

Manual for the manufacture of complementary foods

KENYA



January 2020



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01 | Introduction

This manual has been prepared for use by persons and organisations wishing to manufacture and supply complementary foods in different countries. The manual has been specifically prepared for use in the countries of Ethiopia, Kenya, Mozambique and Rwanda and contains generic information that will be applicable irrespective of the country concerned but also contains specific information relating to the four aforementioned countries.

While a number of different categories of complementary foods exist and the rationale and manufacturing feasibility considerations behind them are discussed below, this manual will focus on the principles behind and requirements for the manufacture of cereal based complementary foods in developing countries and specifically blended porridges that have been fortified with either of or both macronutrients such as protein and fat and micronutrients, namely vitamins and minerals.

The manual is specifically intended for use in Ethiopia, Kenya, Mozambique and Rwanda and will contain information specific to those countries as well as generic information applicable to complementary food manufacture in any country. Its use can thus be extended in future to other countries by means of addition of further specific information relating to the country or countries concerned.

The manual is designed to not only provide the essential principles of complementary food manufacture but also deal with the special requirements relating to their composition. The objective of the manual and any related training courses should be that they will enable any organisation considering the manufacture of complementary foods to have sufficient information available to understand the key aspects of the theory behind complementary foods as well as key information on their composition, ingredients, processing, and quality and regulatory requirements. These in turn will be of value for any initial feasibility study into potential complementary food manufacture as well as once the development process has actually commenced.



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02 | What is a complementary food?

The World Health Organization introduction to complementary feeding states:

'When breast milk is no longer enough to meet the nutritional needs of the infant, complementary foods should be added to the diet of the child. The transition from exclusive breastfeeding to family foods, referred to as complementary feeding, typically covers the period from 6 to 18-24 months of age, and is a very vulnerable period. It is the time when malnutrition starts in many infants, contributing significantly to the high prevalence of malnutrition in children under five years of age world-wide. WHO estimates that 2 out of 5 children are stunted in low-income countries.'

A complementary food can thus best be described as:

'A food that is typically consumed by children between the ages of 6 and 24 months during the process of transition between exclusive breast feeding and the introduction of a normal diet'

The manner in which complementary foods act as an intermediate source of nutrition between the period of exclusive breast feeding and adoption of a normal diet is summarised in the following graphs. Figure 1 demonstrates the trend in energy intake from the various energy sources in the total diet and Figure 2 demonstrates the proportion of energy derived from the various sources.

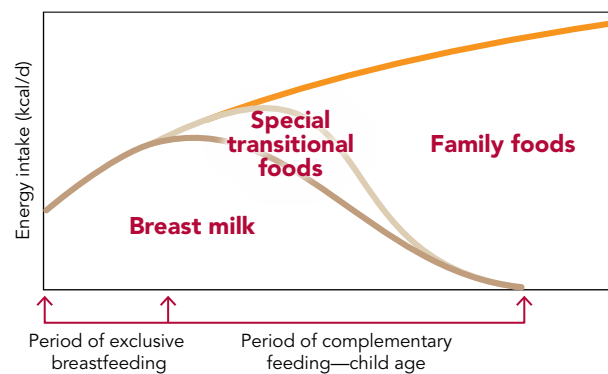


Figure 1

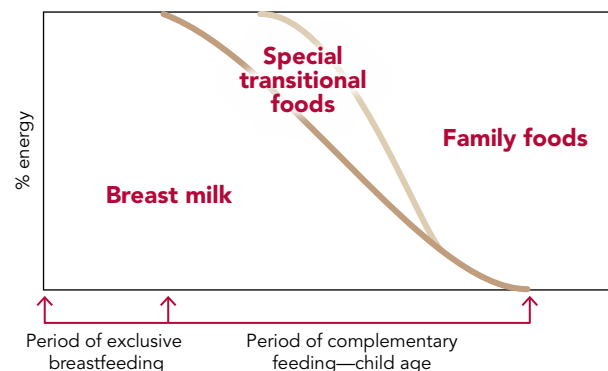


Figure 2

Source: WHO Complementary Feeding Guide 1998

The category of complementary foods comprises a variety of food types. Certain unprocessed food-stuffs such as fruits and vegetables prepared in the home comprise one category, flours derived from basic milled grains and made up into porridge type products in the home are another slightly more sophisticated category. In other instances normal home prepared meals containing a wide range of ingredients are converted into a form suitable for easy consumption by infants and young children by means of pureeing or other means, and these can provide a desirable interim food format which can then progressively move towards a format closer and closer to the original home prepared meal.

However a wide range of processed complementary foods are also manufactured by a wide range of food companies varying from large multinational companies to smaller but often technically quite sophisticated local companies. These products are typically produced in dedicated processing facilities and marketed in packaged form through conventional distribution channels.

Complementary foods are however in some instances also suited to small scale and home industry type manufacturing operations.

Complementary foods can also be divided into perishable and non-perishable categories. Perishable variants such as purees require either sophisticated processing and distribution procedures to provide adequate shelf life and product safety or very basic processing where the products are either consumed immediately after production or used within a short time in small localised environments. Non-perishable complementary foods, comprising mainly dry cereal and other low moisture products are more common and generally easier to produce and distribute.

It follows that complementary food production on an industrial scale in developing countries is likely to focus on non-perishable products. Certain types of products based mainly on cereal ingredients with relatively simple processing requirements are also well suited to production by small and medium sized companies with limited resources.

While many of the principles applicable to the manufacture of complementary foods are those also applicable to any food manufacturing operation, many additional considerations are also applicable to complementary foods. These include:

- Complementary foods have very specific nutritional requirements and need to be formulated using particular nutritional criteria.
- The young age groups consuming complementary foods are inherently more vulnerable to foods produced in an unsafe manner or foods of poor nutritional quality hence high standards of manufacturing and product quality are required.
- Complementary foods are highly regulated and compliance with both global and local regulatory requirements place additional compliance requirements on the manufacturer.



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03 | An introduction to basic nutritional requirements and nutrients in complementary foods

Developing countries are increasingly subject to the phenomenon of the so-called 'Double Burden' in nutrition related health matters, namely the co-existence within a population with some suffering from under nutrition resulting from insufficient intake of both macronutrients and micronutrients and others suffering from over nutrition resulting excessive intake of certain macronutrients in particular. Both these phenomena often have their roots in poor dietary practices at a very young age, in some cases immediately after the transition from exclusive breast feeding in an infant. It is therefore essential that the diet of infants and young children at this critical stage be of an acceptable nutritional quality and this can be brought about to a large extent by consumption of complementary foods of the desired nutritional characteristics during the critical 6-24 month age period.

As acceptable nutritional properties are thus the key criteria for formulating and manufacturing complementary foods, it is essential that these are understood by would-be manufacturers of these products. A broad introduction to nutritional science is included in this manual as Annexure I

however it is more appropriate to focus on the specific needs of the age group for whom complementary foods are intended.

NUTRITIONAL REQUIREMENTS FOR THE 6-23 MONTHS AGE GROUP

The term 'First Thousand Days' is a very well known in the field of nutrition and it refers to the period between conception of the child and the child's second birthday which, assuming a 9 months pregnancy amounts to 1003 days. The period during which complementary foods are introduced approximately represents the last 550 days of this period.

The importance of correct nutritional intake during the entire '1000 Days' cannot be over-estimated. The 2003 publication 'Feeding and Nutrition of Infants and Young Children' produced by the WHO, while originally devised for European countries and encompassing the age group up to 3 years over and above the complementary feeding age group of 6-24 months, provides an excellent summary as part of its foreword:

A child's first 2 or 3 years of life are the most critical for normal physical and mental development. Nevertheless, current feeding practices in some countries may be doing more harm than good to the development of young children. Children under 3 years of age are vulnerable to poor nutrition; the growth rate during this period is greater than at any other time, and there thus exists an increased risk of growth retardation. Also, the immunological system is not fully mature at this age, resulting in a risk of frequent and severe infections.

Both cognitive and emotional potentials start to develop early, and so the foundations of intellectual, social and emotional competencies are also established during this period. In summary, poor nutrition during the early years leads to profound defects including delayed motor and cognitive development, behavioural problems, deficient social skills, a reduced attention span, learning deficiencies and lower educational achievement.

Infants, especially those who have a low birth weight or are otherwise vulnerable, are at high risk of morbidity and mortality during the first 2 years of life, especially after 6 months of age. In the period after birth most infants, even the most vulnerable, grow and develop normally if they are exclusively breastfed. If foods or drinks are introduced too early or are not given safely in the correct quantity at the optimum time, growth rates falter dramatically and can lead to growth retardation. By the time these children are 2 years old, many will be stunted. This is irreversible, and as adults they will remain small and be likely to have reduced mental and physical capacities. To reduce the high prevalence of stunting—common among vulnerable groups in the European Region—national feeding guidelines based on those given in this book should be implemented by health ministries. This will promote normal growth and development in the first 3 years of life, especially for the most vulnerable.

Nutrition related health problems during the first 3 years of life lead to short-and long-term consequences such as cardiovascular disease that limit human potential within society. Improving infant and young child nutrition should thus be a priority, and be seen as an integral part of social and economic development. During times of economic crisis countries face difficult choices, so it is imperative to advocate social sector investments,

notably nutrition policies for young children. Failing to ensure that young children receive optimum nutrition is counterproductive. Faced with limited resources, countries may decide to reduce general expenditure by limiting resources devoted to the development of young children. In the long run, however, failing to invest in the young will be more costly to the state and to society. Future mental and physical capacity will be compromised and, in addition, treating the resulting preventable diseases will be extremely costly. By placing emphasis on the first three years of life and developing comprehensive nutrition policies, countries can avert many preventable deaths, avoid irreversible mental damage, and preserve a child's priceless endowment of emotional, intellectual and moral qualities'

There is also a bigger picture in terms of the overall growth requirements of the child. The GAIN document 'Why Children's Diets Matter' states:

'The 1,000 days from the start of a woman's pregnancy until her child's second birthday offers a unique opportunity to shape not only a child's future, but the future of a society. The right nutrition during this crucial period can have an enormous impact on a child's ability to grow, learn and develop to his or her full potential. Poor infant and young child feeding is typically characterized by poor timing of complementary feeding (too early or too late); infrequent feeding; and poor feeding practices, hygiene, and child-care practices. Added to these is the poor dietary quality of the foods served, characterized as too little variety; inappropriate consistency (food is too thin or too thick); too few essential micronutrients. Globally, only about half (52%) of infants and young children are meeting the minimum meal frequency and less than one third (29%) are meeting the minimum dietary diversity, with large disparities across and within regions. Beyond the crucial 1,000-day period, diets of children of preschool (usually 24 to 59 months of age) and school-age (five to 12 years of age) remain critical for physical and cognitive development, educational outcomes and the establishment of healthy eating habits. Furthermore, recent evidence indicates that accelerated linear growth in childhood following stunting in infancy can occur (i.e. catch-up growth)'

In many instances, the child may be suffering from nutritional deficiencies and appropriate choice of complementary foods will be critical in combatting malnutrition. The GAIN document further states:

‘Despite the considerable progress made over the past decades, millions of children are still affected by acute and chronic malnutrition and many more suffer from some degree of sub-optimal health and/or development due to micronutrient deficiencies. Globally 159 million children are stunted and more than 2 billion people suffer from micronutrient deficiencies; specifically, 43% (range 38% to 47%) suffer from anaemia. Concurrently, childhood obesity affects approximately one-in-five children worldwide and child feeding practices are implicated in the aetiology of obesity’

Poor nutritional intake among infants and young children is accordingly reflected in a number of clinical conditions as can be seen in Table 1 below.

