USE OF ADDITIVES IN INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS

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International Special
Dietary Foods Industries

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DISCLAIMER

This guidance document is intended to provide information on additives directly added to Infant Formula and Formulas for special medical purposes intended for infants in the context of the Codex Alimentarius. It is for general information purposes only and does not constitute legal or other professional advice. It does not replace the relevant Codex Standards and should be read in conjunction with all the relevant texts at Codex Alimentarius level. The information provided is without prejudice to national regulations and interpretations. ***Sections in italic are directly taken from Codex texts or JECFA report.***

TARGET GROUP

The audience for the brochure is food business manufacturers and national authorities.

PURPOSE OF THE BROCHURE

The brochure provides the international background regarding additives used in Infant Formula and Formulas for special medical purposes intended for infants.

The CODEX ALIMENTARIUS international food standards, guidelines and codes of practice contribute to the safety, quality and fairness of international trade. Codex standards are based on sound science provided by independent international risk assessment bodies or ad hoc consultations organised by FAO and WHO.

The brochure is for general information purposes and aims to facilitate the understanding of the Codex Framework applicable to food additives used in Infant Formula and Formulas for special medical purposes intended for infants based on:

- The CODEX STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS.
  CODEX STAN 72-1981
- The CODEX GENERAL STANDARD ON FOOD ADDITIVES (GSFA).
  CODEX STAN 192-1995

The brochure can be used to support Food Business Manufacturers as educational material (e.g. internal trainings) or as a background element for discussions with national authorities regarding additives in Infant Formulas and Formulas for special medical purposes intended for infants.

The brochure does not consider the specific situation of additives in Infant Formulas and Formulas for special medical purposes intended for infants in each country and should not be considered in isolation.

KEY MESSAGES

1. JECFA and Codex Alimentarius Commission principles are the cornerstone for use of additives in foods for infants
2. The Codex Alimentarius process for authorization of additives in infant formula is robust and ensures a science-based risk assessment with unique considerations for the specialized infant population
3. Use of certain functional classes of additives for specific technological purposes play a vital role in manufacturing safe, high quality formulas for infants
4. Food additives when used as authorized in formulas for infants are safe for this vulnerable group

KEY CONCEPTS & DEFINITIONS

Food Additive *means any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result, (directly or indirectly) in it or its by-products becoming a component of or otherwise affecting the characteristics of such foods. The term does not include "contaminants" or substances added to food for maintaining or improving nutritional qualities* **(CODEX PROCEDURAL MANUAL)**.

GOOD MANUFACTURING PRACTICE IN THE USE OF FOOD ADDITIVES *MEANS THAT*:

- *The quantity of the additive added to food shall be limited to the lowest possible level necessary to accomplish its desired effect;*
- *The quantity of the additive that becomes a component of food as a result of its use in the manufacturing, processing or packaging of a food and which is not intended to accomplish any physical, or other technological effect in the food itself, is reduced to the extent reasonably possible;*
- *The additive is of appropriate food grade quality and is prepared and handled in the same way as a food ingredient. Food grade quality is achieved by compliance with the specifications as a whole and not merely with individual criteria in terms of safety* **(CODEX PROCEDURAL MANUAL)**.

DEFINITIONS

Acceptable Daily Intake (ADI) *is an estimate by JECFA of the amount of a food additive, expressed on a body weight basis that can be ingested daily over a lifetime without appreciable health risk* **(CODEX STAN 192-1995)**. *Principles for the Safety Assessment of Food Additives and Contaminants in Food, World Health Organization,* ***(WHO ENVIRONMENTAL HEALTH CRITERIA, NO. 70), P. 111 (1987)***.

Acceptable Daily Intake "Not Specified" (NS) *is a term applicable to a food substance of very low toxicity for which, on the basis of the available data (chemical, biochemical, toxicological, and other), the total dietary intake of the substance, arising from its use at the levels necessary to achieve the desired effect and from its acceptable background levels in food, does not, in the opinion of JECFA, represent a hazard to health.*

For the above reason, and for reasons stated in individual JECFA evaluations, establishment of an acceptable daily intake expressed in numerical form is not deemed necessary by JECFA. An additive meeting the above criterion must be used within the bounds of good manufacturing practice.

