International Special Dietary Foods Industries

ISDI Guidelines

Setting Tolerances for Nutrient Values Declared on Labels for Foods for Special Dietary Uses (FSDU)

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Guidance Document

DISCLAIMER

This guidance document is intended to provide information on Setting Tolerances for Nutrient Values Declared on Labels for Foods for Special Dietary Uses (FSDU). It is for general information purposes only and does not constitute legal or other professional advice. The information provided is without prejudice to national regulations and interpretations.

The development of this brochure has been coordinated by Xavier Lavigne, Vice President of ISDI, and Jean Christophe Kremer, Secretary General of ISDI, and is based on the contributions of the ISDI Task Force on the Setting of Tolerances for Nutrient Values Declared on FSDU Label composed of:

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USER GUIDE

TARGET GROUP

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

PURPOSE OF THE BROCHURE

The brochure provides the background regarding Setting Tolerances for Nutrient Values Declared on Labels for Foods for Special Dietary Uses (FSDU). For more information on FSDU, please refer to the ISDI brochure on Foods for Special Dietary Uses.

Manufacturers of general foods are not required to routinely declare vitamins and minerals on general food unless a nutrition and/or health claim is being made, whereas the declaration of the nutritional content is mandatory for FSDU. This adds a level of complexity which must be carefully managed in FSDU.

The brochure is for general information purposes and aims to be a reference that facilitates the understanding of label tolerances and to establish key principles.

The brochure can be used as a support for food business manufacturers as an educational material (e.g., internal trainings) or as a background reference for discussions with national authorities regarding Setting Tolerances for Nutrient Values Declared on Labels for Foods for Special Dietary Uses (FSDU). The brochure does not consider the specific regulations or guidelines on label tolerances for FSDU in each country, which would prevail, and should not be considered in isolation.

SCOPE OF THE GUIDELINES

These guidelines are applicable to products meeting the Codex Alimentarius definition of Foods for Special Dietary Uses. Foods for Special Dietary Uses are defined at Codex Alimentarius level as "*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 details, please refer to the ISDI FSDU brochure.

When considering nutrition labelling, tolerances are essential as it is not possible for FSDU to always contain the exact nutrient levels as labelled, due to elements of variability addressed in this brochure. However, the nutrient content of FSDU should not deviate substantially from the information on the label in order to avoid misleading consumers. Label tolerance is therefore to be considered as a balance between what is achievable under food good manufacturing practices, will provide adequate nutrition at safe levels to the end user, and not mislead consumers.

DEFINITIONS

Nutrient declaration

Nutrient declaration is a standardized statement or listing of the nutrient content of a food. The Codex Guidelines on Nutrition Labelling (CXG 2-1985) defines the term as follows:

Nutrient declaration – Information supplied should be for the purpose of providing consumers with a suitable profile of nutrients contained in the food and considered to be of nutritional importance. The information should not lead consumers to believe that there is exact quantitative knowledge of what individuals should eat in order to maintain health, but rather to convey an understanding of the quantity of nutrients contained in the product. A more exact quantitative delineation for individuals is not valid because there is no meaningful way in which knowledge about individual requirements can be used in labelling.

This represents the quantitative value of a specific nutrient as shown in the nutrient panel of a product label. The declared value may be based on the manufacturer's analysis of the food (e.g., the average of the obtained values across different batches), or a calculation from the known or actual average values of the ingredients used; or a calculation from generally established and acceptable data.

Label tolerance

The acceptable difference between the value declared in the nutrient declaration on the label of the product and the value obtained by analysis from the time of manufacture through to the end of the product shelf-life. It is to be distinguished from the permissible range of the nutrient content allowed in the product such as regulatory limits of nutrients taking into account minimum and maximum levels for a particular product category: Foods for Special Medical Purposes (FSMPs), infant formula, follow-up formula, etc. The minimum specifications must ensure adequate nutrition is delivered to the end user.

Tolerance range

The difference between the upper and lower level of the label tolerances from the time of manufacture through to the end of the product shelf-life.

Tolerances and compliance

The Codex Guidelines on Nutrition Labelling (CXG 2-1985) define "Tolerances and compliance" in section 3.5 as follows:

"Tolerance limits should be set in relation to public health concerns, shelf-life, accuracy of analysis, processing variability and inherent liability and variability of the nutrient in the product, and, according to whether the nutrient has been added or is naturally occurring in the product.

"The values used in nutrient declaration should be weighted average values derived from data specifically obtained from analyses of products which are representative of the product being labelled.

"In those cases where a product is subject to a Codex standard, requirements for tolerances for nutrient declaration established by the standard should take precedence over these guidelines (CXG 2-1985)."

