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Title

Lean 6S in Food Production. HACCP as a benchmark for the sixth S "Safety"

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Abstract: This article presents the integration of lean 6S methodologies and hazard analysis and critical control points (HACCP) in the food production sector. Through the study, it is seen that non-food industrial production is not very different from that of food and, in many cases, it assimilates protocols and ideas that are already working in the food industry; Such is the case of risk analysis, critical control points or hygiene, which are part of the food production protocol and, increasingly, of the industry in general. After the integrative analysis, the article proposes a common lean 6S - HACCP model, which can be used both in food production and in non-food industrial production.

Keywords: lean 6S methodologies; HACCP; food production; safety

1. Introduction

The quality control of food goes back practically to the origins of civilization [1]. Proof of this is the quality stamps found in *garum* jars, a culinary delicacy made from fish that was made on the Iberian Peninsula and exported throughout the Mediterranean as early as the second century BC (figure 1).

Figure 1. Food product quality stamps in the Roman Empire

The quality of food is vital in the proper sense of the word, since the life of consumers depend on it [2, 3]. It is therefore essential to ensure that the food products that reach the distribution lines are in perfect condition for consumption.

It can be said that current production methodologies have their origin in the studies and developments carried out at the end of the s. XIX in the field of industrial production [4].

Figure 2 shows a chronological analysis of the most relevant milestones in this area. At the end of the s. XIX, industrial production was aimed at obtaining a high number of products, with which the unit cost was supposed to be low, with quality control in the background. In fact, quality control was done at the end of the production chain, simply discarding defective products [5]. With this approach, product quality was the responsibility of that final control unit, not of the global production system, as it is understood today.

At the beginning of the s. XX Carol Adamiecki publishes his schedule, raising the idea of harmonizing the entire production chain. However, many years still have to pass before it is put into practice. Chain production actually started in slaughterhouses, where the slaughtered animals were moved, from one side of the establishment to the other, pushed by a system of chains and pulleys. This is where Henry Ford got the idea of the assembly line.

Throughout the first third of the s. XX it is observed that the quality of the product depends on the quality of the process, so that when the production process deviates from the control parameters, the final product has a high probability of being defective. Statistical control of the process appears, by the hand of Walter A. Shewhart, with the aim of obtaining valid products based on strict control of the production process.

A further step in this line of analysis is achieved when it is observed that the quality of the product does not only depend on production, but also on design; so that a well-designed product, obtained by a well-designed production system, has every chance of not being defective. Here arises the need to take product quality into account from the earliest stages of design.

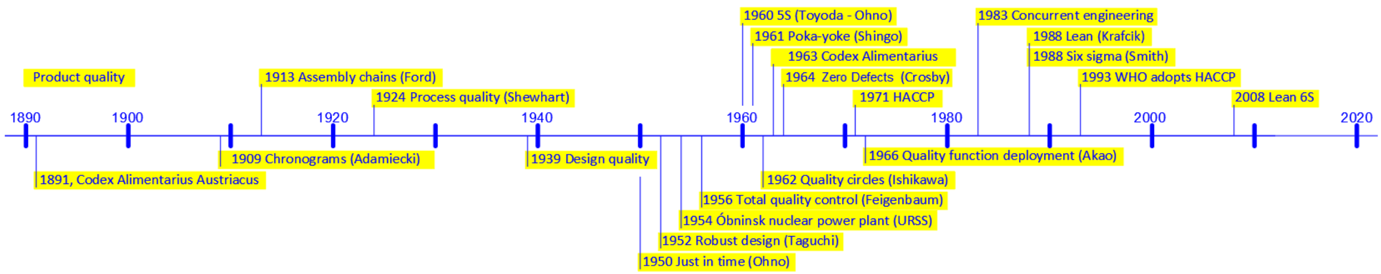

Figure 2. Chronology

In the field of design quality, in the middle of the s. XX appears the robust design methodology, from the hand of Gen'ichi Taguchi [6]. The basic idea of this methodology is that if a robust product is designed, the probability that there will be defective products in the end is very low. With this approach, products and production processes are oversized, which also implies an "extra cost", which will later be defined as "waste".

Along these lines, the introduction of CO_2 into cider produced at the beginning of the last century in Asturias, in northern Spain, for shipment to America can be taken as an example of robust design [2].

Also in the middle of the s. XX, the idea of total quality control arises, from the hand of Armand V. Feigenbaum [7], who formulates that the quality of a product is a function of every one of the departments involved; opening the doors to what later it will be defined as concurrent engineering [4].

Nevertheless, undoubtedly the most important qualitative leap in terms of production methodologies comes from the hands of Kiichiro Toyoda and Taiichi Ohno, responsible for the Toyota production system, who laid the bases of the 5S system [8].

Taiichi Ohno implanted, in the Toyota car factory, his ideas about the just-in-time methodology, as result of his studies on the American industrial production systems of the time. Although Ohno traveled to the United States to find inspiration from their car factories, he finally finished shaping the just-in-time concept when he visited a grocery store, where products on the shelves were replaced as customers bought them [2].

The Toyoda - Ohno tandem revolutionized industrial production systems with three very basic principles: continuous improvement, respect for people and zero waste. In this methodology waste is everything that is not useful to obtain the product, as Philip Crosby later collects [9].

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As an evolution of the ideas of Toyoda and Ohno, a few years later concurrent engineering and lean methodologies appear, as we know them today [10, 11].

Concurrent engineering, also known as simultaneous engineering, collaborative engineering or total engineering, is a methodology where the product design phase is fully interrelated with all the other phases of the life cycle of the product itself. The main objective is to eliminate problems in the production, distribution and consumption phases. In return, the conception and design phase of the product is lengthened; but reducing the total time of the project.

As for lean, a methodology started by Krafcik [12], a Toyota engineer, and developed by Womack, Jones and Roos [11, 13]; it's basically everything about getting the things you need in the right place, at the right time, in the right quantity, minimizing waste, being flexible and open to change.

The key principles of lean are:

- *Quality at the first time*, search for zero defects, detection and solution of problems at their source.
- *Minimization of waste*, elimination of all activities that do not add value, optimization of the use of scarce resources (capital, people and space).
- *Continuous improvement*, permanently evaluating the protocols thinking about what can be improved.
- *Forward processes*, products are pulled (in the sense of requested) by the end customer, not pushed by the buyer of the raw materials.
- *Flexibility*, quickly produce different mixes of a wide variety of products, without sacrificing efficiency due to lower production volumes.
- Building and maintaining a *long-term relationship* with suppliers by signing agreements to share risk, costs and information.

Lean tools include continuous processes of analysis (*kaizen*), forward production (in the sense of the Japanese term *kanban*), and fail-safe elements and processes (*poka yoke*), with the philosophy of doing things right (*monozukuri*), and all from the value area (*genba*).

Finally, in the evolution of quality systems, there is a new turning point when engineers first faced the construction of a nuclear power plant, again in the middle of the s. XX. Traditional quality control procedures are not sufficient due to the serious risk posed by the failure of such a plant. Thus, to "ensure quality", risk analysis and control of critical points are created, through which the technicians responsible for the equipment that were to form part of a nuclear power plant could "ensure" that there would not be any failures such as those that had already occurred in Mayac (Russia) or Windscale (United Kingdom).

The control of critical points was already a common practice in the dairy industries in the first half of the 20th century, since it was necessary to guarantee a quality of the industrially processed or packaged product that came from small-dispersed livestock farms [14].

2. *Codex Alimentarius* and HACCP

The rules regarding food production run parallel to human history itself. In the case of beer, for example, in the Code of Hammurabi you can find a reference of how it should be made. As problems derived from the consumption of poorly prepared or distributed foods have been detected, different standards have been implemented in different parts of the world. With the aim of unifying criteria and making them based on scientific principles, the Codex Alimentarius Commission was created in 1963, combining the views of the Food and Agriculture Organization of the United Nations (FAO) and the World Organization of Health (WHO). This Commission is in charge of keeping the Codex Alimentarius updated, a list of internationally accepted food standards whose objective is to protect the health of the consumer and ensure the application of equitable practices in the food trade.