Under and overweight children are clearly to some extent at risk but the most worrying nutrition related clinical conditions are wasting and stunting:

- Wasting is defined as a condition where the weight-for-height index for the child is more than 2 standard deviations below the mean for the reference population as determined by the WHO. Wasting is a very serious condition, typically resulting from severe weight loss that in turn may result from starvation or severe disease. It is however less prevalent than stunting.
- Stunting is defined as a height-for-age index for the child more than two standard deviations below the mean for the reference population as defined by the WHO. It is considerably more prevalent than wasting and typically results from both low overall nutritional intake but also from deficiencies in specific nutrients.

NUTRITIONAL STATUS OF YOUNG CHILDREN IN THE TARGET COUNTRIES FOR THIS MANUAL

Table 1: Incidence of nutrition related medical conditions in selected countries

**Data for severe wasting, wasting, overweight, stunting, underweight ex UNICEF. Data for anaemia ex national nutrition surveys*

Country	Year data obtained	Source of data	Population <5 years	Sample survey size	% of children surveyed with*					
					Severe wasting	Wasting	Over-weight	Stunting	Under-weight	Anaemia
Ethiopia	2016	Ethiopia Demographic and Health Survey	15,177,181	10552	3.0	10.0	2.3	38.4	23.6	71.9
Kenya	2014	Kenya Demographic and Health Survey	6,950,404	19250	1.0	4.2	4.1	26.2	11.2	26.3
Mozambique	2011	Moçambique inquérito demográfico e de Saúde	4,443,616	10636	2.4	6.1	7.8	42.9	15.6	81.9
Rwanda	2014-15	Rwanda Demographic and Health Survey	1,734,543	3881	0.7	2.3	7.9	38.2	9.6	52.4

It can be seen that there are high incidences of nutritionally related medical conditions. While these relate predominantly to under-nutrition and the incidence of wasting is significantly lower than that for stunting, the data for overweight status indicates some measure of ‘double burden’ syndrome.

RECOMMENDED MACRONUTRIENT INTAKES

Recommended intakes for energy and protein are summarised in Tables 2 and 3

Table 2: Recommended energy intake for 6-23 month age group (figures from WHO 2003 publication 'Feeding and Nutrition of Infants and Young Children')

Energy:

Age group (months)	Recommended energy intake from breast milk (kJ / day)	Recommended energy intake from complementary food (kJ / day)
6-8	1729	1126
9-11	1586	1888
12-23	1448	3123

Table 3: Recommended protein intake for 4-36 month age group

(figures from WHO 2003 publication 'Feeding and Nutrition of Infants and Young Children')

Protein:

Age group (months)	Recommended protein intake (g/day)
4-6	12.7
7-9	13.7
10-12	14.9
12-36	14.5

Fat:

Requirements for fat are expressed as % contribution of energy derived from fat rather than as actual intakes. The WHO recommendation is that for the complementary feeding age group of 6-24 months of age, between 30-40% of energy should be derived from fat, including approximately 3% from linoleic acid and 0.3% from linolenic acid.

Carbohydrate:

WHO does not make specific recommendations regarding total carbohydrate intake but specifically advises limitation of added sugars (mono- and di-saccharides) in the diet of infants and young children. A maximum of 10% of total energy intake derived from added sugars is recommended with a maximum 5% of total energy intake seen as ideal.

RECOMMENDED MICRONUTRIENT INTAKES

The following recommended values for daily micronutrient intake for the complementary food age group are summarised in Table 4 obtained from Codex Alimentarius

Table 4: Recommended micronutrient intake for complementary feeding age group—
source Codex Guideline CAC/GL 8-1991 updated 2017

Micronutrient	Unit	Recommended intake
Vitamin A	mcg	400
Vitamin B1 or thiamine	mg	0.5
Vitamin B2 or riboflavin	mg	0.5
Nicotinic acid	mg	6
Vitamin B6 or pyridoxine	mg	0.5
Folic acid or folate	mcg	150
Vitamin B12 or cyanocobalamin	mcg	0.9
Biotin	mcg	8
Pantothenic acid	mg	2
Vitamin C or ascorbic acid	mg	30
Vitamin E	mg TE	5
Vitamin K	mcg	15
Calcium	mg	500
Copper	mg	0.34
Iodine	mcg	90
Iron	mg	11.6, 5.8, 3.9*
Magnesium	mg	60
Manganese	mg	1.2
Phosphorus	mg	460
Selenium	mcg	17
Zinc	mg	8.3, 4.1, 2.4*

*Value dependent on bioavailability of mineral source



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04 | Nutritional status and consumption data for complementary feeding age group in Kenya

Extensive information is available on the nutritional status and food consumption patterns of the 6-23 month age group in Kenya. Some of the data was generated some years ago and may not be fully representative of the current situation but remains highly valuable for the purpose of the evaluating key nutritional drivers for the development of complementary food formulations in Kenya.

GENERAL COMMENTS

According to the Kenyan Demographic and Health Survey (DHS) of 2014, average stunting prevalence was found to be 26% in children under the age of 5 years with 8% found to be severely stunted. This marked a significant improvement from the level of 38% found in 1998. Levels of stunting however varied considerably with higher levels in the age groups 18-23 months (36% and 24-35 months (34%) and higher incidence among rural children (29%) than among urban children (20%). The DHS also indicated that the level of wasting had reduced from 7% in 1998 to 4% in 2014. A more recent summary document from the USAID Maternal and Child Survival Programme in 2017 also indicates an average stunting rate of 26% for children under 5 years. Incidence of breast feeding for this age group is reasonably good for this age group with

the DHS indicating at least some breast feeding for 93% of infants at the age of 1 year and for 61% of children at the age of 2 years. 61% of children under 6 months were exclusively breast fed.

Dietary intake and role of complementary foods

The 2014 DHS established that 92% of breast fed children in the 6-23 month age group received solid or semi-solid complementary foods. 80% of the children received foods made from grains and 64% received foods from fruits and vegetables rich in Vitamin A but much lower levels of protein rich foods such as legumes, nuts, meat, fish and eggs were consumed.

A review of dietary diversity in the DHS indicated that, while 41% of children in the 6-23 month age group met minimum desirable standards of dietary diversity and 51% had received the minimum meal frequency requirement, only 22% met the minimum overall standards required for infant and young child feeding.

It appears therefore that, particularly in view of the high rates of stunting observed in the critical 18-23 month and 24-35 months ages groups, there is a very real need in Kenya for complementary feeding of good nutritional quality to be available

to children of 6 months and over, coupled with continuing strong emphasis on breast milk as a sizeable proportion of the diet up to 24 months. Cereal based complementary foods will be acceptable in view of the familiarity of the population with grain products.

Micronutrient intake

Data on micronutrient deficiencies among the complementary food age group is available from the Kenya National Micronutrient Survey (NMS) published in 2011 by the Nutrition and Dietetics Unit of the Ministry of Health. While this was produced some time ago, it gives a comprehensive overview of the micronutrient status of the Kenyan population which is summarised in Table 5 below:

Table 5: Summary of micronutrient status in Kenya

Micronutrient attribute	% incidence
Vitamin A deficiency (pre-school children)	9.2
Marginal Vitamin A deficiency (pre-school children)	52.6
Vitamin A supplementation (children < 5 years)	84.3
Anaemia (pre-school children)	26.3
Iron deficiency (pre-school children)	21.8
Iron deficiency anaemia (pre-school children)	13.3
Anaemia (pregnant women)	41.6
Zinc deficiency (pre-school children)	83.3

The above data clearly indicates the desirability of micronutrient fortification of complementary foods in Kenya. Iron and zinc deficiencies are of particular concern as will be selection of suitable mineral sources with good mineral bio-availability.



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05 | Background to the health and nutritional principles behind complementary foods

As discussed above, the transition from exclusive breast feeding to a mixed diet of breast milk and complementary food needs to be undertaken with considerable care from a health and nutrition perspective and the correct choice of foods during the transition is essential.

Considerable effort has therefore gone into formulating appropriate guidelines for the nutritional composition of complementary foods, which, in conjunction with breast milk, not only need to provide the overall nutritional needs of the entire target population receiving the complementary food but should also assist in addressing any specific nutritional deficiencies in individuals. While the latter is likely to require additional clinical or other interventions, it is desirable that complementary foods themselves play a major role in overcoming these deficiencies and the resulting recommended compositional requirements for complementary food formulations are explained further in section V below.

When considering the overall nutritional requirements for complementary foods, we need to consider both the macronutrient and micronutrient requirements of the target group. These can be considered the foundations upon which we

build our complementary foods while taking into account such factors as raw material availability, cost and ease of processing.

Compositional requirements need to consider not only recommendations at global level but also local requirements such as specific micronutrient deficiencies that have been identified in the target group. Initiatives such as the Kenya Demographic and Health Survey (KDHS) referred to above and similar initiatives in other countries can provide helpful information in this area (for example by highlighting the high incidences of anaemia and zinc deficiencies referred to above), alternatively more specific investigations among particular population groups can be of value for more targeted interventions.

We also need to consider broader food consumption patterns for the group concerned and how complementary foods fit into a diet where the child is not only transitioning from exclusive breast feeding but also where conventional foods for older children and adults are going to be progressively introduced into the child's diet. These conventional foods will vary according to local dietary practices which in turn are driven by factors such as historical preferences, local availability of particular

foodstuffs and affordability. Due consideration needs to be given to the nutritional quality of any other foods introduced to the diet during the critical 6-23 month period. For example it is obviously desirable that foods such as fruits and vegetables are introduced during this period in the interest of dietary diversity and familiarisation of the child with foods that should be an ongoing part of their diet going forward. However the reality is that fruits and vegetables provide very little in the area of energy, protein or fat and are also limited in their content of most micronutrients. Complementary foods such as those based on cereals are thus important in ensuring that the correct intake of key nutrients continues throughout the 6-23 month period irrespective of whatever other foods are consumed during this period.

A further factor is level of intake which will be driven by both serving size and frequency of consumption. The objective of successful complementary food development must be to formulate foods which ensure that key nutritional requirements are met while making reasonable provision for the potential nutritional contributions from consumption of other foodstuffs and in particular the proportion of the diet that is still being provided by breast milk. These latter contributions will clearly vary considerably so some element of compromise is going to be necessary.

Arguably the best way to achieve acceptable overall nutrient intake is to ensure that a defined number of servings of a defined portion size of the complementary food provide what is considered to be a reasonable proportion of the daily macro-nutrient and micronutrient needs for the age group concerned. It is not clearly desirable to base the nutritional composition and recommended serving sizes and frequencies on a diet consisting solely of the complementary food, as the consumption of other foods of desirable nutritional quality and in particular breast milk should be strongly encouraged for the sake of dietary diversity. Rather aim for a set of recommendations where the recommended intake of the complementary food is adjusted according to the intake of other foods.

Formulating complementary foods thus requires a balancing exercise between numerous different requirements including nutritional and behavioural issues, coupled of course with practical technical, regulatory and commercial realities. The manner in which these are brought together is considered in section XIV below.



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06

Summary of global recommendations for composition of complementary foods

There are numerous publications from both academia and global nutrition bodies providing recommendations for the format and nutritional content of complementary foods. These include the WHO Complementary Feeding Guide dated 1998, the report of the WHO Global Consultation on Complementary Feeding held in 2001, the Review of Complementary Feeding Formulations published in Food & Nutrition Bulletin in 2009 and the Codex Alimentarius Guidelines on Formulated Complementary Foods for Older Infants and Young Children originally published in 1991 and most recently updated in 2013. Furthermore in 2011, GAIN published a set of Guidelines for complementary foods and supplements. Each of these sets of recommendations in turn contain large numbers of further references. As might be imagined, there is thus a very wide range of permutations based on variables such as age, level of breastfeeding, serving size and type of food.

The key nutritional attributes included in the various sets of recommendations at macronutrient level relate to energy and energy density, protein (both quantity and quality), fat and fatty acid composition of the fat component of the product. At micronutrient level they relate to vitamin and mineral requirements.

