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TRACEABILITY IN DIETETIC MILK SERVICES

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Abstract: Concern for patient safety and the authenticity and safety of health products is increasingly present throughout the world to control the risks to which the patient is subjected. The Dietetic Milk Service is the unit destined to the preparation, packaging, preservation, sterilization and distribution of milk diets, which hospitalized infants receive, when breast milk is not available. The health authority establishes that the Dietetic Milk Service must have a procedure that allows it to trace all stages of production of its formulas, including raw materials and packaging materials; however, there is no regulation, guide and/or manual for the implementation of the traceability system for the Dietetic Milk Service. The objective of this monograph is to propose the incorporation of a traceability policy for the Technical Guidance of Dietary Milk Services.
Keywords: SEDILE, traceability, food supply chain, powdered infant formula, food safety.

THEORETICAL FRAMEWORK

MILK DIETETIC SERVICE (SEDILE)

The SEDILE is the unit intended for the preparation, packaging, preservation, sterilization and distribution of dairy diets, i.e., formulas received by hospitalized infants. The SEDILE unit should be a physical space designed and intended exclusively for the preparation, packaging, preservation, sterilization and distribution of milk and enteral formulas, under strict standards of nutritional quality and safety (1).

Breast milk (BF) is the most complete feeding for the infant, both in terms of safety and quality, provides sufficient nutrients, helps prevent infections, promotes overall development and reduces infant morbidity and mortality (2). However, there are situations in which infants require infant formula milk either because BF is not available, the mother is unable and/or unwilling to breastfeed, or when expressed BF is not available in sufficient quantity and quality (3).

Some liquid milk formulas are available in Chile, but due to their cost and low demand, fewer alternatives are available than in other countries. Unlike liquid formulas, powdered preparations for infants are not sterile, so the risk of microbial growth is even greater (4); the minimum and maximum amounts of microorganisms that can be present in these preparations are established by the Food Sanitary Regulations (RSA) (5).

The Regulations for Hospitals and Clinics govern all closed health care establishments in our country. Article 44 of these regulations states that in "establishments where neonates or infants under two years of age are cared for, there must be a unit specifically responsible for the preparation of dairy diets, which will be organized and governed by the technical standards approved in this area by the Ministry of Health" (1).

Concern for patient safety and the authenticity and safety of healthcare products is increasingly present throughout the world in order to control the risks to which the patient is subjected.

A fundamental pillar to guarantee safe products is to have a traceability record system capable of tracking and identifying a product throughout the supply chain, providing a timely response to a risk situation. Thus, through this control system, the preventive and/or corrective actions recommended by the manufacturer or those required by the health authorities are implemented, focused on quality and safety of care; these measures range from stopping the distribution of the product to its withdrawal (6).

In general, traceability refers to a product and is usually mentally associated with a code, however, SEDILE is a clinical support unit

that focuses on the patient and the effect of food on him/her, in this sense traceability is related to a service and not only to a product, therefore, traceability in SEDILE is a key tool for the improvement of clinical care processes.

SEDILE must have a procedure that allows traceability at all stages of the production of its formulas, including raw materials and packaging materials. The traceability system should provide an objective and accurate response to a problem of quality and safety of milk formulas (7).

Like all systems, a traceability system must meet a series of requirements in order to function optimally; however, there is currently no specific regulation or standard that establishes the requirements for this support unit.

FOOD TRACEABILITY

Traceability is not a trivial term and the literature review shows that there are several different definitions and principles of traceability being used, which makes the concept confusing and makes it difficult to generate a common framework for its implementation (8).

The concept of food traceability originated following the political fallout and damage to consumer confidence and the food industry caused by the bovine spongiform encephalopathy (BSE) crisis, known as "mad cow disease," in 1996. In response, the European Union (EU) undertook a major reform of its food safety policy and regulations, with food traceability being the cornerstone of this reform (9).

According to Article 3 of **European Commission** Regulation 178/2002, traceability is "the possibility of tracing and following the traceability through all stages of production, processing and distribution of a food, feed, substance or animal intended for food production or for incorporation into food or feed or with the potential to be incorporated into food or feed". In other words, it is the possibility of following the steps that a product and its components have gone through from their origin until they reach the consumer's hands (10).

For its part, the **Codex Alimentarius Commission** established in its document CAC/GL 60-2006 that "traceability or traceback should be able to identify at any specific stage of the food chain, from production to distribution, where the food comes from (one step back) and where it was consumed (one step forward), as appropriate to the objectives of the inspection and certification system". In this context, traceability can be used as a tool to achieve 3 main objectives: management of food safety risks (including animal and plant health), assurance of product authenticity and provision of reliable information to customers (11). The requirement for traceability extends to food intended for human consumption and animal feed, and is imposed on all operators, all those involved in the food chain (12).

The **International Organization for Standardization (ISO)** defines traceability as "the property of the result of a measurement or the value of a standard where it can be related to specified references, usually national or international standards, through a continuous chain of comparisons all with specified uncertainties" (13). ISO 22005 defines traceability as "the ability to follow a food or feed through specific stages of production, processing and distribution" (14).

For the U.S. **Food And Drug Administration (FDA)**, traceability means "the ability to follow the movement of a product through its production and distribution stages" (15).

The **British Retail Consortium (BRC)** standard defines traceability as "the ability to follow raw materials, components and products through all stages of receiving, production and distribution both forward and backward" (16, 17).

In simple terms, we can define food traceability as the ability to identify the origin of raw materials (including packaging material), the processing conditions (parameters such as times, preparation and storage temperatures) and the destination of each finished product (18).

