



International Special  
Dietary Foods Industries

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# **Common processes used in the manufacturing of FSDU and the rationale for their use**

# Introduction



## The Codex General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses (CODEX STAN 146-1985), defines Foods for Special Dietary Uses (FSDU) in section 2.1:

*Foods for Special Dietary Uses are those foods which are **specially processed or formulated** to satisfy particular dietary requirements which exist because of a particular physical or physiological condition and/or specific diseases and disorders and which are presented as such (1). The composition of these foodstuffs must differ significantly from the composition of ordinary foods of comparable nature if such ordinary foods exist.*

(1) This includes foods for infants and young children.

For more information, please read the [ISDI FSDU brochure](#).

The purpose of this brochure is to explain the common processes used by manufacturers of FSDU.

All processes serve a purpose that can generally be classified as “Food Safety” or “Nutritional”. The reasons behind the processes and formulations are key elements rooted in the very nature of FSDU. It is also important to note that throughout the manufacturing process the FSDU product is checked for chemical composition, physical stability and microbiological condition.

The following sections provide examples of common processes used in FSDU with an explanation of their purpose, as well as the purpose of common additives, which provide solutions to a range of technical challenges in the manufacturing, processing, packaging, transport and consumer use of FSDU.

These processes provide food safety and nutritional benefits in FSDU<sup>1</sup>, such as baby foods, infant cereals and extruded snacks.

1. Liquid and powder FSDU include infant formula, follow-up formula, products for young children, formula foods for use in weight control diets, formula foods for use in very low energy diets for weight reduction, Foods for Special Medical Purposes, supplementary foods, sports food, etc.

# Examples of common processes and their purpose

## FOOD SAFETY AND NUTRITION

### Ingredient/raw material receipt



For any processed food, including FSDU, the primary responsibility for placing safe products on the market rests with the food business operator (FBO), otherwise known as the manufacturer. This responsibility begins with selecting the appropriate raw materials, including ingredients and packaging. Raw materials used in the manufacture of FSDU are subject to strict supplier controls which can take the form of regular supplier audits, ingredient qualification and in-depth testing using validated methods.

Raw incoming ingredients are tested to confirm they are acceptable, which could include nutritional, sensory and microbiological analyses, among others. For example, liquid milk may be analysed to ensure it contains the correct amount of protein, has acceptable sensory characteristics and is microbiologically safe and sound.

## NUTRITION

### Ingredient blending/mixing — wet processing



Most FSDU products are wet processed, during which major ingredients (e.g. proteins, oils, carbohydrates and water) and minor ingredients (e.g. vitamins and minerals) are accurately weighed and mixed well to ensure that the ingredients are uniformly dispersed through the wet blend.

This process is classified as “nutritional” as it ensures the correct amounts of each ingredient are added to the formulation and that they are mixed appropriately, ensuring the FSDU will meet the nutritional requirements for the intended population.

## NUTRITION

# Dry blending



Certain FSDU products, such as those that do not contain liquid ingredients, do not need to be wet processed. For these products, the ingredients are first processed into a powder form, then added to a “dry blender” to mix them until they become homogenous. The product is discharged from the blender and proceeds to filling. As there is no thermal sterilisation process for dry-blended FSDUs, beside the standard good manufacturing practices and environmental control, extensive microbiological testing is undertaken to confirm the final products are safe for consumption.

This process ensures the ingredients used are safe under this condition of use. A key benefit of dry blending is that it lessens the impact on the stability of ingredients and nutrients that are sensitive to heat treatment.



## NUTRITION

### Homogenisation



FSDU products containing oil and water will naturally separate over time if they are not further processed. To prevent separation, manufacturers employ an additional step, such as high-pressure homogenisation.

During high-pressure homogenisation, the FSDU liquid is pumped through a small opening under high pressure. This causes the large oil particles to break up into many smaller particles which become uniformly dispersed in the mixture and are less likely to separate over time.

This process is critical to the product's overall quality. It is classified as "nutritional" as it helps ensure a uniform distribution of nutrients in the product.

## FOOD SAFETY

### Heat treatment (general)



The heat treatment of FSDU is a critical food safety process. During the heat treatment, the temperature of the product is raised to a level that kills pathogenic and spoilage microorganisms, such as bacteria, yeast and mold, to ensure it is safe for consumption by the intended population.

Depending on the type of FSDU product, it may receive one or more heat treatments, including conventional pasteurisation, ultra-high temperature (UHT) pasteurisation or retort processing.