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One of the general standards established by the Codex Alimentarius (Joint FAO / WHO Codex Commission, 20th Session, 1993), is the Hazard Analysis and Critical Control Points (HACCP). HACCP was defined in 1971, when the Pillsbury Company presented the HACCP system at a food safety conference in the United States. The system later served as the basis for the FDA (US Food and Drug Administration) to develop legal standards for the production of low-acid canned foods.

As currently proposed, the HACCP system includes seven principles [2]:

1. *Hazard analysis*. The potential hazards associated with the food and the measures to control them are identified. Hazards can be biological, such as microbes; chemicals, such as toxins; or physical, such as glass particles or metal fragments.
2. *Identification of critical control points*. They are phases of production that are crucial for the safety of the product as they are the last phases to eliminate the danger, since later phases of production do not allow it. For example, before or during cooking, after cooling, before packaging, or before delivery.
3. *Establishment of preventive actions with critical limits for each control point*. It consists of establishing the tolerance to be admitted, indicating how the danger is going to be eliminated. For example, for a cooked food, the minimum cooking time and temperature required to ensure the elimination of dangerous microorganisms should be indicated.
4. *Establishment of procedures to monitor critical control points*. It consists of establishing how and who is going to monitor that the critical limits are met.
5. *Establishment of corrective actions in case of non-compliance*. For example, re-process the food, or use it for another purpose.
6. *Establishment of procedures to verify that the system is working properly*. It consists of planning periodic checks of the system.
7. *Establishment of the registry to document the HACCP system*. It consists of determining the system's recorded format. It includes a record of the HACCP plan itself and of all derived records (checks carried out, corrective measures taken and verifications).

As will be seen below, HACCP has been integrated into current food quality management systems, based on ISO 9000 standards.

2.1. HACCP implementation in Spain

HACCP began to be implemented in Spain in the 90s and became mandatory for the entire European Union with Regulation 852/2004, about general hygiene requirements for food products, for all operators of food companies that are not primary production or related activities. The new system makes food industry operators responsible for their products, so that administrative controls are now focused on ensuring that self-control is adequate so that only safe food is marketed.

Control with HACCP is systematic, rational and structured, based on preventive measures to reduce risks and make better use of resources. It is intended to minimize risks and improve consumer confidence.

The self-control of a food companies begins with the prerequisites, which are the general hygiene requirements of Regulation 852/2004, together with the traceability requirement of Regulation 178/2002, defined as "the possibility of finding and following the trace, through all stages of production, transformation and distribution, of a food, a feed, an animal destined for the production of food or a substance destined to be incorporated in food or feed or with a probability of being so".

2.2. Food quality management systems

A quality management system (QMS) is a tool, formed by the organizational structure, the procedures, the processes and the necessary resources, that allows the quality of a product in a company. Understanding “quality” as the set of properties and characteristics of a product or service that give it the ability to satisfy expressed or implicit needs.

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In food, quality is achieved with food safety, hygienic sanitary quality, which is mandatory; as well as the nutritional and organoleptic quality, which satisfies the consumer.

The development of quality management systems appears with the globalization of the food trade, which forces the creation of a harmonized regulation that avoids sanitary problems. The ISO 9.001 quality management standard, focused on customer satisfaction, together with the European legislation on the "hygiene package" allows the emergence of private certification standards related to food safety (BRC or IFS, for example) and, later, the publication of ISO 22.000: 2005, on food safety management systems, to which the so-called "pre-requisites" are added, giving rise to the FSSC 22.000 standard (Food Safety System Certification).

ISO 22.000 standard, with which we can compare the other, is divided into 5 blocks:

1. Food safety management system (FSMS)
   a. General requirements: establish, document, and maintain an effective system for controlling hazards, communicating information, and evaluating compliance.
   b. Documentation requirements. The mandatory documents are:
      i. The statement of the organization's policy and objectives.
      ii. Documented procedures and their records.
      iii. The documents for the development and implementation of the FSMS.
      iv. ISO 9001 also includes, in this section, the Quality Manual.
   c. It must be controlled that the documents are available, implemented and updated; and that the records are legible, identified and recoverable.
2. Management responsibility. The commitment of the management must be evidenced through its policy, objectives, reviews carried out and resources provided. The functions of the management are:
   a. Document, implement and review the food safety policy and plan the FSMS.
   b. Define and communicate responsibilities and authorities, and all personnel must communicate with their manager.
   c. Appoints the leader of the FSMS team, who will be in charge of directing and controlling it.
   d. Create external communication, with suppliers and customers, and internal, between staff.
   e. Establish procedures for emergencies.
   f. Carry out the "management review" on the convenience, adequacy and effectiveness of the FSMS.
3. Resource management, which consists of planning the mode of resource provision. Human resources include the FSMS team and other personnel, for whom there must be records and contracts, and they must receive safety training. Infrastructure and work environment resources must also be provided to implement the standard.
4. Planning and realization of safe products.
   a. Prerequisite programs or GPP (best practices programs to avoid hazards) have to be established and verified.
   b. A HACCP plan must be established according to the principles of the Codex Alimentarius, with control measures that will form part of the operational GPP or the HACCP Plan, depending on the hazard and the desired management mode.
   c. Verification must be planned and updated, defining frequencies, responsibilities and methods.
   d. The traceability system must be defined: identify batches and their relationship with batches of raw materials, processing records and deliveries.
   e. Control of non-conformities must be carried out: detection of loss of control or exceeding a limit, corrective actions and handling of potentially unsafe products (where appropriate, foresees the withdrawal).
5. Validation, verification and improvement of the FSMS, carried out by the team that controls it. Improvement can be through communication, management review, internal audit, etc.

FSSC 22.000 standard incorporates more prerequisites than ISO 22.000, those of BSI-PAS 220: 2008 (*British Standard Institute - publicly available specification*), which are: building design, public supplies, hygiene, personnel, storage, etc. This standard has lost importance with the publication of ISO 22002-1, which replaces PAS 220.

IFS stands for *International Featured Standard*, whose food section is IFS Food. It is a certification created by German, French and Italian retail trade associations. It is applied in companies that process or pack products when there is a risk of contamination, applying other IFS certifications if there is no risk. Its technical requirements are similar to ISO 22.000, with the following exceptions:

- It includes a quality management system, in addition to the safety management system.
- Product planning and realization includes further requirements (in line with European legislation): product specifications, factory location and construction and distribution requirements, cleaning and disinfection, waste disposal, pest control, genetically modified organisms (GMOs).), allergens, etc.
- Includes a *food defense* block, on measures to avoid deliberate contamination, on plant safety.

BRC Global Standards is the certification created by the British Retail Consortium, the UK retail trade association. It also has several certifications, the food industry being BRC Food. Its technical requirements are similar to those of IFS Food, but arranged in different blocks, which are seven:

- Management team commitment.
- Food safety plan.
- Management system (quality and safety).
- Facility standards.
- Product control.
- Process control.
- Personal.

All these certifications, some of them private, can be voluntarily implemented in the food companies for which they are intended, and have value for their customers and for official administrative controls, the bases of which specify that the implementation of this type of regulation be taken into account rules for evaluating the risk posed by the company and the food it produces (in accordance with EU Regulation 625/2017, on official controls in the food chain).

3. Lean 6S *vs* HACCP

Lean 6S methodology is the blending of the lean methodology, which engages all the work philosophy opened by Toyoda and Ohno and which includes 5S as work principles, plus a sixth S, included later.

