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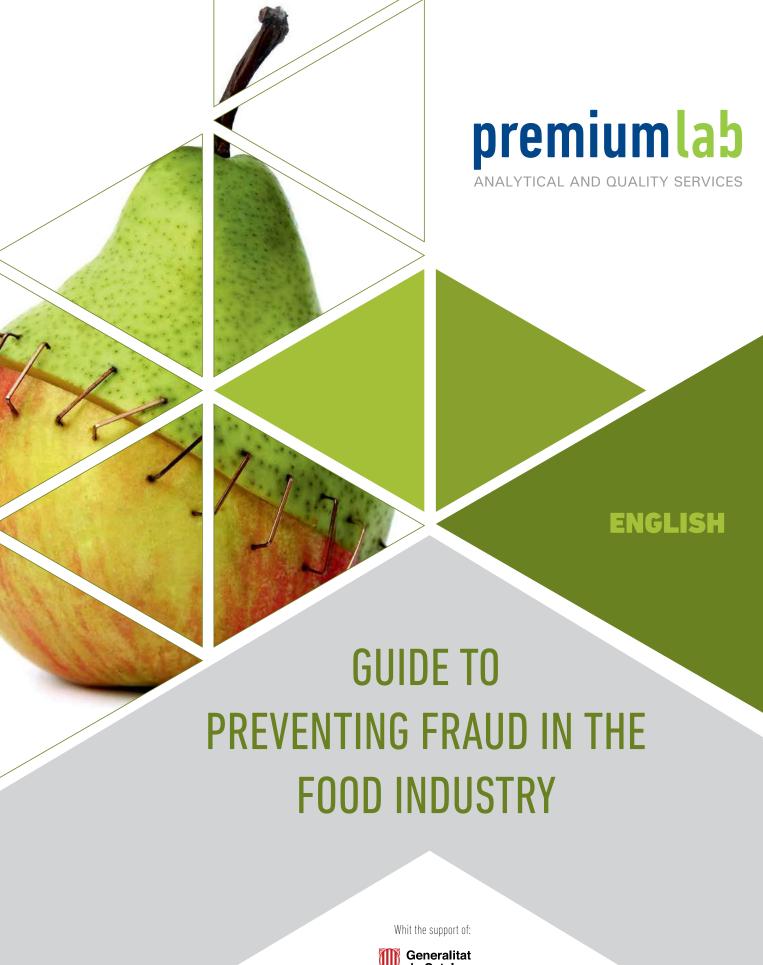
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premiumlab

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/ FOREWORD

This Guide was created to cover the requirements of the food industry regarding control of food fraud, a problem that is a focal point for consumers, the industry and the Government.

At Premiumlab, S.L., a company providing comprehensive quality services (analytical testing, consulting, training, auditing, certification of agrofood products). We aim to facilitate fraud prevention work in food industries by offering them a tool that can be used and integrated into their Hazard Analysis and Critical Control Points System (HACCP).

The drafting of this document was supervised by the Sub-directorate General for Inspection and Control of Food and Agricultural Products of the Generalitat de Catalunya. In addition, it has been analysed by a Commission on the Food and Nutrition Torribera Campus at the Universitat de Barcelona (UB) and has received support from the Catalan Association of Food Science (ACCA), of the Institut d'Estudis Catalans (IEC) and the Official Association of Agricultural Engineers of Catalonia (COEAC), and the Department of Animal and Food Science of the Universitat Autònoma de Barcelona (UAB).

It is important to take into account that as the time goes by and there are changes in production processes, legal and criminal proceedings, this Guide should be updated to fit the new reality.

DR. CATHERINE VIDAL General Manager of Premiumlab

INTRODUCTION

In the absence of an official and universally agreed upon definition, for the preparation of this Guide, we started with the following definition: food fraud is the supply of a food product that is not of the type, substance or quality defined or agreed and that suppose a deceit for the buyer or consumer. We consider it appropriate not to limit this definition to there being a deliberate intention because, as well as taking into account the fact that the deceit may be derived from a deliberate action carried out in the intention of obtaining financial benefit, we also have to acknowledge the fact that it may be derived from bad manufacturing, handling and/or inspection practices.

This guide sets out some generic guidelines, designed so that each company can adapt them to its circumstances.

Depending on the nature of the fraud it can be classified as:

Intentional fraud.

Any deliberate practice that compromises the veracity of the product. There are many types: including adulteration of a raw material, forgery and imitation of packaging, overproduction and diverting of products, theft and sale on the black market.

Unintentional fraud.

Any unwitting practices derived from bad handling, preparation practices, etc. that result in an illegal product.

It is supposed that all users of this guide have an honest commitment to consumers. Thus, the only intentional fraud that they have in mind and wish to avoid is that carried out by their suppliers.

Depending on the consequences involved, it can be divided into:

Fraud that is harmful to health.

The practices carried out compromise the safety of the product, whether because it causes toxicity or because the product marketed has a nutritional deficiency compared to the genuine product. For example, melamine in baby milk or dilution of juices or cumin with ground almond shells.

Fraud that is not harmful to health.

The product that is marketed does not meet the expectations generated in the consumer. For example, a frozen product sold as a fresh product or paprika containing starch.



Food fraud takes place when non-genuine food products are introduced into the market to mislead the purchaser.

There are numerous cases that have had major social impact, such as the case of the presence of horsemeat in minced beef, the presence of melamine in powdered baby milk from China, the marketing for food use of industrial rapeseed oil in Spain, poisoning by alcohol adulterated with methanol in the Czech Republic, the adulteration of chilli powder with Sudan Red colouring or the marketing of catfish labelled as hake.

At present, there are a many other frauds occurring, such as the marketing of more eggs sold as free range than there is the capacity to produce, of organic products that are not organic, of animal or plant species labelled as other species, or nuts with a false origin. In addition, wines are labelled with false ratings (reserve, crianza, etc.) or flavourings are added to them without declaring this; mechanically separated meat is not declared and olive oil is marketed as extra virgin when it is not.

In the above cases, as in many others, a loss of trust in the industry develops among consumers and highlights the vulnerability of the control mechanisms.

Therefore, commitment from all participants in the production chain is very important: on the one hand, from the suppliers who have to provide sufficient and appropriate information to increase their transparency; from the distributors who have to maintain the traceability of the products that they receive and manage, and from the Government, which has to protect legitimate businesses and reduce the number of illegal operations with dissuasive strategies.

Food fraud is a focal point for consumers, the Government and the industry due to the above-mentioned cases, but it is also extremely relevant for the industry because the main European certification standards (BRC e IFS) include requirements about product authenticity and assessment of the risk of substitution or fraud involving the raw materials.

The food fraud prevention system is aimed at all operators that already have their HACCP system and their prerequisite programmes in place, follow good manufacturing and hygiene practices and need support in order to include the risk of suffering or causing food fraud.