Maximum Use Level *of an additive is the highest concentration of the additive determined to be functionally effective in a food or food category, and is established in a way to ensure that cumulative intake from all foods does not exceed the ADI for that additive and therefore can be considered safe. It is generally expressed as mg additive/kg of food. The maximum use level will not usually correspond to the optimum, recommended, or typical level of use. Under GMP, the optimum, recommended, or typical use level will differ for each application of an additive and is dependent on the intended technical effect and the specific food in which the additive would be used, taking into account the type of raw material, food processing and post-manufacture storage, transport and handling by distributors, retailers, and consumers.*

JECFA: *Joint Expert Committee on Food Additives administered jointly by the Food and Agricultural Organization (FAO) and the World Health Organization (WHO). JECFA is an international, independent scientific body meeting since 1956 to evaluate the safety of food additives, contaminants, naturally occurring toxicants and residues of veterinary drugs in food. This expert body provides scientific advice to the Codex Alimentarius Commission through its subsidiary committees.*

GSFA: *General Standard for Food Additives,* **CODEX STAN 192-1995**. *This standard sets forth the conditions under which food additives may be used in all foods. The GSFA uses the Food Category System to assign additives. Food Category 13.1.1 is Infant Formula, and Food Category 13.1.3 Formula for Special Medical Purposes for Infants. Food additive provisions are listed in 3 Tables. Table 1 specifies the food additive applications and conditions, in alphabetical order; Table 2 lists the additive provisions by Food Category; Table 3 lists additives acceptable in foods at quantum satis levels. The GSFA aims to be the single authoritative reference point for food additives in the Codex framework. Of note, while the term infant refers to a person not more than 12 months of age* **(CODEX STAN 72-1981)**, *only Food Categories 13.1.1 (Infant Formula) and 13.1.3 (Formula for Special Medical Purposes for Infants) are specially manufactured to satisfy, by itself, the nutritional requirements of infants up to six months of age or up to the introduction of appropriate complementary feeding. While outside the scope of this document, Food Category 13.1.2 (Follow-up Formula) is intended for infants between 6 and 12 months of age.*

PRINCIPLES FOR THE USE OF FOOD ADDITIVES IN INFANT FORMULA

1971 JECFA REPORT – FUNDAMENTAL PRINCIPLES

In the Codex framework, the **JECFA REPORT OF 1971** describes principles for the use of additives in infant formulas and formulas for special medical purposes intended for infants and has become the cornerstone and guiding values for safe and acceptable additive use in this vulnerable population. These principles are endorsed by the Codex Alimentarius Commission. The objective of the JECFA report was to establish principles that would guide the evaluation of the safety of food additives used in food products for infants. The conclusions of this report include two important concepts that are provided below: great caution should be used in regard to the use of food additives in foods for infants under 12 weeks of age; and several categories of food additives are justified for use in these products.

GREAT CAUTION

"Baby foods should be prepared without food additives whenever possible. Where the use of a food additive becomes necessary in baby foods, great caution should be exercised regarding both the choice of additive and its level of use."

SOME ADDITIVE USE IS JUSTIFIED

The fundamental principle established by JECFA Report in 1971 is that additive use in infant formula should be limited and guided by specific considerations, not that additive use should be completely prohibited in these products. The JECFA report reflects these elements in the following excerpts:

- *"... there are circumstances in which the benefit to the baby arising from the inclusion of some additive, for example a preservative, in its diet may greatly outweigh any possible hazard to health'."*

- *"... there may be certain exceptions on technological grounds to the exclusion of food additives from food for infants under 12 weeks."*

- *"The use of food additives may be justified, for example, to increase shelf life, to ensure adequate sterilization by promoting homogenization, or to maintain consistency and texture in order to ensure safe and acceptable use."*

- *"... in some countries with special difficulties – for example, of storage or supply – additives not otherwise acceptable may confer advantages that outweigh their potential hazards."*

When considering additives for any food category, a fundamental principle is that the use and the level of additives should be limited to the lowest possible level necessary to accomplish its desired effect (CODEX STAN 192-1995). This principle is also reflected in the Good Manufacturing Practice (GMP) or Quantum Satis (QS) concept that is associated with some food additives for which no specific level is established, as the level to be used is then linked to the functionality of the additive – one would use the level that is necessary for the food additive to achieve the intended function in the matrix considered.

