International Special Dietary Foods Industries

Why adaptations to compositional and labelling requirements for Follow-up Formula for Older Infants and Product for Young Children require a transition period of at least 36 months

ISDI POSITION ON THE IMPLEMENTATION OF CODEX STANDARD 156-1987 FOR FOLLOW-UP FORMULA FOR OLDER INFANTS AND PRODUCT FOR YOUNG CHILDREN*

*Other equivalent names for this product are Drink for Young Children with added nutrients, or Product for Young Children with added nutrients, or Drink for Young Children.

In order to ensure a smooth transition to new national regulatory frameworks based on the revised Codex Standard for Follow-up formula for Older Infants and Product for Young Children (**CXS 156-1987**), ISDI recommends that new national regulatory frameworks incorporate the following to ensure practical feasibility:

- A transition period of at least 36 months from the adoption of the new national regulatory framework until new products placed on the market are mandated to comply with the new regulation;
- Clear communication that products placed on the market prior to the effective date may comply with the previous regulation until the end of their shelf-life;
- Permission for companies to put products on the market that are compliant with the new regulation prior to the mandated compliance date.

The duration of the transition may be impacted by the global regulatory landscape for these products, as implementation by countries will take place at different speeds.

ISDI calls on national authorities to consult with ISDI members before implementation to ensure a smooth transition period.

An explanation of the time/transition constraints is in the text below.

Precedents for a transition period

- In 2016, the EU introduced Regulation (EU) 2016/127, which addressed the composition of infant and follow-on formula. Food business operators were granted a **4-year transition period** to adapt to the new requirements for both infant formula and follow-up formula. Additionally, for formulas manufactured from protein hydrolysates, the transition period was extended to **5 years**.
- The EU's Food to Consumer Regulation (Regulation (EU) No 1169/2011) was primarily focused on labelling changes. Under this regulation, the industry was allowed a **5-year transition period**.
- In 2006, the EU industry was granted a **5-year transition period** for a single nutrient change (Manganese) within the product category of **FSMP for infants**, as outlined in Article 16 of Directive 2006/141/EC.
- In the USA, when the Nutrition Facts Panel was put in place, the US FDA originally gave a little over 2 years but later determined they had to extend the compliance period because it was not achievable in 2 years. US FDA explains the need for the extension **here**. **Following the extension, manufacturers had between 3.5 years to 4.5 years** depending on the size of the business.
- Another recent example from the USA, also for labelling only, is the USDA Bioengineering Disclosure Rule. The **final rule** was published on 21 December 2018. The mandatory compliance date was 1 January 2022, **i.e. 36 months**.

It is also interesting to note that some of these examples impacted labelling only, and not formulation, which as highlighted above drastically increases complexity.

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ISDI emphasises that any changes are not related to food safety. Therefore, the transition should allow for the coexistence of products that comply with either the previous regulation or the new regulation for a certain time.

Follow-up Formulas for Older Infants and Product for Young Children will undertake fundamental changes with the revised Standard: the macro- and micronutrient profiles of these products will be changed, and all formulations will be thoroughly defined and controlled.

Manufacturers will need time to adapt to the new requirements once the standard is adopted at national level. In addition, as foods for special dietary uses, these products tend to be more frequently traded globally than general foods and often undergo administrative processes (notification/ registration) in many countries. An appropriate transition period will also benefit local authorities by reducing the complexity of the administrative process caused by multiple regulatory submissions.

Smooth transitions at national level should help as the global regulatory landscape for these products will evolve at different speeds, following the recent publication of the new Codex Standard.

Time/transition constraints

1. **ENSURING COMPLIANCE WITH NEW REQUIREMENTS, ANALYSIS, CALCULATIONS, TESTING, NEW EQUIPMENT - 13 months (minimum)**

   To ensure that all products are fully compliant with the new set of requirements, at least **seven months of thorough analysis and testing** of ingredients and nutrients, pre-mixes and equipment needs to be carried out. During the **first month**, **all products are compared with the new composition levels**, assessing the modifications that need to be made for each product and the potential issues that this might bring with regard to natural contribution of nutrients from different ingredients and the new tolerances required. This is different for each product.

   Depending on what needs to be changed, there may be **a need to qualify a new ingredient or a new mix**, this qualification process can take **6 months given the strict quality requirements applied to these product categories**.

   Additionally, depending on what needs to be changed **new dosing equipment may be needed**. This new dosing equipment will also have to be qualified and built into the factory.

   Then, **the new composition of each formulation is calculated**. Complex scientific and administrative processes take at least **2 more months** to obtain the correct amounts of nutrients needed for each formulation.

   After this, new premixes are ordered from suppliers, who also need time to establish these new premixes according to new specifications (**3 months**). Once arrived, premixes are tested before use (**1 month**). Data processing is also crucial to safeguard the **traceability** of products.

New formulations | **13 months minimum**

2. ENSURING COMPLIANT AND STABLE FINAL PRODUCTS - 12 months (minimum)

Once all separate ingredients are ready, the trial phase starts, which is the longest part of the process.

New formulations or changes in existing formulations (powder and/or liquid) may need **at least one trial to be validated**. For example, in case a manufacturer would have 20 formulations, 20 trials or more would normally be required.

These trials assess both physical properties and stability of products and nutrients, including shelf-life trials (**more than 3 months**), ensuring that they can effectively be produced with the new requirements.

However, disrupting commercial production and innovation needs to be avoided, which means that trials need to be spread out over the year(s).

A limited number of trials can be undertaken each year in one factory. These compliance trials take away time and resources from commercial production as well as from innovation.

Thorough testing of formulations (trials period) | **12 months minimum (25 months)**

3. ADMINISTRATIVE PROCESSES - 18 months

Once trials are finalised for each formulation, labels are changed to reflect new compositions (**6-12m and 12-36m**) and **necessary administrative processes** need to be completed by notification/registrations (could be **up to 18 months** depending on the country).

Administration | **up to 18 months (42 months)**

Conclusion

A transition period of at least 36 months is appropriate for implementing composition and labelling changes of such significance. As previously highlighted, these products are often traded globally, unlike general foods. It is therefore important to recognise that the timelines can also be impacted by factors related to manufacturing, shipment and distribution activities, especially since many countries import products from manufacturing sites located in other countries.

Thus, considering amendments to current legislation and changes required, a transition period of at least 36 months would be appropriate.

ISDI is the leading international expert association on special dietary foods, including foods specifically designed for infants and young children. ISDI members are national and international associations that are active in this sector from more than 20 countries over 6 continents.

Our members manufacture and market foods that are formulated, in accordance with applicable Codex Alimentarius standards, to meet the compositional criteria, quality requirement and nutritional needs of infants and young children.

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