Average label claim value or average value

The value declared on the label (e.g., nutrition fact or panel) which best represents the amount of the nutrient that a given food contains, and reflects allowances for seasonal variability, shelf-life and other factors which may cause the actual value to vary by the end of shelf-life.

Good Manufacturing Practices (GMP)

A program for ensuring that products are consistently produced and controlled according to quality standards.

Inherent nutrient

A nutrient which exists in the finished product through being naturally present in an ingredient of the product (e.g., Vitamin E in vegetable oils, Vitamin B12 or iodine in milk protein, minerals in agricultural ingredients such as chromium in cocoa powders, DHA and ARA in respective algal and fungal oils).

Fortified nutrient

A nutrient which is added to a formulation for fortification or enrichment purposes.

Nutrient variability

- **Source of nutrient variability in ingredients**: The variation in nutrient content of an ingredient caused by the origin, type of processing and its inherent variability due, for example, to seasonality, degradation over time, etc., or the analytical method applied.
- **Source of nutrient variability in finished products**: In addition to nutrient variability in ingredients, the variation in nutrient content in finished products may depend on the product type/form (e.g., accelerated degradation of some nutrients in acidic foods over shelf-life), or the composition of the product (e.g., significant inherent nutrient contribution with natural high variation), the manufacturing process, or the analytical method applied (usually considered as a different source of variability, but essential to take into consideration).

Analytical variability

Analytical methods are validated for the applicable food category to ensure they have an acceptable accuracy (how close a measured value is to the "true" value) and precision (how consistently the method is in producing the same result). Validated analytical methods must allow for some variance because it is not possible to create a method with both perfect accuracy and precision. Therefore, label tolerance needs to account for that. Even the most stringent dispute resolution methods (Type II – see Codex Alimentarius Procedural Manual) allow some variability.

Measurement of uncertainty

Measurement of uncertainty is a parameter reflecting the precision and the accuracy of a measurement. It characterizes the dispersion around the measured value (e.g., 10 mg +/- 10%). The degree of uncertainty is the result of factors that include the limitations of the measuring instruments, sample preparation, measurement conditions, methods of analysis, etc.

Variability due to manuacturing/processing loss

Variability during manufacturing can, for example, be due to the addition of small amounts of ingredient commodities to a large batch (i.e., addition of gram quantities to a large-scale batch, such as a 95,000 kg batch, or rounding of bulk ingredients).

Losses of vitamins and minerals during manufacturing and processing are variable and can depend on multiple factors, such as the type of processing (e.g., liquid versus powder, losses in temperature sensitive nutrients may vary according to the type of thermal treatment applied, such as retort versus aseptic sterilization), or the product matrices themselves (e.g., hydrolyzed protein versus intact protein or pH of the product).

The fortification rate considers the maximum variability and loss to ensure the nutrient content of the product complies with minimum tolerances at the end of shelf-life. Because of the variability in product types, the range in concentrations that nutrients are added and other factors, additional tolerance may be needed to account for this variability.

Variability of nutrient losses over shelf-life

Variable losses of some nutrients occur throughout the shelf-life of products. The amplitude of these losses varies between different nutrients and can also vary depending on product matrices and other factors, including packaging materials and storage and transport conditions.

For FSDUs, the world can be divided into three temperature zones:

a. Zone I: “Temperate” 21°C +/- 2°C
b. Zone II: “Subtropical” 25°C +/- 2°C
c. Zone III: “Hot” 30° +/- 2°C

For example, product storage in Zone III conditions can result in significantly more degradation of some labile nutrients than if that same product is stored in more moderate conditions.

FSDU - A FOOD CATEGORY WITH HIGHLY REGULATED NUTRIENT LEVELS

The FSDU category is specifically designed for a specific purpose or population, a vulnerable stage of life and/or specific medical conditions, therefore it is important that consumers, parents/caregivers, as well as healthcare professionals receive appropriate information on the products and their characteristics, and on the often complex composition of these products.

Certain nutrients (e.g., those present particularly at very low concentration, or when pH levels in products are low) will require the application of wider tolerance ranges. As mentioned above, FSDU are highly complex food products with multiple ingredients that can interact with each other in the product matrix which can increase nutrient variability compared to simpler food products.

Most of the products in these categories are manufactured in a similar manner so it is **strongly recommended to apply the ISDI guidelines for tolerances to all FSDUs.**

TOLERANCES FOR NUTRIENT DECLARATIONS ON FOODS AND FOODS FOR SPECIAL DIETARY USES

Specific vertical legislation governs the compositional requirements of foods which include stated regulatory limits (minima and maxima) for nutrients within which the manufacturers are obliged to operate. These minima and maxima reflect expert scientific opinions (e.g., Recognized Authoritative Scientific Bodies (RASBs)).