The fundamental principle that the use and the level of additives should be limited as much as possible is reinforced for Infant Formula as the JECFA report on 1971 clearly establishes that *"baby foods should be prepared without food additives whenever possible. Where the use of a foo d additive becomes necessary in baby foods, great caution should be exercised regarding both the choice of additive and its level of use"* (1971).

SPECIAL CONSIDERATIONS FOR INFANTS

Food additives intended for infants require special considerations for their safety assessments. The classical risk assessment includes a hazard analysis, one outcome of which is the derivation of a health-based guidance value such as the Acceptable Daily Intake (ADI), to which expected exposure can then be compared. Due to multiple factors, the ADI that is derived for food additives used in general foods may not apply to infants up to 12 weeks of age consuming products in Food Category 13.1.1 (Infant Formula) and 13.1.3 (Formula for Special Medical Purposes for Infants). Therefore, the safety assessments conducted by JECFA for food additives used in these categories now include special consideration for this sensitive population such as by considering data from studies in neonatal animals, clinical studies conducted in human infants, and post-marketing surveillance data when infant formula with the additive is already in use in some countries (79th report of JECFA, 2014).

It should be noted that the distinction for young infants is focused on special consideration for the safety assessment and is not related to the technological effect that additives have in products for this population. The food additives used in infant formula products serve the same technological function in these products as they do in products for non-infants and is related to the physical properties of the food additive. For example, the fact that ascorbyl palmitate has a technological function of an antioxidant in infant formula is related to its physico-chemical effect in that product category, and ascorbyl palmitate has the same technological function in any number of other food products that are intended for non-infants

PURPOSE AND BENEFITS OF ADDITIVES

Additives provide solutions to a range of technical challenges in the manufacturing, processing, packaging, transport and consumer use of foods and beverages. Care is taken by manufacturers that use of technologically justified additives specifically in infant formula and infant FSMP conforms with the principles endorsed by Codex Alimentarius Commission described above.

Selection of additives for use is unique to the formula as their effects may vary depending on the product matrix. The most optimized additive is determined based on the manufacturing process (e.g. wet mix vs. dry blend), thermal processing method (e.g. retort batch sterilization vs. ultra-high temperature pasteurization), ingredients (e.g. intact vs. hydrolysed protein, type and level of lipids), and product format (e.g. powder vs. liquid). Figure 1 below demonstrates the varying suitability of a number of stabilizer additives on phase separation in liquid formula.

BOTTLE 1-4 : Infant formula samples with different degrees of product separation. Without the appropriate food additives, infant formula separates into lipid- (top) and water-soluble (bottom) fractions

BOTTLE 5 : Infant formula product with effective food additives leads to maintenance of homogeneity

Figure 1. Comparison of various additive (stabilizer) effects on phase separation in liquid formula

INTRODUCTION TO TYPES OF ADDITIVES USED IN INFANT FORMULAS

Additives used in foods including infant formulas must have a technological purpose according to one or more of the following general functions:

- *To preserve nutritional quality of the food;*
- *To provide necessary ingredients or constituents for foods manufactured for groups of consumers having special dietary needs;*
- *To enhance the keeping quality or stability of a food or to improve its organoleptic properties;*
- *To provide aids in the manufacture, processing, preparation, treatment, packing, transport or storage of food.*

Additives are further classified into functional categories or technical effects; however, many serve more than one function in a product. In the Codex framework, there are 27 functional classes of food additives in total (see Table) while for additives used in the food categories specific to formulas for infants, only 5 of these functional classes are currently listed in the infant formula standard **(CODEX STAN 72-1981)**: Acidity regulators, antioxidant, emulsifier, packaging gas, and thickener - as shown in the Table below. Two additional functional classes have been recognized as being necessary for infant formulas: the **JECFA REPORT OF 1971** recognizes stabilizers as a class of additives that are necessary for infant formula, and the necessity of carriers in ensuring the stability and safe handling of vitamins and other nutrients is described in the Codex Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children **(CAC/GL 10-1979)**.