Some of the requirements for macronutrient content of complementary foods are summarised in Table 6 and include the requirements for processed cereal based foods for infants and young children as listed in EAS 72-2013. It should be noted that the specifications from different sources are not all expressed in the same manner. For example, Codex Alimentarius Guidelines do not consider requirements per serving or make recommendations in regard to the proportions of energy intake to be derived from protein and fat.

Table 6: Typical macronutrient specifications for complementary foods

Variable	Codex Alimentarius (Guideline CA/GL 8-1991 with updates)		WHO recommen- dations per serving ex Lutter & Dewey 2003	GAIN guidelines fortified blended foods	Kenya Standard KS EAS 72:2013—processed cereal-based foods for infants and children / KS 2515:2014- Formulated Complementary Foods for Older Infants & Young Children
	Cereals to be prepared with milk	Cereals with added high protein food to be prepared with water			
Serving size (g)			50	1 serving per day <175ml	10-50g dry basis
Energy per daily serving (kcal)			220	100-150	
Energy (kcal/g)	>0.8kcal/g			>0.8kcal/g	
Protein (g)	Protein efficiency ratio shall be equal to at least 70% of reference protein casein		3-5.5	Protein Digestibility Adjusted Amino Acid Score (PDCAAS) >70%	14.0 minimum
		2-5.5g			PDCAAS>70%
% calories from protein			5.4-9.0	10-15% of energy	6-15
Fat (g)	<3.3g / 100kcal	<4.5g / 100kcal			8.5.minimum
% calories from fat			26%	>20%. Ratio linoleic: alpha-lino- lenic acid 5-10:1	20 minimum
% calories from added sugar	<7.5g / 100kcal <3.75g fructose / 100kcal	<5g / 100kcal <2.5g fructose / 100kcal	<10%	<10%	

Some of the requirements for micronutrient content of complementary foods are summarised in Table 7

Table 7: Typical micronutrient specifications for complementary foods

Variable	Codex Alimentarius (Guideline CA/GL 8-1991 with updates) daily intake recommendation (50% of INL98 values)	WHO recommendations per serving ex Lutter & Dewey 2003	GAIN guidelines fortified blended foods—recommended dosage per serving	Kenya Standard KS EAS 72:2013—processed cereal-based foods for infants and children Values per 100g
Serving size (g)	Not specified as values are for total daily intake	50	1 serving per day <175ml	
Vitamin A (mcg RE)	200	250	200	150
Vitamin D (mcg)	2.5	1-2	2.5-5.0	7.5-20
Vitamin E (mg)	2.5	5	2.5-5.0	
Vitamin C (mg)	15	70-140	>15	25
Vitamin B1 (mg)	0.25	0.18	0.25-0.5	0.5
Vitamin B2 (mg)	0.25	0.18	0.25-0.5	
Niacin (mg)	3	3.3	3.0-4.8	5
Vitamin B6 (mg)	0.25	0.22	0.25-0.5	
Vitamin B12 (mcg)	0.9	0.26	0.45-0.9	
Folic acid (mcg)	75	41.5	75-140	
Pantothenic acid (mg)	1	0.35		
Biotin (mcg)	4	1.45		
Iron (mg)	5.8 / 2.9 / 1.95 depending on bioavailability	7-11	3.8-9.6 for lower bioavailability forms. 2.0 for NaFeEDTA (high bioavailability)	10
Zinc (mg)	4.15 / 2.05 / 1.2 depending on bioavailability	4-5	4.2-8.3	
Copper (mg)	0.17	0.2-0.4	0.28-0.34	

Variable	Codex Alimentarius (Guideline CA/GL 8-1991 with updates) daily intake recommendation (50% of INL98 values)	WHO recommendations per serving ex Lutter & Dewey 2003	GAIN guidelines fortified blended foods—recommended dosage per serving	Kenya Standard KS EAS 72:2013—processed cereal-based foods for infants and children Values per 100g
Selenium (mcg)	8.5	10	8.5-17	
Calcium (mg)	Not specified	100-200	250-500	1000
Phosphorous (mg)	230	75-100	230-460	250
Iodine (mcg)	Not specified	90	45-90	
Magnesium (mg)	30	40-60	30	
Manganese (mg)	0.6	0.6	0.6	
Potassium (mg)	Not specified	Not specified	Not specified	
Sodium (mg)	Not specified	Not specified	Not specified	

A number of comments can be made on the specifications:

1. The detailed content of the specifications varies considerably but the fundamental requirements for key nutrients are generally similar
2. It should be noted that the Codex recommendations are based on the nutritional contribution from total daily intake whereas WHO recommendations and the GAIN Guidelines are based on contribution per serving.
3. As there is no single globally accepted specification, nor would it be practical or desirable to introduce one, it will rather be preferable to formulate any new complementary food products according to the specific local requirements for the product concerned. These may be prescribed by government bodies, NGOs or other organisations. They are likely to be based on well-established global standards such as those listed above.

4. If however a complementary food is to be developed by a company for purposes of marketing it themselves, then the commercial and technical staff of that company needs to make a decision as to the specification of the product. It would however be unwise to deviate significantly from globally recognised nutritional parameters such as those set out above.

The procedures involved in converting nutritional specifications into actual formulations will be covered in section XIV below. It must however always be remembered that the development of complementary food formulations, while driven primarily by nutritional considerations will also inherently be influenced by local dietary preferences, availability of raw materials and cost.



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07 | Key raw materials for complementary foods

The raw materials used in complementary foods can be divided into four categories and some general comments can be made about them as a prelude to a more detailed discussion of individual ingredients:

Core cereal products

- There are a number of definitions for cereals, varying from 'a plant that is used to produce grain' to 'a plant (such as a grass) yielding starchy grain suitable for food' to '...any grass cultivated for the edible components of its grain'
- These provide the bulk of the product and contribute significantly to its texture and flavour
- From a nutritional perspective they also provide significant quantities of macronutrients, particularly carbohydrates.
- Due to their high levels in complementary foods, they will also be a major contributor to the cost of the product but are probably the cheapest ingredients in terms of cost / kg.

Protein and lipid sources

- They fall into both vegetable and animal derived categories with the vegetable categories comprising oilseeds, legumes and pulses and the animal sources comprising mainly ingredients derived from milk and occasionally egg (although egg products are rarely used in complementary foods).
- These are used primarily to improve the macronutrient quality of the complementary food, as the core cereals are typically lacking in protein and fat.
- Where addition of fat is required, it is also common to incorporate vegetable oils directly into the food.
- They typically comprise a smaller but still significant proportion of the total product but, as their costs are almost always noticeably higher than those of the core cereal products, they will contribute significantly towards the total cost of the product and may constitute the single largest cost component of the finished product.
- A further complication is that some of these ingredients may negatively affect the flavour and shelf life of the finished product although milk products generally improve product flavour.

Probably the most important aspect of formulating complementary foods is therefore to optimise the use of protein and lipid source ingredients to achieve the required nutritional composition while minimising any negative effects on the cost and palatability of the product.

Other ingredients

- These include ingredients such as sugar, salt, flavourings and other food additives.
- They do not normally contribute to the desirable nutritional attributes of the product (and excessive quantities of sugar and salt are in any case undesirable in complementary foods) but are included for the purpose of improving flavour or other consumer driven attributes in the product.
- They do not normally contribute significantly to the cost of the product either because their cost/ kg is low or in the case of specialised more expensive ingredients, the dosages required in the product are low.
- This category of ingredients requires considerable attention by formulators of complementary foods as there may be significant constraints on their use due to either regulatory requirements, technical specifications by purchasers of complementary foods or perceived lack of acceptance by end-users.

Ingredients used for fortification

- These comprise micronutrients such as vitamins, minerals and specialised ingredients such as amino acids and encapsulated lipids.
- They are technically sophisticated ingredients, usually requiring sophisticated and complex manufacturing processes based on chemical synthesis and are generally supplied as premixes although some minerals are supplied individually.
- They are sourced from specialist manufacturers who themselves possess major expertise in meeting micronutrient specifications in a wide range of applications including complementary foods and should be consulted at a fairly early stage in the development of the complementary food.

- Due to their complex manufacturing processes, they are expensive and, while used at low dosages in complementary food formulations, can still contribute quite significantly to the cost of the finished product.
- They will almost certainly have to be imported as they are sourced from a small number of global suppliers such as DSM, BASF, Muenlenchemie and Hexagon Nutrition.

CORE CEREAL PRODUCTS FOR COMPLEMENTARY FOODS

The most important core cereals for complementary foods are:

- Maize
- Wheat
- Sorghum
- Millet
- Rice
- Oats
- Barley
- Teff

Factors relating to their cultivation and use in specific countries will be discussed individually however the following general information is summarised in Table 8 below as it will be applicable irrespective of the country of cultivation and use:

Table 8: Characteristics of core grains used in complementary foods

Cereal	Key physical characteristics and usage considerations	Key nutritional parameters	Organoleptic considerations	Storage and handling considerations	Cost considerations	General comments
Maize (<i>Zea mays</i>)	Both white and yellow maize available—little difference in physical characteristics other than colour. Hard kernels with sizeable germ. Can be used either as is by grinding whole kernels or as de-germed milled product.	Protein 5-12% Protein quality poor, low in lysine Fat content in whole grain 2-5%. Fatty acid content typically 15% saturated, 40% mono-unsaturated, 45% polyunsaturated. Carbohydrate typically 65-75%	Generally bland, can develop puffed flavour when roasted or extruded. Use of whole ground maize will potentially reduce shelf life slightly due to increased tendency for rancidity development relative to de-germed maize	Need good control of moisture content. Harvested crop needs to be dried to ideally <14% in stored grain to reduce risk of mycotoxin formation	Will depend on availability and fluctuations in commodity prices but generally the lowest cost core cereal	Recommended low cost core ingredient in countries where it is readily available
Wheat (<i>Triticum aestivum</i>)	Harvested grain can either be ground and used 'as is' as whole-wheat flour or undergo milling to remove the germ followed by milling to remove bran and achieve required flour particle size. Some whole-wheat flour is produced by adding back bran to flour.	Protein 10-14% Protein quality poor, low in lysine Fat content of whole grain typically 1-2% but concentrated in germ. Fatty acid content typically 15% saturated, 15% mono-unsaturated, 70% polyunsaturated. Carbohydrate typically 70-75% in whole grain but higher in milled flour. Whole-wheat is good source of dietary fibre. Not suitable for persons with gluten intolerance	Generally bland flavour, can develop puffed flavour when extruded or roasted. Typically gives a more gelatinous and smoother mouthfeel than maize when used in same application.	Need good control of moisture content. Harvested crop needs to be dried to ideally <14% in stored grain to reduce risk of mycotoxin formation	Generally low cost but will be more expensive in non-wheat growing areas	Recommended low cost core ingredient in countries where it is readily available
Sorghum (<i>Sorghum bicolor</i>)	Grain is more difficult to mill than maize or wheat. Usually ground to give whole grain flour	Protein 9-11% Protein quality poor, low in lysine Fat 2-3% Fatty acid content typically 15% saturated, 35% monounsaturated, 50% polyunsaturated Carbohydrate typically 70-75% Can contain anti-nutritional factors	Generally bland flavour but some types can impart bitterness due to high tannin content. Colour can vary considerably from white to red / brown. Malted sorghum can be used to impart flavour.	Typically stored at around 10% moisture. Need adequate control to prevent mycotoxin growth	Common crop in sub-Saharan Africa hence pricing generally competitive with other core grains	Not normally a core ingredient but can be used to supplement maize or wheat while imparting amended flavour characteristics.
Millet	Most common form is pearl millet (<i>Pennisetum glaucum</i>)	Protein 11-13% Protein quality poor, low in lysine Fat 4-6% Fatty acid content typically 15-20% saturated, 15-20% monounsaturated, 45-55% polyunsaturated Carbohydrate	Generally bland flavour. Colour can vary from pale to brown or purple so impact on product appearance needs to be considered for darker varieties	As for sorghum	Common crop in sub-Saharan Africa hence pricing generally competitive with other core grains	Can potentially constitute a significant portion of complementary food formulations when this makes economic sense