FOOD STANDARDS

Legislation is identified as an important driving force for traceability, in order to establish methods to monitor food products and quickly remove those that are unsafe for consumers. Legislation is a driver that aims to protect and encourage behaviors in a society, i.e., that the actions that the standard is intended to implement, eventually be adopted by the different parties and cease to be a regulatory pressure mechanism, because awareness was achieved in society and it is this who demands compliance.

INTERNATIONAL REGULATION

Legislative efforts to require food traceability have occurred mainly in the EU and the United States (US).

The European traceability framework is regulated at three levels: European Commission policies, national level policies and private voluntary certification standards. In the case of voluntary traceability methods in the food sector, they are certified by private companies that normally have to comply with legal standards; in addition, European food legislation covers the entire supply chain, in order to be able to trace products and obtain information related to each of them. However, the general legislation does not establish any specific method or technique that food operators have to follow, therefore, the traceability requirement is limited to ensuring that companies are at least able to identify the supplier of the product and the subsequent recipient, i.e. one step back, one step forward traceability.

Prior to 2005, food traceability systems were based on customer needs, but since January 1, 2005 they became legally mandatory with the **General Food Law EU 178/2002** (19).

In the case of the USA, traceability was born with private voluntary initiatives, however, due to the threats of bioterrorism, the **Bioterrorism Act** was signed in 2002, giving way to the implementation of a traceability system for food products regulated by the *Food and Drug Administration* (FDA). Subsequently in 2011 the FDA, with the **Food Safety Modernization Act (FSMA)**, establishes a new food safety oversight system intended to ensure that the U.S. food supply is safe by shifting the dedicated focus from contamination response to prevention (20). Section 204 of FSMA, which went into effect in January 2023 with a compliance date of January 2026, creates a **Food Traceability Checklist (FTL)** that identifies foods for which additional traceability recordkeeping is required; this new rule is intended to allow for faster identification and removal from the marketplace of potentially contaminated foods, resulting in fewer foodborne illnesses and/or deaths (21).

On the other hand, there are standards or regulatory schemes of worldwide influence that are voluntary, but due to their scope and the influence of their promoters, they serve as a guide for the implementation of traceability systems and generate benefits, while allowing compliance with the legal requirements of both the country where the scheme originates and countries with export potential (22). These standards include the Codex Alimentarius and the ISO family.

The **Codex Alimentarius** is a set of internationally adopted food standards presented in a uniform manner. The Codex Alimentarius has two types of provisions:

a) Food standards: to be accepted without alterations at the international level. Their purpose is to protect consumer health and ensure the equal application of their practices in international trade. The World Trade Organization (WTO), through the Sanitary and Phytosanitary Agreement, recognizes that Codex standards are those that govern international food trade.

b) Agreements of a recommendatory nature: to guide and promote the development and enforcement of food requirements. Codex standards are voluntary. However, because of their positions in the WTO, most countries are incorporating them.

Acceptance of Codex food standards must be in accordance with established legal and administrative procedures concerning the distribution of the product in question, whether imported or domestic, within the territory of its jurisdiction. Such acceptance may be total, programmed or with specific restrictions.

The country that accepts the Codex standard is responsible for the uniform and impartial application of the provisions of these instructions, according to its mode of acceptance. In addition, the country should be prepared to advise and guide food producers and exporters to promote understanding and compliance with the requirements of importing countries that have accepted a Codex standard.

The Codex Alimentarius includes standards for all foods (unprocessed, semi-processed and processed) for distribution to the consumer or as raw materials (23).

ISO Standards, on the other hand, set out specified requirements for an organization's food safety management system in the food chain to demonstrate its ability to control safety hazards. This NGO is the world's largest developer of voluntary international standards, however, its typology will depend on how these standards are adopted by member organizations. Some of its members are public sector bodies and may implement ISO standards as either voluntary or mandatory public standards. Other members are private entities, and tend to implement ISO standards as voluntary private standards, although their application may be mandatory in cases where governments refer to such standards in regulatory requirements. Subsequently, ISO plays a fairly formal and influential role in global trade governance and in the international standard-setting arena, as it is recognized by the Agreement on Technical Barriers to Trade (TBT) and has observer status in the SPS Committee at the WTO and Codex (24).

There are 4 families of ISO standards; within the standards related to Safety Management, there is ISO 22000 applicable exclusively to safety in the food sector. Food companies that decide to voluntarily submit to ISO 22000 want to demonstrate that they comply with the legal requirements applicable to their activity and that they control the potential food safety hazards arising from their products and processes. Thus, the intention of this standard is, exclusively, the treatment of aspects related to food safety.

This standard is endorsed by the Codex Alimentarius Commission as it considers that its requirements adequately and clearly apply the Hazard Analysis and Critical Control Point (HACCP) principles; this fact is of great importance given that, in the EU, these principles are included in the mandatory food legislation that came into force in 2006. In addition, the HACCP system considers as a prerequisite the existence of a Traceability Plan, which is also a mandatory element as of January 2005 (25).

Within the voluntary standards, we find private commercial standards, among which the **British Retail Consortium (BRC)** and **International Featured Standard (IFS)** stand out.

The **BRC** standard was first implemented in 1998 to establish a common set of food safety requirements for UK retailers and suppliers, and has since become one of the most important and recognized standards in the food industry worldwide.

It is a global food safety standard that establishes requirements for the production, handling and distribution of food. This standard focuses on ensuring that the food produced complies with the highest food safety standards, and to this end, it demands compliance with a series of specific requirements.

The BRC standard has evolved over time and is currently at version 8, which was published in August 2018. The standard is regularly reviewed and updated to maintain its relevance and ensure the food safety of the products produced (26).

IFS was born in 2003 with the vocation of creating uniform standards focused on food, products and services. Companies certified according to IFS standards manufacture a product or provide a service, which meet customer specifications and always work for continuous improvement of processes.

