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INSPECTION MANUAL FOR OFFICIAL FOOD SAFETY CONTROL PROGRAMMES FOR FOOD PRODUCTS OF PLANT ORIGIN

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OFFICIAL FOOD SAFETY CONTROL PROGRAMMES FOR FOOD PRODUCTS OF PLANT ORIGIN

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DISCLAIMERS

EU DISCLAIMER

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FOREWORD

Official controls simply indicate the use of laws and regulations or a series of actions taken by a Competent Authority in charge of food safety to protect consumer and farmers from risks arising from Non-Compliance with Sanitary and Phytosanitary measures (SPS). Food safety authorities in Kenya as well as around the world are constantly challenged by changes in microorganisms and new chemicals associated with food, as well as changes in food production techniques and consumer behaviours, which lead to new risks to the public. To combat these challenges, it is critical that food safety authorities provide a proactive approach to identify all potential avenues of contamination (hazards) and determine how to control, reduce, and/or prevent them to ensure that food is safe for consumption. That goes to show that food safety authorities around the globe will have to collaborate and share information and experiences since, one country's problem today, could be another country's problem tomorrow and there is a need to learn from each other's' successes.

The Market Access Upgrade Programme (MARKUP) being a regional development initiative supported the Kenyan Government's effort to strengthen the economy through increased agricultural production, value addition, agro-processing, as well as trade expansion in selected horticulture sub sectors including snow peas and peas, mangoes, passion fruit, chilies, herbs and spices and nuts. MARKUP aligned its activities with Kenya's strategic development of its agribusiness sector in 12 counties namely Bungoma, Busia, Homabay, Siaya, Trans Nzoia, Uasin Gishu, Taita Taveta, Kwale, Makueni, Machakos, Kajiado and Embu. Documenting reference/ guiding materials such as the Food Safety Manual and training of the inspectors under this project was the starting point of an effective food control system. The process assisted in standardizing inspection processes for food and food establishments within the food sector as well as enhance capacity of trainers to train inspectors to perform effective risk-based inspections. This eventually will lead to improved institutional and regulatory framework for better conformity assessment services in Kenya's horticultural sector.

Written for inspectors of food of plant origin this forward-thinking manual examines exactly what inspection and official control programmers in packing and processing in food business operators do. The comprehensive manual is brief and concise to help inspectors and managers to implement official food safety controls on plant products during their production, processing and distribution and explore some of the underpinning issues, featuring examples of best practice from successful regional blocks such as the EU.

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ACRONYMS

ADI	Acceptable Daily Intakes
AOAC	Association of Analytical Communities
CA	Competent Authority
CAC	Codex Alimentarius Commission
EC	European Community
EU	European Union
GAP	Good Agricultural Practices
GHP	Good Hygiene Practices
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
GPS	Global Positioning System
HACCP	Hazard Analysis and Critical Control Point
ILAC	International Laboratory Accreditation Cooperation
IPPC	International Plant Protection Convention
MRL	Maximum Residue Limits
PCB's	Polychlorinated Biphenyls
PMU	Project Management Unit
RASFF	Rapid Alert System for Food and Feed
SANCO	DG Health and Consumer Protection, European Commission
SPS	Sanitary and Phytosanitary System

1. INTRODUCTION

This Manual sets out the general principles to be followed in the inspection and official control programmers in packing and processing of food of plant origin. It is aimed at helping inspectors and their managers, primarily from the Ministry of Agriculture, Livestock, Fisheries and Cooperatives and County Governments to implement official food safety controls on plant products during their production, processing and distribution.

The Manual was developed under the auspices of the EU funded MARKUP programme, which aims to help Kenyan producers and exporters to meet requirements for compliance with sanitary and phytosanitary conditions for international trade, with a special focus on horticultural products.

2. SCOPE

The Manual recognizes that there are important linkages along the supply chain, in line with the farm to fork principle. The controls described focused on food safety hazards which may arise during primary production or during subsequent handling, packing and processing.

The importance of management systems such as HACCP and traceability are also considered. Although the main focus is food safety, the procedures described also recognise that inspectors also have a responsibility to ensure compliance with regulations concerning pesticide application to crops. This issue is also addressed in this manual.

Whilst not within the scope of this Manual, inspectors should always also be vigilant for plant pests and diseases which may be spread through the processing and distribution of products of plant origin.

3. STRUCTURE AND APPROACH OF THE MANUAL

The Manual is divided into sections. Key terms are defined and explained. It provides then provides a brief description of some of the important food safety hazards which may occur in foods of plant origin, and which must be addressed in a risk-based system of official controls. The main sections of the guide describe the official controls to be established, from two main angles.

Firstly, the Manual describes the organizational and management of official controls as a system. This section will help managers to decide on the organisations of an efficient system of controls, and how best to direct the staff and financial resources available. It sets out some of the best current practices in applying principles of risk management to the decisions made by Competent Authorities regarding the implementation of the official control functions. These best practices are substantially based on the requirements of the European Union, which represents the most important export market with whose requirements Kenyan horticultural crops must comply.

Secondly the Manual sets out specific guidance for inspectors, regarding the assessment of compliance of food business operators and their establishments, in terms of what and how to inspect establishments and products to assess their compliance with typical food safety requirements.

Finally, the manual considers the organisation of surveillance programmes (sampling and testing) intended to assess the effectiveness of the official control system in preventing non-compliant products from reaching the consumer.

The manual is therefore intended to provide practical advice for the operation of official controls. It is written on the premise that it is impossible for a Competent Authority to control everything within its remit, all of the time. Competent Authorities therefore make choices (whether expressed or implicitly by default, for example due to lack of resource) regarding what is controlled.

The best we can hope is that it will control some of the things most of the time, and that in making such choices, those things will be the most important from the point of view of protecting the health of consumers.

This essentially is the concept of risk management, where the managers and inspectors within the official control system focus their efforts on the most severe hazards which represent the greatest likelihood of harming consumer health. It is concept which is expressed at different levels throughout this manual.

Relevant references are provided at appropriate points in the manual. A full list of references and suggestions for additional reading are provided in Annex 1.

4. DEFINITIONS

4.1 Foods of plant origin

There is no specific definition of foods of plant origin. Such products are usually defined in comparison to foods of animal origin. However there are several classes of food which are neither animal-origin nor plant-origin foods. These include minerals (salt), synthetic additives (e.g.post-harvest crop treatments) and water, which may need to considered during inspection and control, if they are used.

This manual has been prepared to address controls to ensure the safety of a wide range of foods of plant origin. It may be applied to the production of raw materials, processing and packing of:

- Fresh fruit and vegetables, including cut products
- Fruit and vegetable juices
- Herbs and spices
- Animal feeds of plant origin (e.g. soymeal)
- Oils
- Non-alcoholic beverages (tea and coffee)
- Grains and pulses (especially tropical e.g. rice, millet, sorghum, quinoa,)
- Fermented foods and drinks
- Bakery goods
- Alcoholic beverages (beer)
- Plant based food enzymes
- Algae/fungi
- Novel foods

Note that honey, whilst being based on material of plant origin, is regarded in law and official control terms as a product of animal origin and falls under veterinary supervision. It is therefore not considered in this document.

4.2 Official controls

Official control can generally be regarded as the series of actions taken by a Competent Authority to protect consumers and farmers from risks arising from non-compliance with sanitary and phytosanitary measures. It is thus a system of regulatory controls designed to ensure compliance with food safety, plant health and animal health regulations.

At present the legal framework is set out in the Food, Drugs and Chemical Substances Act Ch.254. However the food safety policy and main legislation is undergoing a reform (2021) and final provisions are to be decided. A new Act is expected to define the term “official control”.

In the context of the EU, official control has a specific meaning set out in Regulation 2017/625 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. This defines “official control” as “activities performed by the competent authorities, or by the delegated bodies or the natural persons to which certain official control tasks have been delegated in accordance with this Regulation, in order to verify:

(a) compliance by the operators with this Regulation and with the rules concerning food and feed safety, animal health and welfare and plant health; and

(b) that animals or goods meet the requirements laid down in the rules referred to in Article 1(2), including for the issuance of an official certificate or official attestation.”

The regulation sets out more details as to what is to be included as shown in the box below:

Reg.2017/624 Article 14 defines:

Official control methods and techniques shall include the following as appropriate:

a) an examination of the controls that operators have put in place and of the results obtained;

b) an inspection of:

i) equipment, means of transport, premises and other places under their control and their surroundings;

ii) animals and goods, including semi-finished goods, raw materials, ingredients, processing aids and other products used for the preparation and production of goods or for feeding or treating animals;

iii) cleaning and maintenance products and processes;

iv) (iv) traceability, labelling, presentation, advertising and relevant packaging materials including materials intended to come into contact with food;

c) controls on the hygiene conditions in the operators' premises;

d) an assessment of procedures on good manufacturing practices, good hygiene practices, good farming practices, and of procedures based on the principles of hazard analysis critical control points (HACCP)

e) an examination of documents, traceability records and other records which may be relevant to the assessment of compliance with the rules referred to in Article 1(2), including, where appropriate, documents accompanying food, feed and any substance or material entering or leaving an establishment;

f) interviews with operators and with their staff;

g) the verification of measurements taken by the operator and other test results;

h) sampling, analysis, diagnosis and tests;

i) audits of operators;

j) any other activity required to identify cases of non-compliance.

4.3 Surveillance

Surveillance is a series of additional activities undertaken by Competent Authorities to gather data which is used to assess the extent of compliance of different foods with the national safety requirements. Surveillance is not part of the official control process. The data so collected forms an important element of the risk assessment activities undertaken by Competent Authorities, and therefore complements official controls. The difference is most evident in the different approach to sampling and testing. Taking a sample for official control may result in a legal sanction, and greater attention must there be paid to ensuring procedural integrity of the process. In addition, official controls take place along the supply chain, whereas surveillance takes place at the level of the market and relies on traceability to identify the source of the problem. Surveillance is considered in detail in section 8.

5. HAZARDS IN FOODS OF PLANT ORIGIN

There is a wide range of different hazards associated with foods and feeds of plant origin this section outlines the major hazards specifically associated with foods of plant origin ranging from a selection of naturally occurring issues to a variety of manmade issues.

The inspector should have a sound understanding of the origin of such hazards and the scientific basis upon which they can be controlled or minimised.

5.1 Microbial pathogens

Pathogens are an ever-present issue when dealing with any type of food or feed. However there are some organisms that are particularly associated with products of non-animal origin.

These pathogens can be roughly divided in to four separate groups; environmental based, faecal based pathogenic bacteria, pathogenic parasites and pathogenic viruses[1].

- Environmental based including human, soil and air borne (e.g. *Clostridium perfringens*, *Clostridium botulinum, staphylococcus aurous* and *Listeria monocytogenes*)
- Faecal based (e.g. *Salmonella spp, Shigella spp* and *Escherichia coli*)
- Viruses (e.g. Hepatitis A and Entero virus)
- Parasites (e.g. *Cryptosporidium* and *Cyclospora*)

All of these pathogens are associated with a wide range of negative health effects which can range from relatively minor symptoms such as nausea up to paralysis and death. The specific pathology of the different organisms can be found in more detail elsewhere. However official control of many of these pathogenic organisms share similar methods and practices.

Inspectors should ensure that strict hygienic controls are in place, especially in relation to toilets and hand washing. Periodic medical checks and certification should be place to ensure permanent excreters of pathogens do not handle open food. The medical certificate should include information about the presence of the above hazards, as well as those derived from open wounds and sore throats (*Staph.aureus*).

5.2 Clostridium botulinum in low acid canned foods

Clostridium botulinum although a pathogenic organism is considered separately because of the very specific risk it poses in low-acid canned foods[2].

Clostridium botulinum is a heat resistant, anaerobic and spore forming bacteria. These characteristics make it of particular significance in low-acid canned foods (foods with pH values

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[1]Food and Drug Administration [FDA] (Bad Bug Book - Foodborne Pathogenic Microorganisms and Natural Toxins - Second Edition, Available from : https://www.fda.gov/food/foodborne-pathogens/bad-bug-book-second-edition Accessed [9th of March 2021]

[2]Codex Alimentarius, (2011) Code of hygienic practice for low and acidified low acid canned foods Available from : http://www.fao.org/input/download/standards/24/CXP_023e.pdf Accessed [09th of March 2021]

above 4.6) as if they are incorrectly processed ***Clostridium botulinum,*** if present, may proliferate producing a dangerous neurotoxin that if ingested can cause symptoms including vomiting, diarrhoea, paralysis and potentially death[1].

Heat treatment is a particularly key in controlling this hazard, but other controls are also important such as can seam integrity and safety of cooling water.

Inspectors should therefore confirm that i) heat treatment records are kept and that heat treatment is sufficient for safety; ii) can seam dimensions are monitored continuously during each shift (requiring special equipment and training); and, iii) free available chlorine level in cooling water at the point of use is sufficient to eliminate spore-forming bacteria.

5.3 Mycotoxins

Mycotoxins are a form of toxic chemical produced by a wide variety of fungi. They are considered to be one of the most significant food contaminants because of their negative impact on public health, food security and in turn the economy.

Aflatoxins are mycotoxins produced by several species of fungi of the genus *Aspergillus.* They are well known to be carcinogenic, mutagenic, teratogenic and immunosuppressive and as such present a major concern, especially because of the hugely diverse range of plant products that they can potentially impact, these include maize, rice, groundnuts, treenuts, vegetable oils, seeds and a wide variety of other dried products. Mycotoxins come in many different forms dependent upon the causative agent and product type.

Although *Aspergillus spp.* are widespread they require specific conditions for growth namely warmth and moisture. If these factors are correctly controlled around harvest and during storage then levels of mycotoxin should not reach potentially harmful amounts.

Specific consideration needs to be given in official controls to the processing and storage of any product considered to be at risk from aflatoxins. Good Agricultural Practices during and immediately post-harvest represent the primary defence against mycotoxin contamination. National or international bodies often set limits to aflatoxin content to protect consumers[3].