The 5S methodology covers [8]:

- *Seiri* (整理): discard, subordinate, classify. All unnecessary items need to be removed from work areas. These items are placed in a temporary storage place where, in turn, those that can be used for other operations are selected and those that are considered useless are discarded or discarded, freeing up spaces and eliminating obsolete tools.
- *Seiton* (整頓): systematize, order (figure 3). Part of the principle "a place for everything and everything in its place". Items that were not removed in the previous phase, and that are considered necessary, are assigned a specific place by delimiting their storage space, painting location lines with silhouettes, putting labels or signs, or using modular furniture or shelves.

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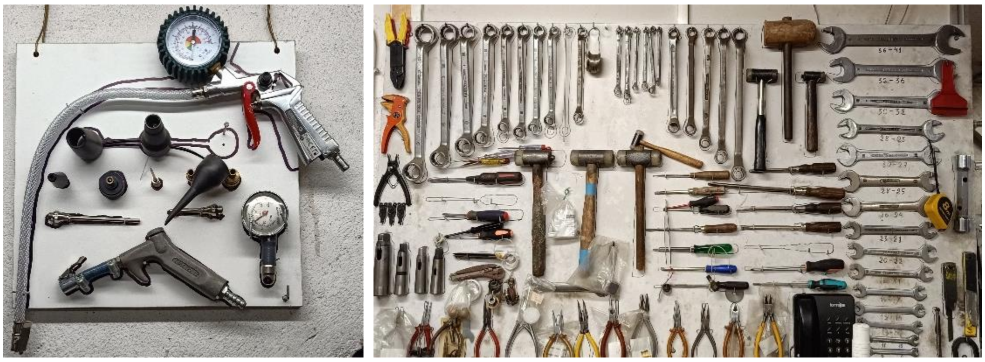

Figure 3. *Seiton* application examples

- *Seiso* (清掃): sanitize and clean. The systematized cleaning as part of the daily work facilitates the inspection and the identification of problems such as breakdowns, wear, leaks, or any type of defect; In addition, it makes the work environment safer by reducing the risks caused by dirt. In the food sector, cleanliness is a legal requirement.
- *Seiketsu* (清潔): simplify, eliminate inconsistencies and standardize. It consists of creating standardized work procedures that are simple and consistent. Thus, the loss of time derived from not knowing how to carry out a certain job and where to locate the materials necessary to carry it out is avoided.
- *Shitsuke* (躾): make the process sustainable in the future, discipline. It consists of verifying compliance with the other 4S (figure 4). This stage is the one that ensures that all the previous steps are carried out step by step, and that the established procedures are not broken. The verification of this execution is carried out by the operator himself, who has to discipline himself, or the technicians and supervisors in charge of it, filling in the pertinent records; and specifying the actions to be taken in the event that these disciplines are not complied with.

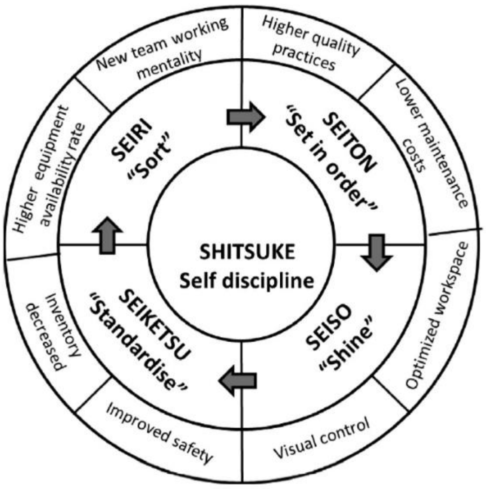

Figure 4. *Shitsuke* structure example [8]

The sixth S is "safety" (zero incidents), is proposed in 2005 by Roll and his team [15]. There are authors who have placed the sixth S in the fourth position, as if it were the next step to cleaning, and before the standardization [16, 17]. This analysis is collected by Jiménez and his team [18, 19], raising safety as a fundamental element in order to maintain a safe work environment, especially in periods of pandemics such as the current one.

It may be interesting to indicate that the studies on the applicability of lean in food already have a relative consolidation [20] although the implementation of lean 6S in this sector cannot be finalized until 2018 [1, 21].

In view of all of the above, the direct correlation between lean 6S and HACCP is clear. The HACCP work philosophy is very similar to the current work philosophy of lean 6S, although lean 6S is much broader as it aims at global quality and not just product safety, and it is not mandatory.

A lean 6S in the field of food production, therefore, places the safety -of the product- at the first level, since it should not be subject to other ideas or previous approaches.

Directly linked to the safety of the food product is cleaning (seiso), but it does not make sense to clean useless items. Therefore, the classification (seiri) with the aim of disposing of useless items would be the second level, closely followed and overlapping in some cases with cleaning, since any item not necessary to be stored for possible later use must be clean. .After these nuances, the order of the S's would remain unchanged.

Therefore, the 6S that are proposed for an industrial production system in the field of food are:

1. Safety (安全).
2. Classification (整理).
3. Cleaning (清掃).
4. Order (整頓).
5. Standardization (清潔).
6. Sustainability (躾).

4. Lean 6S tools applied to food production

4.1. Poka yoke

Poka yoke (in Japanese, ポカヨケ, "fail safe") are devices in charge of detecting abnormal situations that prevent the production line from continuing until the operation is carried out correctly. Placed at critical points in the process, these devices, which are nothing more than common sense devices, were successfully introduced by Shigeo Shingo at the Toyota Company in the 1960s.

Currently, poka yoke are applied at many points in the process, such as slaughterhouses, to safeguard the welfare of animals in accordance with European legislation. Regulation 1099/2009, relating to the protection of animals at the time of slaughter, requires that electronic devices be perfectly visible and capable of producing an audible alarm in the event that a series of critical parameters is not reached in stunning methods. For example, in gas methods, used for pigs and poultry, the concentrations of the gases used must be measured and, if they fall below the critical level, the alarm must sound to stop the process. Similarly, in electrical stunning methods, amps and time must be controlled.

4.2. Kaizen

The word *kaizen*, written in kanji characters like 改善, literally means change for the better or improvement, and is translated as continuous improvement or self-improvement. It refers to any change for the better, be it big or small, punctual or continuous. It does not implicitly include that the process must necessarily be continuous.

It is important to note that the "beneficial" concept used here is more related to Taoism or Buddhist philosophy in the sense of a common benefit, of society, and not of certain individual interests. This concept does not admit that one person can benefit at the expense of another. In addition, the benefit that concerns this concept must be sustainable (forever). Zen is a term that reflects a truly altruistic act that benefits others.

In the food sector, continuous improvement is forced by consumers, who are increasingly demanding that products have certain quality guarantees and are respectful of the environment and animal welfare.

4.3. Zero waste

Sakichi Toyoda exposes, as a production principle, never to manufacture defective products, which quickly leads to the "zero waste" of lean, which aims to eliminate inconsistencies and contradictions (mura, 斑); the expense (muda, 無 駄) and the overload (muri, 無理).

4.3.1. Muda

Muda, is a concept whose translation can be futility, uselessness or waste; It is, in this sense, everything that does not provide added value of interest to the customer. Eliminating muda by itself increases productivity.

One of the fundamental factors of lean technology is to identify which components add value and which do not, in order to progressively advance in the elimination of these second factors.