The IFS standard considers it mandatory to implement a traceability system, which allows the identification of product batches and their relationship with batches of raw material, packaging material in direct contact with the food or intended to come into contact with the food. The traceability system shall include all relevant production and distribution records. Traceability should be guaranteed and documented until delivery to the customer (27).

NATIONAL REGULATION

Food regulation in our country is characterized by a variety of legal regulations. There is no organic law that completely regulates all food issues; on the contrary, there is a significant number of sectoral laws that contain provisions guaranteeing the production of safe and quality food.

The general framework is provided by the Sanitary Code and the Food Sanitary Regulations (FSR).

The **Sanitary Code**, Decree with Force of Law (DFL) No. 725, promulgated on December 11, 1967 (date of publication: January 31, 1968), governs all matters related to the promotion, protection and recovery of the health of the inhabitants of the Republic, except those subject to other laws. Article 102 states that special foods shall be considered those products or preparations intended for human consumption for particular nutritional purposes, used in the treatment of certain pathologies or health conditions, which require non-parenteral administration modalities, such as oral or other, and special supervision by health personnel (28).

In addition, the Code states that the **RSA** is responsible for providing the legal basis for action in all aspects related to health risks and damages associated with food consumption. This regulation will determine the characteristics that food or food products intended for human consumption must meet, the sanitary conditions to which their production, importation, internment, processing, packaging, labeling, storage, distribution and sale must adhere, the special conditions of use, if applicable, those of surveillance of special foods and the other sanitary requirements that establishments, means of transport and distribution intended for such purposes must comply with (4).

The RSA is referenced primarily in Codex Alimentarius and to a lesser extent in the European Food Safety Association (EFSA), FDA and includes country-specific public health situations.

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Article 69 states that "those that the health authority determines within its corresponding area of competence, according to the criteria established by resolution of the Ministry of Health, must implement the Hazard Analysis and Critical Control Point (HACCP) methodologies in their entire production line, as established in the Technical Standard issued by the same Ministry for such purposes. The standard to which this amendment refers is **Technical Standard No. 158 on "Requirements for the application of the Hazard Analysis and Critical Control Point (HACCP) System in Food Establishments"**, which came into force on May 21, 2015 (29).

The purpose of this MINSAL standard is to establish a harmonized regulatory framework among state institutions with competence in food safety. It should be noted that the application of this standard does not present greater requirements and does not conflict with NCh 2861. Of 2011, so that companies that already have the standard of the National Standards Institute (INN) will not see their quality systems affected.

To strengthen the development and implementation of the new standard in the food industry, three technical guides were prepared on: Standard Operating Procedures (SOP), Sanitation Standard Operating Procedures (SSOP) and Design, development and implementation of the HACCP system in food establishments. These guides are based on the new MINSAL technical standard and their objective is to facilitate the use of the standard by companies through examples (30).

In Chile, MINSAL and the Regional Ministerial Secretariat (SEREMI) are responsible for monitoring and ensuring food safety, based on the RSA and the Regional Public Health Plan (PRSP).

SCOPE OF APPLICATION

The traceability system implemented in each company, from upstream to downstream, should help maintain traceability throughout the food chain. Depending on the activity within the food chain, the system may require backward, internal or process and forward traceability (31).

BACKWARD TRACEABILITY

This refers to the reception of products. At this point, records are the key to trace the movement of products back to their origin, i.e. from any point to their previous stage. The traceability of the chain can be completely broken if good records are not available when the products are received.

Information that should be recorded:

- **From whom the products are received:** the origin of the products, details of the contract, a way to contact the supplier (name, address and telephone number).
- **What exactly has been received:** type of product, condition of the product (distribution characteristics), lot number and/or product identification number, date of processing, packaging, expiration date or any equivalent information to limit the size of these should be recorded. Any other information on the products, such as ingredients, quality controls, etc., should also be recorded. It may be sufficient to record the "commercial delivery note" and/or "invoice", provided that these documents provide concrete data on the identity of the product.
- **How much / When to be recorded: at the time** the goods have been received.
- **Quantity of product:** it is important to record the quantity of product received, as appropriate in kilograms, liters, number of packages, pallets, etc.
- **What was done with the products:** for example, entry into the warehouse, direct to processing, etc.

PROCESS TRACEABILITY

It is a matter of relating the products that have been received in the company, the operations or processes that they have followed (equipment, lines, chambers, mixing, division, etc.) within the company and the final products that leave the company. Many companies, in the commercial agreement with their suppliers, are already asking for guarantees related to the application of an internal traceability mechanism. This part of the system, related to the internal process to which the product is subjected within each company, can help in risk management and bring benefits for the company and for the suppliers.

The information that should be recorded in this area:

- **When products undergo some kind of modification: they** are split, change their status or are mixed, it is convenient to generate records. The number of points at which records need to be made depends on the activity.
- **What information is recorded:** identification of intermediate products, during the activity carried out (perhaps this identification is only temporary); identification of the final product to the customer, by means of the corresponding code or information such as the batch number. This code must accompany the product at the time of delivery.
- **What products are recorded:** feed, food, ingredients and additives, spices, and any incorporated products, and stock control records can be used.
- **How the records are created:** the transformation, processing, storage, division, etc. operations to which the products have been subjected generate different types of data (temperature, pH, etc.), which must be recorded in a system created for this purpose by the operator.
- **How much / Quantity of product:** it is important to know how much of this or that product is produced, not only from a commercial point of view, but also to avoid problems in subsequent steps such as storage or deposit of the product, etc.
- **When:** a system should be adopted to ensure the identity of the products incorporated, the date or time at which the modification occurred. In general, this information should be linked to process control data such as temperature records, etc. In some cases it may be possible to identify the causes of any problems that arise.