Cereal	Key physical characteristics and usage considerations	Key nutritional parameters	Organoleptic considerations	Storage and handling considerations	Cost considerations	General comments
Rice (<i>Oryza sativa</i>)	Can either be used as 'brown rice' incorporating the bran but more commonly milled	Protein typically 6-7% for milled rice, 7-8% for brown rice Protein quality poor, low in lysine, slightly higher in brown rice than milled rice Fat content <1% for milled rice, 1-3% for brown rice due to high (15-20%) fat content of rice bran Fatty acid content typically 20-25% saturated, 35-40% monounsaturated 35-40% polyunsaturated	Bland flavour, good as a base cereal and imparts desirable texture and mouthfeel. Brown rice susceptible to rancidity due to fat content of bran	Storage at <14% moisture desirable.	Cost generally low providing it is not significantly affected by importation costs such as transport and customs duties	Excellent as a base ingredient but usually imported from Asia and nutritional quality is limited
Oats (<i>Avena sativa</i>)	Typically supplied as either whole groats, flaked / rolled oats or oat flour	Protein typically 15-17% Protein quality slightly higher than most cereals but still fairly poor. Fat content typically 5-7% Fatty acid content typically 15-20% saturated, 30-35% monounsaturated, 35-40% polyunsaturated. High in soluble dietary fibre. Not suitable for persons with gluten intolerance	Bland flavour, imparts pleasant slightly gelatinous mouthfeel	Not likely to be received or stored in bulk when used in complementary foods. More probably stored in bags but normal requirements for dry pest-free conditions will apply	Likely to be more expensive than more common core cereals	Best of the core cereals from nutritional perspective but availability is an issue as their cultivation is not possible in African countries. Not usually a viable ingredient for complementary foods
Barley (<i>Hordeum vulgare</i>)	Use as ground whole grain flour. Malted barley also available as flour	9-11% protein Protein quality low due to low lysine content 1-2% fat Fatty acid content typically 20-30% saturated, 10-20% monounsaturated, 50-60% polyunsaturated	Bland flavour, but can also use malted barley flour for added flavour	Not likely to be received or stored in bulk when used in complementary foods. More probably stored in bags but normal requirements for dry pest-free conditions will apply	Likely to be more expensive than more common core cereals	Rarely used in complementary foods due to lack of availability and more suitable alternatives
Teff (<i>Eragrostis tef</i>)	Use as milled whole grain flour	12-15% protein Protein quality somewhat higher than other core cereals but still fairly low 1-3% fat Fatty acid content typically 15-20% saturated, 20-30% monounsaturated, 40-50% polyunsaturated	Bland flavour, good as a base cereal component. Colour can vary from white to brown so effect on finished product appearance needs to be considered	Small size of grain necessitates particular handling procedures. Typically stored at moisture content <10%	Staple crop in certain growing areas therefore likely to be cost competitive in these areas	Extensively used in Ethiopia, may have application in other geographical areas providing material can readily be sourced

Key characteristics of core grains:

- There are well established procedures for the processing of all the core grains. They can all be used 'as is' by simply grinding them to flour but in some instances (e.g. rice) the use of milled products is preferable. Use of milled products will however increase the cost of the material.
 - From a nutritional perspective, they must be seen primarily as sources of carbohydrate (and thus energy).
 - For production of complementary foods for which specific compositional requirements in terms of protein and fat content as well as protein quality and fatty acid composition are needed, they will thus need to be blended with appropriate sources of high quality protein and fat such as those discussed in the next section.
 - None of the core grains possess flavour characteristics that render them fundamentally unsuitable for incorporation in complementary foods. However some may require an element of pre-processing (e.g. roasting) to improve their flavour or remove specific undesirable flavour notes such as bitterness, alternatively the manufacturing processes for the complementary food may be tailored in such a way as to assist with flavour improvement. Pre-processing of this sort will have little or no impact on the nutritional quality of the grains.
 - It can be seen that a number of the core grains can vary considerably in appearance from white to much darker colours. The colour of the core cereal can significantly affect that of the finished product, hence this needs to be considered for the purposes of consumer acceptance and consistency.
 - Storage and handling requirements are generally common to all the core grains. Good control of moisture content is required as is the use of suitable precautions to minimise the risk of mould development which in turn can lead to the presence of mycotoxins in the grain.
 - In most instances the choice of core cereal ingredients in a particular country will be driven primarily by their local availability and cost, meaning that locally grown cereals are likely to be favoured. The one major exception is likely to be rice as its particular growing conditions mean that in most instances it will have to be imported from its source countries, primarily in Asia.
- In general, the principle of 'buy local' should normally be the key driver. This is not only because of economic and supply factors but also because local populations are more likely to accept complementary foods based on ingredients with which they are familiar.
 - There are generally only fairly small differences between the nutritional compositions of core grains and choice of core grains is not likely to be significantly affected by their nutritional characteristics but rather by availability and cost factors. However in a situation where more than one core grain with similar costs and availabilities can readily be sourced, it will obviously be beneficial to use that grain with better nutritional characteristics, even if the differences in nutritional characteristics between the alternative grains are relatively small. In general though, the nutritional composition of the finished complementary food is more likely to be driven by the addition of ingredients providing more concentrated sources of protein and fat. These are discussed below.

PROTEIN AND FAT SOURCES

These fall into differing categories.

Protein sources:

- Defatted soy flour
- Soy concentrate
- Soy isolate
- Pea protein concentrate / isolate
- Lentils
- Dry beans
- Chick peas
- Wheat gluten
- Maize gluten
- Skimmed milk powder
- Whey protein concentrate / isolate
- Egg powder

Fat Sources:

- Vegetable oils and shortenings
- Powdered fats

Combined protein and fat sources:

- Peanuts
- Soy beans
- Full fat soy flour
- Full cream milk powder

Key information for these three categories of ingredients is summarised in Tables 9, 10 and 11 below.

PROTEIN SOURCES FOR COMPLEMENTARY FOODS

Table 9: Protein source for complementary foods

Protein source	Key physical characteristics and usage considerations	Key nutritional parameters	Organoleptic considerations	Storage and handling considerations	Cost considerations	General comments
Defatted soy flour	Flour derived by milling of defatted soy meal. Usually toasted to improve flavour and remove residues from solvent extraction. Also used for production of TVP.	Protein content typically 45-50% PDCAAS approximately 0.77	Far more palatable than full fat soy flour due to removal of fat. More highly toasted variants can have nutty flavour. Colour varies from off-white to light brown	Generally stable with shelf life of at least 9 months providing it is kept dry and free from infestation in good quality packaging material such as multi-ply bags with a polyethylene liner	Generally cost effective in relation to other protein sources	Excellent protein source providing flavour is not excessively toasted
Soy concentrate	Flour type product produced by partial removal of non-protein components of defatted soy meal. Most common process involves aqueous alcohol extraction of the meal.	Protein content typically 65-70%	Flavour further improved relative to defatted soya	Generally stable with shelf life of at least 9 months providing it is kept dry and free from infestation in good quality packaging material such as multi-ply bags with a polyethylene liner	Will be more expensive than defatted soy flour	Excellent protein source but defatted soy flour and soy isolate are more commonly used for protein fortification purposes
Soy isolate	Flour type product produced by further concentration of protein component of defatted soy flour. Can be done by isoelectric precipitation of protein fraction or by membrane separation	Protein content typically 85-90%. Good protein quality, PDCAAS typically 0.84	Typically bland in flavour and colour, particularly as only used in relatively small quantities in formulations	Generally stable with shelf life of at least 9 months providing it is kept dry and free from infestation in good quality packaging material such as multi-ply bags with a polyethylene liner	Considerably more expensive than defatted soy flour but generally cheaper than other highly concentrated protein sources	Cost is high but generally a very effective means of boosting protein content without affecting product acceptability
Pea protein concentrate / isolate	Flour type product produced by separation of protein and non-protein fractions. This is normally done by isoelectric precipitation of protein fraction	Protein contents: Concentrate 50% Isolate 82% Protein quality lower than soya, PDCAAS typically 0.54	Fairly bland but with characteristic flavour if used in significant quantities in formulations	Generally stable with shelf life of at least 9 months providing it is kept dry and free from infestation in good quality packaging material such as multi-ply bags with a polyethylene liner	Likely to be more expensive than soy based equivalents	Relatively undeveloped as a protein source in complementary foods. Cost relative to soy based equivalents and lack of availability are a concern
Lentils	Legume that can be ground to flour	Protein content typically 22-28%. PDCAAS 0.54-0.63 depending on cultivar. Contains significant quantities of anti-nutritional factors e.g. trypsin inhibitor Fat content approximately 1% High dietary fibre, typically around 10%	Generally bland when used as a flour. Colour usually brown but can also be green / yellow / red	Shelf life of at least 9 months if stored whole at <10% moisture and kept free of infestation	Cost will depend on availability	Unlikely to be grown in relevant countries hence usage not usually viable in spite of high protein content

Protein source	Key physical characteristics and usage considerations	Key nutritional parameters	Organoleptic considerations	Storage and handling considerations	Cost considerations	General comments
Chick peas	Legume that can be ground to flour	Protein content typically 17-22% PDCAAS approximately 0.52 Fat content typically 5% High dietary fibre content (15-20%)	Bland flavour, colour neutral	Shelf life likely to be at least 9 months if stored whole at <10% moisture and kept free of infestation. Development of rancidity needs to be avoided by suitable control of storage conditions as fat content somewhat higher than other protein sources	Use likely to be economic in countries where it is a staple crop	Although generally not as cost effective as soya, can be a valuable complementary food ingredient in some countries. High dietary fibre content may be a drawback for use in complementary foods
Wheat gluten	Concentrated wheat protein typically derived from wet milling of wheat followed by drying to a powder. Available in 'vital' form where functional properties are retained and 'non-vital' form where it acts purely as a protein source	Protein content 75-80%. Low PDCAAS, typically 0.25 due to low lysine content	Bland flavour but imparts sticky texture to products if used in significant quantities unless 'non-vital' form is used	Not likely to be received or stored in bulk when used in complementary foods. More probably stored in bags but normal requirements for dry pest-free conditions will apply	Likely to be imported hence cost may be high	Unlikely to be readily available in relevant countries and protein quality poor hence usage not usually viable in spite of high protein content
Skimmed milk powder	Spray dried low fat milk, fine powder	Protein content 34-37% Protein quality excellent with PDCAAS generally considered to be optimum (>1.00)	Pleasant milk flavour enhances products in which it is incorporated, particularly beneficial in products that are re-constituted with water	Product is hygroscopic and susceptible to off-flavour pickup. Needs to be stored in a cool dry place in good quality packaging material such as multi-ply bags with a polyethylene liner	Generally expensive and probably imported	Cost offset by excellent protein content and quality along with high palatability
Whey protein concentrate / isolate	Spray dried powder derived from concentration of protein component in whey	Protein content 55-65% (concentrate), 80-90% (isolate). Excellent protein quality	Pleasant milk flavour enhances products in which it is incorporated, particularly beneficial in products that are re-constituted with water	Product is hygroscopic and susceptible to off-flavour pickup. Needs to be stored in a cool dry place in good quality packaging material such as multi-ply bags with a polyethylene liner	Generally very expensive and probably imported	Cost offset by excellent protein content and quality along with high palatability. Only preferred to SMP if concentrated protein 'top-up' is required
Caseinates	Spray dried powder derived from concentration of caseinate component of milk. Normally used as sodium, calcium or potassium caseinate. Normally used for its functional properties rather than for nutritional purposes	Protein content 80-90% Excellent protein quality	Bland flavour but functionality can affect	Product is hygroscopic and susceptible to off-flavour pickup. Needs to be stored in a cool dry place in good quality packaging material such as multi-ply bags with a polyethylene liner	Generally very expensive and probably imported	Whey protein concentrates and isolates are generally preferred for protein fortification purposes but caseinates are an alternative if they are more cost effective
Egg powder	Dehydrated egg white obtained by separation of whole eggs and spray drying of the egg albumen	High protein content, typically around 80-85% Excellent protein quality, comparable to milk protein	Bland if used in small quantities	Product is hygroscopic and susceptible to off-flavour pickup. Needs to be stored in a cool dry place in good quality packaging material such as multi-ply bags with a polyethylene liner	Generally very expensive and probably imported	Not usually used in complementary foods but extremely good protein quality may enable its use in specialised applications

