPERVISION

The Area or Dependent Bodies of Health and Social Policy shall carry out a Supervision Plan on an annual basis, detailing the number of supervisions planned for each annual cycle and the priority actions.

The supervision will be carried out based on a prioritisation based on risk, associated with the correct completion of official controls. For example, the risk assessment must take into account the existence of sufficient human resources, the existence of documented procedures, the training provided by official control agents or the previous supervision results, among other aspects.

In order to obtain a conclusion on the compliance with the aspects verified, the stages are defined in the following table:

1. Document control:	Checking of files, reports, logs, acts and other documentation through the selection of a representative sample of shipments or establishments.
2. Checking of activities	Checking that activities carried out coincide with those presented and that they are carried out in such a manner that allows for the objectives pursued to be reached. This check is conducted at the office itself and, where applicable, complemented with field inspections at the relevant facilities.
3. Report:	After this review, the supervisor shall prepare a detailed report indicating the non-compliances detected and the corrective measures proposed. A copy of this report shall be issued to each member of the unit supervised
4. Drafting of the Plan of Action:	The manager of the unit supervised shall draft a plan of action with the measures to be adopted to remedy the deficiencies or deviations detected during the supervision.
5. Review of Plan of Action and monitoring of corrective actions:	The supervisor shall also be responsible for the plan of action and the monitoring of corrective actions programmed.



### 1.3. ELEMENTS TO BE ASSESSED IN SUPERVISION

The following table contains the minimum aspects that should be assessed during supervision.

ASPECT SUPERVISED	SUB-ASPECT SUPERVISED
1. Qualification/training of personnel	1.1. Knowledge of applicable legislation and documented procedures of the work. 1.2. Attendance of personnel at training activities 1.3. Aptitude of personnel.
2. Documented procedures.	2.1 Availability or procedures, guidelines and updated models.
3. Execution of official control on goods and facilities	3.1 Correct application of procedures, guidelines and models. 3.2 Compliance of the inspection plans and the established terms. 3.3 Detection and adequate classification of non-compliances. 3.4 Drafting of reports, adherence to criteria or established models and correct completion. 3.5 Dissemination of reports and documentation to the relevant parties. 3.6 Adequate registry and archiving of documentation relating to official controls. 3.7 Correct employment of existing IT resources.
4. Adoption of corrective measures	4.1 Proposed adoption of adequate measures in response to non-compliances. 4.2 Application of the actions established as a result of the controls (terms, sanctions, special measures).
5. Monitoring of corrective measures	5.1 Monitoring of measures adopted in the established terms. 5.2 Correct assessment of the efficiency of corrective measures applied. 5.3 Registration of monitoring actions of the corrective measures. 5.4 Adoption of additional measures of greater seriousness where the terms are not met or measures not adopted.

### 1.4. RESULTS OF SUPERVISION

Each unit shall retain, for a minimum period of five years, the information regarding the supervision carried out and the non-compliances detected in the tasks conducted by the Foreign Health Inspection Services.

## 2. VERIFICATION OF THE EFFECTIVENESS OF CONTROLS

The objective is to check the degree of achievement of the strategic objectives. Said verification is conducted quarterly by personnel of the SGSE, determining, after the evaluation of the results, whether it is necessary to adopt corrective measures deemed pertinent.

## 3. AUDIT OF THE OFFICIAL CONTROL PROGRAMME

In accordance with Article 6 of Regulation (EU) 2017/625, the competent Authorities of the official control described in this Plan must submit to internal or external audits, for the purpose of verifying whether the official controls are applied effectively and are adequate for achieving the objectives established by the legislation.

The audit cycle shall have a duration of five years, and shall coincide with the period of validity of the National Programme of Official Control of the Food Chain (2021-2025).

Thus, the **Audits** will allow for the verification that:

- The official control on products for human use or consumption from third countries and kitchen waste from international transport are applied in an effective manner and are adequate to achieve the objectives of national and European legislation; and
- the border control or good storage facilities are suitable and meet the health and hygiene requirements established in the applicable regulations.

Thus, the audit process adequately covers each and every area of activity audited (types of products, types of facilities, etc.) and all the competent authorities involved in the official control of products for human use from third countries.

After the audit, the audit team shall draft a report with a series of recommendations and improvements that the Sub-directorate General for Foreign Health and, where applicable, the Area of Health and Social Policy should take into account to remedy any deficiencies founds, and to proceed with the modification of the Control Programmes, if considered necessary.