FORWARD TRACEABILITY

A very important point to bear in mind is that from this point the products are out of the company's control in some cases. When the products leave for direct consumption, the operator can place on the final label, the data (such as lot number or other type of code) that allow the identification of the origin of the ingredients and other components of the food. When products are shipped, the records should serve as a link to the customers' traceability system. Without an adequate system of records of the products delivered, the traceability of the food chain could be completely broken. Traceability information should be given as clearly as possible; making it easy for the customer to relate the identification and other information of the product being delivered to their own system of records.

The information that should be recorded in this area:

- **To whom it is delivered:** The company or person responsible for the physical reception of the product (record this data).
- **What exactly has been delivered:** The lot number and/or identification number of the products should be recorded. Pro-

vide receipts or accompanying documents together with the customers' purchase order. Other information of interest should also be provided such as: number of boxes, temperatures if applicable, handling conditions of the products, expiration dates, etc.

- **How much / Quantity of product:** it is important to record the quantity of product delivered, as applicable in kilograms, liters, number of packages, pallets, etc.
- **When: at** the time of delivery of the products and if possible in view of the customers. If necessary, an approval of the reception by the customers can be recorded.
- **Means of transport:** Transport data are essential to ensure traceability (e.g. carrier, license number, vehicle registration number, container numbers, steamer name, transport temperature, seals or any tamper-proof system to ensure the integrity of the cargo during transit, etc.).

Attention should be paid to the relationship between the three areas, since the aim is to ensure that the traceability system is seamless and that information flows along all links in the food chain.

In the event of a possible health risk in a food product, it is necessary to have two notions of traceability (downstream and upstream):

- **Downstream traceability** is the ability to locate or find the destination of a product, based on given information criteria, in order to proceed to its immobilization and/or withdrawal.
- **Bottom-up traceability** is the ability, throughout the food chain, to trace the origin and characteristics of a product in question, with the objective of identifying the cause of a quality and/or food safety problem.

This notion of traceability designates the sense of following the trace of a product along the food chain; it is an absolute concept, whereas the types of traceability (backward, internal and forward) are relative and depend, as we have seen, on the position in which the company in question operates (32).

TRACEABILITY IN HEALTH FACILITIES

MEDICAL DEVICE TRACEABILITY

Medical device (MD) or article for medical use is a health product, such as an instrument, equipment, apparatus, material, software or article, including its components, parts or accessories, intended for prevention, diagnosis, treatment, rehabilitation or contraception and which does not use pharmacological, immunological or metabolic means to perform its main function in human beings, but may in the meantime be aided in its function by such means (33).

Technical Standard No. 226 establishes the obligation to implement a data recording system that allows the traceability of MDs at the time of their reception by institutional health care providers (34).

Institutional providers must have a physical or electronic registry to record a minimum set of data or minimum information required by this standard, for all DM that they acquire, import, store, use or deliver.

The information recorded, in whatever medium it is available, must comply with the following requirements:

- Allow traceability of DM acquired by the institution, regardless of their use within the institutional health care provider (for clinical use or delivery to patients; or even those that are deteriorated, expired and/or destroyed without being used).
- Be updated, accessible and available for audit by the authority.
- It may not be altered with amendments, nor leave blank spaces between annotations.

- In case corrections are required, they shall be made leaving evidence of them and indicating the signature of the person who authorized the change, modification or cancellation of the record.

In relation to data records, these should consider, at least:

- Name of the product or medical device, with the designation assigned within the health facility.
- Identification of the supplier.
- Waybill/invoice number, according to the delivery document selected by the supplier.
- Model (only when applicable).
- Lot/serial number; in the cases of DM whose series are assigned individually to each unit and whose registration may delay extensively the reception processes, each establishment may establish internal procedures that allow the registration of a single number, code or key, which groups and relates them unequivocally with the respective Waybill or Invoice, which may be recorded in the traceability records. However, the corresponding records shall be kept for the purpose of achieving traceability on the series of products consigned in the Waybills or Invoices, or the documents accessory to them. In the case of custom-made DM, i.e., those manufactured without industrial processes, the date of manufacture may be indicated as the serial number.
- Expiration date; in those DMs that, due to their nature, use or materials, are not assigned an expiration date by their manufacturer or are indicated as indefinite, the institutional health care provider may record instead a date of its choice, taking into account various criteria, such as:
  - inventory or stock management
  - scheduled maintenance of the DM
  - logistic or accounting criteria or processes
  - obsolescence date
  - production date
  - date of receipt
  - any later date when any activity associated with the product is scheduled (e.g. sterilization process).

TRACEABILITY IN CENTRAL STERILIZATION PLANT

The Sterilization Center (SC), by definition, is the service that receives, conditions, processes, controls and distributes textiles (clothes, gauze, dressings), biomedical equipment and instruments to all sectors of the hospital, in order to provide a safe input to be used with the patient (35).

In Chile, Technical Standard No. 199 defines and regulates the conditions for establishing and maintaining sterilization processes in the EC. The purpose of this standard is to guarantee patient safety and the quality of health care (36).

In addition, within the framework of the Health Reform, the Health Authority Law No. 19,937 established that institutional health care providers, in order to be accredited, must comply with standards that guarantee the safety of the services they provide, including sterilization and disinfection processes (37).

Therefore, the SP should have a traceability system that allows knowing the history of each instrument reuse by reuse, allowing a multi-parametric control of the sterilization process through physical, biological and chemical indicators, and the follow-up of where it was, where it is and where each medical device should go.

With Technical Standard No. 199, the presence of the label on the packaging allows the traceability of the materials. With the following specifications:

- Identification of the person responsible for inspection and packaging.
- Content identification.
- Sterilization method (sterilizing agent used).
- Identification of the equipment used.
- Date of exposure to the sterilization method and expiration date upon processing.
- Load number and operator identification.