FAT SOURCES FOR COMPLEMENTARY FOODS

Table 10: Fat sources for complementary foods

Fat source	Key physical characteristics and usage considerations	Key nutritional parameters	Organoleptic considerations	Storage and handling considerations	Cost considerations	General comments
Vegetable oils and shortenings	Can use a wide range of vegetable oils depending on availability, nutritional requirements and cost	Choice of oil will depend on fatty acid composition e.g. Soy oil 16% saturated, 23% monounsaturated, 58% polyunsaturated; Palm oil 49% saturated, 37% monounsaturated, 9% polyunsaturated May also need specific levels of linoleic / linolenic acids	Direct inverse correlation between level of unsaturated fatty acids and resistance to rancidity has to be factored in to any use of vegetable oils. High levels of fat incorporation will impart unacceptable mouthfeel to the product	Highly unsaturated liquid oils need careful storage with minimal exposure to atmospheric oxygen. Solid fats are more saturated and therefore more stable with longer shelf life	Costs driven mainly by prevailing commodity prices	Choice driven mainly by trade-off between fatty acid requirements and stability
Powdered fats	Vegetable oils converted to solid form by blending with carrier materials such as maltodextrin and spraying to give a powder with up to 80% encapsulated fat content	Wide range of products available based on full range of vegetable oils	Less likely to impact on palatability of finished products due to powdered format. Generally fairly bland but flavour of encapsulated oil can sometimes be detectable particularly for oils with strong flavour such as soy	Generally stable due to encapsulation of fat however need to avoid exposure to high temperatures	Considerably more expensive than original oils also need to incorporate at higher levels than oils. Almost certain to be imported.	Generally too expensive for routine use in complementary foods however can be a useful method of boosting fat content with little effect on palatability or shelf life

COMBINED PROTEIN AND FAT SOURCES FOR COMPLEMENTARY FOODS

Table 11: Combined protein and fat sources for complementary foods

Combined protein / fat source	Key physical characteristics and usage considerations	Key nutritional parameters	Organoleptic considerations	Storage and handling considerations	Cost considerations	General comments
Soy beans	Legume with hard seed hull that is normally removed prior to further processing. Can be used whole but need extensive cleaning.	Highly desirable nutritional composition as it contains significant quantities of both protein and fat. Protein content typically 34-38% with good protein quality due to high lysine content. PDCAAS 0.9-1.0 Fat content typically 17-23%. Fatty acid composition 12-15% saturated, 20-25% monounsaturated, 50-60% polyunsaturated including significant proportions of linoleic & linolenic acids. Contain significant quantities of anti-nutritional factors such as trypsin inhibitor and lectin that need to be removed or destroyed during processing.	Beans have unpleasant raw flavour that necessitates pre-processing by heat and / or moisture. Can obtain a bland flavour providing adequate pre-processing has been used Shelf life of products can be limited if there insufficient pre-processing or excessive exposure to atmospheric oxygen.	Whole beans have good storage properties, providing they are stored at below 10% moisture	Generally the most cost-effective source of both protein and fat	Compositionally excellent, economical to use but need extensive pre-processing to render them suitable for incorporation in complementary foods
Full fat soy flour	Derived from grinding of de-hulled soy beans	As for soy beans. Removal of hull from beans will further improve nutritional content of resulting flour	Flour is very susceptible to off-flavour development and rancidity. Typically produced as required from whole beans and immediately processed to avoid flavour deterioration due to development of staleness / rancidity due to exposure to atmospheric oxygen and / or enzyme activity	Flour normally has limited shelf life and is produced on demand. Some toasted soy flours have better shelf life.	Generally the most cost-effective source of both protein and fat	Compositionally excellent, economical to use but need extensive pre-processing to render it suitable for incorporation in complementary foods
Full cream milk powder	Obtained by spray drying of whole milk	Good source of both protein and fat. Protein typically 23-28% with excellent protein quality (PDCAAS 1.0) Fat content also typically 23-28%. Fatty acid content 65-75% saturated, 23-28% monounsaturated, <5% polyunsaturated	Imparts excellent flavour and mouthfeel to dry products when re-constituted	Stored in bags. Generally stable but susceptible to off-flavour development unless kept cool and dry.	Generally more expensive than skim milk powder	
Peanuts	Shelled whole nuts that are normally roasted or heat treated. Will be ground to a flour for use in complementary foods	Protein typically 20-30%, protein quality reasonably good with PDCAAS of ± 0.7 Fat content typically 40-50%. Fatty acid content 10-15% saturated, 45-60% monounsaturated, 15-30% polyunsaturated. Note potential high allergenicity of some peanut proteins	Highly palatable when roasted and ground, imparting characteristic flavour	Need very careful storage conditions with protection from moisture and mould development due to high risk of mycotoxin formation. Ideal moisture content should be around 7.5% and should not exceed 10%	Very dependent on local sourcing, imported product likely to be fairly expensive	Potentially useful source of protein and fat but protein quality not as good as soy and cost likely to be higher than soy. May be potentially useful in certain geographic areas where they can readily be sourced but risk of mycotoxin contamination is a potential further drawback

Key characteristics of protein and fat source ingredients:

- A number of factors influence the choice of protein and fat sources:
 - » Raw material sourcing
 - » Nutritional characteristics
 - » Effect on product palatability
 - » Cost

It is therefore essential that considerable effort be put into their selection.

- It can be seen that the use of full fat soya is likely to provide the most cost-effective combination of fat and protein for macronutrient fortification purposes however this is to some extent offset by issues with its palatability and potential impact on shelf life unless suitable processing and packaging procedures aimed at removing anti-nutrient factors, removing unacceptable flavour characteristics and preventing flavour deterioration on storage are in place.
- Defatted soy flour is also a good and comparatively low cost protein source, if no addition of fat is required.
- Animal protein, in particular skimmed milk powder is the most palatable source of protein and its protein quality is excellent however it is expensive and has to be imported in many countries.
- Under no circumstances should coffee creamers be used as a source of fat, even though their cost may be low. The main ingredients of coffee creamers are glucose solids and highly saturated vegetable fats, neither of which are appropriate for incorporation in complementary foods.
- Other legumes may be good sources of protein and may be easier to source in certain countries.

- High protein content ingredients such as whey protein and soy isolates are valuable for 'topping up' formulations with concentrated high quality protein but are extremely expensive and can only be used in small quantities otherwise raw material costs will become prohibitive.
- Addition of fat by means of direct addition of vegetable oil is impractical for dry mix products or those derived by roasting but can be incorporated in extruded or drum dried complementary foods.
- Highly unsaturated oils, while desirable in nutritional terms, can negatively impact on shelf life due to their tendency to rancidity development.

OTHER DRY INGREDIENTS

These comprise those ingredients added for flavour or functional reasons but which generally do not contribute significantly to the nutritional content of the product. They include:

- Sugar
- Salt
- Food additives including flavourings

Key information relating to these ingredients is summarised in Table 12 below.

Table 12: Other ingredients for complementary foods

Combined protein / fat source	Key physical characteristics and usage considerations	Key nutritional and regulatory parameters	Organoleptic considerations	Storage and handling considerations	Cost considerations	General comments
Sugar	Normally added as white sugar although brown sugar will impart additional flavour	Solely a source of carbohydrate. Codex guidelines require a maximum of 1.2g sugar per 100kJ	Sweetness is often essential to render complementary foods more palatable sugar but addition should be minimised as far as possible	Hygroscopic and susceptible to caking if stored in bags hence needs to be stored in cool dry conditions	Not normally a significant contributor to product cost, especially if used in small quantities	Although its use tends to be discouraged for nutritional reasons, most complementary foods require a small amount of added sugar
Salt	Added dry in small quantities	Not significant although guidelines for sodium content will limit its use. Use of iodised salt can assist with incorporation of iodine in the finished product	Can enhance flavour in certain formulations	Hygroscopic and susceptible to caking if stored in bags hence needs to be stored in cool dry conditions	Minimal contribution to product cost	Not always required but can be valuable for flavour enhancement
Flavourings	Normally added in dry form	No nutritional contribution. Codex guidelines limit added flavourings to natural fruit extracts, vanilla extract and ethyl vanillin	Vanilla flavouring in particular can considerably improve the flavour of many complementary foods	These are specialised and expensive ingredients and need to be kept cool and dry	Cost of flavourings is high but dosages required are low hence impact on raw material costs is typically small	Not always required but can be valuable for flavour enhancement
Food additives	These include ingredients such as emulsifiers, acidity regulators, anti-oxidants, thickeners and anti-caking agents	Food additives do not contribute to nutritional content. Codex guidelines list those additives permitted in complementary foods, some are permitted without restriction (GMP level) but there are prescribed quantitative limits for some additives	Although acidity regulators contribute indirectly to the flavour profile of the products in which they are incorporated, impact on flavour is normally minimal. However emulsifiers and thickeners are typically used to enhance the physical characteristics of products so will impact on organoleptic characteristics	These are specialised and expensive ingredients and need to be kept cool and dry	Cost of additives is usually high but dosages required are low hence impact on raw material costs is typically small	Use in small dosages as required

FRESH PRODUCE

While the incorporation of fresh produce (i.e. fruits and vegetables) in industrially produced complementary foods is not normally undertaken, it may be possible to consider it for a number of reasons:

- Ready availability of locally produced fruits and vegetables at competitive prices
- Actual or perceived nutritional desirability
- Potential improvement to palatability and consumer acceptance

However, the use of fresh produce as an ingredient in complementary foods also presents a number of challenges:

- Products may be seasonal and year-round availability may be impossible, resulting in the need for ingredient substitution, use of multiple formulations to accommodate alternative ingredients (with consequent difficulties in product labelling and nutritional composition).
- Use of fresh produce requires considerable sophistication in sourcing and may require refrigerated transport and storage. Furthermore the shelf life of fresh produce is limited.
- Use of fresh produce will require more stringent quality control requirements and may increase the risk of microbiological contamination.
- The nutritional value of most fresh produce is fairly low due to its generally high moisture content. Most fruits and vegetables have moisture contents in excess of 80%. Macronutrient content is largely limited to carbohydrate and fibre with only very small and nutritionally insignificant quantities of fat and protein. Micronutrient levels are also low and variable, hence fruits and vegetables cannot normally contribute significant micronutrient content to foods in which they are incorporated.
- The processing techniques involved in the production of complementary foods involve significant heating and this may affect both nutritional content and palatability of the added fruits and vegetables.
- Fresh produce can only be used in extruded and drum dried complementary foods. They cannot be in products manufactured using the roast / grind / dry mix process.

- While the addition of fruits and vegetables may have a beneficial effect on flavour, they need to be added in significant quantities in order to have a noticeable effect. This may result in logistical and processing challenges.

In general therefore, the incorporation of fresh produce as an ingredient in complementary foods tends to be impractical unless special local circumstances apply.

It may be possible to include dehydrated fruits and vegetables as ingredients in complementary foods and add them to final products for flavouring purposes after the various heat processing stages, but this will depend very much on availability and cost.