2 OBJECTIVES OF THIS GUIDE

- PROVIDE A USEFUL AND UNDERSTANDABLE TOOL FOR ALL ECONOMIC OPERATORS.
- REDUCE THE RISK OF PURCHASING ILLEGAL RAW MATERIALS.
- REDUCE THE RISK OF GENERATING A FRAUDULENT PRODUCT AS A RESULT OF HANDLING PRACTICES.



- Inspires trust in consumers and customers.
- Enables compliance with standards and offers
- Increases the value of the brand.
- It is preventive: it has an effect before the problem

- certification with private food safety standards.

3 / LEGISLATION

Regulation (EC) 178/2002 of 28 January 2002 establishes the general principles and requirements of food legislation, which has as its objective the protection of consumer interests and the prevention of fraudulent or deceitful practices, the adulteration of foodstuffs and any practice that may lead to deception of the consumer. Furthermore, it also establishes the responsibility of operators of food companies for the foodstuffs to meet the requirements of the legislation.

Regulation (EC) 852/2004 2004 establishes the general hygiene requirements to be met by food companies in all phases of the chain.

Regulation (EC) 2017/625, of 15th of March 2017 has as its objective guaranteeing legal practices in the marketing of fodder and

foodstuffs and the protection of consumer interests, also regarding labelling and any other type of information intended for consumers. The tool used for this purpose takes the form of official inspections, which are any form of inspection carried out by the competent authority to verify compliance with the legislation. This regulation requires each member state to include in a single Plan all inspections carried out by the competent authorities involved in order to optimise the resources available. This Plan should be multiannual, and in Spain it is called the Multi-Year National Plan of Food Chain Control (MNPFC).

Regulation (EC) 1169/2011 of 25 October 2011 establishes the base for guaranteeing a high level of protection in relation to food information. Therefore, the food information provided has to achieve a high level of protection of health and consumer interests, offering a basis for end consumers to make informed decisions and use foodstuffs safely.

Finally, the standards regulating food quality in the different member states and autonomous communities should also be taken into consideration, for example, in Spain, this is Law 28/2015 for food quality protection and in Catalonia it is Law 14/2003 on Food Quality, as well as all industry food standards, depending on the products made.



Obligations of the operator:

- Ensure the production and marketing of genuine

- Have a quality control plan.

4 PRIVATE FOOD SAFETY STANDARDS

Two of the main current food safety certification standards recognised by the Global Food Safety Initiative (GFSI), the Global Standard for Food Safety (BRC) and the IFS Food, include clauses concerning food fraud.

The Global Standard for Food Safety (BRC), version 8, includes requirements referring to the adulteration of foodstuffs. Specifically, the declaration of intentions in basic requirement 3.5.1 on management of suppliers of raw materials and packaging and packing materials requires companies to have an effective system for approval and monitoring of suppliers that "that any risk is understood and that may lead raw materials (including packaging) for security, authenticity, legality and quality of the final product is controlled. The packaging materials are increasingly taking a greater role in the future and can reach a significant role in food fraud issues." Afterwards, in the chapter dedicated to product inspection, in clause **5.4 about product authenticity**, statements and chain of custody, it says literally "systems must be implemented to minimize the risk of buying a fake or contaminated raw materials." The steps to be followed as stated are: access the information about past and present threats, assess and document raw materials according to their vulnerability and, if the raw materials run the risk of adulteration or substitution, have guarantee and/or testing processes to reduce the risk.

Furthermore, version 6.1 of the **IFS Food** also includes a requirement related to food fraud. Clause 4.4.5 states, literally "the purchased products shall be checked in accordance with the existing specifications and their authenticity, based on hazard analysis and assessment of associated". This version has been added and dedicated exclusively to the food fraud clause, in 04.21.:

- 4.21.1: analysis on documented vulnerability on all raw materials, ingredients, packaging and outsourced processes will be performed to determine the risk of fraudulent activity related to the substitution, mislabeled, forging or falsifying. The criterion for this analysis will be defined.
- 4.21.2: will develop and implement a plan of preventive measures (mitigation) documented based on vulnerability analysis, to control any risk identified. The control and monitoring methods shall be defined and implemented.
- 4.21.3: in case the risks increase, the vulnerability analysis will be reviewed. If the risk is not increased, the vulnerability analysis will be reviewed at least annually. Controls and monitoring requirements of the plan of preventive measures (mitigation) will be reviewed and adjusted when applicable.

Clause 5.6.8 states, literally "based on a hazard analysis, assessment of associated risks and any external or internal information about the risks of the product that may have an impact on food security and / or quality (incl adulteration, and fraud), the company will update its control plan and / or take appropriate measures to control the impact on the final product measures."

At the same time the IFS Food has also released guidance on food fraud highlighting along the guide importance of also controlling fraud in packaging materials and packaging as also performed in all actions or elements of risk they could be the subject of food fraud.

FRAUD PREVENTION SYSTEM IN THE FOOD INDUSTRY

The system follows the outline of the Hazard Analysis and Critical Control Points (HACCP) System, which all food companies have to apply, according to what is defined in the Codex alimentarius and the standards in effect. New items are added for fraud prevention and control. Therefore, the steps to be followed are: creating the work team, vulnerability and severity analyses and assessment of risk, evaluation of the preventive measures in place, identification of critical points for controlling origin of the fraud, establishing a system for monitoring and critical limits, corrective actions and verification and validation of the system.



5.1 / WORK TEAM

The HACCP team is maintained, incorporating, if there is not already one, a person responsible for regulatory affairs who is familiar with the standards that apply to the company context.

Although all food operators should have some knowledge about the laws governing their working environment, in order to act carefully, it is important to work with an expert in the regulations. It is essential to know what can be demanded of a supplier and what cannot, what information should be included on a label, how it should be presented, etc.

FLOW CHART

Based on the HACCP flow chart, the hazard points for entry of possible frauds should be identified. Everyone should adapt it to the production environment, based on the HACCP system flow chart, taking account of each manufacturing unit or machine individually.

RAW MATERIALS AND PACKAGING **MATERIAL**

PROCESSING AND DISTRIBUTION



5.3 / RISK ASSESSMENT

To carry out the assessment of the risk of fraud, there should be measurement, on the one hand, of the vulnerability of it happening, i.e. the likelihood, and, on the other hand, the severity of fraud occurring. In this section, the main risks will be discussed, but every company should adapt them to their own practices.

5.3.1 VULNERABILITY ANALYSIS

The concept of fraud vulnerabilities prevention should be based on the assessment of possible motivations, opportunties and control measures in place.

The vulnerability analysis is carried out in a different way depending on whether the possible origin of the fraud stems from the raw materials, packaging material or its processing and distribution.