Currently, different sterilization centers operate with software that facilitates and automates the different data that must be taken into account when properly tracking sterilized medical devices (38).

There is currently no standardized traceability system for the CE, however, Technical Standard No. 266 for medical devices will lead all plants to modernize their traceability system in the short term.

TRACEABILITY OF MEDICINES

Pharmaceutical product or medicine shall be understood as any natural, biological or synthetic substance or mixtures thereof, originated through synthesis or chemical, biological or biotechnological processes, intended for people for the prevention, diagnosis, mitigation, treatment or cure of diseases or their symptoms or for the regulation of their systems or particular physiological states, including the elements that accompany its presentation and are intended for its administration (39).

In the USA and the EU there are laws on drug traceability. In the USA since 2013 the goal is to build in 10 years a system for traceability of medicines, connected to patients' prescriptions (40).

In Chile, the law requires that each drug must contain information on the producer (and distributor if imported), date of manufacture, expiration date and batch number. Exempt Decree No. 57, Technical Standard No. 147 on "Good Storage and Distribution Practices" talks about traceability, but it is not mandatory to have an integrated traceability system that allows clinical traceability, i.e., to know the history of the drug during all its steps, from its manufacture to its use in the patient.

TRACEABILITY IN POWER PLANTS

The Central Production Unit (CPU), known as the Central Food Plant, is the Food and Nutrition Service unit where the processes are carried out to prepare the culinary preparations planned in accordance with technical norms, criteria and international standards, in order to meet the nutritional requirements of healthy clients, hospitalized users, staff and other beneficiaries determined by the facility (41).

In the case of food service establishments, one of the main factors to consider is the high turnover of perishable raw materials such as vegetables, meat, dairy and fish products, so it is necessary to have information that allows easy identification of the suppliers of each batch, as well as the implementation of the PEPS system (first in, first out).

The date of receipt of each input, the supplier's data such as name or company name and address, as well as the product, including the type of raw material, internal temperature (when necessary), and lot number (when applicable), must be documented. If the size of the establishment allows it, the products should be stored in exclusive conservation chambers for each type of product.

Maintaining a list of approved and evaluated suppliers is vital for traceability of purchased inputs and maintaining quality and safety. It also helps to prevent adulterated (e.g., substituted or diluted) raw materials from entering the facility.

It is important that food prepared in the Central Food Processing Plant, such as sauces or dressings, which have a shelf life of more than one day, be stored refrigerated and have the date of preparation in a visible place.

For the implementation of a correct traceability system, it is recommended to keep records at the stages of: Receipt of inputs, Storage and Preparation (42).

PRODUCT RECALLS

Product Recall or Recall, in the food industry, is the strategy to withdraw from the market those products that are defective or represent a risk to the health of consumers; the recall and/or recovery can be of a food or of a material in contact with a food that presents a serious risk to the consumer. It arises primarily in emergency situations related to food safety to guarantee the consumer the right to receive safe food, free of physical, chemical or biological agents that endanger their health.

There are two types of Recall, the voluntary one carried out autonomously by the manufacturer or supplier upon detection of any defect in the product during the inspection and the mandatory one applied when the health authority, by its legal powers, identifies any defect or violation of the law and forces a company or supplier to carry out a recall.

The main reasons why a Recall might be necessary in the food industry are: labeling error, packaging defects, contamination by pathogenic microorganisms, allergen appearance, chemical contamination and physical contamination (43).

The implementation of this strategy requires a traceability program, which implies the ability to know the history of a product, its distribution channel and its target market; to achieve this purpose, the support and collaboration of consumers and other institutional and commercial actors, such as large supermarkets, is required (44).

The following recalls of milk formula products and childcare articles used in milk feeding have been carried out in the last 5 years (Table 1).

Date	**Infant formula**	**Reason for withdrawal**
April 2018	S 26 gold	Mandatory withdrawal due to the presence of Bacillus Cereus in 2 lots.
July 2018	Nan Premature	Mandatory recall due to the presence of mold in jars marketed in Chile, as of February 2017.
August 2018	Nan Premature	Mandatory recall due to the presence of Staphylococcus aureus above regulatory limits.
February 2019	Blemil Plus 2 hydrolyzed rice	Voluntary recall due to the presence of Salmonella in a lot.
February 2022	Elecare Similac Alimentum HMO Similac Human Fortifier	Voluntary recall due to consumer complaints about the possible presence of Cronobacter Sakazakii and Salmonella Newport.
February 2023	Enfamil ProSobee *Simply Plant-Based*	Voluntary recall due to possible contamination with Cronobacter Sakazakii.
March 2023	Gerber Good Start	Voluntary recall of 5 lots due to the possible presence of Cronobacter Sakazakii.
Date	**Product**	**Detail**
July 2022	Nuk brand "*First Choice*" glass baby bottles	Presence of lead above the permitted limits.
October 2022	Abbott brand bottles	Defective plugs (glands) that do not allow a correct seal.

Table 1. Recall of infant formulas and bottles.

Source: Own elaboration

OBJECTIVES

GENERAL OBJECTIVE

Propose the incorporation of a traceability policy for Diet Milk Services Technical Guidance.

SPECIFIC OBJECTIVES

- Establish the guidelines for the backward, internal and forward traceability system.
- Establish the components of the traceability system.
- Propose implementation scheme.

MATERIALS AND METHODS

A qualitative narrative review of the literature was conducted; the research was first oriented to answer the following questions: What aspects should the conceptual framework on traceability for SEDILEs address; what are the objectives, scope and requirements that a traceability system for SEDILEs should have; and what are the regulatory and legislative elements of traceability in the food and health sectors that guide the adoption and implementation of a traceability system in SEDILEs?