TABLE: Functional classes of additives for all Food Categories. Functional classes listed in the Infant Formula Standard **(CODEX STAN 72-1981)** for FC 13.1.1 Infant Formula and 13.1.3 Formula for Special Medical Purposes for Infants, are shown in orange; functional classes identified as necessary for infant formula in the **1971 JECFA REPORT** but not currently listed in the Infant Formula Standard **(CODEX STAN 72-1981)** are shown in blue; functional classes identified as necessary for infant formula in the Codex Advisory Lists of Nutrient Compounds (CAC/GL 10-1979) are shown in green.

The functional classes of carrier and stabilizer are not currently referenced in the Infant Formula Standard **(CODEX STAN 72-1981)**. However, additives can have dual function (see below), additives with the function of carrier or stabiliser are already covered through the additives allowed in infant formula.

Acidity Regulators	Colour retention agent	Humectant
Anticaking agent	Emulsifier	Packaging gas
Antifoaming agent	Emulsifying salt	Preservative
Antioxidant	Firming agent	Propellant
Bleaching agent	Flavour enhancer	Raising agent
Bulking agent	Flour treatment	Sequestrant
Carbonating agent	Foaming agent	Stabilizer
Carrier	Gelling agent	Sweetener
Colour	Glazing agent	Thickener

In the Codex framework, the International Numbering System (INS) for food additives is used as a harmonized naming system as an alternative to specific or common names. Both the Infant Formula Standard **(CODEX STAN 72-1981)** and the **GSFA** use the INS system, in addition to standardized additive names, to clearly identify which additives are permitted in different food categories.

FUNCTIONAL CLASSES OF ADDITIVES USED IN INFANT FORMULAS

ACIDITY REGULATORS

Acidity regulators, or pH adjustors, are used to maintain or change the pH (acidity or alkalinity) of a food. Maintaining the appropriate pH of an infant formula is important from both a processing and food safety perspective. Use of acidity regulators to control pH limits the growth of undesirable bacteria which could lead to a potential safety hazard while also the preserving the product's shelf-life.

ANTIOXIDANTS

Antioxidants play a major role in preventing and delaying oxidation - a chemical process that occurs when food, particularly those containing fat, is exposed to air, light or heat. Oxidation can lead to rancidity and off flavors, and cause degradation of essential nutrients. Therefore, addition of antioxidants is necessary to maintain product integrity both during manufacture and throughout the product's shelf-life.

CARRIERS

As a sole source of nutrition, infant formula must deliver tightly controlled levels of nutrients. Ensuring the accurate and consistent delivery of these nutrients may require the conversion of vitamins and other nutrients into suitable preparations, which improves stability and the accurate delivery of these substances.

EMULSIFIERS

Infant formulas are typically high lipid matrices with varying types of protein sources. Emulsifiers have hydrophilic and hydrophobic regions that allow immiscible ingredients such as water and oil to join. Emulsifiers are added to infant formula to form and stabilize a lipid-in-water emulsion which is a fundamental step in the manufacturing process.

PACKAGING GASES

Packaging gas is used to ensure packed food is maintained in a modified atmosphere environment. Packaging gases used are typically inert. i.e. have extremely low reactivity with other substances under a set of given conditions. The low reactivity of these gases e.g. CO2/N2 mix, inhibits microbial growth and unwanted chemical reactions such as oxidation, thus maintaining the safety and shelf-life of the finished formula.

STABILIZERS

Stabilizers are added to infant formula to preserve its structure and prevent separation of ingredients by maintaining a homogenous dispersion of two or more immiscible substances. Stabilizers, like other additive categories, can have a dual technological function and some may also act as thickeners in infant formula e.g. xanthan gum has thickening properties which also aids in the stabilization of emulsions.