Until now the mycotoxin risks in Kenyan products have not been fully assessed, but generally nut, seed and grain crops, especially maize, are at higher risk. Checks on mycotoxins should be undertaken in higher risk products on a periodic basis. The operators should be able to demonstrate sampling and testing, and periodic sampling for surveillance should be undertaken by the Competent Authority.

5.4 Heavy metals

Heavy metal is a term that describes a number of metals that if present in food or feed may present a significant hazard to human health. Some heavy metals are essential to life in small quantities and are present in all food stuffs. However some heavy metals present a serious risk

[3]Food and Agriculture Organisation of the United Nations [FAO] (2001) Manual on the Application of the HACCP System in Mycotoxin Prevention and Control, Available from: http://www.fao.org/docrep/005/y1390e/y1390e00.htm [09th March 2021]

to human health and should be carefully controlled[4].

Examples of heavy metals of note include cadmium, lead and mercury. These are not easily metabolised and are all highly toxic causing a range of symptoms depending upon the substance and exposure levels. For example, lead causes tissue damage to a variety of organs and systems and can in extreme cases cause death. Lead can occur naturally in foods from residues in the soil, but contamination is more likely from industrial contamination. Arsenic may also be present in water supplied by aquifers.

Checks on heavy metals should be undertaken in higher risk products on a periodic basis. Until now the risks in Kenyan products have not been identified, but generally nut, seed and grain crops are at higher risk. The operators should be able to demonstrate sampling and testing, and periodic sampling for surveillance should be undertaken by the Competent Authority.

5.5 Additives

Additives is a term that describes a variety of different substances that are not normally consumed as food but are added intentionally to food for a specific purpose. Common examples of additives include sweeteners, colorants, preservatives, antioxidants stabilisers and emulsifiers. The EU recognises 26 separate types of additive.

Additives should be free from appreciable risk if used in accordance with recommended levels. If this level is exceeded than the additive many become hazardous with wide ranging health effects depending on the nature of the substance.

Some additives that are widely used in one region may be considered dangerous by another an example of this is Sudan 1 a widely used colorant that in the past has been frequently used to colour spices but in recent years has been banned by many countries because of its carcinogenic properties.

Additives are general controlled by restricting their use to certain justifiable products. Their usage in production and processing should be carefully monitored by the operator, with all applications measured and recorded against traceability codes. Inspectors should check that only permitted additives are applied, that they applied correctly and that the application is described in production records.

5.6 Phytotoxins

Phytotoxin is a broad term used to describe toxic metabolites produced by plants. There are many different types with significant variation depending upon plant species, strain and environmental conditions.

There are various example of this issue. One common phytoxin is solanine, a glycoalkaloid that naturally occurs within potatoes. This toxin is not destroyed by the cooking process and can cause gastrointestinal and neurological issues, but is easily avoided as its presence is indicated by green discoloration. Some other important phytotoxins are cyanogenic glucosides in cassava,

[4]European food safety authority (2011) Metals as contaminants in food Available from : http://www.efsa.europa.eu/en/topics/topic/metals.htm Accessed [09th March 2021]

or haemagglutinin in kidney beans, where soaking and cooking is an essential step undertaken by the consumer in making the product safe[5].

Given the wide variety of different phytotoxins and origins, they should be dealt with on a case by case basis. Until now, in Kenya there has been no specific assessment of the risks of phytotoxins in foods. Inspectors should however be aware of products that may potentially present this issue, and their associated controls. The official controls applied need to take into account common end uses, as well as any storage or usage information provided by the producer to the consumer (for example in the labelling).

5.7 Dioxins and PCBs

Dioxins are a group of polychlorinated aromatic compounds related by structural properties. They are not produced intentionally but are the by-products of a variety of chemical and industrial processes.

PCBs, or polychlorinated biphenyls are a separate group of chlorinated aromatic hydrocarbons of industrial origin. PCBs are often grouped in with dioxins because of similar toxicological processes and as such are described as “dioxin like”.

These chemicals, often referred to as persistent environmental pollutants (POPs) are fat soluble and bind easily with organic matter and sediment which and is endemic in air water soil and food. Dioxins and dioxin like chemicals are not biodegradable and will easily bio-accumulate in animal and human fat tissues when exposure occurs. Although most commonly found in products of animal origin they can be an issue in products of plant origin, most notably in vegetable oils.

These chemicals have a range of toxic effects some are known carcinogens while other have been linked with reproductive conditions, developmental impairment and a variety of immunotoxic effects[6]. Whilst some of them are highly toxic, the toxicity among them varies 30,000-fold.

These POPs should be addressed in a regular monitoring programme (sampling and testing of higher risk products). No specific risks have been assessed for Kenya, but products with a high oil content are likely to be the most susceptible.

5.8 Residues of pesticides/agro-chemicals

Today a wide variety of different agro-chemicals or plant protection products including pesticides, herbicides, fungicides, insecticides, growth hormones and fertilisers all used to protect and promote the growth of both agricultural and horticultural crops. These plant protection products however may, if not correctly controlled, have deleterious impact on both human health and the environment. These effects vary depending upon the type of chemical used.

These chemicals are generally controlled by setting Maximum Residue Limits (MRL in the

[5]Sprenger, R. (2008) supervising food safety (level 3) 11th Ed. Highfeld ld

[6]EU Strategy on dioxin in feed and food Available from : https://ec.europa.eu/food/safety/chemical_safety/contaminants/catalogue/dioxins_en [9th March 2021]

product. These limits are set to reflect the levels of the product expected if the chemical applied has been used correctly in accordance with Good Agricultural Practices (i.e. that it is effective and applied at the minimum dosage achievable). It is not the case that if the product exceeds the MRL than the product is considered to present an unacceptable risk to human health[7]. In addition, the use of many high-risk toxic substances (to the operator, the environment or the consumer) are often banned.

A pesticide monitoring plan has been periodically implemented by KEPHIS. Inspectors should follow up on each individual case of non-compliance identified. Note that non-compliance is determined with reference to the action level specified in the plan being exceeded, rather than the MRL itself[8]. This requires inspectors to identify the precise operators involved at each stage of the supply chain, taking account the division and combination of batches at different stages. Selective sampling and testing at different levels of the supply chain is the primary diagnostic tool applied to identify causes.

Once the cause (or causes) are identified the inspector should then ensure that i) the cause is removed immediately by the operator; ii) the operators adjusts internal controls to ensure that the event does not recur; iii) products produced under non-compliant conditions are made safe (reprocessing, sorting, destruction). This should include operators who may have received such products (identified using trace-forward). If the product is already distributed to consumers, a public recall should be implemented.

6. OFFICIAL CONTROL SYSTEM

This section sets out some of the main requirements for the management of a system of official controls. It describes the main components of such a system, and the typical management tools which can be applied by a Competent Authority for implementation of an effective and efficient system of controls.

The official controls are applied by a Competent Authority responsible for inspections (e.g. a central government authority (such as the Ministry of Agriculture) or a local authority (County Governments).

6.1 Objectives of official controls

Whilst the responsibility for delivering safe food is that of the producer, the objective of the official control system is to use regulatory controls to ensure that the food is safe for the consumer to eat.

All major sources of hazards must be addressed by the system of official controls, and all possible means of information should be used by the inspector to ensure that the risks to consumers from unsafe food are minimised.

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[7]Europa(2009)Plant protection pesticide residues Available from : https://ec.europa.eu/food/plant/pesticides_en Accessed [9 march 2021]

[8]Action level should be set lower than the MRL, to ensure a confidence limit of 95% in assumed compliance

In terms of the production system for foods of plant origin, controls should be applied throughout the supply chain, from input supplier through the producer and to the consumer. The activities of the inspectors from the Competent Authority must be programmed to cover the entire chain, placing emphasis and priority on those points which are known to present the most risk.

However, in practice, one of the main means of control, particularly for exports, is at the processing and packing establishment. This is because as the final point of despatch to market, it is the most visible and easily controllable point in the distribution chain.

The central approach to official control set out in this manual is that such controls are best achieved by the presence of a well-informed inspector at the point of production.

6.2 Legal basis and principles official control

In relation to processing food of plant origin, official controls are undertaken to ensure compliance with food safety considerations. Inspectors should therefore be fully informed of the precise requirements as set out in the national legislation.

In Kenya, the legal basis for food safety conditions in foods of plant origin is currently set out in several Kenya Standards, of which two of high relevance are:

- KS 1560:2000 Code of general hygienic practice for the horticultural food industry.
- KS 1551-1-3::2001 Code of practice for handling and distribution of fresh fruits and fresh fruit products.

These documents set out the application general hygiene requirements for all food business operators (including primary producers).

The controls set out in this document describe the controls that are typically required to control the *food safety hazards* described in section 5 above. They are based on requirements set out in Kenyan Standards and CAC Codes of practice.

Plant health controls on the other hand, are mostly concerned with the conditions of primary production and concern surveillance and control measures for pests and plant diseases, ensuring application of good agricultural practices, and proper management of plant protection products. Inspection of products of plant origin later in the supply chain (for example during processing or packing) provides additional checks and guarantees that the plant health controls at primary producers are operating effectively.

Therefore, as well as food safety concerns, inspectors concerned with controls on products of plant origin should also be aware of the need to ensure compliance with any relevant plant health measures.

6.3 Registration and approval systems

A pre-condition for official controls is that the Competent Authority is aware of the existence and location of food business operators. It is therefore mandatory for all horticultural business operators who are to be subject to official control to register with the Competent Authority. This requirement is set out in Regulation 7 of the Crops (Horticultural Crops) Regulations of 2020. It

should be noted that there is a fundamental difference between registration and the licensing of farms and packhouses.

Registration	Should be conditional only on the submission of the required information (not subject to any food safety conditions). The CA cannot refuse to register a food business operator providing that the required information is supplied. Since the objective is to register all relevant businesses, registration should be made as easy and cheap as possible. Online registration, or registration at the business operators premises are ways of making the process easy. A registration period should be specified, after which operators should be required to renew registration. Failure to register should be a criminal offence.
Licensing	Should be limited to higher-risk premises with licences issues subject to compliance with a set of technical food safety conditions. The CA may wish, for example to apply licensing conditions to establishments processing for sensitive markets (for example export) or for especially high-risk products (low acid canned foods). Determining which establishments should be subject to approval is a matter of control policy, which should be expressed by the CA. An licence period should be specified, after which operators should be subject to additional inspection and approval. Licence periods can be adjusted depending on risk and compliance conditions (e.g. low risk, fully compliant establishments could be subject to longer control intervals).

The registration process should collect information from every single operator to be subject to control, to allow risk profiling, considering all of the above, as well as other relevant data (for example size of business as evidenced by number of employees). The process should aim to collect the address and contact details.

Consideration should also be given to obtaining GPS coordinates (and equipping inspectors with GPS to identify specific locations). Contact details should include key-holder contacts for out of hours control activities.

The registration system also should collect information regarding the raw materials, ingredients used, the processing technology, type of specialised equipment and the final products. An indication of markets is also required. This information is necessary to be able to perform a risk profiling exercise, one of the factors used to set the inspection frequency.

One of the most powerful tools for official control is the licensing of establishments. This means that as well as being required to comply with regulatory conditions, establishments must have been through an explicit official control process to confirm that they comply with the regulatory requirements.

Licensing is a stricter requirement, and should therefore be used as a tool for official controls applied to higher risk product categories or establishments e.g. those engaged in export supply chains.

6.4 Annual control plan

The official activities should be set out by each Competent Authority undertaking inspections in annual control plan, which guides the routine activities of the Competent Authority. The annual control plan provides the mechanism by which control policy is implemented in practice. The objective of the plan is to guide the decisions of inspectors and their managers in terms of what to inspect, how often, and the nature of the controls in each case.

The annual control plan should therefore set out a programme of inspections. It should list all of the inspection points. For products of plant origin, these could include:

- Farms
- Wholesale markets
- Distribution/storage establishments
- Processing and packing establishments
- Transport vehicles
- Import and export establishments (including port facilities)

The plan should also define the different types of inspections that may be applied to each. Generally, there are four types of inspection which may be applied, although this can be adapted according to requirements. The different kinds of inspection should be reflected in the Annual Control Plan. The Central Competent Authority should provide specific guidance regarding sub-sectoral priorities.

Type of inspection	Activity/Purpose
Preliminary	Initial inspection of establishments/facilities to confirm degree of compliance with conditions, identify works to be undertaken. Often conducted by a team, possibly before commissioning of an establishment
Formal /Licence	Formal inspection Conducted by a team, with an in-depth inspection during operation of the establishment covering all issues in detail often applied to establishments requiring approval or licensing, to establish whether approval should be granted or not.
Interim routine	Interim detailed inspection conducted to check compliance, follow up on compliance, or on progress with works requested.
Spot check	*Ad hoc* inspection of short duration to observe whether there is any obvious defect/malpractice. It could be a follow up to check compliance with previous instructions.

Each type of inspection will be likely to have different team compositions and undertake different activities, and use different checklists. For example, a formal in depth inspection will confirm details which do not change very regularly, such as the nature of the processes and products, address, ownership, names of management and key holders. This information would not normally need to be checked again in a spot checks or interim inspections.

Similarly, an in-depth inspection would be expected to undertake a full audit of the HACCP

plan and its implementation. A spot check might just check that the relevant forms regarding monitoring of critical variables are being completed.

The plan should seek to reflect the food safety risks of different hazards associated with the different inspections of establishments (farms, packhouses, exporters). It should use this information to establish the approximate numbers and types of inspections in each category of establishments to be undertaken during the period. This can be broken down geographically, and by sub-sector if required. This then sets the target for the inspection body. This information can be further broken down to provide workplans to individual inspectors or groups of inspectors.

Where there are multiple Competent Authorities at different levels of the supply chain (for example County Governments and central government CAs) the plan should be coordinated to ensure that all relevant establishments are subject to control without over-lap of inspections. Joint inspections may also be foreseen.