The search for articles was carried out in the following electronic databases: Science Direct, Scielo, Google Académico, Codex Alimentarius, Ley Chile. In the databases Science Direct, Scielo, Google Académico, Codex Alimentarius, the search was conducted in English using the keywords: traceability, food supply chain, powdered infant formulas, food safety. In the Scielo and Ley Chile search engines, the key words were: traceability, SEDILE, medical devices, sterilization, drugs.

A total of 262 published articles were found, of which 80% correspond to publications from the last 10 years (2013-2023), demonstrating the relevance of the traceability topic. The first third of the articles found were selected due to their relevance, and 23 articles were selected. Articles that did not address the central theme of the review, such as chemical studies, molecular studies, DNA analysis and specific studies of products such as steel, wood, etc., were excluded.

In addition, a general search of Chilean and international legislation was carried out in databases and web pages.

ANALYSIS AND CONCLUSION

The global infant formula market is growing due to a boom in demand for baby food. Production of infant formula is expected to increase tenfold in the next few years; some factors driving market growth are the increase in working mothers, higher healthcare spending and growing demand for organic foods for infant consumers.

During the COVID-19 pandemic, health centers, market players and governments invested heavily in maintaining the supply of nutrition and essential foods; subsequent to this health crisis, a substantial change in consumer purchasing patterns has been observed, highlighting the growth of the infant formula market through e-commerce (45).

In addition, given the international contingency, food traceability represents an opportunity to safeguard food security, deal with possible food shortages and address the breakdown of supply chains that could lead to health, social, political and/or military crises.

Food legislation aims to improve two key elements, prevention and traceability. The objectives of prevention begin at the primary producer and continue with traceability in each and every one of the processes, until the food reaches the final consumer. Traceability does not guarantee food safety and security; however, it is a complement to a food safety system such as HACCP (25).

The IFS standard considers it mandatory to implement a traceability system, which allows the identification of product batches and their relationship with batches of raw material, packaging material in direct contact with the food or intended to come into contact with the food. The traceability system shall include all relevant production and distribution records. Traceability should be guaranteed and documented until delivery to the final consumer (27).

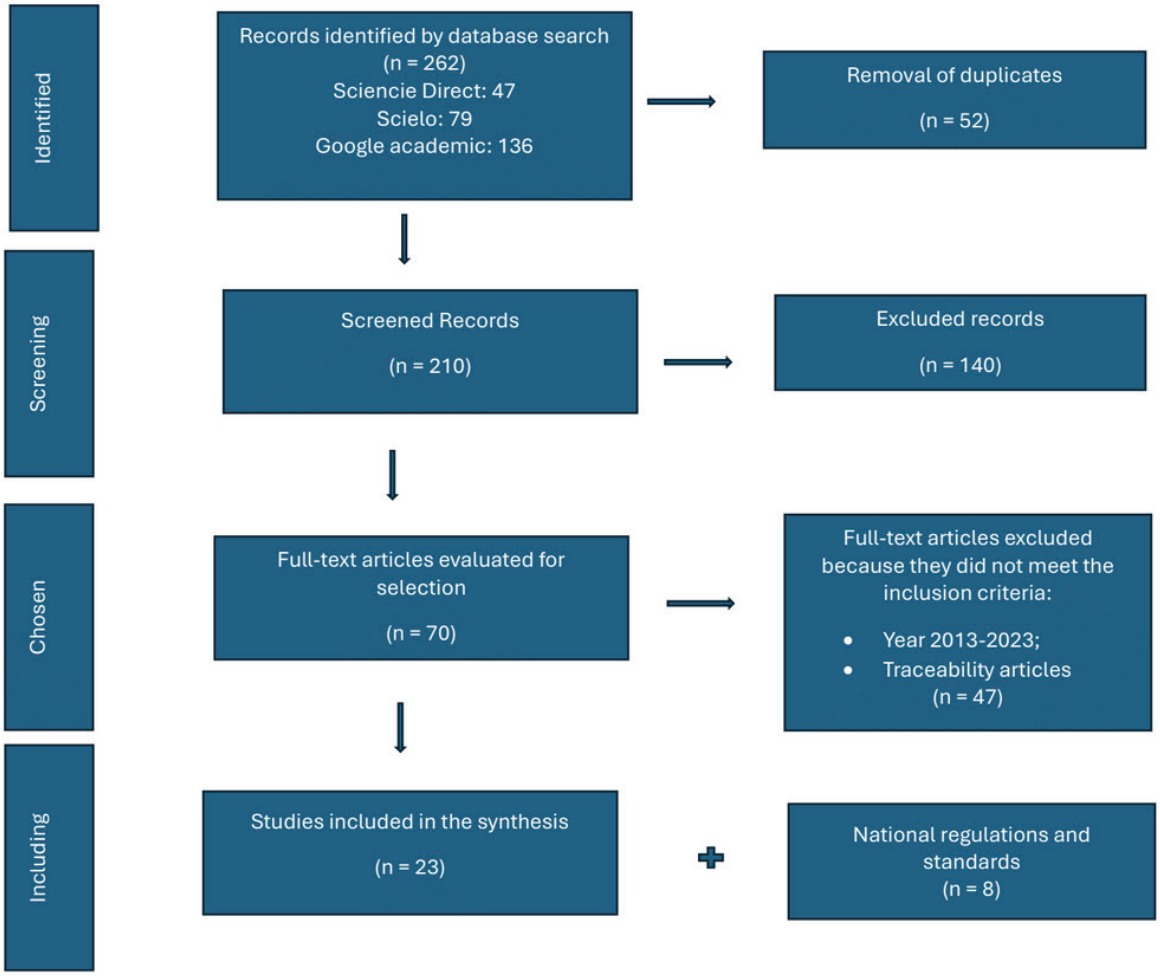

Figure 1. Prism Flow Diagram of the study selection process

In the SEDILE of a hospital, the concern for health risk is greater than in other types of collective catering since consumers, due to their condition as patients and infants, are more vulnerable to food risk.