INGREDIENTS FOR MICRONUTRIENT FORTIFICATION

Micronutrient fortification is almost always a key requirement for complementary foods. While the core cereals and protein / fat contributing ingredients are used to ensure acceptable macronutrient composition in the finished product, their contribution to the micronutrient content in terms of vitamins and minerals, is relatively limited to the extent that their naturally occurring micronutrient content is normally not considered when evaluating the formulation requirements for complementary foods.

The only exception to this will be when a particular ingredient is able to consistently provide sizeable quantities of a particular micronutrient—a good example of this is the contribution to calcium and phosphorous contents when significant amounts of dairy ingredients are included in a formulation. Normally however the very substantial variation in micronutrient content in those ingredients typically used in complementary foods means that they cannot be relied upon to provide guaranteed and consistent amounts of the various micronutrients that may be required to be present in the product.

It follows therefore that the necessary micronutrients in the formulation for a complementary food need to be directly added as ingredients. While it can be seen from section V that there is reasonable alignment in terms of global standards for daily micronutrient intakes, the requirements for actual

micronutrient content of individual nutritionally fortified products such as complementary foods can differ significantly based on local requirements.

A key issue is whether a complementary food should provide the full range of micronutrients for which globally recognised intakes are available. If this is a requirement for the food concerned, the proportion of daily requirements that should be provided by a serving of the product needs to be decided. Factors influencing this decision will be:

- Serving size
- Number of servings typically consumed per day
- Other components of the diet other than complementary foods that may contribute significant quantities of certain micronutrients (e.g. minerals from breast milk or other milks)
- Avoidance of exceeding safe upper intake limits

The alternative is for a complementary food to be selectively fortified with specific micronutrients at particular dosages, normally chosen due to the need to address particular micronutrient deficiencies in the target population. Decisions in this regard must be taken on a product-by-product basis taking into consideration any country-specific requirements in this area.

In most cases, micronutrient fortification is provided by means of specially formulated premixes which are developed and supplied by companies specialising in this area. It is of course possible for manufacturers to purchase the individual vitamins and minerals and blend the premixes themselves. However the resources required to do this and in particular the cost of the quality control procedures required to ensure product consistency in terms of micronutrient content are unlikely to be justified, particularly for smaller manufacturers with limited resources.

The one exception to the use of premixes is where significant quantities of minerals such as potassium, calcium and phosphorous are required to be added. These can readily be added directly in the form of food grade mineral salts such as potassium chloride, potassium phosphate and calcium phosphate. It is comparatively simple to calculate the quantities of the various minerals required and these can be added directly to complementary foods as powders.

KEY FEATURES OF INGREDIENTS FOR MICRONUTRIENT FORTIFICATION

These can be summarised as follows:

Physical characteristics

They are all fine powders which are readily incorporated into dry mix products. Since the dosages involved are small, care needs to be taken to ensure homogeneous dispersion of the ingredients into the bulk product and suitable quality systems are required to monitor this. These are discussed in section IX below.

Key nutritional and regulatory parameters

As discussed above, the correct quantities of the various micronutrients need to be incorporated in complementary foods to achieve the required nutritional delivery without exceeding safety limits. This needs to be closely controlled, hence the desirability of the use of premixes. Regulatory requirements typically relate to specified nutrient content in finished product rather than on the overall use of the relevant ingredients.

Organoleptic considerations

Due to the low dosages required, it is unlikely that addition of micronutrients will impact the organoleptic characteristics of the foods in which they are incorporated. Should very large dosages of minerals such as the various calcium phosphates be added, there may be very a slight effect on product texture. Appearance and colour of pale coloured products can sometimes be affected by addition of certain sources of iron, hence these need to be carefully selected and evaluated before use in complementary foods.

Storage and handling

Both individual vitamins and fortification premixes are potentially sensitive to heat and excessive light, hence they need to be stored under carefully controlled conditions. As these ingredients are likely to also be imported and transported over long distances before use, control of transport conditions is also essential.

Cost

Ingredients for micronutrient fortification are extremely expensive but are used in small quantities, thus reducing the impact on overall raw material costs. However it is essential that dosing of the micronutrient ingredients is accurately controlled as over-usage could significantly increase product costs.



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08 | Complementary food raw material availability in Kenya

Kenya is a large producer of agricultural commodities and it is logical that locally grown crops form as large a proportion as possible of those ingredients used for complementary food manufacture for reasons of sourcing, cost and support of local farmers. Many core grains, pulses and oilseeds suitable for incorporation in complementary foods are available.

In addition agriculture in Kenya has been seriously affected by drought in recent years with considerable fluctuations in crop sizes.

The most recent data for agricultural production of crops that are relevant to complementary food production is that supplied by FAO for 2017. The data in Table 13 below is derived from a combination of official figures and estimates.

It can be seen that a wide range of crops suitable for complementary food manufacture are grown in Kenya however quantities of key protein and fat sources and soy beans in particular are small. There is a clear opportunity to expand soy as a crop.

Regarding other ingredients, salt and sugar are locally produced but other more specialised ingredients such as food additives, flavours and micronutrients are fully imported—this is likely to continue for the foreseeable future.

An interesting potential opportunity however exists for the utilisation of locally produced fresh produce in complementary foods. While these may not necessarily contribute significant nutritional benefits, they can play a potentially valuable role in improving the palatability and consumer acceptance of the foods in which they are incorporated.

Table 13: Crop volumes for key commodities in Kenya—2017

Crop	2017 production (tons)
Maize	3186000
Wheat	165200
Sorghum	144000
Rice (paddy)	81198
Barley	77000
Millet	54000
Soy beans	2012
Pulses (unspecified)	50379
Oilseeds (unspecified)	37702
Cassava	1112000
Dry beans	846000
Sugar cane	4751609



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09 | Potential manufacturing technologies for complementary foods

INTRODUCTION

Complementary foods are in almost all cases cereal based and in the form of dry powders for reconstitution with milk or water. Other types of complementary foods such as pureed products require completely different manufacturing procedures and will not be covered here. The choice of manufacturing process will be driven by a number of parameters:

- Required product volumes
- Formulation and key ingredients
- Availability of existing process equipment which can be used 'as is' or with minimal modification
- Cost of new plant if an entirely new manufacturing operation is planned
- Available factory space for new equipment or modifications to existing equipment
- Services required e.g. water, power, steam, effluent
- Energy costs
- Availability of any skilled labour that may be required to operate and maintain the plant
- Ease of maintenance for selected process

The most commonly used processes for the manufacture of cereal based complementary foods are:

- Roasting / grinding / dry mixing
- Extrusion
- Drum drying

ROASTING / GRINDING / DRY MIXING

This process is the simplest and least capital intensive process and is summarised in Figure 3 below. It involves:

- Cleaning of grains and, where applicable, oilseeds and / or legumes.
- Roasting of the cleaned materials to develop palatable flavour, remove the bitter notes present in some material, improve the gelatinisation properties of their starches and improve digestibility of carbohydrate and protein components.
- In some instances water is added prior to roasting to reduce microbiological loads and inactivate anti-nutritional factors.
- Cooling of the roasted materials.
- Grinding of the roasted ingredients to give flours.
- Blending of the flours with other ingredients such as concentrated protein sources, sugar, salt, flavourings and minerals and micronutrient premixes in controlled quantities to give the finished product.
- Packaging—this will be discussed in section XI



Figure 4: Batch roaster for cereal flours

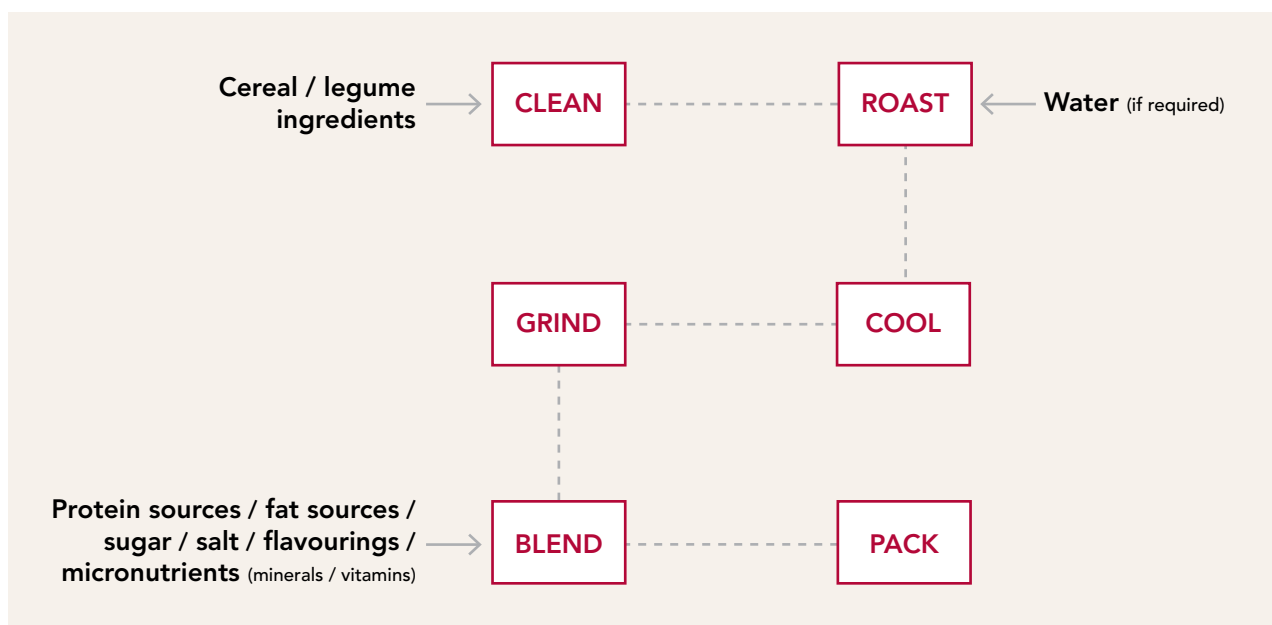


Figure 3: Roasting / grinding / dry mixing process for complementary foods

EXTRUSION

Extrusion technology is essentially a process for the continuous heat treatment and cooking of ingredients. It involves continuous feeding of a cereal / oilseed / legume mixture, usually containing added water, into one end a heated cylindrical barrel containing rotating screws (single or double screws may be used) which convey the material through the barrel, increasing its temperature to well above 100°C and cooking the ingredients. Pressure within the barrel increases to well above atmospheric pressure and the cooked product is continuously discharged from the end of the barrel through a suitable die with emission of steam. The extruded product is normally puffed due to the simultaneous formation of a cooked cereal matrix which puffs on discharge due to the release of pressure from within the cereal matrix and is usually cut into pieces after discharge by means of a rotating knife mounted against the die face. The puffed product will still contain a significant amount of moisture and will in most cases require a separate drying / toasting process after extrusion. The technology is used to produce puffed products such as snack foods and breakfast cereals but is also a highly effective manner of cooking cereals and other ingredients for use in complementary foods as an alternative to conventional roasting.

A typical extrusion process for complementary food manufacture is set out in Figure 5 and will comprise:

- Cleaning of grains and, where applicable, oilseeds and / or legumes.
- In some case pre-roasting of certain ingredients, particularly soy beans
- Grinding of the various grains / oilseeds / legumes
- Blending of the ground flours in controlled quantities to match formulation requirements. Water may also be added to the mixture.
- In some cases, water or steam will be continuously injected into the mixture prior to the extruder in a process known as pre-conditioning. This improves the efficiency of the cooking process in the extruder and can enhance product quality.
- Feeding of the mixture, with or without pre-conditioning into a suitable single or twin screw extruder.
- Cooking of the mixture in the extruder, giving a puffed product.
- Drying of the puffed product in a belt or other suitable dryer to reduce the moisture content of the product to the desired level.