The annual plan should be published by the Competent Authority. Variances from this plan should also be foreseen by the preparation of appropriate emergency or crisis management plans, which set out foreseeable circumstances requiring actions additional to the annual plan, and describe those actions, responsibilities and procedures.

6.5 Risk based approach to profiling of official controls

It is important to remember that official control is always a matter of risk management. It is not possible to eliminate all risk from the food supply chain, since food and its associated health hazards are products of a biological system which is naturally variable. Combined with human decisions which vary the sources of raw materials and the processes to which they are subject, this means that official controls will never be able to control everything all of the time[9].

The advantage of a risk-based approach to official control is that it improves efficiency in the allocation of control resources, allowing them to be focused where they are most likely to have the maximum effect on food safety and public health.

A typical approach is to classify the establishments according to high, low and medium risk[10]. This should be undertaken by the Competent Authority, based on scientific knowledge of the hazards in the situation in which they are located. Table 1 shows an example which may be adapted by risk assessors to suit the circumstances of Kenya.

[9]This is the essential difference to recognise between the approaches of "official control" of sanitary and phytosanitary hazards, and the "conformity assessment" of industrial products subject to technical standards.

[10]For example see FAO. 2020. "FAO guide to ranking food safety risks at the national level", Food Safety and Quality Series No 10. Rome., https://doi.org/10.4060/cb0887en (09 March 2021)

Table 1: Examples of risk-categorisation of establishments processing products of plant origin

Risk category	Extent of risk	Examples (products of plant origin)	
		Process	Hazard
High risk	Significant potential to put at risk vulnerable groups (elderly, infants, immuno-suppressed) or large numbers of consumers.	Ready to eat prepared cut fruit pieces in modified atmosphere	Pathogenic bacteria e.g. *E.coli, Listeria*
		Low acid canned foods pH>4.5 (e.g. canned moambe)	*Cl.botulinum*
		Nuts susceptible to growth of Aspergillus moulds	Aflatoxins
		Packing of seeds and production of salad sprouts e.g. beanspouts, cress)	Pathogenic bacteria e.g. *E.coli, Listeria*
Medium risk	Reduced potential to put vulnerable groups at risk, where the distribution may be limited or where the product is to be cooked before consumption, or the health risks reduced	Dried ground spices	Pathogenic bacteria e.g. *Salmonella*
		Canned fruits with pH<4.5 (e.g. pineapples, grapefruit)	Tin
		Fresh peas and beans	Banned pesticides Pesticide levels >MRL
Low risk	Only a minimal potential to harm consumers	Pre-packed whole fresh fruits and vegetables;	PCBs, Dioxins, other heavy metals, radiation
		Bread and other)non-confectionery) bakery goods	PCBs, Dioxins, other heavy metals, radiation
		Fried plantain chips	Minimal

Note that risk classification of an establishment should be related to the highest risk activity undertaken. It should also be remembered that a product may present more than one hazard with different risks. The approach needs to take into account the specific hazards and risks in the territory covered by the Competent Authority (which may vary considerably due to crops, varieties and climate).

The risk categorization would then be used to establish a number of operational parameters applied by the inspector:

- Requirements for the design and layout of the establishment
- Frequency of formal approval (and whether required)
- Frequency of interim and spot check inspections
- Nature, and depth of checks made during official controls

In addition, at the level of the establishment the assessment of risk may be factored to take into

account the compliance record of the individual establishment. Thus, establishments with a good compliance record could be subject to a less vigilant regime of official controls than those which were not compliant.

This allows the inspectors to focus additional control resources on the problem establishments.

Similarly, very small establishments (with limited production) or those which sell only to limited markets (for example sales within the locality of production) may also be considered as presenting a reduced risk.

6.6 Licensing system for establishments

Where an establishment is required to be licensed (for example in the case of high-risk or export establishments) the requirement and the technical conditions for approval should be set out in the relevant legislation.

The approval process should be clearly defined in the procedures of the Competent Authority. The applicant should also be provided with information setting out the requirements and the actions available in case the applicant disagrees with the decision of the Competent Authority or is dissatisfied with the service rendered.

The process will formally start with the reception of the application form, in which the applicant requests the licence. The form should set out the basic information required for the approval conditions. This should include:

- the name and address of the establishment
- sources and species of raw material
- processes to be undertaken
- products to be produced
- specific markets of destination.
- the number of employees
- the production and storage capacities

The Competent Authority may wish to specify the documents which should be submitted with the application. These may include:

- Plans of the establishment setting out:
  - the establishment facilities and their respective utilization
  - the flow of products fit for human consumption and that of products non fit for human consumption
  - the equipment lay-out and its respective utilization
  - the sanitary facilities (shower rooms, changing rooms and toilets), wash basins and taps
  - the air, smoke and moisture exhaust systems
  - the waste water disposal system

- water reticulation plan (water outlets or taps serially numbered on the map and in the plant) and treatment faclities
- list of suppliers
- specification of process conditions
- HACCP and quality documentation and record
- Technical staff CVs
- the system for handling, storage and disposal of by-products
- the pest control system
- the product(s) flow diagram(s)
- the traceability system
- food handler medical certificates
- any other formal information (company deeds, land title, lease etc)

For new establishments it is essential that the operator discusses the hygiene conditions with the Competent Authority at the design stage. Otherwise, there is a risk that costly alterations will be required to a newly constructed establishment before it can be approved.

The Competent Authority may consider awarding a provisional licence for new establishments which are in the phase of construction, based on a review of the documents submitted. Final and full approval may only be awarded on the basis of a full inspection of the establishment once it is in operation. This is because the award of licence should take into account the implementation of the hygiene requirements, for example the application of a HACCP- based control system.

The Competent Authority should always issue an approval document where an establishment is approved. The approval document should specify details of the establishment and the conditions of the approval follows:

- Name of establishment
- Location
- Approval number
- Date and period of approval
- Species (or groups of species) and sources of raw material
- Processes to be applied
- Markets authorised (or groups of markets)

The Licence should apply to these circumstances only. Should the establishment wish to undertake any activities which are not within the terms described, then a request for a variation of approval conditions should be made to the Competent Authority. This procedure is necessary to prevent an establishment from trying to market potential high risk products (e.g. bean sprouts) when it has received a licence only for low risk products (e.g. packing tree fruits).

The licence period should be finite. It should be subject to periodic renewal. One year is frequently chosen for the validity period. However this is arbitrary and a more effective approach would be to choose validity periods based on relative risk in relation to control resources available.

As noted above, higher risk establishments or establishments with a record of compliance difficulties would be subject to a more frequent renewal (and interim inspections). Low risk establishments and establishments with good compliance records, and well implemented HACCP systems could be subject to licence periods with longer validity. Since renewal will be associated with a cost incurred by the enterprise, a variable pricing approach could be used to create an additional financial incentive for compliance.

6.7 Use of checklists

Inspections of establishments (and the processes which take place within them) are a central element of official control. Inspectors often use inspection checklists as a guide for the things to be checked under each type of inspection, with different checklists for each type of inspection in different sectors.

The main advantage of checklists is to ensure that the inspector does not omit to consider an important element of the controls. They also allow for comparison and benchmarking of the inspection system. The main disadvantage is that there may be risks present in the establishment which are not expressed in the checklist categories, which are thus not identified by the inspector.

To address this disadvantage the inspector must be adequately informed. He/she must be capable of conducting inspections without checklists, using the checklist simply as an *aide memoire*. The use of a checklist can never compensate for a less than well informed inspector.

The checklist should be designed to reflect the objectives and type of inspection being conducted. It should also reflect a logical approach to the inspection procedure and its progress through the establishment. For example, it may be logical to follow the process flow from reception of raw material to final product. Alternatively, a counter-flow inspection may be indicated where there is a need to avoid contamination from dirty to clean processing areas (unless the inspector wishes to change protective clothing).

Checklists may adopt a scoring system, which provides a numerical score for different food safety attributes. Typically these apply the concept of negative demerit points (where points are awarded for the presence of a non-compliance). Thus low overall scores represent better compliance. This approach has the advantage that where a factor is not present in an establishment it is simply ignored and not scored, and does not affect the overall score. This avoids having to adjust the scoring system to account for differences in establishments and processes.

The advantage of having a scoring system is that it permits benchmarking of:

- the inspection system (by comparing scores of different inspectors for the same establishment) and
- the establishments (by comparing the score of a different establishments or groups, for example different processing segments, or of a single establishment over time)

Relevant inspection checklists for value chain operations dealing with horticultural crops are shown in Annex 1.

Period reviews involving front line inspectors, should address the need for updating and introduction of new checklists.

6.8 Categories of compliance

Overall categories of compliance may be allocated to the establishment which reflects the overall score or rating. This is often useful since in practice, it is often difficult to categorise a plant as simply compliant/non-compliant. For example, although plants must be clean, vegetable washing and preparation is a dirty process and the plant cannot be kept clean all the time during normal operations. In practice the inspector accepts this and allows a lack of cleanliness to a certain degree during normal operations, subject to limitations. There are therefore issues of judgement and degree introduced, which can be reflected in grades of compliance. Another example is a plant which has no major non-compliances, but several non-critical non-compliances

The allocation of grades of compliance is also desirable since it provides an incentive for compliant establishments to improve their standards. The category assigned may be used to determine the frequency of the follow-up inspections, and/or the cost of approval (if charges are made). In this way the Competent Authority can introduce financial incentives for compliance.

The allocation of grades of compliance also allows for a quantifiable assessment of the overall standards of the sector (broken down by different variables such as product, size, ownership etc). This allows the Competent Authority to monitor development of compliance standards over time, and in response to specific actions or campaigns.

The approach is to allocate the establishment with a category of compliance. One example is shown below, where the classification ranges from “Very good”, through “good” to “Acceptable” if it meets the minimum standards, and “Deficient” if it does not. The categories can be adapted by the Competent Authority to suit their specific purposes.

CATEGORY	STATUS	INSPECTION FREQUENCY
A	Very Good	Every three months
B	Good	Once to twice a month
C	Acceptable	Every week (depends on risk)
D	Deficient	Continuous inspection to up-grade, once the critical deficiencies are corrected

For new premises or systems the frequency of official control could be fixed for the initial period. Thereafter the above schedule may be applied, depending on the on-going performance and compliance record.

6.9 Sampling for official controls

Sampling for official control should only be undertaken by inspectors responsible for official control. This is to ensure that the sample is drawn from the batch which is subject to control. Otherwise sampling may be biased. Under no circumstances should samples for official control be supplied by the establishment.

An inspector may wish to take a sample as part of the official control activities. Circumstances in which a sample may be taken include:

- Following evidence of practices or conditions which give rise to the risk of a hazard being present, to confirm or otherwise its existence in fact (for example, on observing observe mouldy groundnuts, the inspector may wish to take samples to establish compliance with aflatoxin limits).
- Alerts received from the EU RASFF and other Competent Authorities in export market may be followed up with an investigation which includes sampling and testing.
- Checks on efficacy on internal controls applied by the business operator (for example validation of HACCP plan)
- Check on effectiveness of standard operating procedures (cleaning and sanitation systems, handwashing, water sanitising systems such as chlorination or UV sterilisers)

There is no fixed approach to sampling and testing for compliance. The inspector is expected to use his/her experience and technical knowledge to identify potential risks and a scientifically rigorous approach to acquiring the data required to make decisions to protect consumer health.

Note that sampling for official controls does not need to consider only finished products. Depending on the decisions of the inspector, samples may include raw materials or semi-processed products, water, swabs of hands or equipment or chemicals used in the establishment or on farm.

The inspector should consider whether it is strictly necessary to take a sample to establish a breach of regulations. This can only be decided on the basis of the observed facts and knowledge of the legislation. For example if the inspector observes failure in hand washing practices, this may in itself be a contravention of food safety legislation, and it may not be necessary to take samples from the product or swabs from hands to establish that the hand washing failure results in contamination and risk to health.

However, where samples are taken and the results are likely to be used in evidence of a contravention, then it is important that the sampling and sample treatment is undertaken in strict accordance with written sampling procedures.

Important principles expressed in the sampling procedure may be set out in legislation.

Sampling procedures should set out:

- Technical procedure for sampling (specifically to ensure sample integrity such as avoidance of bacterial contamination during selection and taking a sample for microbiological testing). Handling and storage procedures should also be specified
- Recording of relevant information regarding the sample and its selection, to include:
  - name and address of provider of sample
  - nature of sample and state (fresh/frozen/dried etc)
  - tests to be conducted
  - date of sampling
  - treatment applied to preserve the sample such as freezing, addition of stabilisers
- Ensuring fair opportunity for analysis by the provider of the sample (typically a sample

may be divided into three parts, and one part selected by the provider to keep for his/her own analysis a seen fit)

- Requirements for sample integrity during storage transport and despatch to the laboratory (to avoid the possibility that it may be tampered with, or otherwise adulterated). This may include sealing the sample container, and recording transference of possession from one person to another, so as to establish the "chain of custody".

It should be noted that monitoring and surveillance programmes are used to help the Competent Authority assess whether the control system is working to prevent contaminated products from the market. These activities are distinct from official control.

Sampling and testing for surveillance purposes requires a different approach, not least of which is that samples are often taken at the point of sale to the consumer (although this may also be the case in official controls undertaken at retailers). The differences in sampling approach therefore depend on the testing objective. Since official control may result in prosecution, rules of evidence must be upheld. However a non-compliance detected during surveillance does not usually result in prosecution, since strict sampling protocols required for official control cannot be economically applied.

6.10 Management of laboratory testing for official controls

6.10.1 Organisation of laboratory testing

The availability of accredited laboratory services is an essential tool which should be available to the Competent Authority for testing official controls.

An important task of the Central Competent Authority is therefore to manage the laboratory testing for official controls. The Central CA will often nominate a person to responsible for this task, since it demands technical knowledge of laboratory practices and analytical methods. The role of this position is to manage the technical aspects of the relationship between the Competent Authority and the laboratories performing tests.