Although the Technical Guidance for SEDILEs recommends the implementation of HACCP, it is not mandatory, limiting the traceability prerequisite only to backward and forward traceability.

Legislation is a driver that aims to protect and encourage behaviors in a society, that is to say, that the actions that the regulation intends to implement are eventually adopted by the different parties and cease to be a regulatory pressure mechanism, because awareness was achieved in society and it is society that demands its compliance.

An update is required to the Technical Guidance for Dietetic Milk Services and Enteral Formula Central, which incorporates a Traceability Policy for the SEDILE system model.

The **Traceability Policy** should consider:

THE SCOPE OF APPLICATION IN THE THREE STAGES OF TRACEABILITY: BACKWARD, INTERNAL AND FORWARD

BACKWARD TRACEABILITY:

This refers to the reception of all raw materials, i.e. milk formulas, supplements and nutritional modules, and transfers (flavorings, sweeteners, etc.). They must be recorded:

- ***Suppliers' data:*** company name, address, contact number, contract and/or marketing authorization.
- ***Entry of raw materials ("product")***; to make the record, each type of raw material must be grouped by lot number (numerical and/or alphabetical denomination), therefore, the name of the product, the format (e.g.: jar), the weight of the package, the quantity received, expiration date and inspection of the package must be entered. If necessary, it is recommended to enter the invoice number or order request number, provided that this provides concrete data on the identity of the product.

It is important to note that at this stage all products must, even administratively, enter the sub-area of raw materials and liquid formulas (milk storage), a place for the storage of closed products.

INTERNAL TRACEABILITY:

This refers to the entire process of preparation, packaging and labeling of milk formulas, from their reception in the preparation area to the delivery of the finished product (milk ready for consumption).

At this stage the relevant processes are:

- ***Entry of raw materials into the preparation area***; at this stage, the date of entry, product name, batch and expiration date, date and time of opening, and date and time of exit of the container from the production area, either by empty container or expiration date, must be recorded for each unit (e.g., 1 jar).
- ***Preparation and packaging of the material;*** this is understood as material for bottles and their accessories (pacifiers, etc.). In this stage, all the material to be sterilized is prepared (including washing, disinfection and drying processes) and packaged, which will later be used as a container for the already prepared formulas.

At this stage, each package must be identified with the following data: name of contents, lot number, expiration date and initials of the person responsible.

Proper package labeling allows for identification of the load, storage, shelf life and traceability of the sterilized packages in case of technical problems with the equipment or an infectious event attributed to the failure of the sterilization process.

- ***Initial Sterilization*** corresponds to the sterilization process of the material (e.g., bottles), previously packaged, that will have direct contact with the milk formulas. At this stage the operator of the sterilization equipment (autoclave) should record the process cycle detailing: Start date and time, No. of load, liters of equipment and cycle (sterilization program) of the equipment; Biological control, indicator result and name of the reader; Description of the load and quantity of packages; Voucher (equipment cycle printout); Detail of the package label (lot, expiration date and responsible initials), Name of the operator.
- ***Preparation, labeling and packaging of milk formulas***; at this stage the raw materials are processed according to the dietary and therapeutic prescription of each patient.

At this stage, each bottle should be identified with the following data: Date and time, Name of the patient, Unit (Room) and bed number, Name of the milk formula, volume, and any other characteristic that will ensure its traceability.

A record of the daily production should be kept, in this document the quantity prepared (grams) should be noted for each formula/module/transfer, indicating the date and clinical unit of destination (e.g. Pediatrics, Neonatology, etc.), as well as the name of the handler responsible.

- ***Terminal sterilization*** corresponding to the sterilization process of bottles with milk formula. Bottles that can be processed due to their nutritional characteristics will have an external chemical control added to the external side of the bottle prior to sterilization.

At this stage the operator of the sterilization equipment (autoclave) should record the process cycle detailing: Start date and time, No. of load, liters of the equipment and cycle (sterilization program) of the equipment; Description of the load (bottles with formulas); Voucher (equipment cycle printout); Name of the operator.

FORWARD TRACEABILITY:

This corresponds to the stage when finished products leave SEDILE for direct consumption by hospitalized patients. When the bottles are dispatched, the records should serve as a link to the consumer traceability system.

At this stage it is important to keep a record of dispatch or distribution, where the person in charge of the delivery notes: date and time of delivery, patient name, unit (ward) and bed number, data on the finished product and any other characteristic that will ensure its traceability; for example, in cases where delivery is not direct to the patient, the name of the recipient, storage characteristics (temperature of refrigeration equipment, etc.) should be recorded.

CODING AND IDENTIFICATION OF RAW MATERIAL, PACKAGING MATERIAL AND FINISHED PRODUCT:

It is mandatory to identify all incoming products that are transformed in the production process until they are delivered to the patient. In SEDILE we find:

- Raw materials: milk formulas, modules and transfers (flavorings, etc.) which, in order to be transformed into finished products, require some prior treatment.
- Containers: bottles, pacifiers, pacifiers and pacifier covers, previously sterilized (sterilization can be performed, depending on the complexity of the SEDILE, in the same unit or in the hospital's Sterilization Center).
- Finished product: packaged milk that is ready for delivery to the patient.