The Codex Alimentarius international food standards, guidelines and codes of practice contribute to the safety, quality and fairness of international food trade. Codex standards are based on sound science provided by independent international risk assessment bodies or ad hoc consultations organised by the Food and Agriculture Organization (FAO) and World Health Organization (WHO).

As described in the Codex Guidelines on Nutrition Labelling (CXG 2-1985) (see section on Definitions above), "*Tolerance limits should be set in relation to public health concerns, shelf-life, accuracy of analysis, processing variability and inherent liability and variability of the nutrient in the product, and, according to whether the nutrient has been added or is naturally occurring in the product.*"

FSDU are formulated most often with the addition of small quantities of vitamins and certain minerals, the levels of which, are appropriate to the intended users which comprise vulnerable groups of the population, such as infants and young children and those requiring medical support.

If tolerances are outside of regulatory limits, it is up to the manufacturer to have justification for the deviation. Where they go beyond, the amount must be evaluated for safety for the intended population.

KEY PRINCIPLES AND CONSIDERATIONS IN RELATION TO LABEL TOLERANCES

Food manufacturer responsibility

It is the responsibility of the food manufacturer to establish processes, product specifications and product labels claims that ensure the safety of the product and that the consumer is not misled. Manufacturers do this by using Good Manufacturing Practices (GMPs) and Hazard Analysis and Critical Control Points systems (HACCP) and setting accurate product specifications to assure that products are safe and that the amount of nutrients declared on the label is representative of the product over shelf-life.

Broader tolerance for FSDU vs. general food

Foods for Special Dietary Uses are highly complex food products with several ingredients often comprising more than 40 nutrients and, as previously discussed, have numerous factors influencing nutrient stability. Therefore, **label tolerances for FSDU should be different than for general food. FSDU tolerance should be adapted and in some cases broader to reflect the specific characteristics of this category of food. Safety remains a pre-requisite.**

In addition, the tolerance ranges are often expressed as a percentage. However, some of the nutrients considered are present in very low amounts. The ranges, therefore, may appear broad in percentage but correspond to small amounts in absolute values.

Additionally, there could be negative consequences of establishing narrow label claim tolerances for these labile nutrients, including:

- Decreased shelf-life of products, which has a negative economic impact to consumers and the overall supply chain
- Challenges that could result in an inability to manufacture and could impact the availability of some FSDUs that are produced for a very targeted small group of consumers
- FSDU that could fall out of these narrow tolerances would be deemed non-compliant and destroyed, which would lead to an increase in food waste and environmental impact when the food is technically fit for purpose and safe

Label tolerance and regulatory limits for FSDU

FSDU are highly regulated categories which leads to an extra level of control when it comes to the levels of nutrients in these products.

FSDU categories such as Infant Formula, Follow-up Formula, Low Calorie Diet and Very low-calorie diet formulas, Ready to Use Therapeutic Foods (RUTF) and Foods for Special Medical Purposes (FSMP) are formulated to meet the specific nutritional needs/conditions of vulnerable groups of the population and thereby often have complex compositions.

Specific regulations relating to these product categories often oblige manufacturers to include specific nutrients in their design and formulation. Although various nutrients will be present naturally in raw materials used in the product recipes, the amounts are, more often than not, insufficient to provide the necessary levels to meet the compositional requirements set in legislation.

Guidance on label tolerance

ISDI considers it is an essential point that the maximum level considered when establishing tolerances should reflect post-processing losses and not be based on the actual nutrient fortification level. This would better represent the actual zero-time result for the finished product. This maximum must also be within limits that are considered safe when the finished product is used at the highest daily intake by the intended population. Minimum tolerances must be set to guarantee that the consumer/patient receives a minimum amount of nutrients for optimum growth, performance, or nutritional support/disease management.

The maximum label tolerance is a combination of the highest range of all factors that contribute to nutrient variability. This would be considered the highest potential result and does not likely represent the true "accurate" value in the product over its shelf-life.

Impact of nutrition and health claims

Manufacturers of general foods are not required to routinely declare the vitamins and minerals on general food labels unless a nutrition and/or health claim is being made - whereas FSDU are mandated to declare nutrient content.

It is important to note that the presence of a claim on the label of an FSDU product can impact the label tolerance in relation to the nutrient considered in some specific contexts related to national or regional regulations and/or health policies. For example, it could trigger no minimum or no maximum in the ranges of the considered nutrient in the context of the national or regional regulations and/or health policies.

Procedure for discussion with FSDU manufacturers to justify deviations to authorities: a need for flexibility

To ensure consistency and compliance, label tolerances need to be defined or updated when already existing at a national level to reflect the complex nature of FSDU formulations while not compromising safety.

In the event that manufacturers are not able to achieve these tolerances, **a procedure should be in place to allow for manufacturers to provide authorities with scientific and technical rationale justifying the deviation, when appropriate**. For example, low pH products could need further deviations due to higher rates of degradation and should be able to provide justifications for higher tolerances to the competent authorities when needed.