RAW MATERIALS AND MATERIALS FOR PACKING AND PACKAGING

This section analyses the level of vulnerability to which the company is exposed in relation to selection of suppliers and quality control at the reception. As for raw materials, derived history of fraud vulnerability of each is analyzed, the associated economic and geopolitical considerations, the supply chain and the relationship with the supplier. Furthermore, the analysis looks at the type of quality control being carried out on each raw material.

For its part take into account that for the integrity of the container that must contain the final product, it is essential to maintain the optimal conditions and necessary to ensure the product as it has been established and informed to the consumer. There are known fraudulent actions of authenticity or quality of the containers in order to lower costs or to directly obtain an economic benefit.

A package not explicitly fulfilling its function, and therefore does not preserve food in optimal conditions may lead to large-scale consequences. It is necessary to ensure the material and behavior of containers continuously and especially in cases where a change of container is made or want to innovate in preserving the product.

REVIEW OF THE HISTORY OF FRAUD

It is necessary to conduct a literature search of possible fraud associated in both raw materials and packaging materials and also on the final product. Evaluation of the incidents that have occurred previously and observation of the market situation can help to understand the vulnerabilities that have to be faced and will put production into a global context.

There are two basic sources of information: the Rapid Alert System for Food and Feed, RASFF, which is based on the rapid exchange of information about risks for health in relation to food and feed. On its website, every food alert that has taken place throughout Europe can be found. At national level, management of the food alert network takes place through the Coordinated System of Rapid Information Exchange (SCIRI), which can also be consulted online.

Elsewhere, a good source of information is the USP Food Fraud database, which contains a collection of articles published in scientific journals and press reports about adulterated ingredients.



Low vulnerability (value=1)

There are no bibliographical references in any similar or equivalent ingredient and there is no substantial evidence.

Medium vulnerability (value=3)

Moderate-high number of reports. There are no alerts from the authorities.

High vulnerability (value=5)

High number of reports. There are alerts from the authorities.

Finally, by decision of the European Commission on 22 October 2015, the system of administrative assistance and cooperation (AAC system) was established as a structured format for the exchange of information between competent authorities on possible violations, specifically in cases of fraud that is not harmful to health. However, this system is not publicly available, although the Commission may provide a consolidated summary.

Furthermore, the knowledge and experience acquired over time should be taken into account. Depending on the result of this search, the company is at a higher or lower vulnerability level.

GEOPOLITICAL AND ECONOMIC CONSIDERATIONS

The origin of the ingredient, the regions it passes through and where it is handled should be taken into account. There is more likelihood of fraud in developing countries due to strong political and social pressure, in regions with a less advanced regulatory framework, where there is more political instability or prevalence of corruption. In addition, the more different regions it passes through, the greater the risk.

Furthermore, temporary circumstances that raise suspicion that something unusual is happening should also be taken into consideration. Some examples are price below the market rate, fluctuating prices or those that increase disproportionately in the same sector or prices that are unusually steady in respect of competitors. Finally, and most of all, for ingredients that are solely produced in a specific region or that are seasonal, if the prices remain steady after a natural catastrophe or a poor harvest, there may be suspicion of fraud.



Geopolitical and economic considerations

Low vulnerability (value=1)

One or more components with geographical origins giving little cause for concern.

Medium vulnerability (value=3)

High vulnerability (value=5)

Anomalies related to one another are frequently detected.

SUPPLY CHAIN

Is directly connected to the traceability of the raw material. Vulnerability will be related to the level of control by the various interested parties involved in fraud prevention. In addition, the supply chain influences the likelihood of incorrect labelling of origin or false source of raw materials, either because it is a product unfit for consumption or by-product diverted for human consumption, a frozen product sold as fresh, or it is illegally slaughtered meat, among other examples. Furthermore, the longer the journey from origin and the greater the number of intermediaries involved, the more opportunities there are to commit fraud.



Low vulnerability (value=1)

quality policy.

Medium vulnerability (value=3)

High vulnerability (value=5)

Set of ingredients, each manufactured by a different supplier or the ingredient is processed by another producer before final processing by the supplier, for example, a distributor. Any other scenario not mentioned.

RELATIONSHIP WITH SUPPLIER AND HISTORY

The supplier is the final intermediary in the supply chain and over which a more direct influence may be held. A close relationship with the supplier gives more knowledge about the environment and more trust. The type of problems that have occurred and the time taken to solve them have to be taken into account. It is important to assess the frequency with which quality and food safety issues arise and how quickly and completely they are resolved. It has to be taken into account whether the supplier has a certificate recognised by the GFSI since if this is the case, it will already receive annual audits by the certification companies, and will therefore be subject to greater control.



Relationship with supplier and history

Low vulnerability (value=1)

Known and trusted supplier, in charge of always supplying the same product. No issues are directly known about or if there have been any they have been resolved quickly and appropriately. The supplier holds valid certification from IFS, BRC or FSSC 22000. If a new ingredient is provided, it is mandatory to obtain approval for this ingredient.

Medium vulnerability (value=3)

Established supplier with a short period of previous business or supplier respected in the market, with which a business relationship has not been previously established. Has had an issue that was not resolved appropriately.

High vulnerability (value=5)

Non-established supplier, which has been involved in ongoing issues, which it has not corrected appropriately or quickly enough. There is evidence that appropriate checks are not made and that the level of cause for concern is unacceptable.

QUALITY CONTROL AT RECEPTION

The quality of the received materials is essential for the quality of the product to be produced. This quality mainly depends on the conditions of delivery and receipt and on adultteration of materials. Various methods of producing non-authentic raw materials such as dilution, substitution, addition of substances to masking lower quality ingredients or adding water without declaring it are known.

When using processing aids for a specific purpose during processing it is necessary to ensure that they contain no DNA from foreign species to those of the product itself, because if they do, the result could be positive for a species not declared on the label.





Quality control at reception

Low vulnerability (value=1)

Raw materials and packaging materials are homologated and analyzes and checks before are conducted are transport by means of a temperature recorder and effective weight control is carried out on all batches prior to acceptance on calibrated scales and using validated procedures.

In the case of processing aids, the supplier is required to produce a certificate of absence of traces of DNA of foreign

Medium vulnerability (value=3)

The raw materials and packaging material are approved but no control testing is performed. A check of the without any validated procedures or calibrated scales.

High vulnerability (value=5)

Materials are no homologated nor analyzed or tested. Before or during the supply. No checks are made before acceptance of the batches, nor are there any conditions of delivery or effective weighing.

Regarding the processing aids, there is no certificate of absence of traces of foreing species DNA demanded, and





PROCESSING

To analyse the vulnerability of the processing of the raw materials and subsequent packaging the following aspects are taken into account: storage and traceability, cleaning, calibration, training of workers and sub-contracting. By analysing the degree of robustness that the set of internal measures implemented in the company has, we can find out what the vulnerabilities are.

STORAGE AND TRACEABILITY

It is necesary for the materials to be arranged in their proper place and labelled individually and unmistakably. In addition, they should be able to be located quickly and monitoring should take place throughout the entire production process. Raw materials and intermediate products that are incorrectly labelled or are not identified may confuse the operator when it comes to adding them to the production process, leading to errors in the formulation.