THICKENERS

A thickening agent or thickener is a substance which can increase the viscosity of a liquid without substantially impacting its other physical properties. They are typically large molecular weight carbohydrates which form gels or thickened dispersions when placed in contact and interact with water. Thickeners are added to infant formula to maintain the liquid mix from packaging to consumption and may also minimize reflux during feeding.

ADDITIVES SERVING MORE THAN ONE FUNCTION

As described above, some food additives used in infant formula can serve dual technological functions. For example, Xanthan Gum can act as both a thickener ("a food additive which increases the viscosity of a food") and a stabilizer ("a food additive which makes it possible to maintain a uniform dispersion of two or more components"). Xanthan gum builds viscosity in the reconstituted formula matrix and helps to stabilize the emulsion of protein or free amino acids, fat and water. This minimizes phase separation ensuring the formula is uniform and delivers the appropriate level of all essential nutrients. Additionally, some food additives used in infant formula also have nutritional purpose in additional to their technological function.

For example, according to the **CODEX STAN 72-1981** on Infant Formula and Formulas for Special Medical Purposes intended for infants, ascorbyl palmitate (INS 304i) may be used as an antioxidant in infant formula and infant FSMP.

When ascorbyl palmitate is used in a food, its function is primarily a technological one, with the purpose to prevent oxidation of sensitive constituents however ascorbyl palmitate is also a source of vitamin C, and is permitted as a nutrient source per the Codex Advisory List of Nutrients **(CAC/GL 10-1979)**.

The fact that many of the additives authorized for use in infant formula are also recognized as permissible forms of essential nutrients further supports the safety of these food additives.

Examples of Additives authorised for use in Infant Formula that have both Technological and Nutrient functions:

INS Number	Substance	Primary Technological Function	Nutrient Source
524	Sodium hydroxide	Acidity Regulator	Sodium
500ii	Sodium hydrogen carbonate	Acidity Regulator	Sodium
500i	Sodium carbonate	Acidity Regulator	Sodium
525	Potassium hydroxide	Acidity Regulator	Potassium
501ii	Potassium hydrogen carbonate	Acidity Regulator	Potassium
501i	Potassium carbonate	Acidity Regulator	Potassium
526	Calcium hydroxide	Acidity Regulator	Calcium
331i	Sodium dihydrogen citrate	Acidity Regulator	Sodium
331iii	Trisodium citrate	Acidity Regulator	Sodium
332	Potassium citrate	Acidity Regulator	Potassium
339 i, ii and iii	Sodium dihydrogen phosphate, disodium hydrogen phosphate, trisodium phosphate	Acidity Regulator	Sodium, Phosphorus
340 i, ii and iii	Potassium dihydrogen phosphate, dipotassium hydrogen phosphate, tripotassium phosphate	Acidity Regulator	Potassium, Phosphorus
307b	Mixed tocopherol concentrate	Anti-oxidant	Vitamin E
304i	Ascorbyl palmitate	Anti-oxidant	Vitamin C

INFANT FOOD ADDITIVES AUTHORISATION PROCESS IN CODEX ALIMENTARIUS

The Codex Alimentarius process in relation to all provisions regarding food additives is described in the **CODEX PROCEDURAL MANUAL** as follows:

All provisions in respect of food additives contained in commodity standards will require endorsement by the Committee on Food Additives, on the basis of technological justification submitted by the commodity committees and on the recommendations of the Joint FAO/WHO Expert Committee on Food Additives concerning the safety-in-use (acceptable daily intake (ADI) and other restrictions) and an estimate of the potential and, where possible, the actual intake of the food additives, ensuring conformity with the Preamble of the General Standard for Food Additives.

When forwarding a food additive section of a commodity standard for endorsement by the Committee on Food Additives, the Secretariat should prepare a report to the Committee that includes the International System (INS) number, the Acceptable Daily Intake (ADI) assigned by the Joint FAO/WHO Expert Committee on Food Additives, technological justification, proposed level, and whether the additive was previously endorsed by the Codex Committee on Food Additives.