Laboratory testing for official controls should be conducted in a laboratory which is approved by the Competent Authority for the tests to be undertaken. However it should be noted that there is no requirement for the Competent Authority to operate a testing laboratory. It is acceptable for a Competent Authority to purchase testing services from any laboratory, providing that it is technically competent to provide them.

The testing capacity of the laboratory will be dependent on the nature of the hazards encountered within the territory of the third country, the types of controls and the official control and testing requirements.

Note that it is not a requirement that there is capacity for all tests within the national territory of the Competent Authority. Some tests with relatively low demand may require high capital expenditure with costly operating costs to maintain the capacity. In such cases it may be cheaper for the Competent Authority to make arrangements for the samples to be transported for the test to be undertaken at a laboratory in another country. The Competent Authority must be

able to demonstrate that it has made the arrangements for all of the tests it requires for official control.

Laboratory functions should be organizationally independent from the risk management decisions of the Competent Authority. If the Competent Authority does operate a testing laboratory, then there should be a clear separation of laboratory functions and control functions. Tasks of laboratory staff should be limited to laboratory testing functions; they should not perform as inspectors, and should never take samples, since this compromises their impartiality as analysts and is in direct contravention of the accreditation standard. Analytical staff should not be aware of the provenance of the samples which they analyse.

The Competent Authority must designate the official laboratories which may undertake the analysis of samples for official controls. These laboratories must be assessed and accredited in accordance with EN ISO/IEC 17025:2005 standard on 'General requirements for the competence of testing and calibration laboratories". The testing services may be provided by any such laboratory, whether private or public sector.

Accreditation of a laboratory goes some way to assuring that when a sample is submitted:

- the laboratory will be using appropriate and validated methods.
- that the laboratory will have applied its own quality assurance and quality controls to ensure that the test results will be valid (measuring what it says) and reliable (reproducible)

By specifying an agreed standard method, a true comparison of results is possible.

Accreditation is an independent process undertaken by an established accreditation agency. The agency must be clearly established and must comply with the general criteria for accreditation bodies laid down in ISO/IEC 17040:2005 "Conformity assessment -- General requirements for peer assessment of conformity assessment bodies and accreditation bodies".

This could be the Kenya Accreditation Service (https://www.kenas.go.ke/) or any other body with a mutual recognition Agreement with the International Laboratory Accreditation Cooperation (ILAC)[11].

The Competent Authority cannot accredit the laboratory. It may only nominate accredited laboratories as official testing laboratories.

Often the Competent Authority will negotiate standard test fees as part of an annual contract with the designated laboratories (or a protocol in the case of state owned laboratories).

Note that it is often desirable that several laboratories are designated as official laboratories by the Competent Authority (to cover different needs and regions). A laboratory may be designated in respect of only some of the tests it undertakes. For example a laboratory may be designated for pesticide residue tests, but not for heavy metal testing.

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11 More information available at http://www.ilac.org/

6.10.2 Standard analytical methodologies

There is no single source of standard testing methodologies used for official controls for horticulture products. Harmonised methodologies should be applied where there is an official method specified in the legislation. Where this is not the case, but there is an appropriate ISO or EN standard method then this should be used.

Otherwise the choice of method is not standardised. Some laboratories may choose to use national standards, others to adopt methods from other organisations (e.g. AOAC). The Competent Authority should maintain an updated list of standard laboratory testing methods and source documentation required for official control, with alternatives where available.

6.10.3 Delivery of samples and receiving results

The inspector should deliver samples to the laboratory, identifiable only by a code. The following information should also be supplied.

- nature of sample and state (fresh/frozen/dried etc)
- tests to be conducted and method (if appropriate)
- date of sampling
- treatment applied to preserve the sample such as freezing, addition of stabilisers
- name/contact details of person/authority delivering the sample
- reporting instructions

Laboratories should design their application for testing services and reception forms to ensure that this information is collected.

Note that it is the responsibility of the inspector to specify the test parameters to be analysed. This decision should not be left to the laboratory since a single sample could be analysed for several different parameters, some of which are not relevant to the hazards being considered by the inspector.

The laboratory applies the required tests and should deliver test results to the inspector only, showing in a test certificate the value of the parameter tested. The certificate should not consider compliance or otherwise with a standard (unless specifically requested and the standard specified).

Judgment regarding compliance and non-compliance should therefore be made by the inspector based on the results and the circumstance of the sampling.

6.10.4 Reference laboratories

The Central Competent Authority should consider the nomination of reference laboratories for different parameters. The function of the reference laboratory is to co-ordinate the activities of laboratories whose task it is to conduct analyses for official controls. It is therefore a vitally important element of ensuring the quality of service of the national testing laboratories.

The reference laboratory should advise the Competent Authority on the organisation of the laboratory testing system. It should periodically organise comparative tests of standardised samples, and ensuring that all laboratories maintain internal systems of quality assurance

(method validation, record keeping, reagent storage, safety, routine calibration of equipment and introduction of intra-calibration activity). The other main task is the dissemination of information to the Competent Authority and other laboratories carrying out analyses.

A reference laboratory should therefore develop and maintain the capacity to test for a parameter using more than one method. It will be the national centre of expertise on the analytical methods being applied and will promote research to develop new analytical methods and compare them with the existing ones.

It will have a training role and will offer training courses in the different tests to staff from other laboratories (including industry laboratories). At a minimum the reference laboratory will be accredited and it will provide examples of the GLP approach and maintain a Quality Assurance system.

It should also participate in international inter-calibration tests and will maintain and supply standard reference materials and organise the national level tests. It should keep a network of contacts with laboratories in the region and in the main export market countries and will research and divulge up-to-date technical information and documentation. A reference laboratory will also promote inter-calibration both to governmental and private laboratories and provide a forum for discussions on laboratory problems between the Competent Authority, industry and testing laboratories.

As can be seen the role of reference laboratory is one of great responsibility, and is costly to sustain. The nomination of a laboratory as a reference laboratory should be accompanied by the allocation of an appropriate budget by the Competent Authority to allow it to function adequately in these tasks.

Also, it should be noted that the level of expertise required cannot be developed in the short term. The reference laboratory and the Competent Authority will need to work together closely over a period of years to develop the level of analytical expertise required.

6.11 Non-compliance procedures

To ensure that official controls are implemented, there is a need for a procedure to be set out and followed when non-compliances are identified. Without a formal, defined and verifiable non-compliance procedure there is a risk that negative findings from inspections will not be fully corrected and corrections confirmed.

The outcome of the non-compliance procedure should be that either corrective actions are undertaken by the non-compliant horticulture business operator, or that sanctions are applied by the Competent Authority.

The Competent Authority should ensure that the following are in place:

- Clear written procedures which indicate how the Competent Authority will deal with non-compliances detected during inspections, including how the non-compliance is to be notified to the food business operator, and crucially, procedures for follow-up

inspections; all inspectors should be trained in the procedures.

- Classification of non-compliances according to the severity of the health risk; severe non-compliances should be treated more urgently and with stronger sanctions than less severe ones; For example:
  - Critical non-compliance could be a non-compliance which presents a severe and/or immediate risk to public health; critical non-compliances may only occur in establishments in operation
  - Non-critical non-compliance could be a non-compliance which presents only limited or minimal risk to public health
- Inspectors should periodically conduct joint inspections to ensure that there is a consensus on the classification of non-compliances.
- Non-compliances for each establishment should be recorded on a non-compliance record form, which is a key part of the file on each establishment.
- When a non-compliance is detected, preparation of a non-compliance summary record sheet for each establishment, which records the following information in relation to each non-compliance:
  1. Non-compliance Number.
  2. Date of inspection
  3. Details of non-compliance
  4. Severity of non-compliance
  5. Date of notification for correction
  6. Deadline for correction
  7. Date of follow-up
  8. Finding of follow-up
  9. Date of notification for correction
  10. Deadline for correction
  11. Date of follow-up
  12. Finding of follow up
  13. Decision on sanction
  14. Sanction

Record keeping on non-compliances and follow up actions is very important; it should be possible to see at a glance the record of a particular operator in terms of non-compliances identified, corrective actions implemented, and outstanding non-compliances. Key data about the non-compliances are therefore transferred from the inspection record sheet to an establishment non-compliance record sheet.

A follow-up check is required to establish whether the non-compliance has been corrected in

line with the notification. If it has not been corrected then there may be additional steps taken, leading to launch of the sanctions procedure.

Over time such a record (especially if computerised) provides a powerful tool, for example in risk assessment in relation to establishments, or in terms of benchmarking the sector and strata within it. The data may also form part of an annual report, showing the number of non-compliances addressed and providing a verifiable basis for monitoring developments in sanitary compliance and conditions within the sector being controlled.

6.12 Sanctions

Ultimately the official control system should deliver safe food to consumers. This requires the availability of sanction procedures, which aim to remove unfit food from the market, close down unsafe establishments or cause the cessation of unsafe processes.

The sanction procedure must be set out in the legislation and be in line with the future legislation for food safety. Competent Authorities may therefore have several tools available. The choice of tools provided by the law is a key element of official control policy. Some typical approaches are:

Suspension/revocation of approval	Removals licence/approval to operate
Improvement notice	Requires changes to premises, plant, equipment or personnel hygiene
Prohibition notice	Prohibits certain acts or practices from taking place (for example high risk processes)
Emergency notice	For short term actions in case of imminent risk to health where above procedures would not protect consumers
Withdrawal order	Requires food business operator to issue a product recall/ withdrawal to remove suspected non-compliant products from distribution
Seizure of food	Removes a specific item of food from sale
Prosecution	Criminal/administrative penalty for contravention (prison or fine)

Note that the use of prosecution as the exclusive tool for official control is regarded as ineffective, since it allows the establishment to continue operator pending the legal process, and does not prevent others (for example managers or new owners) from continuing the operation of non-compliant businesses at the same premises.

6.13 Reporting and record keeping

6.13.1 Documentary record keeping

Proper records should be kept of all inspections made, along with completed checklists.

In the longer term, this is best kept on a computer database, with the inspector inputting data directly from inspection forms. The database will retain information for each food establishment/ food business operator, regarding:

- Basic identification data
- Licensing information
- Risk classification
- Inspection records (completed checklists)
- Samples taken
- Results of tests
- Non-compliance records (classification, follow-up and outcome)

The system of record keeping creates the basis for monitoring and audit of the food safety control system. It also permits the creation of an annual report on the activities of the CA.

6.13.2 Monitoring indicators

The data system should allow the generation of monitoring indicators from inspection and control records. This allows the performance of the CA to be monitored.

Examples of Key Performance Indicators for official controls may include:

- Average no. of inspections/establishment during one year
- Average no. of critical non-compliances detected/premises
- No. and % of food establishments inspected which are compliant
- No. and % of non-compliant establishments which become fully compliant
- Nos. of notices issued (improvement, prohibition, emergency prohibition and withdrawal orders) and outcomes.

6.13.3 Annual reports

Competent Authorities should seek to publish an annual report on the official controls undertaken in the previous period. In its simplest form this reflects the extent to which the annual control plan was implemented. Typical sections in the annual report will consider:

- Competent authority resources
  - Staff
  - Vehicles
  - Operating budget
  - Sampling and testing budget
- Reporting on some of the monitoring indicators (above)
- Reporting on food poisoning outbreaks/crises
- Plans for the next period

6.14 Official border controls for imported and exported products

6.14.1 Organisation of border control system

In general, the Competent Authority should endeavour to avoid creating parallel control systems for domestic and export markets. Food safety should be a fundamental requirement for products destined to all markets. Imported products should of course comply with national

requirements. Exported products should comply with national requirements, but may have additional requirements set by the regulations of the importing country.

Therefore when dealing with exports there is often a need to ensure compliance with the relevant regulations applicable in the export market. These may differ in the detail from the national system. Furthermore export markets may require different ways of establishing evidence of safety. Therefore the inspectors must be fully conversant with the regulatory framework of the destination market so as to ensure that certification statements are factually correct.

It is also important to note that there are essentially two different kinds of certification:

a) Certification which states something about the nature of the product (for example its composition or a process to which is it has been subject). One example might be that it has been analysed and found to comply with a certain standard e.g. a Codex Standard. Another may be that it has been processed in a certain way (for example that fresh mangoes have been hot water treated to kill fruit fly larvae).

b) Certification which states something about the control system under which the product was produced; one example would be to certify that groundnuts have been produced and harvested in conditions which were subject to routine inspection by the Competent Authority and packed in an approved establishment under HACCP conditions.

The key points to be established in the integrity of any certification system established by the CA are:

- That there is in place a system of traceability which can be used by the inspector to prove that the consignment which is presented for certification has been subject to the relevant conditions or process (and that it is not for example derived from a supply chain which is outside the official control system). It is a common fraud that products from non-authorised sources are intentionally exported under the label of an authorised exporter. Inspectors should be aware of this risk and the tools to be applied to detect it (for example through checks on invoices pad and performing a mass balance on volume of inputs and outputs).
- That once a sample is taken, or a certificate is issued, that there is in place a system which guarantees the integrity of the consignment subject to certification. This eliminates the risk that non-compliant products are added or exchanged with those which are subject to the certification. For example, containers may be placed under seal of the CA, with a final check on seal integrity by port authorities.

6.14.2 Implementation of import border controls for food safety

Typically border control checks for import apply three levels of checks:

- Documentary checks
- Integrity checks
- Physical checks

For imports the inspector may cross check invoice and health certificates from the exporting country, or check that the signature on the export certificate corresponds with the list of authorised signatories for that country. Increasingly CAs place their export certificates online, to allow import authorities to check validity directly.

The integrity check will establish that the products listed in the documentation are physically consistent with those present in the consignment, in terms of both nature and quantity of products.

The physical check will undertake some measurements of critical parameters deemed important for the food safety condition of the consignment. This may include checks on cross contamination risks from previous cargoes, pest control measures, temperature of the cargo. In some cases, the inspector may decide to take a sample for analysis in a laboratory.