The process of action in the event of deviations, shall consist of the drafting of a plan of action, the adoption of corrective actions and the correct monitoring of the corrective measures proposed.

## E. ANNUAL REPORT OF RESULTS

Article 113 of Regulation (EU) 2017/625 establishes that by 31 August every year, each Member State shall submit to the Commission a report setting out:

- any amendments ultimately made to its Multi Annual National Control Plan (MANCP);
- the results of the official controls carried out in the previous year under its MANCP;
- the type and number of cases of non-compliance with the rules referred to in Article 1(2) of Regulation (EU) 2017/625 detected in the previous year;
- the measures taken to ensure the effective operation of its MANCP, including enforcement action and the results of such measures, and
- a link to the web page of the competent authority containing the public information on fees or charges referred to in Article 85(2) of Regulation (EU) 2017/625.

Furthermore, in accordance with the regulation, Law 17/2011, of 5 July, on food safety and nutrition, establishes that: *on an annual basis, the General State Administration shall submit a report to the European Union containing the result of the execution of the National Plan for Official Control of the Food Chain, developed by the competent public administrations.*

It is, therefore, the responsibility of the Area and Dependent Bodies of Health and Social Policy to send the necessary information for the drafting of this report in the manner and terms established.

For their part, it is the responsibility of the SGSE to compile and analyse the data available on the different official control programmes for products for human use or consumption from third countries, to draft the part of the annual report corresponding to said programmes and to submit these items to the Sub-directorate General for Coordination of Alerts and Programming of Official Control (AESAN) within the term agreed. The SGSE are also responsible for publishing the information relating to their control programmes on the Ministry of Health website.

## A. STRATEGIC OBJECTIVE

**Strategic objective 4.3.** Guarantee the achievement of a high level of food quality through:

- Border control of compliance with the legislation applicable to ecological production of imported third party products across Spanish borders.
- The identification of potential fraudulent or deceptive practices in relation to marketing standards applicable in certain agri-food products for overseas trade with third countries through border control.

The competent authority responsible for the coordination for achieving strategic objective 4.3 is the Sub-directorate General for Inspection, Certification and Technical Assistance for Foreign Trade, of the Ministry of Industry, Trade and Tourism (MINCOTUR)

## B. GENERAL ORGANISATION: COMPETENT AUTHORITIES, COORDINATION MECHANISMS AND OFFICIAL CONTROL RESOURCES

### OFFICIAL CONTROL OF COMPLIANCE WITH THE LEGISLATION APPLICABLE TO INTERNATIONAL COMMERCE OF AGRIFOODS WITH THIRD COUNTRIES

#### 1. Introduction: justification of the programme

The SOIVRE Inspection Service of the Territorial and Provincial Directorates of Trade (SI SOIVRE) is responsible for the official controls of the commercial quality of the products subject to marketing rules and subject to foreign trade (including intra-community) to the extent that this control is considered in the applicable framework legislation (common market organisation and derived regulation). The list of the products subject to this control in the framework of trade with third parties is contained in the annex of [Order PRE/3026/2003](#). The purpose of these controls is to guarantee the presence of products of adequate commercial quality in import and export transactions with third countries and shipments to the European Union, on Spanish borders, contributing to a high level of quality of products subject to foreign trade in benefit of the producers, economic stakeholders and consumers.

High-level Objective 4 of the PNCO is to reduce the risks to people's health and their interests and to the health of animals or plants through compliance of operators with the regulation in force on food safety, animal health, plant health, animal welfare, business quality, organic production, guaranteeing the achievement of a high level of food safety as well as fight against fraudulent or deceptive practices in animals, plants and food introduced or imported across Spanish borders

Framed within this high-level objective, the SI SOIVRE is responsible for delivering strategic objective 4.3 which is to guarantee a high level of food quality through border control of compliance with the legislation applicable to organic production of products imported from third countries across Spanish borders and the identification of possible fraudulent or deceptive practices in relation to marketing rules applicable to certain agri-food products for overseas trade with third countries through border control.

Part of this strategic objective is developed in the National Programme of Official Control of Organic Production, relating to controls of imports of organic agriculture products, while the rest of the objective is developed in this document.