While there are many factors that can impact the stability of nutrients in different product matrices, key aspects to consider are:

- **Ingredient variability**
- **Variability during manufacturing/processing loss**
- **Analytical variability, including uncertainty of measurement and uncertainty of measurement across laboratories**
- **Variability in nutrient losses during shelf-life**

Differentiation of tolerances between labile and non-labile nutrients

ISDI considers that it is not suitable to hold labile nutrients to the narrow tolerance ranges of less labile nutrients because of the technological challenges that may be associated with them. Labile nutrients are those nutrients that can be degraded, contrary to non-labile nutrients.

For nutrients with analytical methodology that is both accurate and precise, that are stable over shelf-life, that are not subject to manufacturing losses, and that come only from added sources which can be tightly controlled, the label claim tolerances can be narrow while still assuring that label claims are met over shelf-life. In contrast, for labile nutrients that experience manufacturing and/or shelf-life losses, or where multiple sources (inherent or fortified) of addition are used, or for which less accurate or precise analytical methods are available, then broader label claim tolerances may be necessary. These broader tolerances have to be consistent with the variability observed under GMPs.

Consideration for nutrient variability

Setting label claim tolerances that encompass all food is challenging and must consider the worst-case scenario for nutrient variability across all foods. Foods are available in many different compositions and forms. It is important to note that nutrient variability is highly dependent upon the composition of the food (e.g., amount of fat present, and/or type of protein, liquid vs. powder product), amount and complexity of ingredients, amount and variability of inherent nutrients, manufacturing processes, analysis variability and variability across laboratories and other factors.

Furthermore, variability will also be greatly dependent upon the specific nutrient and the added form (e.g., encapsulated or not, difference between salts), with some nutrients experiencing significantly greater variability than others. While some of these factors are within the control of food manufacturers, many are not (e.g., seasonal fluctuation, geographical fluctuation in the supply and nutrient degradation rates at a particular temperature or processing condition).

Differentiation between liquid and powder FSDU

ISDI notes that due to the increased degradation rates of certain labile nutrients, like vitamins, in liquids, a distinction for label tolerance between powder and liquid products may be necessary, with broader tolerance ranges for liquids than powder.

Flexibility for low/very low levels of certain nutrients

ISDI notes that flexibility and sometimes even exclusion from label tolerance ranges are necessary for FSDU products specifically formulated to be very low or extremely low in certain nutrients (e.g., fats or sugars). For example, products with a sugar or fat content below 2 gram/100ml are in need of more flexibility considering that deviation from such a low amount appears important in percentage but not in absolute values.

Absolute or wider tolerances may be appropriate when 1) the allowable tolerance conflicts with the rounding rules for labelling per regulation or 2) when the nutrient may be labeled as 0 when its content is below a threshold defined per regulation (e.g., 0.5 g/100 mL). ISDI recommends that these considerations be incorporated into any discussions in relation to label tolerance and that a sufficient level of flexibility be permitted to ensure that products manufactured under GMPs can comply with the defined tolerances.

Analytical variability

ISDI notes that analytical methods may vary based on numerous factors including, but not limited to, nutrient type, nutrient form, amount of nutrient in the product, or the product form and matrix. There may also be analytical variation between laboratories (e.g., a manufacturer's laboratory versus external laboratories utilized by customs imports and exports agencies and market surveillance of products on the shelf by competent authorities). This variability needs to be accounted for within the label tolerance.

JUSTIFICATIONS FOR WIDER TOLERANCE RANGES

Justification for wider tolerances on products with low pH

'Low pH' or 'acid food' is defined as a food that has a pH of 4.6[1] or below. Examples include acidified milk-based products and products containing fruit-based ingredients. A low pH can result in significant degradation of vitamins (e.g., vitamin A, vitamin C, Pantothenic acid) compared with products having a more neutral pH. 'Low pH' or 'acid food' therefore need wider tolerance values due to this degradation.

Justification for wider tolerances on products with low homogeneity

Some products are more heterogeneous than others, which could impact the inherent content and the distribution of the nutrients. This is the case, for example, for powdered infant cereals. In this context, wider tolerances will be needed to cover this aspect.

Justification for wider tolerances for naturally occurring/inherent nutrients

When a nutrient is contributed solely from naturally occurring (inherent) sources in a food, nutrient variability may be even greater due to fluctuations between seasons, geographical location, etc. In addition, minerals sourced from mining processes may have significant inherent differences in nutrient content based on the region from which they are sourced.

This is often the case for baby foods with vegetables and cereals. In this context, wider tolerances will be needed.

1. Section 2.2. from the Codex Code of Hygienic Practice for Low and Acidified Low Acid Canned Foods (CXC 23-1979)

NOTES

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