Taiichi Ohno identified seven types of muda:

1. *Overproduction*. It is the one that most affects an industry, since it consumes resources and does not produce benefits of any kind. It is caused when continuous operations should have been stopped or when forecast products are (wrongly) manufactured, for inventory, before the customer asks for them.
   Producing more products than are going to be sold is clearly a waste, a very normal consequence when working with large batches. Overproduction can be classified as one of the worst kinds of waste, this problem being of special application in the food sector, as the consumption and preferential consumption periods must be strictly controlled.
   In 2015, the UN approved the 2030 Agenda on Sustainable Development [21, 22], an opportunity for countries and their societies to embark on a new path to improve the lives of all. The Agenda has 17 Sustainable Development Goals [23], two of which are directly related to overproduction: objective 12, which advocates sustainable production; and objective 2, which defends food security as defined by the FAO, that is that everyone can eat.
2. *Delay*. Term applied in those periods of inactivity of a process since this action does not add value, that is, they are not productive and, normally, it results in an extra cost of the product.
   When a product in the production phase is on hold, normally in a work queue, capital is again generated and immobilized, which is in itself a waste. In perishable foods, this point is of vital importance, especially regarding the control of environmental conditions during the delay. Controlling the cold chain, that is, maintaining a low temperature, can make the process more expensive if it takes too long.
3. *Transportation*. It refers to the unnecessary movement of materials from one operation to another without being required, when their transport does not contribute anything to the process and the client does not have to pay for it.
   Additionally, each time a product is handled or moved unnecessarily there is a risk of damage, loss or delay. In food, the flow of raw materials and processed products must be taken into account to avoid cross contamination between raw and processed products, and between packaged and non-packaged products.
4. *Movement*. The waste of movement has two elements, the human movement and the movement of the machines, when these are out of place or do not contribute anything to the process. These movements are related to the ergonomics of the working place, thus affecting quality and safety.
   This point is similar to transport, but refers to the useless movements of people, equipment and machines. These movements are not always easily detectable. For example, when an operator leaves a tool outside his site, a movement that does not add value will inevitably occur when that or another operator has to look for that tool to perform another operation. Search time is downtime.

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In the food industry, the movement of people performing sensitive operations contributes to the dispersal of contaminants, which is one more reason to avoid it.

5. *Unnecessary or over-processed processes*. It refers to extra operations such as rework, reprocessing, handling of unnecessary materials and return to the warehouse due to a defect, or insufficient inventory. They are the result of the use of unsuitable tools or poor planning of the production process.
Dedicating more time to the production of a product than required causes delays and unjustified cost increase. It is usually associated with the use of inappropriate tools and equipment, either because they are too sophisticated or expensive, or the opposite.
Double packaging has become fashionable in the food sector. For example, in the image on the left of the figure 5, the legumes are packed in a plastic bag, to maintain the tightness conditions against moisture or insect attack, and inserted into a plastic bag. It is on this second container that all the information related to the product is indicated. In the image on the right, only a cloth container has been used, avoiding double packaging and single-use plastics.

Figure 5. Double packaging

6. *Stored stocks*. It is the set of components, ingredients and finished products that are in the different warehouses. As waste, inventory refers to conditions that occur when production or downstream distribution is not proceeding at the proper rate. Continuous flow and "just in time" of products on production lines is the best way to ensure that this problem is not incurred.
Raw materials, products in the elaboration phase or finished products represent an important capital, and if this capital is idle or immobile it is, at the very least, a loss of opportunity. The preparation of food that is not requested by any customer causes wasted space, possible damage, obsolescence and expiration dates in the products.
In the food sector, the correct management of raw materials and perishable products is of vital importance, especially fresh ones with a shelf life marked by their expiration date. The longer the product stays in the warehouse, the more likely it is to reach and even exceed that date.
7. *Defects and correction*. The defects, in addition to not adding value, entail an added cost in their detection and correction. Defective products have to be corrected, which is a waste of materials, time and energy.
Having to rework or dispose of a defective product causes many losses, added to the delays that this causes. In food, the detection of contaminants (chemical or microbiological) is a legal requirement, and the admitted correction procedures are also legally established in some cases. For example, fish infected by the Anisakis parasite must be frozen at a minimum of -20 °C for at least 24 hours.

Other muda added later:

8. *Incoordination*, which is caused when there is no coordination between the company and its customers or suppliers, which directly affects inventory.
9. *Underutilization of the capacity of workers*, having a highly qualified worker performing tasks well below his qualifications.

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10. *Confusion*, the uncertainty caused by not knowing what to do or how to do something; this is usually caused by the lack of documented procedures and training time. Undoubtedly, the best way to work without errors is based on correct training, and in this sense, the work of Yahyaee and his team [24] should be mentioned, where they propose playful tools to advance in the field of training.
11. *Lack of confidence*, when the operator doubts himself and thinks that he cannot do a task that he really can do. This waste can never be attributed to the worker, and is a reflection of poorly structured tasks, poor documentation and very poor worker training.

4.3.2. Muri

Muri is a Japanese word that means unreasonable, illogical, out of reach, too difficult; and it can be avoided with normalization and standardization work. To achieve this, a condition or a standard alternative that has previously proven to be effective must be defined, thereby ensuring a positive quality result.

Although the normalization that avoids muri refers to internal procedures, through standardized work procedures, in the food field it is necessary that these are congruent with the standardization external to the company, that is, the legislation that is applicable to them. In this context, it is worth mentioning that, in Spain, Decreto 2484/1967 is still in force, which maintains the Spanish Food Code (Código Alimentario Español - CAE), entered in 1974 as an organic body of basic and systematized standards, relating to food and everything related to them (materials, condiments, etc.). The CAE was created in the likeness of the Codex Alimentarius Mundi, and developed by sectors in the Technical-Sanitary Regulations and Quality Standards, which have undergone strong derogation to adapt to European legislation.

Currently, the CAE continues to be the cornerstone of food legislation in Spain since, in its 38 chapters; it includes provisions for practically all food groups.

In the CAE and in the standards derived from it, as well as in European legislation, criteria and limits of acceptability for commercialization for human consumption are established, which must be taken into account when drawing up internal work procedures.

The definition of requirements, and in particular the establishment of tolerance limits, is one of the key factors and, on many occasions, the decisive factor of good design. It must be ensured that the cost of precision is outweighed by its value, although this is not always achieved due to a lack of interest, time or data on the part of the designer.

A requirement is a provision that entails criteria to be met, and "intrinsic" requirements must be clearly distinguished from "collateral" ones, since action on one or the other can drastically influence production costs and product suitability. The intrinsic requirements are essential as they ensure the proper use of the product, its useful life, and avoid risks. The collaterals inform the department in question of the methods to be used, facilitating the process in question or making it more efficient.

Most of the procedures that reach production have information on both types of requirements, but they do not usually report membership in one group or the other, which means that some advantages of belonging to one of the groups are lost. Distinguishing between the two types of requirements also helps to reveal who is authorized to accept a breach of a requirement and who is not. In this sense, the design department is responsible for deciding which requirements are intrinsic, ensuring their compliance, and which collateral, whose compliance, they do not usually control.

For example, the case of a ham that has to be dried until it reaches a certain water activity (A_w). The intrinsic requirement would be the maximum level of water activity to be achieved, while the collateral would be the recommendation to keep the ham in the dryer for seven months. On certain occasions, the head of the dryer may decide that the ham is longer or shorter, but under no circumstances can it decide that it should leave the dryer without having reduced its water activity to the level established by design.

Product requirements are listed in the "specifications". A specification may reference or include diagrams, models or other appropriate sections and indicate the means and criteria by which conformity can be checked.

Once the specifications of a product have been defined, they have to be fulfilled as if it were a law. Any action that deviates from the norm must pass the corresponding authorization. The fact will have to be justified and documented. This also shows that, when writing the specifications of a product, it will be necessary to foresee the form of action against defective products and non-conforming products.

A tolerance defines the precision required for a variable in a product and can greatly influence production costs. Specifying very narrow ranges of tolerances or very high quality values is the best way to increase, in most cases unnecessarily, the value of the cost of production. The designer should, therefore, specify the widest tolerance band and the least strict quality that provide an acceptable degree of finish in the product, but always within the margins determined by the legislation applicable to the product. For example, in the case of common bread, according to Spanish regulations [25], the maximum permitted salt content must be 1.66 grams per 100 grams of bread, measured as total sodium. Therefore, given that it is interesting to approach the maximum allowed because the consumer is used to it, and it is what he demands, the limit of grams of sodium per 100 grams of bread could be 1.56, with a tolerance of ± 0.10.