The Regulation of official control 2017/625 (RCOPA) provides for the establishment of general rules for the completion of official controls in order to guarantee a high level of protection of human and animal health, the environment and the interests of consumers.

Ensure that commercial quality of the products imported or exported across Spanish borders impacts directly on safeguarding the interests of final consumers, of the companies receiving the products and guaranteeing fair practices between companies at this point of the marketing chain.

The commercial quality requirements that might be expected of products are contained in the marketing rules applicable to same. The marketing rules applicable on Spanish borders are contained in the EU legislation, in several community regulations that are centralised in two common frameworks:

- Common organisation of the markets in agricultural products (Regulation (EU) 1308/2013)
- Common organisation of the markets in fishery products (Regulation (EU) 1379/2013)

In the case of controls arising from the common organisation of the markets in agricultural products (Regulation (EU) 1308/2013), there is a specific control system well established by different community regulations. Regulation 2017/625 establishes that they should not apply for verification of compliance with Regulation (EU) 1308/2013, except where the controls are applied with respect to the marketing rules by virtue of Regulation (EU) 1308/2013 of the European Parliament and the Council that indicate the existence of possible fraudulent or deceitful practices.

Thus, the sphere of the application of Regulation (EU) 2017/625, of 15 March 2017, encompasses, among others, official controls applied by virtue of Article 89 of Regulation (EU) 1306/2013 where said controls identify possible fraudulent or deceitful practices in relations to the marketing rules referred to in Articles 73 to 91 of Regulation (EU) 1308/2013.

With regard to controls for the verification of the commercial quality rules in the framework of the organisation of markets in fishery and aquaculture products, no exceptions are established as applicable in the scope of Regulation (EU) 2017/625.

Therefore, the framework of the national plan encompasses the controls carried out based on the regulations that introduce marketing rules and the verification and compliance system of same in the event of fraudulent or deceitful practices detected in the framework of the single CMO in the fishery and aquaculture products sector.

Within the single CMO, the sectors with marketing rules subject to control on the part of the SOIVRE Inspection Service are: fruit and vegetables, aromatic herbs, olive oil, eggs, poultrymeat, hops, bananas and fishery products.

The purpose of this Programme is the control of the commercial quality of the products, subject to foreign trade contained in Order PRE/3026/2003, verifying compliance with the marketing rules applicable, through the completion of border controls at Spanish customs prior to import or export from/to third countries; for the detection of those fraudulent practices arising in transactions of certain products subject to foreign trade.

## 2. Human, technical and material resources

Regulation 2017/625 establishes that to conduct official controls for the verification of the correct application of EU legislation relating to the food chain, and other official activities that said legislation assigns to the authorities of the Member State, these must designate the competent authorities that act in the public interest, avail of the adequate resources and equipment and offer guarantees of impartiality and professionalism. The competent authorities must guarantee quality, coherence and efficiency of the official controls.

The general obligations relating to the competent authorities for control are contained in Article 9.2 of Regulation (EU) 2017/625 (EU).

To develop this programme and comply with the provisions established in the official control regulation, the SI SOIVRE is equipped with sufficient human resources.



## 2.1. COMPETENT AUTHORITIES OF THE PROGRAMME

The Sub-directorate General for Inspection, Certification and Technical Assistance for Foreign Trade (SGI-CATCE), a body under the jurisdiction of the Directorate General for Trade Policy, of the State Secretariat for Trade, is competent for the inspection and quality control of products for foreign trade, including intra-community trade, and control of imported organic products, with the SOIVRE Inspection Service of the Territorial and Provincial Directorates of Trade responsible for functional coordination.

At the same time, the Territorial and Provincial Directorates of Trade, regulated by Royal Decree 1456/2005 1456/2005, of 2 December, regulating the Territorial and Provincial Directorates of Trade, under the organic jurisdiction of the Ministry of Industry, Trade and Tourism through the State Secretariat of Trade and, functionally, the senior or governing bodies of the MINCOTUR based on the matters subject to action. They are also assigned the competency for inspection and commercial quality control of products for foreign trade, including intra-community trade, in terms of rules and specific techniques, containers and packaging, storage, deposit, transport, etc. The completion of the controls in accordance with the common marketing rules in the fresh fruit and vegetable sector as well as controls of imported organic products.