CODING AND IDENTIFICATION OF DOCUMENTS:

As with the products, the documents that will be stored as part of the traceability system's operational tools must also be coded and identified to facilitate access and identification. There are a variety of documents that will be used as part of the traceability system information record, which can be classified into the following groupings:

- Technical Data Sheets: These are documents detailing the information related to the description of all products (milk formulas, modules and transfers), specifying their characteristics and information related to their use.
- Process records: These are documents that present the results obtained or provide evidence of the activities carried out; for example: Reception of raw materials, initial sterilization of empty bottles and pacifiers, terminal sterilization of milk formulas, etc.
- General Forms: These are documents that serve as a basis for recording specific information, which does not imply the daily filling of the same; for example, audit forms, product recalls, etc.

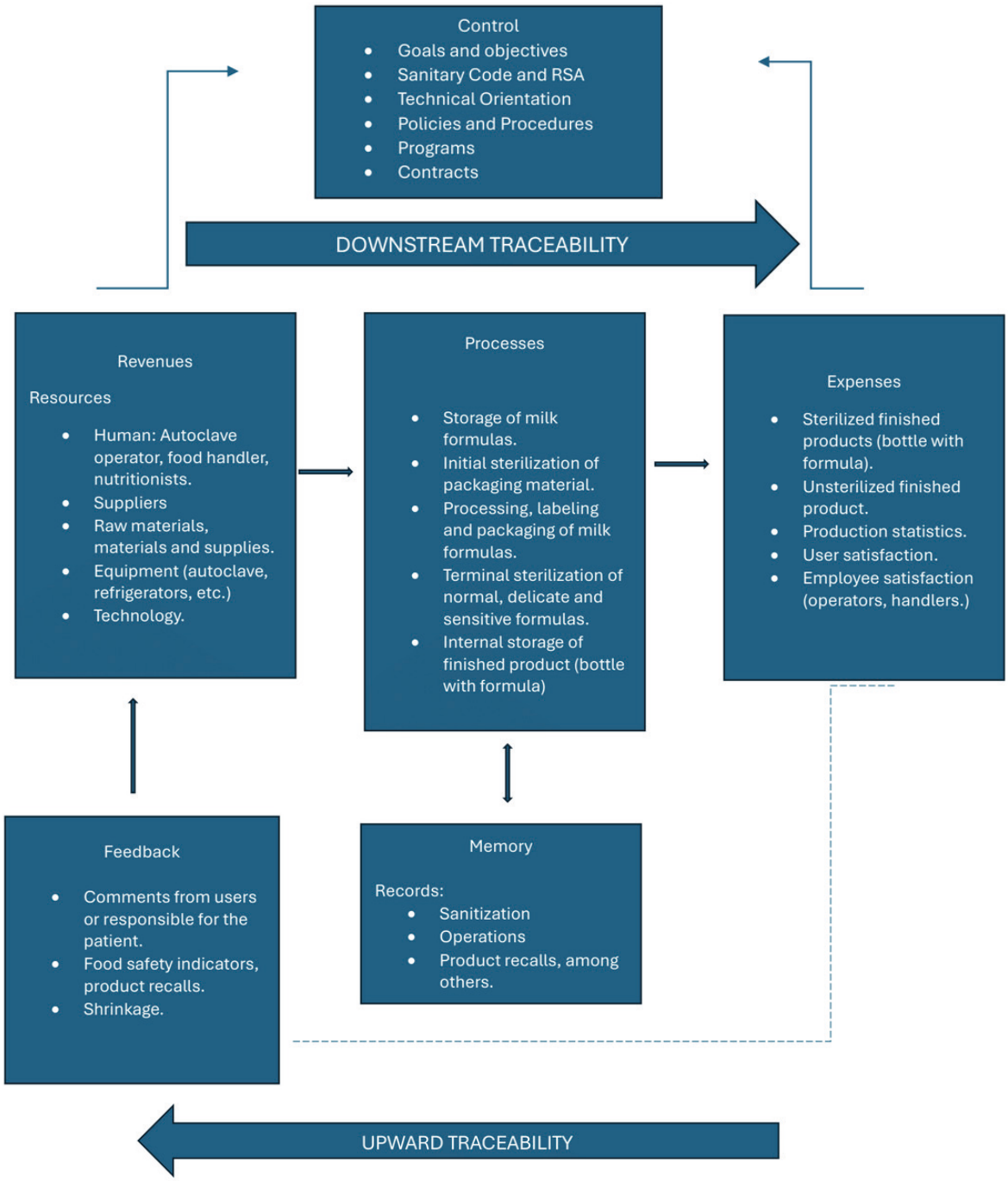

Figure 2. Diet Milk Service System Model

ESTABLISH COMMUNICATION MECHANISMS BETWEEN COMPANIES:

An effective traceability system involves and commits the entire chain, i.e. all production links. It is the responsibility of each one to avoid breaking traceability in the link they represent. If this happens, operators who are sufficiently complying with the development of the traceability system in their establishment may be harmed. For this reason, communication should be maintained and information should be requested from suppliers (companies such as laboratories) to provide information on their traceability system (34).

ESTABLISH VALIDATION / VERIFICATION MECHANISMS BY THE COMPANY:

System reviews should be performed to verify that the system is working effectively and to record that such verification has taken place. The system should be evaluated in terms of the accuracy of the information stored, the efficient communication between all links in the system, the response time (which should be as short as possible for possible patient risk), the changes made if any, and the reason for those changes.

These reviews are expected to validate and verify that downstream and upstream traceability occurs in the system. Thus, in the event of a health risk (due to labeling errors, packaging defects, contamination by pathogenic microorganisms, appearance of allergens, chemical contamination and physical contamination), raw materials, packaging and/or finished products can be located and recalled.

Model of the Dietary Milk Service system.

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