6.14.3 Implementation of export border controls for food safety

The Competent Authority should prepare an export certification protocol which sets out the required documentary, integrity and physical checks for each kind of product for each destination market.

Before issuing an export certificate for a specific consignment, a documentary check should be used to establish the consistency of the paper records, invoices etc, to ensure that provenance and traceability conditions are met. For example, the inspector may check the HACCP records for the batch code numbers indicated on the request for certification to ensure that a) HACCP monitoring was carried out correctly and b) process parameters were within critical limits for that batch. Sampling and testing of export consignments should be subject to the requirements of the importing country. Unless it is a specified requirement, the sampling protocol should be based on risk. Most low-risk consignments can be certified on the basis of documentary and integrity checks, and basic physical checks without sampling and testing.

The certification protocol would normally require the specified physical checks to be applied on the basis of frequent sampling of export consignments (thus one consignment in every 100 of ground nut oil may be sampled for dioxins, but one consignment in every 3 of groundnuts for aflatoxins).

As well as establishing sampling frequency on the basis of consignments, the protocol should also set out the sampling procedures and sampling rates within consignments.

In view of these requirements it is clear that in order to perform an effective official control the inspector must be presented with the full consignment, so as to allow for example, a proper sample to be drawn and to check important information (such as temperature of consignment). For these reasons, official controls for export certification must be performed on the export consignment and at the moment of consignment (for example during loading of a container/ vessel). They cannot be performed remotely. Inspectors should use official seals to guarantee container integrity once the batch is inspected.

Special considerations may be required for inspection and certification of processed products consigned in bulk (such as flour, soy meal etc).

The principles to be applied in the design of an effective food import control system are set out by the FAO in the "Risk Based Imported Food Control Manual"[12]. This document provides detailed guidance to competent authorities in shaping a customized plan of action, based on an analysis of their specific country situation, with illustrations on how Codex standards and guidelines can be implemented in border controls. It describes how the options for control measures can be selected and combined to implement a coherent set of import controls to best fit the needs of each country. Particular emphasis is given to risk-based programming in order to support countries in allocating available resources to manage the priority risks.

7. OFFICIAL CONTROL OF INDIVIDUAL ESTABLISHMENTS

This section sets out some of the issues that should be addressed by Competent Authorities when performing official controls on foods of plant origin and establishments in which they are handled, processed, packed and stored.

7.1 Raw material checks

7.1.1 Checks on raw material

Inspectors should check that raw materials of plant origin (both materials directly from the farm, as well as imported raw materials) are safe and free from potential hazards. If there are any relevant national or international criteria required, the inspector should be aware of these and ensure that they are complied with.

In the case of imported raw materials, the inspector should at a minimum check that import documentation, which should include a health certification by the relevant CA responsible for sanitary and phytosanitary border inspections and controls. The certification provides the guarantee that food meets relevant standards and the goods imported are accurately described.

7.1.2 Supplier audits and third-party certification

An important tool available to inspectors in ensuring that raw materials used in processing meet food safety requirements is to check whether the establishment has in place a system of supplier audit. This provides a guarantee that the suppliers have complied with specific standards which include parameters for food safety.

In general for such systems to perform their intended function, the supplier should be audited on a regular basis to ensure they are meeting the specified requirements.

There are different approaches which can be adopted. One the one hand the purchaser can perform the audit directly according to an internal standard. However, this requires a significant investment, and most operators now engage third party certifying bodies to certify compliance against a standard promoted by private operators, in many cases collective groups of food industry operators.

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12 Risk Based Imported Food Control Manual" FAO, Rome 2016, available at http://www.fao.org/3/i5381e/I5381E.pdf (9 March 2021)

Third party certification therefore provides is a clear indication that products are manufactured and handled to a specified standard. This form of certification is neither mandatory nor a legal requirement but indicates the existence of good practice and may be a requirement of the intended final customer for the product.

There are numerous such schemes available. However for processing of products of plant origin, the most relevant requirement is to show that good agricultural practices have been employed during production. The Global GAP Standard is one of the most common standards used by the food industry to demonstrate this. Certification of farms is undertaken by accredited certification bodies, which act as independent auditing companies[13]. Other examples are certification to BRC or ISO2000 standards.

Inspectors should have a good knowledge of the different certification schemes applied in the sector for which they are responsible. In official control of establishments, they should check whether such a certification scheme is in place covering the raw material inputs to processing.

The inspector should also check that the certification is real and not forged, and from an approved third-party certification body with relevant experience and qualifications to provide a third-party audit. The presence of a valid and reliable third-party certification of supplies may also allow the inspector to apply a more limited level of checks on raw material origins.

7.1.3 Plant health checks

Whilst the official controls described in this manual concern sanitary measures (i.e. related to food safety) inspectors should be aware of the need to observe that any requirements applying to phytosanitary (i.e. plant health) conditions are met.

Plant health checks are undertaken to ensure that plants are not likely to transmit important plant diseases or pests. A plant health check may include:

- Documentary evidence of plant heath most notably a phytosanitary certificate (These certificates should conform to the International Plant Protection Convention (IPPC),. This is especially relevant in the case of imported products, where such certificates may be mandatory for certain products from certain regions.
- Checks that the product corresponds with associated documentation
- Verification that plant material is free from harmful organisms

In some cases there may be a requirement for “plant passports” for example under the EU’s new plant health regime[14]. These are essentially plant health certificates which can be issued by growers for a given period following and official inspection. They are required for some products of plant origin which host the most serious ‘quarantine’ pests and diseases. The passport

[13] Global GAP (2012) System Integrity via Certification Body Administration Available from: http://www.globalgap.org/cms/front_content.php?idcat=30 [5th of August 2012]

[14]Europa (2012) Harmful Organisms - Third Country Imports - Inspection of Imported Products Available from: https://ec.europa.eu/food/plant/plant_health_biosecurity/non_eu_trade/inspections_en [9th of March 2021]

facilitates its movement across international borders and between zones with different plant health status. The inspector should be aware of the kinds of products subject to such controls and apply checks during official controls.

7.1.4 Transportation

Food may easily become contaminated during the transportation phase if not handled correctly. This is especially important for raw materials, where product is often transported in bulk, without the benefit of packaging to protect it from contamination. It is therefore important that vehicles used in transport are under official control. It should be noted that sanitary requirement apply to all forms of transportation including motor vehicles, rail transport, vessels or and other form of vehicle used in the transportation of foods.

Inspectors should be aware of regulations laying down any specific requirements for the transportation of feed and foodstuffs including those of plant origin. Some of the key requirements to be checked are that:

- conveyances and/or containers used for transporting foodstuffs are to be kept clean and maintained in good repair and condition; they should be designed and constructed to permit adequate cleaning and/or disinfection.
- vehicles and/or containers should not to be used for transporting anything other than foodstuffs especially in the case of bulk foodstuffs in liquid, granulate or powder form
- where necessary, conveyances and/or containers used for transporting foodstuffs should be capable of maintaining foodstuffs at appropriate temperatures and have a means of monitoring temperatures

An inspector should also examine transportation practices to ensure that these cannot potentially damage or compromise the product in such a way as to present a hazard. An inspector may wish to view the loading or unloading of goods to ensure that all relevant procedures and practices required are being implemented[15].

The inspector may also check records surrounding transportation to confirm:

- compliance with specific transporting conditions ie temperature records or moisture/ CO_2 levels
- vehicle cleaning records
- records of previous good carried

Certain products of plant origin may require special transportation considerations for example fresh and leafy vegetables may require refrigeration and atmosphere controls to prevent deterioration. Some products of plant origin may require transportation that minimises the risk of water activity such as herbs, spices, legumes, groundnuts and a variety of grains as these products are susceptible to toxigenic moulds growth.

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[15]U.S food and drugs administration [FDA] (2012) Investigations Operations Manual (Establishment inspections) Available from: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references [9th of March 2021]

7.2 Checks on processing and packing establishments

7.2.1 Establishment location and layout

The design and construction of the establishment is important to the hygienic handling of produce and inspectors should ensure that requirements are met in terms of[16]:

- **Location:** the general nature and conditions of the area surrounding a food processing establishment may significantly impact the hygiene of the product. For example factors such as the proximity of rivers and other water courses, proximity to sources of airborne pollution or dust should be examined
- **Size and layout:** Size must be appropriate to the dimensions of the production, without overcrowding. Layout should consider hygiene product flows, without crossing of lines and with separation of raw from ready to eat or cooked products. The positioning of equipment should be position to allow for easy access for operators, any necessary maintenance and that the equipment and surrounding areas may be cleaned and sanitised in a suitable manner

7.2.2 Storage facilities

Subject to the specific process requirements, in general the processing establishment should possess adequate facilities for storage of:

- raw materials
- other food ingredients storage for additives and other ingredients.
- chemicals which may potentially be considered contaminants (cleaning and sanitising materials, lubricants, hydraulic fluids etc.)
- packaging materials
- final products

The storage of both the raw materials and the final products can significantly impact on the safety and the quality of a product, and some foods of plant origin present particular hazards from poor storage conditions. An inspector should take into consideration storage conditions ensuring they are suitable for the product and note storage patterns, general stock rotation and the housekeeping of the storage areas. All raw materials and final products should be easily assessable for inspection and there should be no evidence of adverse conditions present such as rodent or insect infestation.

7.2.3 Plant construction

Construction of the establishment is another critical area to be checked during official controls. Some of the main factors to be considered are:

- Hygienic design and materials; the establishment's walls, floor, ceiling, windows, wiring, piping etc should all be designed hygienically to avoid dirt traps, and be constructed of

[16] Codex Alimentarius, (1969, revised 2003) General principles of food hygiene Available from: www.codexalimentarius.org/input/download/.../23/CXP_001e.pdf [10th of August 2012]

materials which are smooth, impermeable and easy to clean. Inspectors need a good level of technical knowledge to be able to identify deficiencies in these elements.

- Lighting should be sufficient, with higher levels of illumination over key areas. Inspectors may check lighting levels with a light meter.
- Ventilation: should be adequate, especially in areas where the process generates significant heat and water vapour (for example steaming/cooking). Checks should be made on the functionality of extraction systems. Inspectors should check to ensure that water vapour does not condense on surfaces, and present a risk of contamination of food. Attention also needs to be paid to proper ventilation of storage facilities, where excessive moisture may lead to the growth of pathogenic organisms and mycotoxins. Inspectors should check that air can circulate around the products (i.e. stored on pallets, with gaps between them for air circulation.
- Maintenance: when viewing a plant or production facility and inspector will wish to check the plant for any form of defect such broken windows, lack of insect screening, damage to walls, floors and ceilings or any other defect that may potentially lead to hygiene failure. It is important to establish who is responsible for repairs and maintenance[17].

7.2.4 Provisions of sanitary facilities

Sanitary facilities should always be checked against requirements since they are key to ensuring the basic hygiene of the establishment. Checks should be undertaken to ensure that:

- There are adequate numbers and types of toilets and hand washing facilities (sufficient to avoid congestion and long waits to use tem) and that there is adequate separation between toilets and food handling areas
- Hand washing facilities are located in places where they must be used (toilets, staff entrances, work areas)
- There is an adequate water supply of both hot and cold water, soap and hand drying facilities
- There is adequate provision for the disposal of both liquid and solid waste
- Adequate changing facilities are provided
- That suitable measures are undertaken for the correct cleaning and sanitisation of any protective clothing worn which may include the provision of laundry facilities or the use of a suitable contractor[18].
- The facilities are clean

7.2.5 Hygiene of equipment and utensils

The hygiene of equipment and utensils should be checked during official controls, to ensure that

[17]Codex Alimentarius, (1969, revised 2003) General principles of food hygiene Available from: www.codexalimentarius.org/input/download/.../23/CXP_001e.pdf [10th of August 2012]

[18]U.S food and drugs administration [FDA] (2012) Investigations Operations Manual (Establishment inspections) Available from: http://www.fda.gov/ICECI/Inspections/IOM/default.htm [10th of August 2012]

their design and construction meets requirements and that they are kept in good condition. The inspector should therefore check:

- That equipment is designed, constructed, and installed in such a way as to allow for correct maintenance and sanitation
- That equipment is appropriately cleaned, maintained and stored to ensure sanitary conditions
- That records are kept of sanitisation and maintenance of equipment and utensils
- Where products of plant origin are processed using corrosive substances (such as pickling brine and vinegar) that process equipment and materials are non-corrosive[19].

7.2.6 Hygiene of personnel

Poor personal hygiene practices can render even the best establishments dangerous, so inspectors should take special steps to check that all personnel working at any stage of food processing should maintain a high standard of personal hygiene while on duty.

Good personal hygiene practices that should be observed include:

- Clothing including headgear and footwear should be suitable for the operation being undertaken and be kept clean
- Hands should be washed as often as required to maintain sanitary conditions
- Unsanitary practices such as chewing, smoking, spiting, eating and drinking in the food production area should be prohibited.
- Adequate first aid procedures should be in place to deal with minor injury's such as cuts and abrasions
- Food handlers should be free from communicable disease gastro-enteric and skin and should not be involved in food processing until they have been declared medically fit or have been free of symptoms for a sufficient period

An inspector should observe staff carefully, noting the state of their attitudes and actions throughout the inspection process ensuring compliance with the conditions stated above. The inspector should also therefore determine the type, duration and adequacy of the establishment's training programs and any documentation associated with the training and the facilities personal hygiene policies.

Additional focus should be placed by the inspector on these checks when ready to eat products are being processed, as these may not be subject to further processing that could remove any hazards that might be introduced during the process.