It must be clear that the correct way of working is that all the departments involved in the product life cycle, starting with the sales department and ending with the quality department, have to collaborate in the development of new products, including here the decision-making on the characteristics of the product. This means that the design department is not solely responsible for setting tolerance and specification margins. Sales, which is the one who deals with the client, will expose the client's needs and requests, design can give technical limitations, production will expose its point of view against costs, machinery and personnel, and thus all departments. The final design has to collect all these points of view and translate them into one or more technical documents. Normally the depository of these documents, and the person responsible for their maintenance and updating, is the design department, the technical office or the quality department; so that all the documents related to the same product that are handled in the different departments have the same degree of updating.

4.3.3. Mura

Mura is a Japanese word that means unevenness, irregularity or lack of uniformity, and it is the third key concept in the waste disposal system in a lean project.

Mura, in terms of process improvement, is avoided through just-in-time systems (ちょうど間に合う), which are based on keeping little or no inventory. These systems deliver raw materials and ingredients at the right time, in the right quantity, and typically using the 'first in - first out' flow of components. Just-in-time systems create a "pull system" in which each thread withdraws its needs from previous threads and, ultimately, from an external provider. When a thread does not receive a request or withdrawal, it does not make more products. This type of system is designed, as can be seen, to maximize productivity by minimizing fixed assets in warehouses.

The use of different types of *kanban* to control the flow in the different stages of the process is essential to ensure that the system works correctly, that is, each substation "pulls" from the previous station requesting materials to process. Production levelling, even when different products are produced on the same system, will help schedule work in a standard way that encourages lower costs.

Some threads have a long execution time. Others have unusually high waiting costs. When these circumstances arise, it is a good idea to try to predict the next demand for a thread before the order itself is generated.

For example, in a cheese-making industry, it is certainly more effective to have the brine prepared in advance, and to be "on hold" than to have cheeses waiting to come in, with the consequent risk of spoiling. Not so the cold storage chambers, whose oversized design would lead to an unjustified cost in electricity.

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4.3.4. Zero waste benefits

Following zero waste guidelines should bring benefits to the company and the workers. A series of benefits that should be obtained with the implementation of a lean 6S methodology are listed below:

- The employee acquires a sense of belonging, security and feels motivated.
- A culture of the organization is generated.
- The use of working time is enhanced and saved.
- The useful life of the equipment is increased.
- Losses and losses due to defective productions are reduced.
- Higher quality products are produced.

4.4. Concurrent design in food

Concurrent design is an idea generation process where two or more business units come together to carry out the objective of this process, which can be to generate a new product or improve an existing one.

In the design phase is where all the ingredients that could form the food will be evaluated, while their elaboration is studied in detail. In this sense, the corresponding labelling will have to be considered, among other things, and which must take into account the special mention of ingredients that may cause allergies or intolerances. For example, a company that makes meatballs that flours before frying, in addition to having to label the meatball plate indicating that it contains cereal flour, whether it is wheat, barley, rye or oats; It must control what other products are fried in the same oil, since these may contain traces, transmitted during the frying of the flours used.

In this way, in the design of the production system, the separation of the processing lines of allergenic ingredients should be considered from the beginning. In the example above, if non-floured meatballs were made in the same plant, they would have to have a separate production line from the floured ones.

In a production system, the design process of a product goes through the following phases:

- Analyse the environment, know the strengths and, above all, know the weaknesses and problems that must be solved.
- Articulate the strategy based on the concurrent methodology, previously defined.
- Create a business model based on objectives. We must quantify what point we want to reach with the project and the company.
- Implement an information system, based on collaborative engineering. Through planning tools, integrated with collaborative engineering, it should be possible to carry out measurement plans of the scope or not of the proposed goals.

In the concurrent design, each new project is presented as a multidisciplinary work group. The work team, as far as possible, should be made up of heads of the different departments of the company. The four main fundamentals of design, which will be developed in the following sections, concurrently, are:

1. The life cycle concept.
2. The models of the product design process.
3. The structure, composition and components or ingredients of the product.
4. The flow of information in the design process.

Concurrent engineering is especially recommended in food products, where various multidisciplinary technologies converge and a high number of details must be taken into account, which means that significant time must be dedicated to the detailed design of the project.

In the development of the product, the target audience for which it is intended must be thought from the beginning. Food for children is not the same as another for adults or older people. Products intended for young children should have a significant nutritional component as well as suitable mild flavours. Products intended for certain adults can afford an extra calorie intake, while products intended for seniors should limit calories and salt.

4.4.1. Life cycle concept

The life cycle of a product is the set of stages that an individual product goes through (or an interrelated set of physical or intangible components) destined to satisfy a need from the moment it is created until its end of life. In this one, several stages are recognized:

- Conceptual or preliminary design.
- Detailed design or development.
- Obtaining permits and validations.
- Commercial launch.
- Production or elaboration.
- Verification and analysis.
- Distribution and control of expiration date or preferential consumption.
- Product consumption.
- Recycling of containers and waste treatment.
- End of life and completion of the project.

In this methodology, it is not necessary to have the product manufactured to develop the commercial launch, which means that the production lines can adapt to what the market is really demanding.

Quality and food safety is a fundamental factor in the food product. This quality must be analysed in the design phases, but it must be developed throughout the life cycle: maintaining the food preservation chain, without losing the freezing line, verifying expiration dates or preferential consumption.

It is important to keep an eye in the production phases, but in the case of food, vigilance in the distribution, commercialization and consumption phases is just as or more important. The product can be very good, but if the consumption is inappropriate, the result can be disastrous. That is why it is important to warn of allergy risks, clearly indicate the storage procedures and, of course, indicate expiration periods or preferential consumption that guarantee the quality of the product.

In the food sector, the use of containers is normally necessary. These containers are necessary because they are the ones that will allow the quality of the product to reach the consumer. Nevertheless, once the product has been consumed, the packaging begins to be a problem. It is necessary to consider the recycling and treatment of waste. It is curious the case of certain unprocessed fruits and vegetables that are placed in an expanded polystyrene tray and wrapped with transparent plastic to give a higher quality image. Some customers will be interested in buying this option, but for many others it will be a reason to discard it due to their environmental conscience.

4.4.2. Models of the product design process

Multiple models can be handled in the process of designing or improving a product. However, two types are broadly identified:

- Model of the basic design cycle, based on an iterative approach: analysis, synthesis, simulation and evaluation.
- Stages model, raised with a sequential structure:
  - Idea.
  - Conceptual and basic development.
  - Advanced development.
  - Design of the production system (developing prototypes and tests).
  - Launch campaign design.

There is no doubt that these two models are ultimately two variations of the same approach, because after the design of the launch campaign, if the set is not satisfactory, one must start over from the idea in an iterative process.

The concurrent design takes into account different nuances depending on whether the products being manufactured are produced in series or to order. This would be the

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case of a food factory, which undoubtedly must produce in series, and a company that supports events and celebrations that, even though it has a catalogue of products, is always open to the possibility of developing customized solutions for a specific customer.

In either of the two alternatives, the feedback of information from all the departments of the company to design is vital. This feedback must be carried out when the department is developing the detailed design phase, so that in this detailed design phase (or development), it is where all the information will have a very decisive influence on the entire product life cycle later on.

4.4.3. Structure, composition and components or ingredients of the product

In production engineering it is said that a final product has four basic components: raw materials, technology (knowledge), machinery and energy.

In-depth knowledge of each of these four basic components will allow us to improve the final product, acting on each of them, individually or jointly, to achieve better qualities, reduce costs or reduce the time to market.

Therefore, when developing a product, both the physical components (ingredients, packaging, etc.) and the intangible components (technology) must be taken into account, among which are the specific standards that this product must meet, the trials and tests to be carried out, etc. It should be noted that the rules for making the product include the rules and regulations that must inevitably be complied with.

When the number of ingredients is high, it is convenient to make a pyramid scheme, from the basic ingredients to the final product, passing through the intermediate products.