The SOIVRE Inspection Service is the competent authority responsible for strategic objectives:

4.3. Guarantee a high level of food quality through border control of compliance with the legislation applicable to organic production of products imported from third countries across Spanish borders and the identification of possible fraudulent or deceptive practices in relation to marketing rules applicable to certain agri-food products for overseas trade with third countries through border control.

In terms of the part of strategic objective 4.3 relating to compliance with the legislation applicable to organic production of products imported from third countries across Spanish borders, it participates along with MAPA in pursuing the objective (3.1.2.), National Programme of Official Control of Organic Production.

In terms of the part of strategic objective 4.3 relating to official control of compliance with the marketing rules of agri-food products for foreign trade with third countries, it is indicated in this document.

### 2.1.1 Spain national point of contact for the Control Programme

With regard to the official controls of commercial quality carried out on products for foreign trade referred to in the annexes of Order /PRE/3026/2003, the point of contact is the Sub-directorate General for Inspection, Certification and Technical Assistance for Foreign Trade:

#### **Sub-directorate General for Inspection, Certification and Technical Assistance for Foreign Trade**

State Secretariat for Trade  
Ministry of Industry, Trade and Tourism  
Paseo de la Castellana 162, 6ª planta

[sgsoivre.sccc@mincotur.es](mailto:sgsoivre.sccc@mincotur.es)

Tlf.: 913493754

### 2.1.2 National competent authorities

The competent authorities for commercial quality control in the sphere of foreign trade are:

- Coordination authority and central control services: Sub-directorate General for Inspection, Certification and Technical Assistance for Foreign Trade

Contact: [sgsoivre.sccc@mincotur.es](mailto:sgsoivre.sccc@mincotur.es)

- Control authority (GSA): The SOIVRE Inspection Service of the Territorial and Provincial Directorates of Trade (Territorial Trade Network) (SOIVRE Inspection Service). The list and contacts can be found at:

[https://comercio.gob.es/Red\\_Oficinas\\_Economicas/Red\\_Territorial/Paginas/Inicio.aspx](https://comercio.gob.es/Red_Oficinas_Economicas/Red_Territorial/Paginas/Inicio.aspx)



### 2.1.3 Human resources

Allocation of personnel The SOIVRE Inspection Service inspectors are found in the Territorial and Provincial They share these control functions with other functions in other areas.

Both the inspectors of the Territorial and Provincial Directorates such as the SGICATCE have been selected by the following selection processes (civil service examination, selective course and work experience) and have adequate qualifications and training to conduct the controls tasks and related work effectively and efficiently.

### 2.1.4 Economic resources

The budget of the State Secretariat for Trade, MINCOTUR include the budgetary allocations for the maintenance of the SOIVRE Inspection Service and the equipping of the laboratories and inspection points.

## 2.2. LEGAL ADVICE

The regulations and technical rules on quality and marketing or any other provision that affects products for foreign trade and which, being compulsory, establish quality or marketing characteristics, and establish the conditions for labelling, packaging, storage, conditioning, transport, unloading and stevedoring. Furthermore, the regulations, rules and other provisions that, being compulsory, regulate the activities relating to inspection, control and commercial planning.

### 2.2.1 National regulation

- Law 39/2015, of 1 October, on the Common Administration Procedure of public administrations (BOE of 2 October).
- Law 40/2015, of 1 November, on the Public Sector Legal Regime. (BOE of 2 October)



- Order Pre 3026/2003 dictating the inspection and control rules for Territorial and Provincial Directives of Trade, amended by Order ECC/2566/2015.
- Order ECC/2566/2015, of 27 November, amending Order PRE/3026/2003, of 30 October, dictating the inspection and control rules for the Regional and Territorial Directorates of Trade and repealing certain foreign trade rules