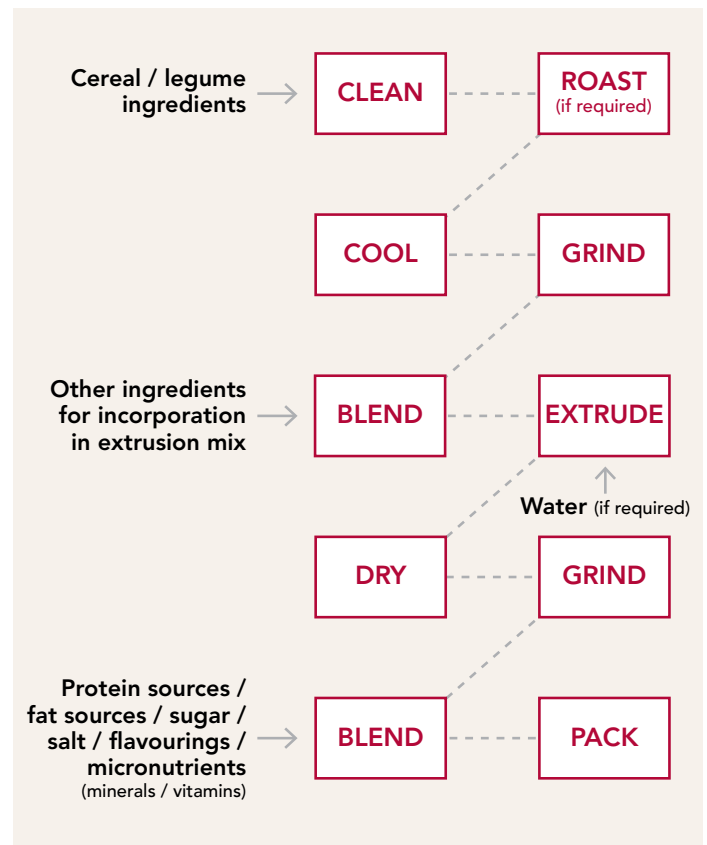


Figure 5: Extrusion for complementary foods



Figure 6: Twin screw extruder

- Grinding of the puffed product to give a powder which is effectively a cooked flour.
- Blending of the ground cooked product with other ingredients such as concentrated protein sources, sugar, salt, flavourings and micronutrient premixes in controlled quantities to give the finished product.
- Packaging—this will be discussed in section XI

A typical twin screw extruder is shown in Figure 6.

DRUM DRYING

This process is nowadays rarely used in food processing but imparts a characteristic texture to those products for which it is used. It is normally used for the manufacture of certain commercial baby cereal products, hence its potential application in complementary foods. Drum drying involves preparation of a slurry of ingredients in water to give a mixture containing approximately 20-30% of dry material. The slurry is pumped on to the surface of a steam heated rotating drum and forms a thin film on the surface of the drum. The material undergoes very rapid heat transfer and is cooked and dried while rotating around the drum. The dried film is then scraped off the drum by means of a suitably positioned knife mounted at an angle to the surface of the drum. The cooked dried material is scraped off the drum as a continuous sheet which is very brittle and is broken up into small flakes or powder by means of agitators.

A typical drum drying process for complementary food manufacture is set out in Figure 7 and will comprise:

- Cleaning of grains and, where applicable, oilseeds and / or legumes.
- In some case pre-roasting of certain ingredients, particularly soy beans
- Grinding of the various grains / oilseeds / legumes.
- Blending of the ground flours and possibly other ingredients in controlled quantities to match formulation requirements.
- Water is simultaneously added to the mixture to give a slurry
- In some instances, the slurry undergoes heat treatment to pre-cook the product prior to drum drying
- The slurry is pumped to a drum dryer and discharged in a controlled manner on to dryer surface.
- The slurry is cooked and dried then scraped off the dryer as a sheet.
- The dried cooked material is broken up to fine flakes or a powder by means of suitable agitation or grinding.

- Further ingredients and in particular those sensitive to heat such as flavourings and fortification premixes are added to the cooked base and dry mixed.
- Packaging—this will be discussed in section XI

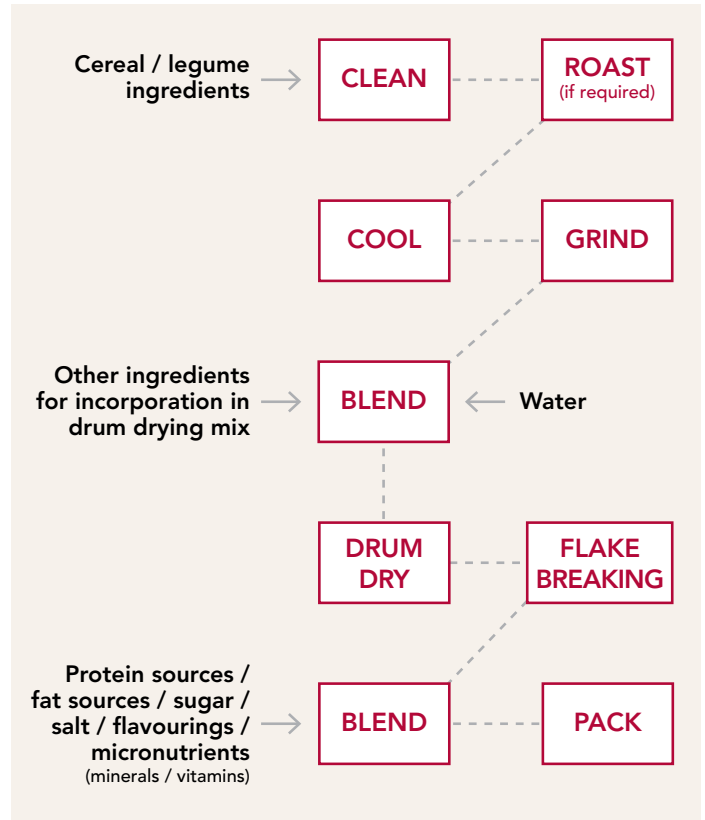


Figure 7: Drum drying process for complementary foods



Figure 8: Double drum dryer

COMPARISON OF THE THREE MANUFACTURING PROCESSES

These are summarised in Table 14 below:

Table 14: Comparison of manufacturing processes for cereal based complementary foods

Comparison parameter	Roasting / grinding / dry mixing	Extrusion	Drum drying
Capital cost	Relatively low, can be done on a small-medium scale using batch processing for roasting and dry mixing. Roasting and grinding sections of process could be incorporated in a larger continuous plant at a later stage but large scale batch roasting likely to require sizeable capital expenditure.	Likely to be higher than a basic roasting / grinding / dry mixing process but higher cost likely to be offset by other benefits for higher capacity plants— see below.	High as liquid slurry mixing, storage and pumping facilities required over and above dry pre-processing and also requires significant additional infrastructure for steam generation.
Plant capacity	Flexible, can be as low as 100kg / hour for low capacity roasters but increasing capacity will require duplication of existing equipment and labour requirements.	Lowest commercial extruder capacity \pm 250kg / hour. Larger extruders with capacity up to 5000kg / hour are available. Desirable to source an extrusion plant with reasonable excess capacity as incremental cost of new extruders will be high.	Commercial drum dryers operate at around 100-150kg / hour. Increased capacity will require purchase of additional individual dryers even if rest of plant and infrastructure can handle additional throughput.
Operating cost	Comparatively low as processes are simple however supervisory requirements can become costly for higher capacity plants.	Low as plants are generally automated and process is continuous. Likely to be highly cost-effective relative to roasting / grinding / dry mixing once capacity exceeds 500kg / hour.	Fairly high as plants are more complex and include both wet and dry processing.
Labour requirements	Can be labour intensive due to extensive manual or semi-manual transfer of materials through the plant. Increase capacity requires corresponding increase in labour requirements.	Low due to continuous processing and automation.	Individual drum dryers require considerable supervision hence labour costs likely to be closer to those for roast / grind / dry mix rather than extrusion.
Energy requirements	Energy efficiency of batch roasters tends to be poor. Use of direct vs indirectly fired roasters will influence energy requirements but use of gas or diesel firing tends to be expensive.	Electric power requirements can be high due to use of high capacity motors in extruder but other power requirements are low. Reliable power supply and generator backup are essential as power failures can seriously affect efficiencies.	Drum dryers require large quantities of steam and there is considerable unavoidable loss of heat during the process.
Maintenance requirements	Relatively low due to simple equipment used.	Extruders require specialised maintenance and cost of spares can be high however correctly designed and operated plant likely to require fairly limited maintenance.	Maintenance costs can be high and frequent specialised grinding of dryer blades is essential. Overhauling of drum dryers is a major and costly process normally requiring dismantling of the unit and transport to overseas suppliers.

Comparison parameter	Roasting / grinding / dry mixing	Extrusion	Drum drying
Recipe flexibility	Most cereals, oilseeds and legumes can be handled in the roasting process. Addition of specialised fortification ingredients would be done during dry mixing. Addition of liquid vegetable oils is difficult.	Extrusion can handle most cereals, oilseeds and legumes. High levels of fat in extrusion mixes can cause poor extrusion performance and / or exudation of fat—only possible to include low levels of free oil. Addition of specialised fortification ingredients would be done during post-extrusion dry mixing.	Drum drying can handle most cereals, oilseeds and legumes. Addition of specialised fortification ingredients would be done during post-drum drying dry mixing.
Process control requirements	Process requires fairly basic controls but nature of process means that process is difficult to control accurately without close supervision.	Modern extrusion plants are highly automated and enable sophisticated control systems to be used. Less sophisticated plants are also fairly easy to control but require supervision during plant start-up and shutdown stages.	Drum drying plants typically require more manual control systems. Limited automation is possible but generally require higher levels of supervision than extrusion plants.
Quality control requirements	Need good control of product moisture content as this will tend to vary due to less sophisticated roasting process.	Assuming extrusion conditions are settled, consistent product can be expected with only minimal quality control required.	Product moisture content needs to be well controlled as over-drying and under-drying are possible.
Microbiological safety	Process not conducive to microbiological growth however microbiological contamination still possible if dry mixing process is not carried out under suitable hygienic conditions.	Process not conducive to microbiological growth however microbiological contamination still possible if any subsequent dry mixing process is not carried out under suitable hygienic conditions.	Use of a high moisture processing method increases the risk of microbiological contamination within the plant however high cooking temperature will reduce risk for product itself.
Process impact on nutritional quality	Over-roasting can cause burning and loss of protein quality. Addition of water required prior to roasting to assist in removal of anti-nutritional factors.	Process conditions need to be set in such a manner as to minimise risk of loss of nutritional quality by means of unwanted side effects such as dextrinisation (where the carbohydrate molecules are broken down resulting in a loss of functional properties) and protein denaturation (where the protein quality suffers deterioration). Extrusion generally effective in removing anti-nutritional factors.	Process generally beneficial in terms of maintenance of nutritional quality and particularly effective in removal of anti-nutritional factors. Only risk is burning of product.
Palatability of finished products	Acceptable product flavour and texture providing roasting process is adequately controlled to avoid burning.	Acceptable and easily controlled flavour and texture that can sometimes be modified by adjustment of extrusion conditions.	Flavour generally good. Texture of drum dried products is characteristic and cannot be altered.



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10 | Fortification of complementary foods

The bulk raw materials do not themselves provide sufficient quantities of the minerals and vitamins required to deliver the dosages needed for adequate nutritional requirements for the age group concerned. It has already been indicated in section VIII above that these are typically added to the bulk processed products as pre-prepared premixes. This is normally done by dry mixing of the products immediately prior to packaging. It can be seen from the descriptions of the various manufacturing processes in section VIII above that all of them require a dry mixing stage after the various heating and cooking processes in which further dry ingredients such as milk powder, sugar and flavouring are added to the cooked product. It makes sense to also add fortification premixes at this stage.