For example, in the preparation of a yogurt with raisins and cereals (figure 6), we need:

- Raw materials: milk, dairy ferments, grapes, cereal grains and the intended packaging (plastic, cardboard, labels, etc.).
- The technology: a series of documents that contain the preparation procedures and tests (documented work procedures), and which must take into account the applicable regulations.
- The machinery: fermenter, packer, labeller, cleaning machinery, etc.
- The energy needed to run all the above.

In intermediate phases, we will have yogurt, raisins and cereal flakes.

In the final phase, we will have all the previous ingredients, mixed or not, packaged and ready for distribution.

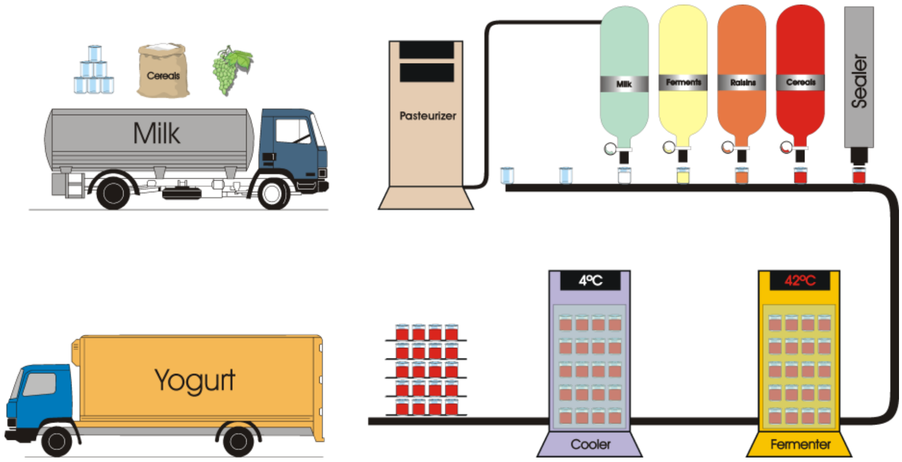

Figure 6. Yogurt production process with raisins and cereals

4.4.3. Information and communication in the design process

Regarding the information flow in the design process, within the concurrent design environment, the first point is the analysis of the needs that must be satisfied; and information regarding these needs should be obtained from all project and product related technicians. These needs are known as customer or user needs and are the starting point in the design process (figure 7).

Figure 7. Information and communication

It is also important to see what characteristics or requirements are necessary for concurrent engineering to be applied. On the one hand, the organization where it is applied needs to be flexible and well-structured. On the other hand, supporting technology is very important in each of the company's departments, as well as a clear focus on product design and customer needs and desires.

Concurrent engineering is based on the convergent work of the different stages and requires more time to be invested in detailed product definition and planning.

5. Implementation of a system based on lean 6S - HACCP

5.1. Lean foods

The Spanish Food Code defines foods as substances or products of any nature, solid or liquid, natural or transformed, which, due to their characteristics, applications, components, preparation and state of preservation, are capable of being habitually and appropriately used as nutrients or fruitive.

Some authors translate the lean methodology as "skinny methodology" or "fat-free methodology". It could be said that the robust design of the middle of the last century, which in food would be, for example, a good stew or a good bean stew, is moving to a slim design, which would be a low-fat and balanced meal, such as a salad with chickpeas, for example. With this idea, we could conclude that a "lean food" would be a fat-free food, but concepts should not be confused. A very fatty food, such as olive oil, can be a lean food consumed in the appropriate amount, and a fat-free food, such as a soft drink, may not be read for a sedentary person, by providing an excessive amount of sugars that his body does not need. Lean foods, therefore, are those that are adjusted to the real needs of the customer.

Regarding the real needs of the client, in the field of food it is necessary to refer to nutrients:

- *Nutrient* is a component of food useful for metabolism. Essential nutrients are those that must be obtained preformed because the body is not capable of synthesizing them.
- *Nutritional need* is the minimum amount of a nutrient to meet the body's needs, for example, 1 ng of iron.
- *Dietary recommendation* is the amount necessary to satisfy nutritional needs. In the example of iron, it would be 10 ng because its absorption is difficult.
- *Balanced diet* is the combined consumption of foods that provide the necessary energy, allow weight maintenance, and provide nutrients - including vitamins and minerals - in adequate proportions.

The EU Regulation 1169/2011, on food information supplied to the consumer, sets out the reference intakes for the average European adult of the nutritional components that must be included in the label (table I).

Table 1. Nutritional components

Energy or nutrient value	Reference intake
Energetic value	2,000 Kcal
Total fat	70 g
Saturated fatty acids	20 g
Carbohydrates	260 g
Sugars	90 g
Protein	50 g
Salt	6 g

No primary food contains all the nutrients, and traditionally the responsibility has fallen on the consumer to combine them appropriately to follow a balanced diet. However, at the time that primary foods are industrially processed, modifying their characteristics, and prepared meals become popular, the food industry must acquire part of that responsibility and create foods that allow maintaining a balanced diet, controlling that the size of the servings and their nutritional composition are appropriate for the customer.

Currently, the challenges for the food industry in relation to nutrients are:

- Reduce the energy value of food by reducing the amount of fat and sugars.
- Decrease the total amount of salt.
- Replace saturated fatty acids with monounsaturated or polyunsaturated ones, and eliminate trans fatty acids.
- Increase the total amount of fibber.

5.2. Phases for the implementation of the system

Below is a summary of the steps necessary to start up a production system under the premises of the lean-6S methodology in food:

- Design a simple production system, eliminating complications that do not add value and simplifying procedures.
- Come up with a continuous improvement plan and never stop applying it. Remember that there is always room for improvement.
- Organize the production flows based on demand. In this type of production setup, inventory is only moved through each production centre when it is necessary to fulfil a customer's order. Under this approach, the first benefits are quickly obtained:
  - Cycle time reduction.
  - Less inventory, reducing the number of ingredients in stock.
  - Increase in productivity, organizing the production schedule.
  - Greater and better use of productive equipment.
- Never forget the first S: safety.

An approach to continuous improvement is essential to achieve the objectives set, which implies the creation of an incremental improvement plan for products, processes or services in the medium and long term, seeking to reduce waste to improve the functionality of the workplace, customer service or product performance.

A setback in the implementation of the lean methodology is that technicians focus on tools and procedures and forget about the lean philosophy. It is important not to lose sight of the methodological objective since otherwise the operator will limit himself to following some protocols, probably without understanding them, and will enter a routine that will probably not achieve the proposed objectives. Consequently, proper management is needed to avoid the failed implementation of lean methodologies.

The general lean-6S system will be outlined below, with the widest possible scope of application: the entire food chain, from primary production to retail; so that it can later be adapted to each sector. Reference is made to European regulations, which must be replaced by the corresponding one depending on the market to which it is intended.

5.2.1. System creation and initial planning

The first point of the system, basic, and which encompasses all the following blocks of points is the first that of the 6S: safety. An effective system must be established, documented, and maintained to control defects (including physical, chemical, and biological hazards that may occur in food), communicate information, and assess compliance.

The planning of the activity of a company must begin with the definition of the product and the production phase to be developed within the food chain. It involves, at a minimum, establishing:

- The sector: primary production, secondary production or service sector.
- The type of products: of animal origin (meat, dairy, egg products, etc.), of vegetable origin (vegetables, cereals, fruits, infusion plants, etc.) or mixed (prepared dishes).

Immediately afterwards, the concurrent design plan of the entire food chain must be drawn up, from the fields and farms to sale to the final consumer. The strategy to be followed together to avoid loss of value must be defined through meetings with those responsible for the different phases of the process.

They have to be defined, with all those involved:

- The target customers are those who are going to acquire the company's product, and their forecast of demand is what will determine the productive level to be achieved in the company, avoiding overproduction.
- Collateral customers, which are those who will acquire the waste and unwanted by-products, so that they acquire value in another production chain. They must be enough to absorb them.
- Suppliers, who are those who provide raw materials or products to the company. They must cover the necessary diversity and be sufficient, according to their productive capacity, to allow the desired productive level.