Proper storage and a correct traceability system make it possible, as well as better control of stock, to avoid confusion between one product and another, which would compromise the authenticity of the finished product. Not forgetting, of course, proper storage to preserve product quality, for example, maintaining the cold chain when necessary.

All of this is particularly relevant in the case of ingredients that are not distinguishable to the naked eye, such as powdered ingredients that have the same colour and texture which, if they are not well identified, an error may be difficult to detect.



Low vulnerability (value=1)

There is a storage place established and indicated for each **material**. A computer system is available that helps to manage the information about traceability of the materials throughout the production chain. Ingredients are identified individually and uniquely throughout processing. Full traceability of all finished product batches can be monitored.

Medium vulnerability (value=3)

Although there is no area clearly dedicated for each product, they are clearly identified. Traceability management is performed manually.

High vulnerability (value=5)

The location of materials is not established in the warehouse and they are not individually identified. There is no monitoring of traceability.

CALIBRATION

Consideration should be given to which equipment may have a direct effect on the authenticity of the product that is prepared. Accuracy at the time of measuring out the raw materials will be of the utmost importance for the finished product to meet its specifications. Furthermore, in the packaging process it is essential for the dispensing machine to deliver the quantity of product specified on the technical datasheets or labels.

In addition, consideration should be given to ensuring that the equipment for measuring temperature and relative humidity and the equipment for measuring the composition of the modified atmosphere is correctly calibrated so that the characteristics of the end product are in line with the specifications.



Low vulnerability (value=1)

defines the tolerances that should be met by the various items of equipment.

Medium vulnerability (value=3)

There is a calibration and verification plan, but not all instruments are calibrated periodically.

High vulnerability (value=5)

There is no calibration plan.

HYGIENE AND CLEANING PLANS

The hygiene and cleaning plans followed by each company condition their vulnerability. It is necessary to consider which procedures, utensils and products are used, how often and any aspects considered relevant. In addition, the correct flow of people and materials has to be taken into account to prevent any cross-contamination.

If cleaning is not performed correctly when a change of raw materials takes place on a machine, traces of the previous raw material may be found in the second product prepared, which may compromise the formulation and authenticity of the product prepared. If a machine only comes into contact with one type of raw material there is no risk of cross-contamination.

On the change of containers in the packaging line, it must be taken into account to be taken off all the material before beginning packaging another product.



Hygiene and cleaning plans

Low vulnerability (value=1)

Medium vulnerability (value=3)

There are generic cleaning procedures that do not take changes of raw materials into consideration.

High vulnerability (value=5)

There are no generic cleaning procedures.

HUMAN RESOURCES

It is necessary to assess the training requirements of workers and the best strategy for meeting these requirements. Also to be taken into account are staff motivation and working and salary conditions. There is no comprehensive plan, instead each company has to adapt to its characteristics. The importance of this aspect can easily be understood by means of an example: some workers disgruntled with the company for which they work, divert to the black market some of the phosphates necessary for this company's production, so that their products contain fewer phosphates than expected.



Human Resources

Low vulnerability (value=1)

Operators have received extensive training in Good Manufacturing Practices (GMP) and traceability, including perceptions about food fraud. Specific training is delivered to those responsible for the internal traceability of the products. Refresher

Medium vulnerability (value=3)

Generic training is delivered on GMP and traceability. Workers are not trained on specific food fraud issues and no refresher

High vulnerability (value=5)

INFORMATION GIVEN TO CONSUMERS

The information given to customers or consumers, whether on the label or in a technical data sheet, should be legal, truthful and should not lead to any error. This includes declarations about processing, origin of raw materials and packaged quantity, amongst other things.



Information given to consumers

Low vulnerability (value=1)

Regular checks are made on the correlation between the origin of the raw materials and the processes carried out with the packaging material.

Medium vulnerability (value=3)

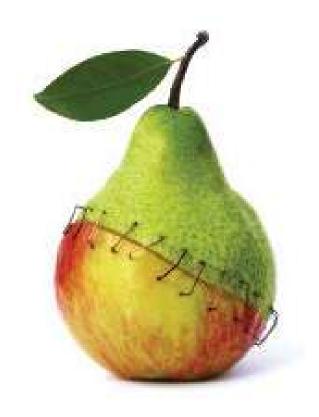
The legality of the information given to customers or consumers is checked regularly but not the correlation between the

High vulnerability (value=5)

SUB-CONTRACTING

Part of the processing may be carried out by a sub-contractor company that performs various procedures at its facilities with the product that will ultimately be sold by us. The distribution process may also be subcontracted.

Distribution is a stage that has increasingly given higher levels of fraud especially in the food sector. Since the beginning of 2017 the OFECOMES (Economic and Commercial Office of Spain Abroad) in The Hava said that it has detected an increase in fraud attempts in distribution with increasingly elaborate methods. It is for this reason that we must have basic prevention strategies such as sealing products to detect whether they have been opened improperly, transporting products with safety boxes with security codes, among others.





Low vulnerability (value=1)

The service provider is known and trusted. It follows the process according to previously established instructions. It has a good history. It is submitted to an approval procedure and has regular audits performed. It holds valid certification from IFS, BRC or FSSC 22000.

Medium vulnerability (value=3)

The service provider is approved but the type and conditions of processing carried out are defined and controlled by it. It is submitted to an approval procedure and has regular audits performed. It holds valid certification from IFS, BRC or FSSC 22000

High vulnerability (value=5)

The service provider is not approved and does not have food quality and safety certifications. It does not have any audits performed.

To make the calculation, the vulnerabilities can be scored in a table like the one below:

	VULNERABILITY		SCORE	
RAW MATERIALS AND PACKAGING MATERIALS	History of fraud		3	5
	Economic and geopolitical considerations		3	5
	Supply chain	1	3	5
	Relationship with supplier and history	1	3	5
	Raw material quality control		3	5
PROCESSING AND DISTRIBUTION	Storage and traceability	1	3	5
	Calibration	1	3	5
	Hygiene and cleaning	1	3	5
	Human Resources	1	3	5
	Information given to consumers	1	3	5
	Sub-contracting*	0 1	3	5
	TOTAL			

Table 1. Calculation of vulnerability level. *Vulnerability is equal to 0 if no process is sub-contracted.

For some companies, it may be of interest to calculate the global vulnerability. In this case, it will be low if the score is between 10 and 25, medium if it is between 25 and 40 and high if it is between 40 and 55.

5.3.2 SEVERITY ANALYSIS

To measure the severity three important aspects that are very closely related to one another have to be taken into consideration: whether it is a harmful fraud that may lead to a health risk or a non-harmful fraud where the economic prejudice and/or effect on public opinion should be assessed.