7.3 Checks on water supply

Water quality is a key issue in the processing of products of plant origin. Water can present a variety of hazards and can carry chemical, physical or microbiological contamination. Tests should be undertaken to ensure the water used in processing meets the national or international

[19]Codex Alimentarius, (1969, revised 2003) General principles of food hygiene Available from: www.codexalimentarius.org/input/download/.../23/CXP_001e.pdf [10th of August 2012]

requirements for water quality (such as Codex Alimentarius or WHO standards). These set limits for heavy metals, chemical contaminates like pesticides and herbicides and for a wide variety of pathogenic organisms associated with water. Inspectors should be aware of the innate quality of the water in the areas they are responsible for.

Water may be used for a variety of different post-harvest processing activities including washing, rinsing, blanching, cooling, chilling or a means of transportation. Generally water used in processing should be potable, although clean fresh water may also be used for primary processing (such as washing, removal of gross contamination, soil etc). Water used in secondary and tertiary processes and for inclusion in the product should be potable. This is a critical point in the production of ready to eat foods.

There are various official controls that should be undertaken to ensure the quality of the water meets requirements:

- Water sampling of water sources to assess microbial quality of water used
- Proper application of any necessary procedures to ensure or prevent contamination of the water supply i.e. proper arrangement and routine cleaning of storage tanks, separation of waste and potable water, backflow devices to prevent contamination.
- Checks to ensure that water treatment functions correctly to maintain or improve water quality (such as UV treatment , chemical treatment, filtration or any other suitable safety procedures). This should include checks on maintenance and inspection records for any equipment used in the treatment of water used as part of the production process. More details are provided below.

Chlorination and UV treatment are the two common treatments applied to water to ensure that it is potable. It must be noted that it is better to prevent a water source from becoming contaminated in the first place, than to actively rely on any form of treatment. In this case treatment provides the safeguard.

The active element in chlorination is the hypochlorite ion (OCl). This can be typically applied by the use of gaseous chlorine, or by addition of a solution of sodium or calcium hypochlorite (the principal component of household bleach). The use of hypochlorite is highly effective and a relatively inexpensive and common form of water treatment. However, it is easily inactivated by organic material in the water, and requires at least 30 minutes of contact time to be effective. As a result, checks should be made to ensure that there is a residual free chlorine at the point of use. Municipal water supplies are often chlorinated, however the establishment should check and undertaken additional treatment if necessary. The monitoring of chlorine levels should be carefully documented and recorded by the establishment to ensure safety and allow for corrections if an issue develops. Records, processes and corrective actions should be checked during official controls to ensure that all relevant safety procedures are being complied with. Additional checks on water chlorination may be undertaken by the inspector with relatively cheap and easy to use colorimetric test kits.

Ultraviolet irradiation treatment is a common method of treatment for water in which the water passes through a treatment chamber where it is passes in front of a UV fluorescent lamp. The UV

radiation kills bacteria and viruses. However the UV lamps have a finite life, and the key factors in official control of such systems is to ensure that bulb usage is monitored and that it is regularly replaced in accordance with manufacturers recommendations. Water flows should also be checked to ensure that the correct exposure levels are being reached. In regions where power supply is not reliable the inspector should check that the power source remains uninterrupted.

Both of these systems should be supported by maintenance records and sampling of water for microbiological testing to provide evidence that the systems are operating effectively. If a treatment fails or the water does not meet the criteria needed for the production process the production should not continue until an appropriate substitute has been found or the issue corrected.

7.4 Checks on additives

There are a wide variety of additive treatments available to food processors which perform various functions in the product (such as preservatives, anti-oxidants, emulsifiers and stabilisers, colours etc). In general additives are generally strictly regulated by national or international regulations. Regulations may express non-permitted substances (in which case certain substances are banned). Regulations may also provide permitted lists, with some additives allowed to be applied subject to certain limitations (for example in specific products and within maximum limits in the final product). Some additives may be used relatively freely in a wide range of products, subject to principles of good manufacturing practice. Others may be species or product specific. The regulations on additives may be regularly revised. Whilst detailed knowledge of all additives is a specialised subject, inspectors should be aware of the key elements of the control of additives, and be able to locate information regarding compliance.

The key point for official control is to check to that that any additives applied to products are permitted to be used, and that they are applied in accordance with the legal requirements. Inspections should always include a check on ingredients and chemical stress and to record what chemicals are in use. Records should show precise dosages applied to each batch.

A particular problem in some countries is the use of unauthorised additives. Typically certain unauthorised chemicals are commonly used as functional ingredients because they are cheap, widely available, effective and/or easy to apply. Some common examples are the use of hypochlorite solution to reduce bacteriological loads on foods, the application of illegal dyes such as Sudan Red to colour spices and sauces or the addition of melamine to boost nitrogen levels and apparent compliance with minimum protein specifications. With some fruits, acetylene (generated from the action of humidity on calcium carbide) may be used as a ripening agent. The problem is that these additives present health risks to consumers and these applications are therefore banned. The inspector should be aware of the most common malpractices in the sectors in which he or she is performing official controls.

However, it should be considered that it is not simply a matter of ensuring that illegal additives are not used, or that maximum levels of legal additives are not exceeded. In some products, the correct use of additives can be also regarded as a critical point in the process and provide an essential protection against potential food safety risks. One example would be acidifiers and

acidity regulators in fruit drinks, which helps to maintain the correct pH to prevent the risk of growth of *Cl.botulinum*. Inadequate control of food additives may therefore lead to a final product that may present a serious microbiological or chemical hazard. The inspector should therefore ensure that:

- No unauthorised additives are used in the process
- A written formula is available for any additive used and additional information required for its safe usage, for example the concentration of an additive and specific ingredients.
- The additives used in the production process meet the requirements of any relevant food safety legislation.
- Relevant documentation is available such as additive specifications, data sheets, dose levels, and certification from additive manufacturer confirming quality of product
- Calculations have been performed to ensure that the correct dose of the required additive is being used and is within the maximum levels specified by food legislation.
- Relevant controls are in place to ensure the correct amounts of additive are added to the product, that they are correctly distributed throughout the product and that any other procedures relevant to the product are in place and being followed correctly.
- The storage of additives is appropriate and in line with basic hygiene requirements and ay specifications lay down by the manufacturer.

If it is suspected that an additive is being used incorrectly, inappropriately or against national legislation then action must be taken as the misuse can potentially lead to serious health issues.

Finally, if the inspector suspects that additives are being misused by the establishment, then he/she should consider taking a sample for subsequent laboratory analysis to confirm the suspicion.

7.5 Checks on internal control systems

7.5.1 Checks on pest controls

Food processing establishments should be free from pests including rodents, birds, and flying and crawling insects due to the risk of contaminating or damaging the product. To ensure that this is the case they should possess a written pest control plan (a pre-requisite for HACCP). The role of the inspector in official controls is generally to check that the plan is adequate and that it is implemented effectively.

Products entering the facility should be carefully checked to ensure that no form of pest contamination is present in incoming goods as this is a common source. Food should be stored in such a way as to discourage pests and allow for easy inspection.

An inspector should be able to see records of regular pest checks and the routine and *ad hoc* pest control actions undertaken. The inspector should also check the establishment's capacity to correctly store any pest control equipment or chemicals used. In general such items should be kept in a separate storage area which should be kept clean and in good order.

In particular an inspector should check that:

- The facility is free from signs of pests such as excrement, larval cases, dead pests, pest

damage to produce or structure

- That the product is stored and produce in a way that minimises risk or pests and allows for easy inspection for pests
- Any pest control measures taken are effective an appropriate to the problem
- That any records relating to pest control measures such as contractors reports, maintenance schedules, product checks and inspection records are up to date and have been checked by the responsible party.
- That any pesticides that are being used are appropriately stored and used in such a manner as to prevent contaminating the product.

If any evidence of pests is found by an inspector then appropriate action should be taken, including a review of the pest control plan.

7.5.2 Checks on cleaning and sanitization systems

The cleaning and sanitation of a processing establishment is one of the basic hygienic operating requirements and potentially impacts every stage of production.

The establishment should have detailed written procedures set out for the cleaning of the facility, equipment and utensils with the main objective of removing any form of contamination present that might present a potential hazard to the product. The possession and implementation of an effective cleaning and sanitizing plan is a pre-requisite to HACCP.

Cleaning generally consists of the use of some form of appropriate detergent and physical means to remove residues or odours.

Sanitization is the disinfection of an object used in the production process, and is generally achieved either through chemical or thermal treatment[20].

An inspector will wish to see a clearly documented regime for the cleaning and sanitation of all parts of the establishment, its facilities and equipment. A documented system may include any key factors like cleaning methods, frequency of cleaning, cleaning chemicals used, safety data sheets, staff training records, specific cleaning instructions for more complicated equipment and inspection sheets.

All documentation should be up to date and have been checked and updated frequently. Theoretically it should be possible for an outsider to view the system and be able to follow the cleaning procedure.

The inspector will wish to confirm during official controls that the procedures are being appropriately applied. This may be done through:

- Visual inspection of equipment (it should be free of obvious contamination or residue)
- Visual observation of practice and staff to ensure procedures are undertaken fully and correctly

[20]Schmidt, R H. (2012), Basic Elements of Equipment Cleaning and Sanitizing in Food Processing and Handling Operations Available from: http://edis.ifas.ufl.edu/fs077[Accessed 20 August 2012].

- Taking hygiene swabs from relevant surfaces to check whether cleaning and sanitation is effective

Any cleaning and sanitation products should comply with national or international regulations.

7.5.3 Checks on Hazard Analysis Critical Control Points (HACCP) systems

An essential element of the official control in the processing of products of plant origin is the check that the operators has in place an effective system for managing food safety hazards. The typical requirement is for a system which employs the principles of the Hazard Analysis and Critical Control Points system, known as HACCP[21].

HACCP is food safety management system based on 7 separate principles. The wording varies depending on who is defining the system, but the core principle remains the same. EC regulation 852/2004 offers a good official definition of HACCP principles as follows:

(a) Identifying any hazards that must be prevented, eliminated or reduced to acceptable levels;

(b) Identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels;

(c) Establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;

(d) Establishing and implementing effective monitoring procedures at critical control points;

(e) Establishing corrective actions when monitoring indicates that a critical control point is not under control;

(f) Establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively;

(g) Establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).

These steps should create a strong well documented preventative system that should be easily applicable to any form of food business or producer. The important point for official control is that the system is auditable.

HACCP plans are specific documents which apply only to the process and establishment in which they are implemented. Because of the huge flexibility of the HACCP system, the plans will vary hugely between manufacturers and producers depending upon the nature and type of the product produced. However there are elements in common that an inspector should assess. In general the inspector should be able to check that:

- The development of the HACCP plan has followed established procedures (which may be set down in the regulations)
- The HACCP plan as documented is scientifically valid, and that this has been confirmed

[21]Food and Agriculture Organisation of the United Nations, FAO, (1998), Food quality and safety systems. A training manual on food hygiene and the Hazard Analysis and Critical Control Point (HACCP) system. Available from: http://www.fao.org/3/w8088e/w8088e.pdf [Accessed 9 March 2021].

and periodically re-confirmed
- The HACCP plan is implemented correctly and in line with the documentation

However before auditing the system, the inspector should be satisfied that all of the pre-requisite controls are in place. This means that there should be compliance with hygienic and sanitation requirements (such as Good Manufacturing Practices), along with proper maintenance, pest controls, training, sanitation and traceability systems, many of which are discussed in further detail elsewhere in this document.

An inspector should expect to see a fully documented HACCP plan for each product/plant species concerned, which should contain at a minimum:

- description of the raw material, origins, product and process, composition, packaging, distribution, validity, storage conditions etc
- adequate nomination of HACCP team and allocation of responsibilities
- document describing critical points and controls
- other potentially pertinent documentation relaying to the process, including charts showing the plant layout / products, materials and personnel flow
- description of batch identification codes providing suitable traceability
- description of end users and potentially sensitive consumers with adequate instructions provided for the distribution, storage and utilisation of the product

In terms of the content of the plan the inspector should check that the HACCP Principles have been correctly applied in a manner consistent with scientific evidence. The inspector should therefore consider whether:

- all relevant hazards which present a realistic risk to consumer health have been considered at each step
- preventive measures are correctly identified to ensure control of each relevant hazard
- critical control points (CCPs) and preventive measures are correctly identified
- critical limits are established taking into account published or experimental evidence
- a monitoring procedure is established for each critical parameter which specifies what to check, where, when, how, who, frequency of monitoring and data recording system
- corrective measures are established for each critical parameter and that these are realistic and effective (including appropriate treatment of non-suitable products)

In addition to ensuring the validity of the plan, the inspector should also check to see that the plan is implemented. This means checking that the required critical process variables are in fact monitored, that data is recorded, and specified corrective actions taken when critical limits are reached, and that the plan is periodically re-validated.