### 2.2.2 European regulation

- Commission Implementing Regulation (EU) No 29/2012 of 13 January 2012 on marketing standards for olive oil.
- Commission Regulation (EEC) No 2568/91, of 11 July 1991, on the characteristics of olive oil and olive-residue oil and on the relevant methods of analysis.
- Commission Implementing Regulation (EU) No 543/2011 of 7 June 2011 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of the fruit and vegetables and processed fruit and vegetables sectors
- Commission Regulation (EC) No 543/2008 of 16 June 2008 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 as regards the marketing standards for poultrymeat.
- Commission Implementing Regulation (EU) No 1333/2011 of 19 December 2011 laying down marketing standards for bananas, rules on the verification of compliance with those marketing standards and requirements for notifications in the banana sector.
- Commission Regulation (EC) No 589/2008, of 23 June 2008, laying down detailed rules for implementing Council Regulation (EC) No 1234/2007 as regards marketing standards for eggs.
- Regulation (EU) No 1379/2013 of the European Parliament and of the Council, of 11 December 2013, on the common organisation of the markets in fishery and aquaculture products, amending Council Regulations (EC) No 1184/2006 and (EC) No 1224/2009 and repealing Council Regulation (EC) No 104/2000.
- Council Regulation (EEC) No 1536/92 of 9 June 1992 laying down common marketing standards for preserved tuna and bonito.
- Council Regulation (EEC) No 2136/89 of 21 June 1989 laying down common marketing standards for preserved sardines
- Commission Regulation (EC) No 1850/2006 of 14 December 2006 laying down detailed rules for the certification of hops and hop products



## 2.3 LABORATORY RESOURCES

### 2.3.1 LABORATORY NETWORKS

The SOIVRE Inspection Service of the Territorial and Provincial Directorates of Trade has a network of its own laboratories that carry out, among other trials for the quality parameters to investigate to ascertain the degree of compliance with the applicable marketing rules.

The SOIVRE Inspection Service tests the samples collected during official control exclusively at the aforementioned official laboratories designated for that purpose.

The SOIVRE Inspection Service is made up of a total of 16 laboratories. The list is kept up to date at this link: [SOIVRE Inspection Service laboratory network](#)

SGICATCE executes the designation of laboratories to use in control according to the document “Designation of laboratories for the official control of compliance with marketing rules for agri-food products for foreign trade with third countries. SOIVRE Inspection Service” (in progress), designating the laboratories of the network of Territorial and Provincial Directorates of Trade responsible for tests relating to the control of compliance with marketing rules in relation to the detection of fraudulent and deceitful practices.

### 2.3.2 TOOLS FOR CONTROL AT THE INSPECTION POINT

The inspection point is equipped with the tools necessary for field control of each of the products.

To conduct the control tasks, these inspection points have the rights, refractometers, calibrators, colour charts, sampling tool, laboratory material required for immediate results, such as indices of maturity and all the material necessary for the verification that may be necessary for verifications of compliance with the requirement and that do not need to be sent to a laboratory for testing.

As commented, through the applications mentioned the inspectors have access to:

- The applicable legislation and rules, the instructions protocols and internal directives to apply
- Documents help with the interpretation of the rules.
- A forum for questions to clarify interpretations of legislation to ensure coordinated action throughout the SOIVRE Inspection Service.
- The records containing the information on the operators, results of controls, storage data, information on non-compliances detected.



## 2.4. IT RESOURCES FOR OFFICIAL CONTROL

The SOIVRE Inspection Service has an extensive network of interconnected IT applications that have several uses:

- Management of control by the inspector
- Communication with economic stakeholders involved
- Communication and coordination between the different authorities involved and with external authorities.
- Databases of economic stakeholder

The following are notable:

- <https://webgate.ec.europa.eu/agriportal> “Agricultural a rural development AMIS WEB PORTAL”. This is the “Notifications of Non-Compliances” module of Webgatea, to be used by the EU control authorities to notify the other authorities of member states of non-compliances issued on fruit and vegetable for import from third countries.
- AAC-FF System (Administrative Assistance and Cooperation System – Food fraud (European Union Application) [Administrative Assistance and Cooperation System](#). Secure coordination and communication tool for fraud or suspected fraud between the au thorities of different member states
- ESTACICE (national). IT platform developed for the management of commercial quality controls on the border This management platform is used by the stakeholders for sending control requests. These requests reach the acting inspectors who manage the files from this platform, issuing the results of the control through same. Transfer the certificates of compliance and non-compliance records to the stakeholders and to the AEAT (through the VUA).

It can be access

- on the website <https://estacice.comercio.es/>
- Through the website SOIVRE/Operator that allows us to present the control requests and receive the results of same in XML format
- To access, stakeholders should register with their local SOIVRE Inspection Service and should hold the corresponding digital certificates. You can find more information at this [link](#).

It incorporates an automatic risk analysis that streamlines the process and conducts controls on a selective basis, the adequate frequency for each type of control, always with the purpose of ensuring compliance with marketing standards.

ESTACICE is encompassed within the Single Window for Customs implemented by the Customs department.