Low severity (value=1)

Does not necessarily cause damage to health. The adulterant corresponds to a negligible percentage of the total product. Furthermore, the product complies with all standards that apply and does not have an impact on public opinion.



Medium severity (value=3)

The adulterant may cause consequences considered non-fatal or harm to health in the long term or by accumulation. The adulterant corresponds to a non-negligible percentage of the total product. Furthermore, it may be that the adulterated product does not comply with the standards in force and the operator may be committing a serious breach.



High severity (value=5)

The fraudulent product contains an allergen or may cause illnesses with serious or potentially fatal consequences. In many specific cases, depending on the guidelines for consumption of the product, if the adulterant considerably reduces the nutritional content, it may lead to a Public Health problem. In addition, there also has to be consideration as to whether the adulterant corresponds to a high percentage of the end product or forms part of many other products. Furthermore, the adulterated product may not comply with the standards in force regarding food safety and the operator might be committing a serious crime. Finally, it may be a product on which there is a lot of media pressure and its adulteration generates major controversy among public opinion.

5.3.3 RISK ASSESSMENT

Once the vulnerabilities and severity have been analysed, the relationship between them both has to be defined.

RISK - Vulnerability-Severity Ratio		VULNERABILITY - Probability of occurence					
		HIGH -5-	MEDIUM -3-	LOW -0/1-			
SEVERITY- Impact of occurrence	HIGH -5- Critical hazard						
	MEDIUM -3- Major hazard						
	LOW -1- Minor hazard						

Table 2. Relationship between vulnerability and severity.

"RED": high risk (8-10)	"YELLOW": medium risk (3-6)	"GREEN": low risk (1-2)
REB : mgm non (6 16)	TEEEOTT : IIIodidiii Tiok (o o)	ONLEH TON HON (1 2)

In order to approach intermediate cases (yellow), the probability of detecting and controlling the adulterant has to be examined. If the adulterant is analytically impossible to detect or difficult to detect, the raw material should be considered as having a high risk. If it can be detected with analytical methods in the laboratory but the price is high, the company should consider whether or not to have these analyses performed. In the event that the cost of the analyses cannot be met, this raw material should be considered as high risk. Finally, if the presence of the adulterant can be determined by routine analyses, which are fast and inexpensive, the raw material is considered as low risk.

5.4 / PREVENTION AND/OR MITIGATION MEASURES

Mitigation measures are classified into two main groups:

Measures concerning internal processing

The operator may be involved in the **control or reduction of fraud at its facilities**. The tools for carrying out these measures should be implemented before production and should be applied and maintained throughout processing. The main ones are: staff training and qualification, traceability of all raw materials, packaging materials and products, health and safety plan and instrument calibration.

Measures concerning the supplier

The operator's actions are intended to discourage fraudulent practices or avoid inadequate practices by its suppliers that might subsequently compromise its product. All measures are encompassed in a robust supplier control plan. Most of them should be applied before the arrival of the raw materials, even before placing the orders, and other measures should be taken on receipt. This includes all sub-contracting relationships, whether distribution, processing or storage operations.

5.4.1 MEASURES CONCERNING INTERNAL **PROCESSING**

The main tools for controlling fraud within the facility are already known resources, which should be expanded in order to cover the new vulnerabilities that have to be addressed.

5.4.1.1 Traceability plan

This is used to avoid incorrect labelling and storage as well as confusion of materials. These and intermediate products have to be unmistakably identified at all times and recorded in the relevant system.

At the time of receipt, all products received from the supplier should be labelled correctly. In the successive stages the identification and recording of semi-finished products should be maintained, as well as the finished products at the end of production.

The use of barcodes and computer systems that allow better management of traceability is recommended.

In addition, the place of storage for each material and product has to be decided and recorded.

5.4.1.2 Hygiene and cleaning plans

They are used to avoid the presence of traces of other material and possible cross-contamination. Above all, special consideration should be given to those production lines that share equipment or utensils. Consider the need to increase the frequency of cleaning at these points in the chain. Therefore, removal of traces should be ensured on changing product, by means of the most appropriate methods according to their efficiency and the machinery.

5.4.1.3 Calibration plan

This is used to avoid fraud in the effective weight of the products and the addition of quantities and proportions of the wrong ingredients.

On the one hand, it is important to follow the formulation of each product. The formulation must be checked and must comply with the specifications that appear on the label; therefore, any variation of composition made will become a fraud. One of the measures that helps to control this is the calibration of the measuring and metering instruments.

5.4.1.4 Staff training and qualification plan

This is used to avoid incorrect labelling and storage, mixing of raw materials or handover and use of one raw material instead of another. The factory workers are the company employees who have direct contact with material and products. This is why it is very important for them to be aware of the significance of their work.

Training has to be across-the-board: operators need to be instructed so that they can perform appropriate cleaning and disinfection and a suitable traceability methodology is implemented.

In addition, they have to receive specific training on fraud so that they can be aware of the most common errors. Practical training for the operators responsible for receipt of raw materials should be enhanced because this is a critical control point in the production chain. Before starting a new package there should be a visual check that no crosscontamination could have occurred, checking that no seals are open.

5.4.1.5 Product quality analysis

This is used to check the condition of the product and compare it with its specifications. It is highly relevant for avoiding introducing into the market a product that is not authentic or of a lower quality than required.

5.4.1.6 Production planning

A good way to avoid mixing material is to organise the manufacturing sequence of the different products in such a way as to minimise the risk of mixing them by accident. Furthermore, the manufacturing schedule can be organised in such a way that the minimum number of possible changes of material takes place.

5.4.2 MEASURES CONCERNING THE SUPPLIER

Various options exist for controlling the supplier. Each company must assess which method is best suited to each case taking into account the reliability it offers, and the associated cost it involves.

5.4.2.1 Sending out of questionnaires

This is the least expensive and easiest solution because the only time to be invested is that taken for checking the replies sent by the supplier.

However, the reliability it offers is low because, in the first instance, the truth of the replies to the questionnaires cannot be verified.

It will be used in the event that it is not possible to perform an audit.

5.4.2.2 Audit of paperwork

This is an examination of the written

information from the supplier. There should be a comparison of the result or the performance of an activity reflected in records with what is stated in the documents that apply to this activity.

No direct economic cost is involved. The supplier sends all the documentation for review. Time has to be invested to check the consistency and truth of the paperwork provided by the supplier.

The main disadvantage involved is that the supplier can falsify the information. In addition, not all activities are nor should be recorded

5.4.2.3 Scheduled audit in situ

It is necessary to travel to the supplier's facilities to check the processes that are carried out there.

However, as the supplier knows what day to expect the visit, it can prepare for it. It may be that what is observed on that day is not representative of the everyday operation of the facility.

5.4.2.4 Unscheduled audit in situ

In the same way as for a scheduled audit, it is necessary to travel to the supplier's facility. However, the basic advantage is that the supplier is not expecting a visit from the customer and therefore a normal day's operation can be observed and what is observed will be representative.