Communication channels must be established between the company and all those involved. At the beginning, as many meetings as are necessary to carry out the concurrent design should be held, and later, periodic meetings will be held to discuss improvements.

When establishing the overall strategy, it may be necessary to redefine the product or the production phase. In any case, the specifications of all food products are established, both those that will be produced in the company and those that will be provided by suppliers:

- Product shelf life studies must be carried out, in accordance with EU Regulation 2073/2005, on microbiological criteria. These must make it possible to determine the expiration date or preferred consumption date, whichever corresponds.
- The nutritional adequacy must be evaluated, to avoid the production of foods whose nutritional characteristics, in relation to the intended use, are not optimal. The use of nutritional or health claims must be made in accordance with the regulations (EU Regulation 1924/2006).
- If the food product is to be marketed packaged, the packaging must be appropriate to keep the product in optimal conditions for the time foreseen until its latest consumption.
- The labelling must be correct and it must comply with the applicable regulations.

5.2.2. Commitment and responsibility of the management team

In order to implement and maintain any quality management system, it is necessary to start from a propitious wish of the top managers of the company. Lean-6S is no exception. The management team must know the principles of the philosophy and show interest in its implementation by:

- The statement of the company's policy and objectives. Mention should be made of customer satisfaction through the monozukuri philosophy (environmental responsibility and work ethic), continuous improvement (kaizen), genba rides and waste elimination tools (mura, muri and muda): just to time, poka yoke and kanban.
- The performance of its functions, which are:

- Appoint or hire one or more lean teachers, who will train the rest of the staff in the lean philosophy and supervise its implementation.
- Appoint or hire one or more experts in food safety, who advise lean teachers in this area.
- Establish the organizational structure of the company, with heads of each department for internal communication. In each department, the means for the creation of kaizen groups are given.
- Establish external communication procedures, with suppliers and clients, and internal, among the personnel; to avoid incoordination.
- Participate in product and process planning, including emergency procedures.
- Periodically carry out genba walks, with or without the company of a lean teacher, to find out the real situation and detect problems to seek solutions.
- Check that the quality management system implemented meets the objectives.

- The contribution of the necessary resources, materials and personnel.

5.2.3 Product and process planning

Once the external factors have been defined, but which are essential for proper waste management, internal operating plans must be drawn up, taking into account the statement of the company's policy and objectives.

The internal plans, which together form the 6S, are:

- The *safety* plan, of security. Beyond its global importance, it includes:
  - HACCP (Hazard Analysis Plan and Critical Control Points), designed to avoid hazards in processed foods.
  - Protection of workers. Measures should be put in place to prevent workers from being injured by machinery or getting sick from their contact with food or other workers.
  - Defence against attacks, with measures to avoid deliberate contamination in the company. Areas and times with potential for sabotage should be identified and the necessary procedures to avoid them should be established. Staff and visitors must be identified.
- The *seiri* plan (classification), facilities and their maintenance. It must include the maps of the facilities and the lists of the equipment and materials present in each of the rooms. Its objective is that there are no objects in places where do not belong.

  Planning of the location and characteristics of the plant (figure 8):
  - The location must be determined by comparing available sites that are more valued after the joint evaluation of: proximity to customers and suppliers, access for transport vehicles and personnel, available natural resources and distance from unhealthy sources (landfills, farms with poor hygiene), insects or rodents (abandoned places with humidity and food).
  - The size must be the necessary to allow operations without space obstacles and without unnecessary gaps. Future expansion in response to increased demand is to be anticipated.
  - Different rooms must be foreseen for those operations that the legislation establishes that they have to be separated in space, such as the warehouse for cleaning and disinfection products or, in an ungulate slaughterhouse, the gut cleaning [26]. In addition, the independence of other operations must be valued, either to facilitate hygiene or for other reasons.
  - The distribution must be such that it allows the flow of personnel, food products and waste without cross contamination or changes in transport or movement.
  - The reception and dispatch areas must be independent, and designed to allow the loading and unloading of goods from transport vehicles.

  The facilities and needs for water, electricity and gases:
  - Determine the foreseeable consumption and the adequate reserve, which must cover the needs until the application of the emergency plan. The need for electricity

must take into account the possibility of obtaining natural light and ventilation or not.
- Water, electricity and gas installations must comply with regulatory safety measures, including fire protection equipment.
- The necessary machinery, its useful life and the foreseeable maintenance that they will require, including the personnel in charge of carrying it out. Given the risk of transmission to food products of foreign bodies (screws and the like), the need for detection equipment for them (metal detectors, for example) must be assessed.
- The required tools. All of them must comply with the legislation on materials in contact with food, both the general one (EU Regulation 1935/2004, on materials in contact with food, and the CAE) and the specific one according to the material in question, if exists. Its suitability is confirmed with the corresponding certificates.

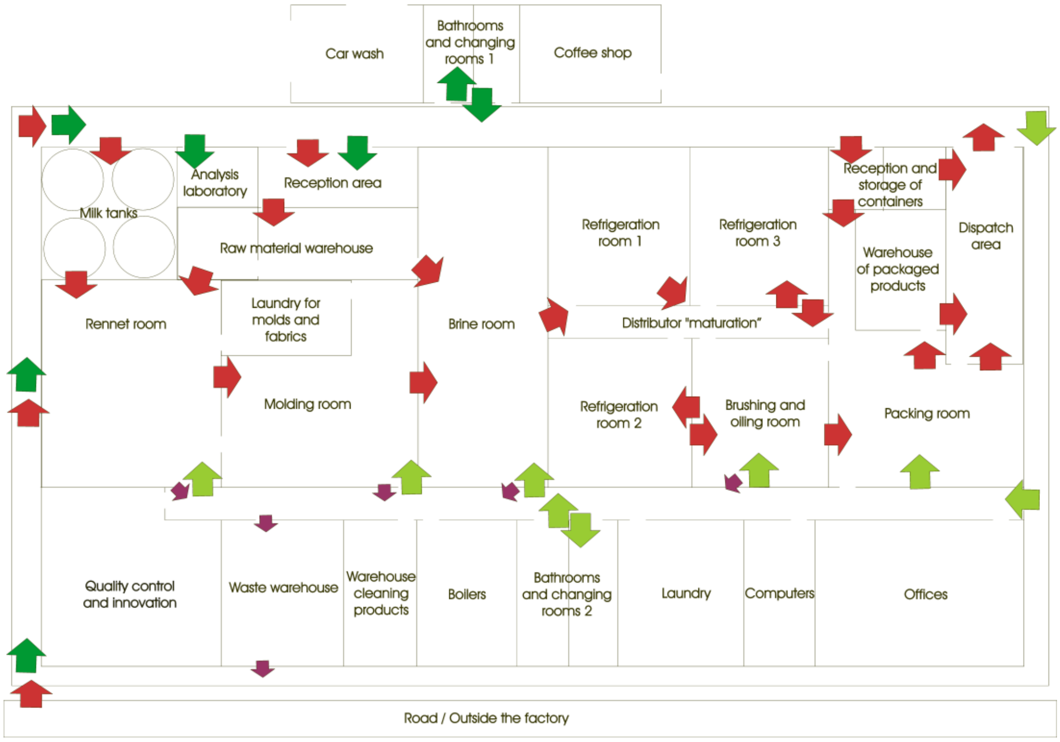

Figure 8. Flow chart in a cheese manufacturing plant: products (red), outdoor staff (dark green), indoor staff (light green) and waste (purple)

- The *seiso* plan, hygiene. Made according to international standards. The following HACCP prerequisite plans are included in this plan:
- Cleaning and disinfection. The frequency, the methodology and the personnel in charge of cleaning and disinfection of the different areas are established according to their risk.
- Disinsection and rodent control (integrated pest control plan). Constructive preventive measures and adaptation of the environment outside the building must be included.
- Personal hygiene. Means should be provided and maintained for personnel to wash and dress in appropriate clothing.
- Water control. The different types of water, potable and non-potable, must be channelled independently (figure 9).
- Waste. The flow of the different wastes and the periodicity of their removal are designed to avoid them being a source of contamination. The place for cleaning and disinfection of used containers should be provided if they are to be returned to clean areas.