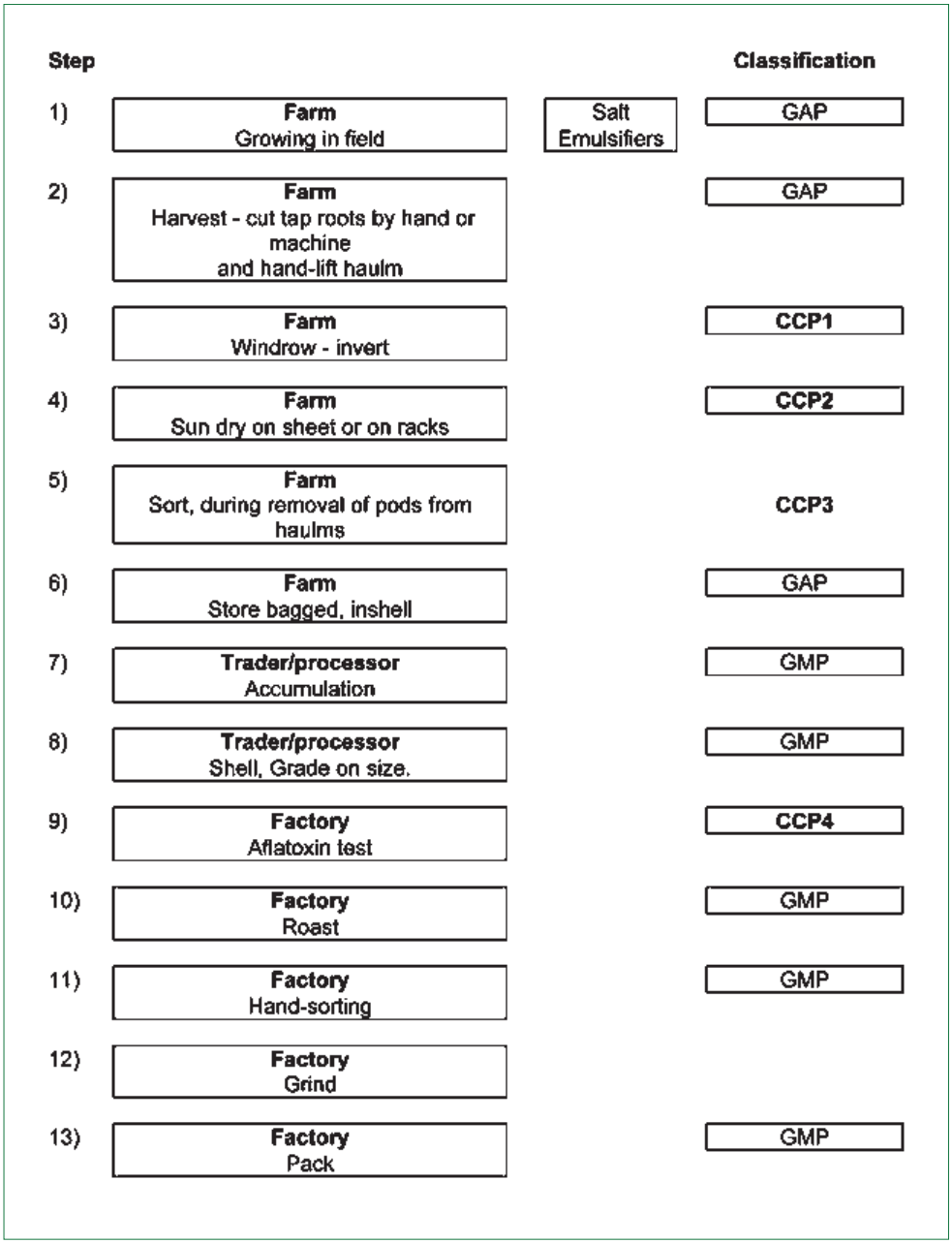
In general, checking the validity of the plan is only undertaken during in-depth inspections, and periodically thereafter when for example there is a change in the product or process. The inspector should check the implementation of the plan on a more frequent basis, with the most frequent checks being that adequate records are kept. If the operator cannot provide relevant documentation, then the system is not correctly implemented and this could result in a risk to consumer health.

To verify that the HACCP system is being implemented correctly the inspector may wish to make some measurements of his/her own. In HACCP plans for the processing products of plant origin, many of the critical variables applied by the food industry relate to time and temperature, acidity, water activity, and salt and sugar content. Most of these process variables can be checked with relatively simple equipment (either on the spot or in a basic laboratory). Inspectors should be familiar with the use of equipment such as probe or infra-red thermometers, refractometers, pH meters or colorimetric comparators, and conductivity meters etc. Simple and cheap equipment (and especially thermometers) can greatly assist both in the evaluation of the HACCP plan, and allow the inspector to cross check the calibration of the establishments' own instrumentation systems.

The inspector may also wish to review the results of the food business operators own sampling and testing regime to ensure that HACCP system is performing effectively. If at any stage, the inspector identifies a problem in the HACCP system which gives rise to doubts regarding its efficacy, the inspector may wish to take an official sample for testing.

Official control of HACCP is perhaps one of the most technically challenging elements of the work of the inspector. It demands a scientific knowledge of the hazards which may arise in a particular product or process, and the conditions under which they may be controlled. It also requires knowledge of the capacities of the process technology and engineering systems employed. It also requires that the inspector has full awareness of the implementation of GAP, GMP and HACCP controls systems along the supply chain.

An example which illustrates the system level checks to be addressed in official controls throughout the supply chain is provided in Figure 1.



Source: Manual on the Application of the HACCP System in Mycotoxin Prevention and Control FAO/IAEA Training and Reference Centre for Food and Pesticide Control Rome, 2001 Reprinted 2003[22]

Figure 1: Example of GAP, HACCP and GMP controls for production peanut butter

7.5.4 Checks on traceability

The Codex Procedural Manual defines traceability as "the ability to follow the movement of a food or feed through specified stage(s) of production, processing and distribution". The movement of a product can include the origin of a product and of its component parts, as well as what has happened to it along the way. In practical terms it means: the ability to know where the product has originated, and what has happened to it.

[22]Can be downloaded from http://www.fao.org/docrep/005/y1390e/y1390e00.htm#Contents

Traceability is critical for consumer protection since it allows tracing back to the beginning of the supply chain. It thus provides a mechanism for identification of the origin of unsafe foods and correction of the circumstances which gave rise to the problem. Through tracing forward from this point traceability also provides the ability for food business and Competent Authorities to ensure the withdrawal and recall from the market of potentially harmful products affected by the same circumstances.

A good traceability system will comprise several elements of data record keeping regarding transfer of ownership (purchase and sell) and product flows within the establishment The official controls should check documents that include the following information in relation to a specific batch:

- Names and addresses of the supplier and customers
- Origin of product
- Volume and quantity of product
- Nature of product (i.e. raw or Processed)
- Delivery dates and records
- Batch numbers and sort codes
- Detailed description of product

The traceability system should also contain a detailed recall plan, to allow the food business operator to trace and physically recall from the distribution chain any batch product in which food safety hazards may potentially be present. This system should be tested on a regular basis to ensure that the system is effective throughout the supply chain and official controls should check that this is done.

There may also be some national or international system in place to help Competent Authorities implement this process across international boundaries. In the EU the Rapid Alert System for Food and Feed (RASFF) is a system that facilitates and coordinates the transfer of information that is key to tracing non-compliant consignments of food products through the food chain[23].

7.6 Special considerations for official controls on some specific products/processing operations

Some products of plant origin present more specific and higher risk of food safety hazards than other products. As such, special consideration must be given to these products where official controls seek to manage the risk through specific checks.

7.6.1 Herbs and spices

Herbs and spices like most products of plant origin can potential present a number of different hazards including pesticide or herbicide contamination, infestation with insects, foreign objects, contamination with plant or mineral material, poor microbial quality and a susceptibility to moulds, including mycotoxic varieties[24].

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[23]More information on this is available at: http://ec.europa.eu/food/food/rapidalert/index_en.htm

[24]Matthews, M. and Jack, M. [FAO] (2011), Herbs and spices for a home market Available from: http://www.fao.org/docrep/015/i2476e/i2476e00.pdf [10th of August 2012]

Also some herbs and spices are ether used directly on foods, either in a raw or in a dried form, which means that after initial processing little or nothing will be done to reduce the potential microbial hazards. Even if dried, they may only undergo minimal heat treatment during the drying process, as strong heat treatment may alter the flavour and nature of the final product. Official controls may therefore need to consider such products as ready to eat foods which demand special hygienic considerations (see below).

If the product is not adequately dried after harvest or is subject to adverse storage conditions at any stage during the supply chain, there is potential for the growth of moulds associated with aflatoxins. Typically, specifications for such products should state a maximum moisture content or water activity for safety (i.e. below which the relevant hazard cannot develop). This is checked by sampling and analysis, and the official controls should regard this kind of inspection as a high priority. Since such products may also be susceptible to heavy metal contamination and application of banned additives import control authorities will usually require sampling and testing of herbs and spices upon importation.

7.6.2 Ready to eat foods

Food that is considered as ready to eat will receive no further processing or cooking which might normally be expected to eliminate heat sensitive hazards before consumption. In all cases the inspector undertaking the official controls should consider all possible end uses of the product concerned. Some ready to eat products include:

- Cut fruit
- Fresh salad vegetables
- Fried or roasted snacks (plantain or cassava chips, roasted nuts)
- Dried fruits (of all kinds)
- Herbs and spices
- Seeds produced for salad sprouts

The inspector should give careful thought to the potential end uses of the product, to consider whether product will be consumed without further processing, with or without peeling etc. Examples are beans and spices which are traditionally consumed after cooking by the consumer. However, beans may also be used for salad sprouts, and spices may be used as table condiments. A case study of such an outbreak is described in the box below

E.COLI OUTBREAK IN EUROPE TRACED TO SPROUTED FENUGREEK SEEDS[25]

In 2011 a sudden increase in the number of cases of severe haemolytic food poisoning outbreaks in France and Germany were associated with a shiga toxin- producing *E. coli* 0104:H5. This is a rare serotype of *E.coli* associated with fresh salad vegetables. Initially the outbreak was blamed on cucumbers produced in Spain but the outbreak was later traced to a sprouted seed producer based in Germany. When examined this plant met the hygiene prerequisites required for the hygienic production of food. The suspected source of the outbreak when traced back to the producer was freshly sprouted fenugreek seeds that had been imported for Egypt and were likely contaminated with faecal bacteria prior to their growth in Germany. This outbreak lead to over 50 deaths and 4000 others suffering from a range of symptom ranging from the relatively minor up to long term kidney damage. Any producer or manufacture of sprouting seeds needs to be aware of the risks associated with this product and take appropriate actions to minimise them and ensure that hygiene conditions are appropriate to ready to eat foods. There is also a need for a robust traceability system to allow for fast identification of the source of an issue.

Some products of plant origin that are considered as ready to eat may undergo some other form of processing by the consumer such as hulling peeling or washing which removes potentially harmful agents. Some ready to eat foods may be considered potentially hazardous and as such require controls such as low temperatures or low moisture contents to ensure there continued safety. Many countries operate comprehensive sampling regimes on products they consider to be hazardous and this is a key part of any national control system dealing with ready to eat foods when considering there microbiological safety[26].

A key example of a ready to eat food that has a demonstrable history of presenting a health hazard is sprouted seeds often used in salads. These have been associated with a variety of pathogens including *E.coli*, *Salmonella spp.* and *Listeria monocytogenes*. Footnote 20 illustrates the importance of such controls.

Where ready to eat foods are minimally processed (for example cut fruit, or salad sprouts) special considerations need to be given to both to:

a) minimise the risk of pathogenic organisms contaminating the product (the application of GAP in production, special post-harvest treatments and aseptic packing techniques for example) and

b) the application of additive or other treatments which may reduce or eliminate the hazards (for example the application of potassium permanganate treatment for salads, or the use of sodium metabisulphite in cut or peeled fruits).

These are specialised areas and require the inspector to possess the scientific and technological

[25]European food safety authority (2011) Shiga toxin-producing E. coli (STEC) O104:H4 2011 outbreaks in Europe: Taking Stock Available from: https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/j.efsa.2011.2390 [9th March 2021]

[26]Health Protection Agency [HPA] (2009) Guidelines for Assessing the Microbiological Safety of Ready-to-Eat Foods from: https://www.gov.uk/government/publications/ready-to-eat-foods-microbiological-safety-assessment-guidelines [9th March 2021]

expertise to assess the efficacy of the process applied by the establishment and to apply the necessary official controls, including sampling and testing where required.

7.6.3 Low acid canned foods

Low acidity canned foods (with a pH of 4.6 or below) present the ideal environment for the growth of *Clostridium botulinum* an obligate spore forming anaerobe which produces a potent neurotoxin. The toxin has no odour or flavour, and *Cl.botulinum* itself does not produce gas, so cans and the product in them may appear normal[27].

There are various factors and considerations that should be undertaken to prevent the occurrence of this hazard. The official controls should check that:

- can seam dimensions are within proper tolerances
- heat processing is sufficient to eliminate practical risk of survival of heat resistant spores of *Cl.botulinum*
- proper heat processing records are kept
- cooling water is treated to prevent micro-organisms from entering the can via the double seam during its cooling phase

It is important to remember that the heat treatment and the acidification of the product are the key controlling factors for this type of product and any disruption in these processes may cause a potential serious health hazard. Given the potentially direct lethal consequences of failure of internal and official controls, this is a vitally important task. More detailed information of how to dealing with this type of product can be found in the Codex Alimentarius Code of hygienic practice for low and acidified low acid canned goods (CAC/RCP 23-1979)[28].

8. NATIONAL SURVEILLANCE OF PROCESSED PLANT PRODUCTS

8.1 Reasons for surveillance

National surveillance is a risk assessment activity, and is used to assess the degree of compliance of foods with the national safety requirements. It forms an important element of the risk assessment activities undertaken by Competent Authorities, and therefore complements official controls. As a part of the monitoring system it allows the Competent Authority to improve the effectiveness and efficiency of the official control system by providing data which allows control resources to be focused on areas of weakness in the system, and where significant risks to consumer health are most likely arise.

The output of the surveillance system is therefore an adjustment of the official control actions of the Competent Authority. It may result in a change in procedures or in the re-allocation of inspectors to areas identified with emerging hazards. Normally, non-compliant product identified

[27]U.S food and drugs administration [FDA] (2012) Guidance for Industry: Acidified Foods Available from: www.fda.gov/downloads/Food/GuidanceComplianceRegulatoryInformation/Guidance Documents/AcidifiedandLow-AcidCannedFoods/UCM227099.pdf [5th of August 2012]

[28]Codex Alimentarius, (2011) Code of hygienic practice for low and acidified low acid canned foods Available from : http://www.fao.org/input/download/standards/24/CXP_023e.pdf Accessed [9th March 2021]

in surveillance programmes do not lead to a launch of legal procedure, but result in a follow up investigation to identify the origin and reasons for the non-compliance. This leads to a risk assessment and a subsequent risk management decision regarding what, if anything, should be done to address the problem in future.