However, it may create an atmosphere of distrust.

5.4.2.5 Certification requirement

This is a fairly reliable measure and the

supplier can be asked to have certification. The certifying body and the scope of the certification, which should cover the product manufactured for the customer, have to be taken into consideration.

5.4.2.6 Requirement of audits of the supplier's suppliers

The supplier should be expected to know about its own suppliers. The best way is for them to be subject to audits (steps 5.4.2.3 or 5.4.2.4).

5.4.2.7 Sampling plan

Once the raw materials have been received, an accredited laboratory checks the accuracy of the results of the analyses of the samples from the supplier's laboratory. In the event of a discrepancy in the results, the result from the accredited laboratory will prevail.

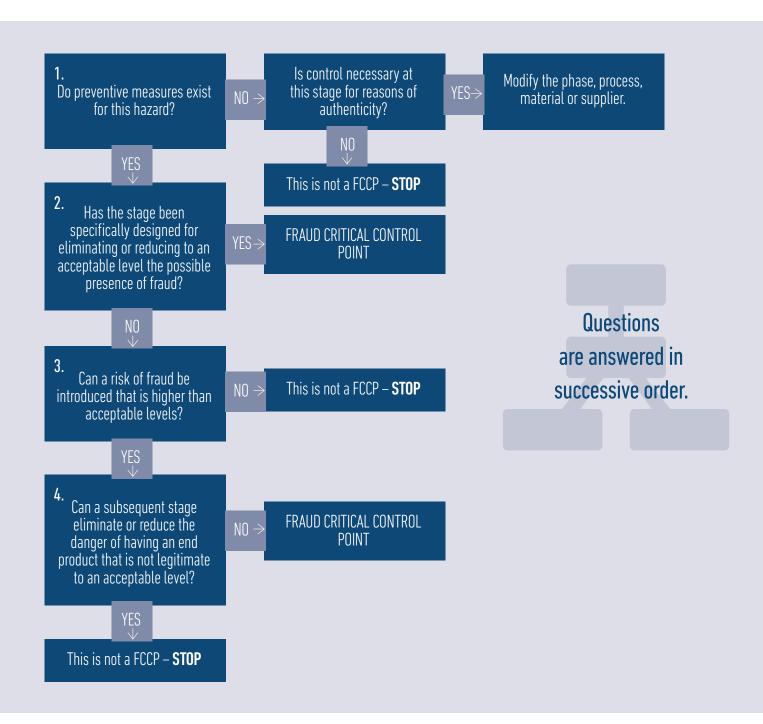
This is an expensive method and it generates unease in the audited party.

STAGE	VULNERABILITY	PREVENTIVE MEASURES		
Incoming RAW MATERIALS AND PACKAGING	History of fraud	No preventive measures exist. Change raw material or supplier, if possible.		
	Geopolitical and economic considerations	No preventive measures exist. Change raw material or supplier, if possible.		
MATERIALS	Supply chain	Audit of supplier's supplier.		
	Relationship with supplier and history	Questionnaire. Audit. Certification requirement.		
	Quality control	Sampling plan. Temperature monitoring. Checking of effective weight.		
	Storage and traceability	Electronic identification.		
	Calibration	Validated calibration plan and procedures.		
	Hygiene and cleaning	Validated cleaning plan and procedures.		
PROCESSING AND DISTRIBUTION	Human Resources	Training plan that includes traceability, Good Manufacturing Practices and fraud prevention. High motivation of workers, sense of belonging.		
	Information given to consumers	Written review. Checking of flow chart. Checking of weight according to Royal Decree 1801/2008 and its amendments.		
	Sub-contracting	Audit of sub-contractor.		

Table 3. Summary of preventive measures.

5.5 / IDENTIFICATION OF CRITICAL POINTS OF FRAUD CONTROL

The decision tree applies to all stages of the process and for raw materials with a high risk.



To help to answer the first question, the questions detailed in Appendix I may be answered.

5.6 / SURVEILLANCE SYSTEM AND CRITICAL THRESHOLDS FOR EACH FCCP

The surveillance system used should be described. It should be easy and quick to implement. It is important for surveillance to be continuous. As performed in the HACCP system, there should be definition of what is being monitored, how and where, how often, who carries it out and how the results are recorded.

In addition, the critical thresholds should be defined and they should be quantifiable and, the more objective the better. There should be justification of the reference values and the critical thresholds considered to be acceptable.

Therefore, any allocation should be justified and the decision should be updated and always available.

5.7 / CORRECTIVE MEASURES

It is necessary for corrective measures to be implemented when the critical threshold established are exceeded, in other words, when there are non-conformities.

These non-conformities should be reviewed, their causes determined and the need should be assessed to adopt actions to ensure that they are not repeated and these actions should be implemented. There should be definition of who is responsible for introducing the corrective measures and how they will be recorded.

5.8 / SYSTEM VALIDATION AND VERIFICATION

In addition to implementing a good fraud prevention system, it is important to keep it updated because a system that is obsolete will not guarantee its correct operation.

The purpose, method, frequency and responsibility of the verification activities should be defined.

It is necessary to record the results of these activities and inform the work team about them.

5.9 / RECORDS

5.9.1 Table of Risk assessment and Preventive measures

STAGE	HAZARD	Vulnerability	Severity	Summation	Detection	PREVENTIVE MEASURES
	History of fraud					
Incoming RAW	Geopolitical and economic considerations					
MATERIALS and PACKAGING	Supply chain					
MATERIALS	Relationship with supplier and history					
	Quality control					
	Storage and traceability					
	Calibration					
PROCESSING	Hygiene and cleaning					
and DISTRIBUTION	Human Resources					
	Information given to consumers					
	Sub-contracting					

5.9.2 Table of identification of Critical Points, Critical Thresholds and Surveillance

		IDENT	IFICATIO	N OF CR	ITICAL P	CRITICAL	SURVEILLANCE	
STAGE	HAZARD	P1	P2	P3	P4	FCCP?	THRESHOLDS	SYSTEM
	History of fraud							
Incoming RAW	Geopolitical and economic considerations							
MATERIALS and PACKAGING	Supply chain							
MATERIALS	Relationship with supplier and history							
	Quality control							
	Storage and traceability							
	Calibration							
PROCESSING and	Hygiene and cleaning							
DISTRIBUTION	Human Resources							
	Information given to consumers							
	Sub-contracting							

6 / PRACTICAL EXAMPLE

Product: BEEF- dried powder from fresh or frozen meat.

1. VULNERABILITY History of fraud: 3

This year a search was made in English using the word beef.

The RASFF website showed several cases, all related to the presence of horse DNA in beef. Furthermore, in the USP Food Fraud database there are numerous previous cases of fraud: addition of sulphur dioxide, the presence of pork, glazed meat, sale of meat from animals fed with feed sold as if it were from grazing animals, composition based on meat offal, etc. The latter two cases are not relevant in the case under study since the origin of the meat does not appear in the technical data sheet.