## FOOD SAFETY

### Drying (Powder FSDU)



Drying is performed to convert the liquid product into a powder, as some users of FSDUs may prefer this format. Drying of the concentrated mixture occurs in a spray dryer. During spray drying, the mixture is sprayed out of a nozzle into the dryer, which is filled with hot air. As the mixture passes through the dryer, water is evaporated very fast and removed as vapour. The remaining material is the dried powder.

The process is vital to ensure microbiological safety and quality in the final product, and to manage characteristics such as density, moisture, powder physical properties and sensory aspects.

## Packaging



Packaging protects the product from extrinsic factors (i.e. temperature, humidity, light and oxygen) through several barrier properties that vary from one type of packaging to another (i.e. different abilities to prevent external light, ultra-violet light, oxygen and humidity from affecting the product).

The seaming and capping process plays a key role in this step, with consideration for the size of the headspace and the fill height/weight. For example, the headspace may be filled with air or with an inert gas (e.g. nitrogen or carbon dioxide). If the headspace is filled with an inert gas, oxidation reactions and nutrient degradation in the product can be prevented or decelerated.

Final quality checks are performed to confirm the FSDU meets all applicable requirements prior to being placed on the market and ensuring that a product with the highest quality will reach the intended population.

For powder FSDU, prior to packaging, such as in cans, sachets or pouches, the powder passes through a sieving step, which is the final step in the process to prevent the presence of foreign objects.





# Common additives and their purpose

Food additives provide solutions to a range of technical challenges in the manufacturing, processing, packaging, transport and consumer use of foods and beverages, including FSDU<sup>2</sup>.

The use of food additives and the products in which they are allowed to be used is highly regulated worldwide and periodically reviewed by food authorities. The existing strong regulatory framework for additives is based on safety evaluations.

Selecting the most appropriate additive is based on the unique needs of the product formula as their effects may vary depending



2. For examples, ISDI Brochure [‘Use of additives in infant formula and formulas for special medical purposes intended for infants’](#)

on many factors, including the manufacturing process (e.g. wet mix vs. dry blend), thermal processing method (e.g. retort batch sterilisation vs. ultra-high temperature pasteurisation), ingredients (e.g. intact vs. hydrolysed proteins, type and level of lipids) and product format (e.g. powder vs. liquid).

Each additive used in FSDU has a specific purpose, such as:

- **Antioxidants** prolong shelf-life by preventing oxidation;
- **Emulsifiers** help to prevent separation of ingredients during manufacturing and over shelf-life;
- **Anticaking agents** allow powders to flow freely and prevent them from caking over shelf-life;
- **Sweeteners** improve the flavour profile of FSDU highly fortified in vitamins and minerals, masking potentially unpalatable aftertastes;
- **Thickeners** may be used in products intended for patients with dysphagia who have difficulty swallowing certain foods and liquids;
- **Acidity regulators** ensure the pH of the product remains at the desired level, which helps to maintain the physical stability of FSDUs.

In the FSDU category, additives are also permitted in order to improve the functionality of the food towards health: e.g. additives that provide the sensory characteristic of salt but with less sodium. This means that additives are used only if technologically needed and in the appropriate, permitted amount. The authorisation of an additive in an FSDU category does not mean that all products in this category contain this additive.

Moreover, food additives have undergone extensive toxicological assessments by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and other food safety entities worldwide, which ensures their safety and healthiness.



# Glossary of terms

- **Baby food**  
Baby foods are foods intended primarily for use during the normal infant's weaning period and also for the progressive adaptation of infants and children to ordinary food.
- **Extrusion**  
A combination of mechanical and thermal technologies in a single machine including mixing ingredients, forming a dough, cooking under pressure and pushing the cooked dough through an orifice to create different shapes or a dough sheet.
- **Food safety**  
The practices and conditions used by food business operators to ensure the foods they produce are safe to eat.
- **Foods for special medical purposes (FSMP)**  
Foods for special medical purposes are a category of FSDUs which are specially processed or formulated and presented for the dietary management of patients and may be used only under medical supervision.
- **Infant cereals**  
Processed cereal-based foods intended for feeding infants as a complementary food, generally from the age of 6 months onwards, taking into account infants' individual nutritional requirements, and for feeding young children as part of a progressively diversified diet.
- **Conventional pasteurisation**  
Mild heat treatment used for products such as milk and fruit juices where the liquid is heated at 80°C and quickly cooled back to below 4°C.
- **Shelf-life**  
The period of time during which the manufacturer expects the product to remain at its best quality, including aspects like taste, texture, colour, and nutritional content.

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