- GARFYH (national). (Management of Risk Analysis of fresh fruit and vegetables). Used for the fresh fruit and vegetable sector, in the module that contains the Database of Economic Stakeholders in the fruit and vegetable sector, created to comply with Article 10 of Regulation 543/2011, establishing that Member States shall create the database of economic stakeholders in the fruit and vegetable sector, including all the stakeholders who participate in the marketing of fruit and vegetables for which standards have been adopted in application of Article 75 of Regulation 1308/2013 (113 of Regulation (EC) 1234/2007).

This application allows for management of the results of control visits in storage of operators and used to feed the risk analysis applicable in ESTACICE.

- Legisla (national). Application developed as a document database containing the information necessary for the controls of the SOIVRE Inspection Service.

Contains internal instructions and protocols, national and European legislation applicable to products subject to control, including the marketing rules applicable to control, supranational reference standard such as CODEX, UNECE, and pamphlets developed by the OECD for the interpretation of marketing standards for fruit and vegetables and other relevant information.

It is accessible for inspectors on their version of the Intranet, to check public information for these users involved in control. <http://legisla.comercio.es/>

- Internal Inspectors' FORUM (national). Communication tool between SI SOIVRE in the different Territorial and Provincial Directorates of Trade, and the Central Services of the SGICATCE, for the resolution of debts and clarifications and instructions.
- External FORUM (national). Communication tool with other competent authorities for control of fresh fruit and vegetables (such as the Regulation Coordination Authority).
- Rehúsos Application (national). tool for the processing of non-compliances detected in control. This is an internal tool used to manage non-compliances detected, for communication between the authorities of the SOIVRE network and local customs to comply with the obligations of coordination and exchange of information imposed by the Regulation.
- Samples Application (national). For the management of the logging of samples taken during control and which will be sent to the laboratories of the network.
- Subsequently, the laboratories include the results of control on this application.

## 2.5. STANDARDISED PROCEDURES.

In accordance with the provisions of Article 12 of Regulation (EU) 2017/625, the SGICATCE periodically issues internal instructions, manual, guides, action protocols and communications with inspectors involved and senior officials. It also maintains permanent contact with the SOIVRE Inspection Centre for the resolution of doubts and ensuring uniform action on all borders.

Principal instructions applicable to the programme



### LIST OF INTERNAL INSTRUCTIONS

## 2.6. EMERGENCY PLANS

Contingency plans have been established for the maintenance of the service for economic stakeholders in the event that the ESTACICE IT platform were not operational for technical reasons, to guarantee communication between the administration and the parties concerned.

In the event of service downtime, users should submit control requests on paper or by email to the regular inspection service centre.

In these cases, certificates are issued on paper, signed manually by the inspector with the stamp of the corresponding SOIVRE Inspection Service. They are valid for import or export customs clearance.

Subsequently, once service is resumed, the files issued urgently during the incident are integrated into the system with the real date on which they were issued on paper.

## 2.7. DELEGATION OF OFFICIAL CONTROL TASKS.

There are no official control tasks delegated in this Control Programme

## 2.8. TRAINING OF PERSONNEL

In accordance with the provisions established in Article 5.4 of Regulation (EU) 2017/625 which obliges them to provide adequate training of inspection personnel who carry out official control, the SGICATCE organises numerous specific training activities aimed at inspection personnel responsible for official control described in the Programme.

The annual Programme also included the specific training of the Ministry of Industry, Trade and Tourism, with courses and training activities of various types:

- Training courses for new inspection personnel.
- Specific courses for training of inspection personnel responsible for official control.

The SGICATCE also organises training video-conferences on legislative developments.

## C. CONTROL PROGRAMME

### ■ Programme 4.3.1.

Official control of compliance with marketing standards applicable to food products trades externally with third countries.

#### PROGRAMA 4.3.1. CALIDAD COMERCIAL



## D. VERIFICATION OF THE QUALITY OF OFFICIAL CONTROLS

### Evaluation of the programme

#### 1. Supervision of official control

The SGICATCE verifies the compliance of the instructions issued by the SOIVRE Inspection Service with the provisions of Article 12(2) of Regulation (EC) No. 2017/625. To do so, it analyses the information contained in the records and databases that reflect all the information and details of controls and activities carried out.

The deviation of the inspection action conducts at the border in relation to the risk analysis proposed for the completion of official controls is also checked.