The authorization of food additives is therefore based on three pillars: Technological Justification for Use, Safety Assessment, and Consumer Protection. The following section will provide information on these important aspects for the case of additives used in formulas for infants, starting with an overview of the process in the Codex framework.

1

Process Overview

The commodity committee has the responsibility and expertise to appraise and justify the technological need for the use of additives in foods subject to the commodity standard.	CCFA manages the priority list of substances for JECFA (Joint Expert Committee on Food Additives) evaluation	Any substance used as a food additive needs to be assessed and determined to be safe by JECFA prior to its inclusion in the GSFA or commodity standards	Additives for which technological justification (Step 1, CCNFSDU) and safety (Step 3, JECFA) have been confirmed may be added to commodity standard(s) by the CCNFSDU	The provisions in the General Standard for Food Additives (GSFA) should be aligned with those in the commodity standards	Final adoption of additive provisions in the commodity standard and the GSFA is completed by the Codex Alimentarius Commissio
CCNFSDU has developed criteria and decision tree for technological justification, based on Section 3.2 of the GSFA	The procedures for managing the JECFA priority list are defined in the Codex Procedural Manual	JECFA applies special considerations for the risk assessment of additives in infant foods	There are nine commodity standards under the mandate of CCNFSDU	All CCNFSDU commodity standards fall under Food Category 13.0 and its subcategories in GSFA	Adoption of provisions in both the commodity standard and GSFA ensures alignment

2 Technological Justification for Use – CCNFSDU Framework

The technological justification for use is to be submitted by the Codex Committee on Nutrition and Foods for Special Dietary Use (CCNFSDU). The Codex Procedural Manual stresses that to support the *Justification for the use and technological need of the food additive* there must be:

> • *Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives should be included.*

The GSFA provides that:

The use of food additives is justified only when such use has an advantage, does not present an appreciable health risk to consumers, does not mislead the consumer, and serves one or more of the technological functions set out by Codex and the needs set out from (a) through (d) below, and only where these objectives cannot be achieved by other means that are economically and technologically practicable:

A) *To preserve the nutritional quality of the food; an intentional reduction in the nutritional quality of a food would be justified in the circumstances dealt with in sub-paragraph (b) and also in other circumstances where the food does not constitute a significant item in a normal diet;*

B) *To provide necessary ingredients or constituents for foods manufactured for groups of consumers having special dietary needs;*

C) *To enhance the keeping quality or stability of a food or to improve its organoleptic properties, provided that this does not change the nature, substance or quality of the food so as to deceive the consumer;*

D) *To provide aids in the manufacture, processing, preparation, treatment, packing, transport or storage of food, provided that the additive is not used to disguise the effects of the use of faulty raw materials or of undesirable (including unhygienic) practices or techniques during the course of any of these activities.*

CCNFSDU has developed the ***CCNFSDU framework for appraising the technological need for food additives.***

3 Safety Assessment – CCFA and JECFA

The safety assessment is under the responsibility of the Codex Committee on Food Additives (CCFA). In relation to the *Safe use of the food additive* the Codex Procedural manual emphasizes the need for

> • *An intake assessment of the proposed use of the food additive, in accordance with Section 3.1 of the Preamble of the General Standard for Food Additives, should be included as appropriate.*

The Joint FAO/WHO Expert Committee on Food Additives is to support the process for pillars 1 and 2.

It is also to be noted that the expertise required for the safety assessment of additives used for infants below 12 weeks calls for the organization of a specific Panel of JECFA.