Of all the information found, the most relevant was the presence of horse DNA and pork.

Geopolitical considerations: 1

According to the technical data sheet for the product in question, it should come from the European Union and therefore its geographical origin is of little concern. The manufacturer is Dutch.

Supply chain: 5

The product is supplied by a distributor of intermediate products for the food industry.

Relationship with supplier and history: 1

This is a known supplier that has been supplying this product for 3 years and has public health registration. There have not been any non-conformities. It was approved by questionnaire, in which it stated that it does not handle the manufacturer's product. This manufacturer has valid FSSC 22000 certification and also provides a declaration of allergens, a declaration of packaging suitable for consumption, a statement of EEC origin, non-GMO statement, statement of absence of heavy metals, pesticides, antibiotic traces and dioxins. In their purchase agreements both the distributor and the manufacturer agree to receive audits if appropriate and they are obliged to sign the specifications.

Quality control at reception: 3

The supplier sends a certificate of analysis of each batch, of raw material which is reanalysed on receipt. The parameters analysed are the percentage of fat and humidity. A microbiological analysis is also performed.

The effective received weight of the product is not checked nor is the temperature checked on receipt, which, since this is a dried product, is not of any great importance. Since it is packaged in 25 kg sacks it is not a determining factor to check the effective weight at the time of receipt.

All labeling texts are reviewed upon receipt as to their legality.

Storage and traceability: 1

There is a dedicated storage place for each raw material. A computer system is available for managing traceability. Full traceability of all finished product batches can be monitored.

Calibration: 1

There is a robust calibration plan. The equipment is calibrated according to a defined frequency.

Hygiene and cleaning: 1

There is a robust cleaning plan: detachable parts are cleaned before a change of raw material.

It is monitored that no packaging material remains in the packaging line.

Human Resources: 3

Operators receive training in Good Manufacturing Practices and traceability. Refresher courses are held every year. The training plan does not include perceptions of food fraud, although it does include Food Defense.

Information given to consumers: 1

Regular reviews are conducted concerning the truth and legality of the information given.

Sub-contracting: 1

A logistics operator is sub-contracted to carry out distribution of the finished product. This operator has been approved for four years and receives regular audits, for 6 months ago...

	VULNERABILITY			
Incoming	History of fraud	1	3	5
RAW	Geopolitical and economic considerations	1	3	5
MATERIALS	Supply chain	1	3	5
and PACKAGIN	Relationship with supplier and history	1	3	5
MATERIALS	Quality control	1	3	5
PROCESSING	Storage and traceability	1	3	5
	Calibration	1	3	5
	Hygiene and cleaning	1	3	5
and DISTRIBUTION	Human Resources	1	3	5
	Information given to consumers	1	3	5
	Sub-contracting	0 1	3	5
	TOTAL		21 LOW	

2. SEVERITY: Medium

This is a product for the elderly. The raw material in question forms a high percentage of the end product. The adulterants most likely to occur are the presence of horse meat or pork which, although both products are not harmful nutritionally, means that the quality will not be as it should be. In addition, public opinion is very sensitive to fraud involving the substitution of the meat of one animal for that of another.

3. DETECTION

To detect the presence of horse meat or pork in the raw material a DNA analysis should be conducted with specific primers of the species that are to be detected. This DNA analysis is expensive and companies cannot always afford it.

	HAZARD		RIS	SK	PREVENTIVE	
STAGE		Vulnerability	Severity	Summation	Detection	MEASURES
Incoming RAW MATERIALS and PACKAGING MATERIALS	History of fraud	3	3	6	high	Surveillance for alerts.
	Geopolitical and economic considerations	1	3	4	high	Assessment of supplier. Surveillance of changes to environment.
	Supply chain	5	3	8	medium	Assessment of supplier. Airtight packaging. Sealed containers.
	Relationship with supplier and history	1	3	4	high	Questionnaire. Audit. Certification requirement.
	Quality control	3	3	6	high*	Assessment of supplier's suppliers required. Performance of DNA analyses.
	Storage and traceability	1	3	4	high	Electronic identification.
PROCESSING and DISTRIBUTION	Calibration	1	3	4	high	Validated calibration plan and procedures.
	Hygiene and cleaning	1	3	4	high	Validated cleaning and hygiene plan and procedures.
	Human Resources	3	3	6	high	Training plan that includes traceability and Good Manufacturing Practices. Training concerning food fraud.
	Information given to consumers	1	3	4	high	Regular written reviews. Checking of flow chart.
	Sub-contracting	1	3	4	high	Audit of sub-contractor

^{*}detection is considered to be high if DNA analyses are performed. If they are not performed, detection is low.

		IDENTIFICATION OF CRITICAL POINTS					CRITICAL	SURVEILLANCE
STAGE	HAZARD	P1	P2	Р3	P4	FCCP?	THRESHOLDS	SYSTEM
Incoming RAW MATERIALS and PACKAGING MATERIALS	History of fraud							
	Geopolitical and economic considerations							
	Supply chain	Υ	N	Υ	N	YES	Do not accept deliveries that do not meet the specifications.	Checklist on receipt of products.
	Relationship with supplier and history							
	Quality control							
PROCESSING and DISTRIBUTION	Storage and traceability							
	Calibration							
	Hygiene and cleaning							
	Human Resources							
	Information given to consumers							
	Sub-contracting							

4. PREVENTION MEASURES

- 4.1 Audit of distributor's supplier: to reduce the vulnerability of the supply chain an audit of the distributor's supplier should be performed. The distributor can be approached to find out whether it already does this and, if so, to accompany it on the next one conducted. In the same vein, the use of airtight containers and sealed containers for the transport of raw materials should be required.
- 4.2 Training that includes food fraud: to reduce the vulnerability derived from training of workers, it is advisable to include training about food fraud or include this knowledge in other training.
- 4.3 Performance of DNA analyses: to guarantee the quality of the product manufactured, a DNA analysis may be performed to detect the possible presence of species other than cattle.

7 / GLOSSARY

Audit: systematic and independent examination to determine whether activities and results comply with the plans in place and whether they are implemented effectively and are suitable for achieving objectives.

В

Batch: set of sales units of a foodstuff produced, manufactured or packaged under practically identical conditions.

C

Competence: a demonstrated ability to apply skills, knowledge and understanding of a task or subject to achieve desirable results.

Competent authority: central, regional and local administrations, within the scope of their respective powers.

Control measures: any action or activity that can be used to prevent or eliminate a hazard for the safety of the product to reduce it to an acceptable level.

Control: conducting of a planned sequence of observations or measurements in order to obtain an overview of the degree of compliance with the legislation on feed and foodstuffs, as well as the animal health and welfare regulations.