On the other hand, MINCOTUR's General Inspectorate of Services and Citizen Engagement conducts periodic audit visits to the SOIVRE Inspection Service, verifying the compliance of the instructions from the inspectors and issuing reports subsequent to the SGICATCE.

For the purpose of procuring a better performance of the official control tasks, the SGICATCE carried out an annual assessment of the controls carried out, encompassing:

- An annual report of the commercial quality controls, which contains the information of the controls based on the different data for each control operation. It analyses the type of control and the result of control (the units of study being the volume of goods and number of shipments presented for control) based on the flow, the destination or country of origin, type of product, variety of same, economic operator, control centre, area of Spain of origin or destination of the goods, quality categories and more.
- Analysis of the data for the use of reference indicators to check each of the operating objectives



## ■ Non-compliance with the Programme

On occasion, deviations may arise with respect to the programme in terms of the completion of minimum controls, monitoring the instruction of inspection personnel or the correct inspection of the Risk Analysis. This may be due to the lack of personnel in a certain moment. The SGICATCE has IT tools to detect these deviation and re-establish compliance with the Programme.

## ■ Measures to be adopted after detection of non-compliances

If any non-compliance is detected, the officials of the SOIVRE Inspection Service involved are contacted and sent to correct this deviation. If the non-compliance reveals a weakness in the system, the instructions are corrected for all centres.

Soon, the SOIVRE will manage this control with a new IT tool, which will automatically detect the non-compliances arising in terms of the development of the programme and will display alerts to inspectors and the SGICATCE, thus helping with the supervision of the programme.

The reports issued are taken into account by the SGICATCE for the supervision of the centre involved and, where applicable, for the correction of instruction or for sending reminders to the entire network.

## ■ Audit of Official Control Programme.

In application of Article 6 of Regulation (EU) 2017/625, internal audits are carried out.

The auditors in the commercial quality area are set out in the Audit Plan of the SOIVRE Inspection Service

Two groups of internal auditors trained by SOIVRE inspection personnel shall review and verify the correct compliance of the instructions for the achievement of the official control objectives. Part of these audits are focussed on reviewing compliance with the guidelines and objectives of the programme.

These audits are conducted on a programmed basis and include field visits and online interventions to detect deviations and propose the relevant corrections.

The reports of the audits, which show the findings detected, are passed to the SGICATCE which will give the corresponding instructions and reminders for the correction of deviations.

The audits are conducted based on the document "*Guide for internal audits relating to commercial quality controls and organic products. SOIVRE Inspection Service*" (in progress).

## E. ANNUAL REPORT OF RESULTS

Article 113 of Regulation (EU) 2017/625 states that each Member State must submit to the Commission by 31 August each year, a report indicating the results of the official controls carried out in the previous year in accordance with the PNCO, as well as the type and number of cases of non-compliance with the rules detected by the competent authorities.



The SGICATCE will draft an annual report with the results of the programme described, following the model established in Commission Implementing Regulation (EU) 2019/723. It will be based on the records of the controls carried out by the SOIVRE Inspection Service and kept at its headquarters. The annual report on commercial quality control conducted at borders on products for foreign trade will be sent to AESAN for its contribution to the drafting of the Annual National Report.

## A. STRATEGIC OBJECTIVE

### ■ Strategic objective 4.4.

Guarantee compliance with the requirements established in the applicable regulation in Article 1.2 of Regulation (EU) 2017/625, when said requirements are applicable to animals and goods to be exported from the European Union.

The competent authority responsible for the coordination for the achievement of strategic objective 4.4 is the **General Secretariat for Agriculture and Food of the Ministry of Agriculture, Fisheries and Food (MAPA)**

## B. GENERAL ORGANISATION: COMPETENT AUTHORITIES, COORDINATION MECHANISMS AND OFFICIAL CONTROL RESOURCES

(See objective 4.1)

## C. OFFICIAL CONTROL PROGRAMMES

National Programmes of Official Control of the MAPA for the High-Level Objective 4.

- PNCO for exports of products subject to veterinary certification

PNCO EXPORTACIONES CV



- PNCO for exports of products subject to phytosanitary certification

PNCO EXPORTACIONES CF



## D. VERIFICATION OF THE QUALITY OF OFFICIAL CONTROLS

(See objective 4.1)

## E. ANNUAL REPORT OF RESULTS

(See objective 4.1)





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