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Based on the assessed risk, appropriate sampling and analysis are established in critical phases of the manufacturing process (on raw materials, semi-finished or finished products, packaging materials and areas in contact with food). The results of these analyses must be obtained before the product leaves the company or, if this is impossible due to the deadline, this circumstance and the results must be transmitted to the next link in the chain, when they are obtained.

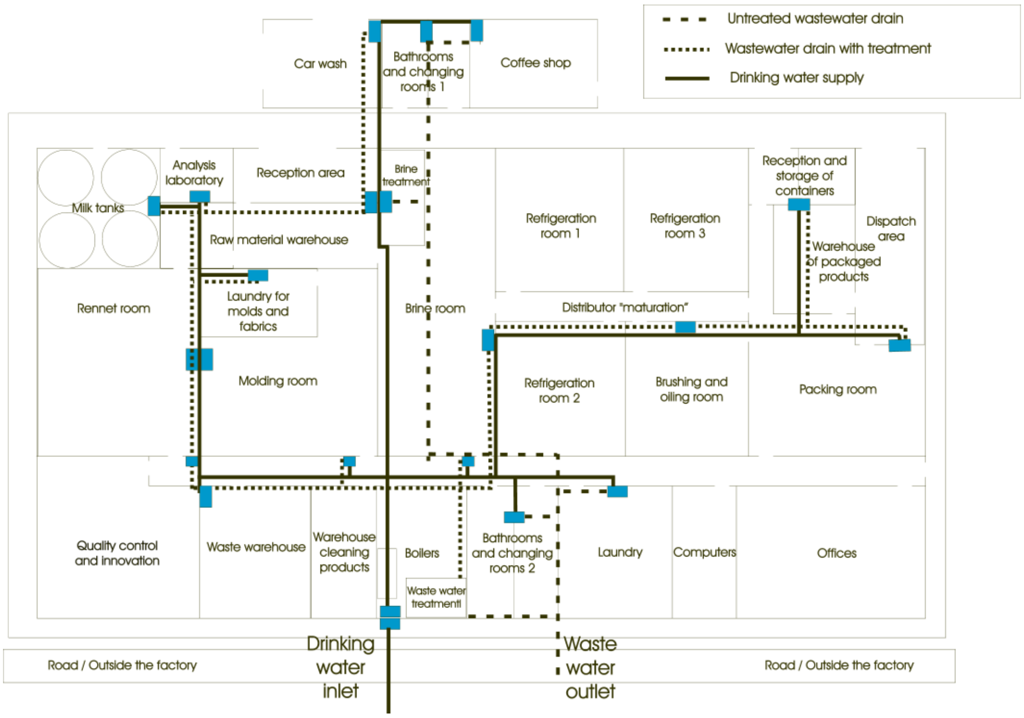

Figure 9. Example of a drinking water supply network and wastewater evacuation in a cheese farm

- The *seiton* plan, order. All workstations must be equipped with the equipment and utensils necessary for the tasks to be carried out in them, and the silhouettes must be marked to show the absence of a required instrument.
- The *seiketsu* plan (standardization), with documented work procedures, which must include all the activities carried out in the company, indicating how and when they are to be carried out, who carries them out and what controls are associated with them. Includes procedures for:
  - The reception and storage of goods. The first-in-first-out (FIFO) principle must be adhered to. If a controlled temperature is required, warehouses must have poka yoke-type systems, which alert in case of failure.

  - The operation of the different equipment.

  - The work stages of each process.

  - Monitoring of traceability. The complete and truthful transmission of the identification information (correspondence with suppliers) and characteristics of the food products issued from the company must be ensured:

  - The packaging and labelling of food products.

  - Transport.

  - Actions in cases of crisis or emergency.
- The *shitsuke* plan (sustainability), for process controls, which must establish the control methodology for the entire system, and the derived records. Compliance checks must be carried out by the operators themselves, with or without the help of the poka yokes, so that they are the ones who paralyze the chain in the event of a defect:

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- Corrective actions must be provided for the process and destination of the affected products (reprocessing, transformation or withdrawal). These rulings should be discussed in the kaizen groups convened later.

- The calibration of the measurement systems should be planned (not only to comply with the process control plan, but for any other control).

Periodic supervision and verification of the work by competent personnel should be foreseen. It should be distinguished:

- Inspections. The personnel with specific training are in charge of supervising and periodically verifying that the company is operating according to the planned plan based on the established indicators. The inspector must be familiar with all established procedures and routine controls, and have the communication and persuasion skills to enforce them. These personnel carry out tours on site (genba walks), listening to the operators and taking note of the problems detected.

- Audits. At least once a year, depending on the assessed risk, internal audits of the different plans must be carried out, in particular of the critical activities for food safety. Auditors must be objective and impartial, so they should not audit their own work. The possibility of audits being carried out by external companies should be evaluated.

It must be controlled that the documents are available, implemented and updated; and that the records are legible, identified and recoverable.

5.2.4. Human resources management

Human resources include both the lean team and the rest of the staff, of which there must be contracts and records. It has to be planned:

- The appropriate training: in food safety, lean philosophy, company organization, procedures, safety standards, etc. Confusion (muda) should be avoided.
- The suitability in qualification and number for the position held. It must be determined, for each of the processes, which personnel will be necessary, so that no change is incurred due to undervaluation, lack of trust, waiting (if there are more personnel than necessary) or movement (if less, and an attempt is made to fill the gaps).

5.2.4. System upgrade

It must be established:

- *Kaizen groups*. They must have space for their meetings, and the advisers of each group must be designated. The methodology to be followed to define the discussion priorities and the communication system between groups and kaizen managers must be established.
- *Kaizen managers*. It is the team with the capacity to estimate or reject the proposals of kaizen groups and put them into practice. They receive the results of routine controls and inspections and audits, as well as customer complaints, thus compiling the possible improvements needed, for which they can seek a solution independently or with the help of kaizen groups.

From the global point of view of concurrent design, and to facilitate the aforementioned meetings with all those involved in the food chain to maintain continuous improvement, experts who carry out genba walks in the different phases of the chain should be exchanged. These experts verify that the companies that supply theirs comply with what is expected, and that the companies that are their clients are satisfied with the products received. In addition, with regard to customer satisfaction, a complaint management system should be put in place to avoid a recurrence of non-conformity.

5. Conclusions

It is still interesting that the origin of Ford's idea of chain production came from a visit to a cattle slaughterhouse, where the animals were hung on hooks and moved from one side of the cutting plant to the other with chain mechanical mechanisms. It is also interesting to note the origin of the idea of just in time: in a food distribution centre, a supermarket. This makes us think that the food production industry is truly at the fore in many aspects, sometimes out of pure necessity, such as cleaning and sanitary controls, and other times because in this sector, as in all sectors in industrial areas where production problems arise, there are serious professionals who seek solutions to emerging problems and innovations to improve what they already have.

Therefore, proposing the application of lean technologies in the quality food production sector is nothing more than the logical consequence of the chain of reasoning that arises in this and all industrial sectors, which is customer satisfaction and, with it, the consequent industrial benefit that allows companies to survive, evolve and improve their production systems day by day.

After analysing the structure of a lean 6S system, we can conclude that the system is perfectly applicable to food production and that it adds value by being fully compatible, even overlapping to a great extent, with internationally accepted food safety regulations.

Author contributions

R.D. is the originator of the initial idea for the work. M.M.E, M.D. and L.R. developed the proposed models and methodology. All authors provided the state of the art, supervised the research work and analysed the implementation plan and the conclusions. The authors participated in the writing and revising of the manuscript. All of them have read the paper and agree the publication of the manuscript.

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