Corrective measure: action to be taken when the results of monitoring at the Critical Control Points indicate a loss of process control.

Critical Control Point (CCP): phase in which control can be applied and which is essential to prevent or eliminate a hazard related to food authenticity or to reduce it to an acceptable level.

Critical threshold: criterion that differentiates the acceptability or unacceptability of a specific stage of the process.

Customer: person or food chain economic operator to whom the food is sold or supplied.

D

Decision Tree: logical sequence of questions and answers that enable an objective decision to be made on a particular issue.

Distribution: process of physically getting the product to the consumer.

Ε

End consumer: ultimate consumer of a food product who will not use it as part of any commercial operation or activity in the food industry.

Flow chart: systematic representation of the sequence of phases or operations carried out in the production or preparation of a specific foodstuff.

Food authenticity: consists of ensuring that food and raw materials purchased and for sale, are of the expected type, content and quality.

Food business operator: natural person or legal entity responsible for ensuring compliancewithfoodlegislationrequirements in the business that it controls.

Food business: any entity, public or private, with or without profit, that carries out any activities related to any stage of production, processing and distribution of food.

Food chain: a succession of activities

undergone by a foodstuff, from primary production, through production of animal feed, to sale or supply of foodstuffs to the end consumer.

Food Defense: protection of food products against intentional adulteration by biological, chemical, physical or radioactive agents.

G

Good Hygiene Practices (GHP): combination of processes, staff and/or service control procedures designed to ensure that products and/or services consistently reach adequate hygiene levels.

Good Manufacturing Practice (GMP): practices procedures and that are implemented using the principles of best practice.

Н

Hazard Analysis and Critical Control Point (HACCP) System: system that identifies, evaluates and controls significant hazards for food safety.

Hazard: biological, chemical or physical agent present in food, or the condition this food is in, which can cause an adverse effect on health.

Ingredient: any substance or product, including flavourings, food additives and food enzymes and any constituent of a compound ingredient used in the manufacture or preparation of a foodstuff and remaining present in the finished product, albeit in a modified form; traces are not considered ingredients.

Inspection: examination of any aspect concerning feed, foodstuffs and animal health and welfare, in order to verify that they meet the legal requirements regarding feed and foodstuff set out by the legislation, as well as regulations on animal health and welfare.

Net quantity: indicates the quantity of food. It is expressed in units of volume for liquid foods, units of weight for solid foods and in units of weight or volume for viscous foods. Most products state the net amount preceded by symbol e, which guarantees the manufacturer's commitment to controlling the weight of the product.

Nominal amount: weight or volume of product marked on the package label; i.e. the amount of product that the package is estimated to contain.

Official control: any form of control performed by the competent authority to verify compliance with the legislation on feed and foodstuffs, as well as the animal health and welfare regulations.

Package: unit formed by the package itself and its contents, such that the quantity of product contained cannot be changed without the package itself undergoing detectable opening or modification.

Packaging material: Is everything that serves to condition, display, manipulate, store, preserve and transport goods.

Preventive measure: any activity that can be carried out to prevent or eliminate a hazard for the authenticity of the food or to reduce it to an acceptable level.

Processing aid: a substance that is intentionally used in the processing of raw materials, foods or their ingredients to fulfil a certain technological purpose during treatment or processing.

Production, processing and distribution

stages: any phase, including import, ranging from primary production of food to storage, transport, sale or supply to the end consumer.

R

Raw material: any base material or semifinished material used by the industry to manufacture a product. Raw materials include packaging materials.

Risk: weighting of the probability of an adverse effect for health and the severity of this effect.

S

Sampling plans: documented plan that defines the number of samples that are selected, the criteria for acceptance or rejection and the statistical reliability of the results.

Severity: seriousness of the consequences for health due to exposure to a hazard. Specification: explicit or detailed description of a material, product or service.

Supplier: immediately preceding person or economic operator in the food chain that sells or supplies the food.

Т

Traceability: ability to reconstruct the history of food products and materials and elements for food production and marketing.

V

Validation: confirmation that the elements of the Fraud Prevention system are effective.

Verification: confirmation by examination and study of objective evidence that specified requirements have been met.

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9 APPENDIX I. Identification of the adequacy, or inadequacy, of the preventive measures.

To answer the first question in the decision tree, there may be complications in deciding whether the preventive measures that exist are adequate. If the answer is NO to more than one question in each stage then it is considered that the preventive measures are not sufficient.

RAW MATERIALS	YES	NO	NOT APPLICABLE
Is the information received corroborated by questionnaires to suppliers?			
If applicable, is the scope of certification corroborated with the company certifying private quality standards?			
Is a comparison made between the ingredient label and its technical data sheet?			
Is the origin of the raw material checked?			
Before accepting the raw material, is there a check of the quantity received?			
Is there a European regulation governing the PDO/PGI contained in the specifications of the ingredient in question?			
Is the operator registered with the appropriate regulatory council of the PDO/PGI?			
Is the regulatory council with which the operator is registered officially registered as a certifying body by the Ministry of Agriculture?			
Is the raw material in question certified as an organic product by the CCPAE (Catalonia) or its equivalent in the rest of the Spanish autonomous communities?			
Is the temperature of the transport vehicle checked at the time of receipt?			
Is the condition of the packages visually checked at the time of receipt?			
Is the supplier asked to provide a declaration of absence/presence of traces of DNA?			
Are processing aids used before they are approved?			
Are batches accepted without a purchase slip?			
Are batches accepted outside the terms of purchase in place?			
Are all batches analysed by basic analysis methods before they are accepted?			
Does the operator in charge of receiving orders have specific training in relation to the traceability system?			
Are raw materials labelled at the time of receipt?			
Are computerised systems used to manage traceability?			

PROCESSING	YES	NO	NOT APPLICABLE
Have storage operators been trained in all matters related to traceability?			
Do the different raw materials have assigned a specific location within the warehouse?			
Is there a procedure for delivery of raw materials to production?			
Is such a procedure applied and periodically checked?			
Is there control for supplying only what is needed for immediate production?			
Is there a plan in which the calibration frequency as recommended by the manufacturer is established, taking the operating history into account?			
Are different raw materials measured using the same spatulas, pans, etc.?			
Are disposable weighing accessories used in contact with the raw material?			
Can it be seen from the outside what packages contain?			
Is there a specific method of cleaning when a change of raw material takes place?			
Is a check of the effective weight of the finished product and packaging carried out in accordance with Royal Decree 1801 of 2008 or its amendments?			
Are checks made by written review of the agreement between the information on the label and the formula book?			
Are checks made by written review of the agreement between the information on the label and the raw materials technical data sheets?			
Are checks made by written review of the agreement between the information on the label and the manufacturing process used?			
Are changes tracked?			
Is the finished product packaged in airtight conditions?			
Is the product included in a container with safety lock?			
Are the conditions in which the finished product is delivered monitored and recorded?			

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