In products of plant origin, the surveillance programme will address the common hazards which arise during the production. It is important that they consider all stages of production and processing, including possible hazards arising from agricultural inputs such as pesticides and fertilisers. They will also seek to identify common hazards such as mycotoxins, illegal additives, residues of heavy metals and microbiological contaminants.

8.2 Sampling approach

Typically sampling for surveillance purposes is undertaken at the level of the market (i.e. final products). This means that samples are usually taken from retail or catering outlets. However, it may also be necessary to take samples during the production and processing stages (usually when seeking to identify the use of unlawful substances, such as a prohibited pesticide).

The supplier of the sample is therefore not necessarily the person responsible for any food safety non-compliances in the product. Many legal system approaches to food safety provide defences related to non-compliances which are the fault of another, or where the operator exerts due diligence, or otherwise takes steps to guarantee product safety such as warranty clauses in the contract terms. This is one of the reasons why surveillance results cannot be used as the basis for legal action against non-compliance.

Sampling is usually stratified by product, process, region and sometimes origin (for example import/national products). This means that the design of the sampling frame (number of samples and the parameters to be assessed in each case) will be focused on certain areas at the expense of others. This is essentially a policy decision and should reflect other risk assessment information (such as previous studies, health indicators, consumption trends, concerns arising from official control, international trends etc).

Sampling procedures should follow the technical requirements for preserving the conditions of the sample. Normal protocols regarding recording of data and preservation of sample identity and integrity should be followed. However, since the process is not one of official control, sampling does not have to be undertaken by an authorised inspector (surveillance sampling is often contracted to external bodies), nor does it require that sampling procedures set out in laws governing official controls be followed (such as division of sample).

Surveillance is frequently limited by resource availability, and this is expressed in the number of samples and the types of tests to be undertaken. The Competent Authority should set out the relative priorities (in terms of expenditure proportionate of the different products/hazard combinations, according to the prevailing interest and demand for information), and these priorities are then applied to the budget available.

It should also be considered that a single sample may be used for testing for several parameters. For example a single sample of ground chilli pepper may be submitted for tests for heavy metals,

mycotoxins, illegal colours and microbiological contamination. In this way sampling costs may be reduced.

8.3 Testing methods

It is not always necessary to apply the official testing method to the analysis of all samples for the surveillance programme. Such tests may be more time consuming, and demand a higher level of analytical inputs, and are therefore often more expensive. Testing in surveillance programmes often therefore applies an analytical cascade, which employs one or more screening tests. These tests are usually quicker and cheaper than the official test method, but lack the level of validity and reliability required for official testing. The screening test is used to select which samples go forward for testing by the official test. One example is the multi-residue testing approach for identification of excess levels of pesticides.

They therefore provide an indication of compliance, and by a judicious choice of protocol (for example selecting non-compliant and border line samples, plus a proportion of compliant ones at screening) the impact of false negative results can be minimised. False positive results of screening will be identified in most cases by the subsequent official test.

The results, even from screening tests must be as reliable as possible, since they inform national risk management decisions. Therefore all testing in laboratories for surveillance programmes should take place in laboratories which are accredited to ISO 17025.

8.4 Follow up on surveillance results

When non-compliance is identified through the surveillance programme, the Competent Authority should follow up with a view to investigating the circumstances which gave rise to the non-compliance. This will invariably mean returning to the business operator who provided the sample, conducting an interview and examining any relevant records. In many cases, if the sample was taken at retail or wholesale level, the Competent Authority may need to trace back through the supply chain and conduct the investigation at each transaction level, sometimes at the processor/packer or at the farm level. This may also involve investigations which cross international boundaries where the corresponding Competent Authority is requested to conduct the follow up.

The objective in all cases is to identify the circumstances which gave rise with regard to the non-compliance, describe them fully and consider what changes to the official control system could be applied to prevent a recurrence in future. Finally the CA should consider whether such changes should be applied, this being a risk management policy decision determined by practicality, best use of resources or other considerations. It should always be borne in mind that no control system can guarantee that all risks are controlled all of the time, and that random events can intervene to cause non-compliances. Sometimes it is not possible to identify the cause of the non-compliance due to lack of evidence

8.5 Reporting and use of results

The Competent Authority should always publish the results of the surveillance programme, since it can provide a useful guide to the implementation of internal controls by food business operators in the supply chain, as well as valuable information for consumers, health professionals and others concerned about the health status of the national diet and associated risk assessment data.

The data base of findings provides scientific basis for formal risk assessment activities since it provides scientifically valid data regarding the presence and level of hazardous agents in different categories of foods. Combined with consumption data, this allows risk assessors to compute the exposure of different groups of consumers to the hazard concerned. Once exposure is known, this can be assessed in combination with toxicological data regarding the hazard to allow the risk assessment to be made.

ANNEX 1: INSPECTION CHECKLISTS

Checklist for inspection of markets

INSPECTION OF WHOLESALE/RETAIL MARKET	
Reason for the inspection	
Site	Official Inspection
Date	Name of inspector

Sanitary requirements related to the construction and equipment			
Elements to inspect	**yes**	**no**	**observations**
1. Products protection against: Weather conditions (sun) Dust and engine exhaust gases Rodents and other pests Place fenced with lockable system			
2. Building construction and finishing 2.1 Easy to clean, impervious materials 2.2 Smooth surfaces 2.3 Maintained in good condition			
3. Supply of potable water 3.1 Water available at any time 3.2 Water treated and microbiologically safe			
5. Sufficient lighting whenever necessary			
6.Waste disposal 6.1 Adequate drainage system 6.2 Containers for solid waste available			
7. Toilets and washing basins available 7.1 Toilets in sufficient number 7.2 Hand washing basins w/soap and disinfectant			

Requirements for a hygienic operation			
Elements to inspect	**yes**	**no**	**observations**
Handling done properly Products not in contact with floor Adequate cleaning and disinfection			
Unloading/loading operations quick and hygienically done			

Adequate hygiene of delivery vehicles			
Presence of non-authorized personnel Presence of animals/birds/insect pests into the fenced area			

Checklist for inspection of road transport vehicles

INSPECTION OF ROAD TRANSPORT VEHICLES	
Reason for inspection	
Vehicle: Vehicle registration: Authorisation:	Stowing: Refrigeration: Owner:
Date	Name of inspector

Sanitary conditions related to the construction and hygienic operation			
Elements to verify	**yes**	**non**	**commentaries**
1. Container, box or lorry: 1.1 Product not exposed to exterior 1.2 Easy to clean 1.3 Hygienic and adapted to the purpose 1.4 Clean & well maintained, with drainage			
2. For refrigerated trucks 2.1 Temperature under regime below –18°C 2.2 Recorded and readable temperature (from out-side)			
3. Loading / unloading 3.1 Quick and hygienic 3.2 Packaging materials appropriate materials			
4. Hygiene control Cleaning of vehicle/container after and before use Vehicle periodically subject to general cleaning			
5.Contamination control: 5.1 Oil & fuel kept separate from food 5.2 Containers used only for food			

6. Health & hygiene of crew 6.1 Medical checks up to date 6.2 Personal hygiene satisfactory			
7. Temperature under control 7.1 Lorry 7.2 Product			

Checklist for the initial assessment of a HACCP plan

FORM FOR THE INITIAL ASSESSMENT OF A HACCP DOCUMENT AND HACCP PLAN, OR RENEWAL OF APPROVAL	
Name of establishment:	Approval/register number:
Date of inspection:	Name/s of inspector/team:

HACCP System – Documentation			
a) Facilities and process description	**Requirement complied with**		**Comment**
	yes	**no**	
Company/section general description providing sufficient information?			
Commitment for quality clearly expressed, including HACCP?			
Management lay out & description of responsibilities given?			
HACCP team: HACCP team assembled? Coordinator designated? Adequate qualification and experience available in the team? External resources employed to increase technical capacity?			
Project schedule and objectives (if applicable).			
Personnel informed about the objectives and the company quality commitment.			
Products: Products description clear and complete? Origin and specifications of raw material given? Composition, packaging, distribution, validity, storage condition? Lot identification code providing suitable traceability?			

End-user identified: Sensitive consumers identified? Instructions given for the distribution, storage and utilisation?			
Processing specification: Detailed flow diagram for each product or type of similar products? CCPs indicated on diagram?			
Flow diagram confirmed.			
Chart showing the plant lay out / products, materials and personnel flow			
Process description & narrative of Standard Operating Procedures (SOPs) clearly documented?			

b) Pre-requisite programmes	yes	no	Comment
PP1. Proper general condition of facilities & interferences with surrounding areas under control.			
PP2. Lay out preclude cross contamination and dangerous air currents			
PP3. Adequate pest control			
PP4. Personnel health monitoring: • Systematic initial medical check • Systematic periodic monitoring • Daily/Frequent- Random verifications			
PP5. Personnel hygiene control.			
PP6. Personnel continuous training/sensitised to hygiene concerns			
PP7. Facilities cleaning and sanitation: Properly designed &programmed: feasibility? Adequate hygiene control of toilets and other facilities for the personnel			
PP8. Water quality control. Water available as necessary, distribution diagram? Automatic treatment system adapted and operational? Monitoring of residual chlorine content if added? Surveillance of contamination indicators in place. Sampling plan adequate and systematically followed?			
PP10. Raw materials specifications addressed: Regarding freshness/quality. Regarding the reception conditions/specifications Regarding the condition of transport and storage Regarding the origin verification and coding to keep the trace			
PP11. Other ingredients and packaging materials specifications? For the ingredients. For the packaging materials			
PP12. Codification and labelling system making able to keep the traceability up and down			

PP13. Operations and systems for the disposal of solid and liquid waste			
c) Application of HACCP Principles	**yes**	**no**	**Comment**
P1. Hazard analysis: - All reasonable hazards have been considered at each step. - Their incidence/probability was evaluated, and the relevant risks addressed (risk assessment) - Preventive measures identified to control each relevant risk.			
P2. Determination of critical control points (CCP): - The Critical Control Points were identified - Adapted preventive control measures were identified for each CCP.			
P3. Adoption of Critical Limits for each critical parameter: - All critical limits established. - Are limits valid taking into account published or experimental evidence.			
P4. Adoption of a monitoring procedure for each critical parameter The system mentions what to check, where, when, how, who? Monitoring continuous or frequent? Systematic recording and verification established? (forms?)			
P5. Corrective measures established for each critical parameter - Realistic and effective corrective measures adopted for each CP - Destination of non-suitable products established			
P6. Verification procedures in place? Are the procedure providing real tools for verification? Specific forms are adopted, including signatures			
P7. Documentation system: Are all the records included concerning control actions? - Data from monitoring procedures - Information on corrective actions taken/rejection/ destination - Data on the verifications done - Calibration of instruments			
P8. Internal audits plan for the system verification adopted?			
P9. Rapid alert system established for the defective products retrieval?			

P10. Procedure for the annual plan review adopted and documented?			

When using this form, it should be considered that all the points included relate to obligations required for the application of the HACCP system and the regulatory prerequisites. All should be considered in a company file for a facility approval. That is why the questions are answered by "yes" or "no" only.

Checklists for assessment of implementation of a HACCP plan

INSPECTION FORM FOR HACCP IN PACKING AND PROCESSING ESTABLISHMENTS (for use during operations)	
Name of establishment:	Licence number:
Date of Inspection	Name of inspector(s):
Product audited	Product description:

AUDIT OF HACCP STRATEGY APPLICATION AND FOLLOW-UP				
ELEMENTS OBSERVED/ASSESSED	**DEFECTS***			
	Mi	**Ma**	**Se**	**Critical**
MODIFICATIONS Modifications non-communicated or approved		[ ]	[ ]	
Modifications of critical parameters non-approved				[ ]
Trained technician non-available			[ ]	
2. RECORDS 2.1 Records not up-to-date		[ ]	[ ]	
2.2 Falsified or non-trustable records		[ ]	[ ]	[ ]
2.3 Documents falsified				[ ]
2.4 Records non-available			[ ]	
3. OWN-CONTROL PLAN MANAGEMENT 3.1 Preventive Measures not followed		[ ]	[ ]	
3.2 Monitoring procedures not followed			[ ]	
3.3 Corrective measures concerning critical aspects regarding consumer health, not taken /registered				[ ]
Total deviations				

*Explanatory note:

Not all non-compliances have the same potential impact, and therefore their severity, and response of the Competent Authority should reflect this. In this form any deficiencies or non-compliances identified by the evaluation should be classified according to their seriousness.

The scale used is based on four classifications, which correspond to the definitions of the following table.

The abbreviations set out in the brackets on the forms serve as a guide to the inspectors.

Type of non-compliance	Code	Description
Critical Deficiency	**Cr**	Any condition or malpractice observed in the establishment which can lead to the product becoming unsafe or unwholesome.
Serious deficiency	**Se**	Any condition or malpractice observed in the establishment that can preclude proper implementation of hygienic practices or obtaining appropriate level of hygiene; and thus, lead to the production of a contaminated or spoiled fish product, but with no immediate safety implications.
Major deficiency	**Ma**	Any condition or malpractice observed in the establishment, which precludes general hygiene and leads to the spoilage of the product.
Minor deficiency	**Mi**	Any observed condition or malpractice, which does not comply with the sanitary requirements, but is neither major nor serious or critical.

Checklist for assessment of traceability conditions

TRACEABILITY VERIFICATION			
Company/ Licence No:	Description of product/packing :		
Lot/s code	Description of traceability coding (include examples):		
Criteria	**Satisfactory**	**Non satisfactory**	**Comments**
Supplier/origin of batches clearly identified			
Receiving raw material batch identified by unique code n°			
Lots separated during transport			
Lots identified during process			
Codes include all essential information			
Separation/ or addition of lots recorded			
Label codes permits to trace back the product			
Recall plan formalised and operational			
All the data on suppliers and clients available			
Product distribution plans available			
Recall plan in place and verification recorded			

ANNEX 2: RECOMMENDATIONS FOR FURTHER READING

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EU-EAC MARKET ACCESS UPGRADE PROGRAMME

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