The GFSA provides that:

Food Additive Safety

A) *Only those food additives shall be endorsed and included in this Standard that, so far as can be judged on the evidence presently available from JECFA, present no appreciable health risk to consumers at the use levels proposed.*

B) *The inclusion of a food additive in this Standard shall have taken into account any ADI, or equivalent safety assessment established for the additive by JECFA and its probable daily intake from all food sources. Where the food additive is to be used in foods eaten by special groups of consumers (e.g. diabetics, those on special medical diets, sick individuals on formulated liquid diets), account shall be taken of the probable daily intake of the food additive by those consumers.*

C) *The quantity of an additive added to food is at or below the maximum use level and is the lowest level necessary to achieve the intended technical effect. The maximum use level may be based on the application of the procedures of Annex A, the intake assessment of Codex members or upon a request by the CCFA to JECFA for an independent evaluation of national intake assessments.*

4 Consumer Protection

Justification that the use does not mislead the consumer is the third pillar as the Codex Procedural manual stipulates that:

> • *A reasoned statement that consumers will not be misled by the use of the additive should be provided.*

ISDI notes:

1) That this aspect is being directly covered by the ***CCNFSDU framework for appraising the technological need for food additives*** in Q2.4 *Would the use of this food additive in the intended food(s) modify any characteristic of the food that might mislead the consumer?*

2) Infant Formula labels identify food additives used in the list of ingredients as per the requirements in the General Standard for the Labelling of Pre-packaged Foods (STAN 1-1985). This General Standard specifies that the functional class shall be used together with the specific additive name or INS number in the ingredient panel (or per national legislation), providing transparency to consumers.

LABELLING

Without prejudice to the provisions established by national regulations in relation to the labelling of additives, the General Standard for the Labelling of Prepackaged Foods (**CXS 1-1985**) establishes the provisions applicable to the labelling of additives in infant formula.

The GENERAL PRINCIPLES of the GSLPF apply and call in general for transparent and factual information.

3.1 *Prepackaged food shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect.* (Footnote 1)

Footnote 1: *Examples of descriptions or presentations to which these General Principles refer are given in the Codex General Guidelines on Claims.*

More specifically for additives, section 4 on MANDATORY LABELLING OF PREPACKAGED FOODS applies and stipulates that *the following information shall appear on the label of prepackaged foods as applicable to the food being labelled, except to the extent otherwise expressly provided in an individual Codex standard:*

An example of ingredients labelling of an infant formula:

LIST OF INGREDIENTS:

Nonfat milk (milk), lactose (milk), vegetable oils (high oleic sunflower oil, coconut oil, soy oil), whey protein concentrate (milk), minerals (potassium citrate, calcium carbonate, sodium chloride, magnesium chloride, potassium hydroxide, ferrous sulfate, zinc sulfate, calcium chloride, tricalcium phosphate, copper sulfate, manganese sulfate, sodium selenate, potassium iodide), soy lecithin (EMULSIFIER), vitamins (ascorbic acid, d-a-tocopheryl acetate, niacinamide, calcium d-pantothenate, retinyl palmitate, thiamin HCl, pyridoxine HCl, riboflavin, folic acid, phylloquinone, d-biotin, cholecalciferol, cyanocobalamin), choline chloride, myo-inositol, taurine, L-tryptophan, choline bitartrate, ascorbyl palmitate (ANTIOXIDANT), mixed tocopherols (antioxidant), L-carnitine

Under the List of ingredients (Section 4.2 of the GSLPF):

4.2.3.3 *For food additives falling in the respective classes and appearing in lists of food additives permitted for use in foods, the following functional classes shall be used together with the specific name or recognized numerical identification such as the Class Names and the International Numbering System for Food Additives (CXG 36- 1989) as required by national legislation.*

Acidity Regulator

Anticaking Agent

Antifoaming Agent

Antioxidant

Bleaching Agent

Bulking Agent

Carbonating Agent

Colour

Colour Retention Agent

Emulsifier

Emulsifying Salt

Firming Agent

Flavour Enhancer

Flour Treatment Agent

Foaming Agent

Gelling Agent

Glazing Agent

Humectant

Preservative

Propellant

Raising Agent

Sequestrant

Stabilizer

Sweetener

Thickener

KEY REFERENCES

- JECFA REPORT OF 1971
- GENERAL STANDARD FOR FOOD ADDITIVES (CODEX STAN 192-1995)
- CCNFSDU framework for appraising the technological need for food additives

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