Some of the key considerations applicable when adding fortification premixes to complementary foods are:

- The premixes are extremely expensive and need to be stored under controlled conditions in order to ensure their quality is acceptable.
- In particular a number of vitamins such as Vitamin A, Vitamin B1 and Vitamin C are sensitive to excessive heat. Others such as Vitamin B2, Vitamin D and Vitamin K are sensitive to light.
- The premixes are added to the product in low dosages (typically less than 0.5% by weight) hence accurate weighing of the recipe quantities is essential.
- If insufficient quantities are added, micronutrient specification requirements will not be met whereas if excessively high quantities are added, this will increase the cost of the product but could also result in unacceptably high and possibly even dangerous levels of some micronutrients in the finished product. It should be remembered that there are both minimum and maximum recommended intake levels for most micronutrients.
- Batch rather than continuous mixing of premixes into the bulk product is strongly recommended in order to ensure fortification consistency. Fortunately complementary food manufacturing processes almost always use batch mixing with continuous mixing of premixes more normally used for high volume processes such as fortified flours.
- Good quality monitoring of fortification is essential and a combination of both quality assurance and more direct quality control procedures is normally used. Quality systems for complementary foods are discussed in detail in section XI.

Key features of the premixes themselves are:

- They are produced by blending the vitamins and mineral sources in very accurately controlled proportions, depending on the requirements of the finished premix.
- The premixes also often include so-called carriers which dilute the components, enabling them to be easier to prepare and use. This is because a larger quantity of more dilute premix is required in the finished product, making it easier to disperse uniformly throughout the bulk product. Carriers are typically inert food ingredients such as maltodextrin which have no effect on the finished product but simply enable easier use of the premix.
- The premixes often also contain anti-caking agents such as amorphous silicon dioxide. They are used in small quantities to improve the dispersibility of the premix and preventing the formation of lumps which could result in uneven distribution of the vitamins and minerals throughout the finished fortified product.
- Premixes are manufactured by large multinational companies who possess both the nutritional knowledge and the capacity to produce to the very demanding quality standards required. Companies such as DSM, BASF, Muhlencemie, Nicholas Piramal and Hexagon Nutrition are key global suppliers.
- The premixes are typically added to the finished product at low dosages, often less than 0.5% of the finished product.
- Special quality control procedures are required for both the premixes themselves and for the purpose of checking the vitamin and mineral content of the fortified products. A detailed discussion of the procedures is beyond the scope of this manual but some further details are included in Appendix II



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11 | Packaging and storage of complementary foods

Complementary foods require good quality packaging for several reasons:

- They are intended for consumption by potentially vulnerable populations and hence require good protection from external contamination
- Their palatability and nutritional quality may be adversely affected by pickup of moisture or reaction with atmospheric oxygen and some complementary foods may be fairly hygroscopic
- They are often stored and distributed in geographical areas where weather conditions are conducive to product deterioration due to high ambient temperature and / or humidity
- They may be transported and stored under less than optimal conditions, hence robust packaging will be required
- Their distribution often requires longer than average shelf life. Normal retail shelf life requirements for non-perishable products rarely exceed 9-12 months however complementary foods may be required to have a shelf life of as much as 2 years.

PACKAGING MATERIAL REQUIREMENTS

Dry complementary foods are normally powders or fine flakes. Due to their physical characteristics and the need to limit exposure to moisture and atmospheric oxygen, they are thus best packed in typical cereal product packages namely a high barrier flexible packing material sachet produced using either form-fill-seal machinery or premade sachets which are hand sealed after filling. The bagged product is then packed either into cartons which are in turn packed into corrugated cases or packed directly into corrugated cases.

Considerable attention needs to be paid to the material used for the sachets as these will provide most if not all of the protection from moisture and oxygen. For short shelf life products (up to 9 months), it is possible to use a medium gauge (50-70 micron) low density or high density polyethylene but this unlikely to be suitable for complementary foods, for which a higher barrier laminated material incorporating a metallic barrier layer will be required. Typical constructions for this purpose will include either a metalised film such as polypropylene or polyester or aluminium foil which gives better barrier properties than metalised film but is likely to be more costly when used in laminations. These materials are laminated to an outer

layer which may be kraft paper, polypropylene or polyester and is required for printing purposes and an inner layer which is usually low-density polyethylene and is required for the purpose of heat sealing of the sachets. The finished laminated material will typically have a thickness of 75-90 micron. Choice of material will be influenced by cost, availability and barrier properties of the material and expert advice should be sought from flexible packaging suppliers.

Should it be decided to use a carton as well as a sachet for individual packs, a suitable carton of appropriate dimensions and board thickness must be designed in conjunction with a carton supplier. While the carton may provide little in the way of direct physical protection to the product, it will to some extent reduce the risk of perforation of the inner sachets and provide shelf visibility in a retail environment. Choosing the correct board type and thickness is important as an incorrectly specified carton may be subject to crushing during transport and handling. Care should also be taken to ensure a suitable space (known as ullage) between the top of the sachet and the lid of the carton. Too small a space will make it difficult to insert sachets in to their cartons, whether manually or by machine whereas too large a space will reduce the strength of the pack and is also seen as misleading by consumers.

It is also possible to pack complementary foods in rigid containers. Cans, although used for products such as infant formula, are not a recommended option for complementary foods for reasons of cost and ease of packing. However rigid plastic containers made from polyethylene, polypropylene and other suitable materials with heat sealed membrane lids and screw-on caps may be a viable option as they provide good barrier properties and good physical protection, particularly in demanding transport and storage conditions. The containers may also be useful to consumers for other storage once the product has been consumed. However in view of the global trend to reduce the use of single-use plastics for environmental reasons, this may not always be a desirable option.

Good quality corrugated cases are essential in order to provide adequate physical protection, particularly in view of the potential rough handling and demanding conditions under which complementary foods are likely to be distributed and stored. High quality corrugated board is essential and the use of recycled board content may be undesirable. If particularly rough handling is expected, the use of double rather than single flute cases is to be preferred. Cases must be correctly designed to ensure headspace at the top of the case is minimised in order to prevent crushing and possible case collapses. If palletisation is to be used, case dimensions must be such that a suitably strong pallet configuration can be adopted and double stacking of pallets is to be avoided. If pallets are not used, the maximum stacking height for cases during storage and transport must be agreed and enforced.

PACKAGING MACHINERY REQUIREMENTS

In all but the very smallest and least sophisticated manufacturing operations, some form of mechanisation is used for packaging. In a very simple system, the product is packed into premade sachets which have been sealed on 3 sides by the packaging supplier and into which product is weighed and filled manually after which the sachet is sealed manually using a suitable heat sealer. This process is labour intensive and may be feasible for small product volumes but is inefficient and seal quality may be variable, resulting in ingress of moisture and potential product contamination or insect infestation.

Use of form-fill-seal (FFS) machinery is thus to be preferred for the purposes of producing filled sachets. FFS machines form the sachet from a continuous reel of packaging material which is formed into a tube shape and then heat sealed by vertically mounted jaws along the back of the tube to give a continuous tube. The base of the tube is then sealed by reciprocating horizontal sealing jaws after which the required weight of product is discharged into the top of the tube using a suitable dosing mechanism such as a filling auger screw or a rotary volumetric discharge plate. The top of the tube is then heat sealed and cut away from the rest of the tube to form a sachet that is sealed at both ends as well as along the back of the sachet. A typical form-fill-seal machine is shown in Figure 9



Figure 9: Vertical form-fill-seal packaging machine

FFS machines are available in a wide range of capacities and degrees of engineering sophistication. They require adequate supervision and regular maintenance to replace items such as heating elements and cutting knives but, if properly handled, will deliver consistent sachets with good seal quality. A machine must be used that can:

- Handle the fairly thick sachet material typically used for complementary foods
- Have sufficient throughput to cater for the planned capacity of the plant in order to avoid build-up of unpacked material
- Be easily maintained and have essential spare parts readily available.

Due to the requirement for some complementary foods, particularly those with high fat content, that atmospheric oxygen be excluded from the sachets, some FFS machines can be fitted with a mechanism that flushes the sachet with inert gas (usually nitrogen) after it has been filled and immediately before it is sealed. It may be desirable to incorporate this feature in any FFS machine that is purchased for use with complementary foods, even if the gas flushing is not immediately required as it is not always possible to retro-fit a gas flushing mechanism on to an existing FFS machine.

Packing of sachets into cartons (when required) is more commonly conducted manually although labour requirements can be high in a high volume manufacturing facility. Automated cartoning machines are available but can be expensive.

Packing of cartons into cases or direct packing of sachets into cases is normally done manually but can also be automated in high volume manufacturing facilities.

STORAGE REQUIREMENTS

Complementary foods are fairly easy to handle once properly packed but should be stored and handled with due care and away from damp and direct sunlight. Storage facilities should be kept clean and dry with suitable pest control measures in place for both rodents and insects as cereal based foods are very susceptible to infestation. Transport conditions are typically more difficult to control but lengthy journeys in open or poorly protected trucks should be avoided and product should not be allowed to be left in the open for any longer than absolutely necessary during transport.



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12 | Quality systems for complementary foods

Complementary foods require comprehensive quality systems for several reasons:

- The nature of their consumers, who may be particularly susceptible to any potential adverse effects on their health resulting from consumption of poor quality products.
- Their nutritional requirements which need comprehensive monitoring to ensure the relevant specifications are met
- They are typically highly regulated, hence compliance with both overall regulatory requirements for foods and those specific to complementary foods is essential. This necessitates comprehensive monitoring of quality standards.

Further factors influencing quality systems for complementary foods are:

The increasing use of formal food safety systems such as HACCP, ISO 22000 and FSSC 22000 which require substantial resources and management attention.

The use of auditing in implementing and maintaining these systems, both internally by the manufacturers themselves and externally by customers and regulatory bodies.

The move from quality control systems which focus on inspection and monitoring of finished products (i.e. more of a 'policing' principle) to quality assurance systems which focus rather on ensuring products are always produced to agreed standards in order to prevent the production of non-compliant material (i.e. a 'get it right first time' approach). Quality assurance is seen as more cost-effective than quality control, although many manufacturing operations make use of both quality control and quality assurance.

Specific quality requirements for complementary foods are as follows:

- Acceptability of manufacturing premises and machinery (hygiene, sanitation, pest control, staff working practices, safety, prevention of contamination)
- Raw and packaging material quality and storage in order to ensure that the properties of both remain acceptable for use for an acceptable period after they have been supplied to the manufacturer, particularly when imported materials with long lead times where considerable amounts of stock have to be held by the manufacturer.

- Process control including adherence to required manufacturing procedures for both production and packaging of product
- Finished product standards and safety including compliance with nutritional and organoleptic requirements
- Finished product storage and handling

FOOD SAFETY CONSIDERATIONS

We need to consider the following factors that can affect the safety of complementary foods:

- Microbiological hazards
- Natural toxicants
- Chemical and physical contaminants
- Pesticides

Due to their low moisture content and extensive heat treatment during manufacturing, complementary foods are typically considered to be fairly low risk from the perspective of microbiological safety. However designated standards for complementary foods usually contain fairly stringent microbiological specifications hence suitable procedures need to be in place to ensure firstly that unacceptably high levels of microbiological contamination are not present in raw materials and secondly that risk of microbiological re-contamination in the finished product after heat processing is minimised.

Natural toxicants are a real concern for complementary foods, due mainly to the potential for contamination of key raw materials by mycotoxins such as aflatoxin and fusarium which are not readily removed during processing and can thus be carried over to the finished product. Control systems must thus focus on preventing the development of mycotoxin contamination in raw materials. This preventative approach involves extensive liaison with the farmers supplying the raw materials and ensuring sound drying procedures for the grain are implemented after harvesting in order to reduce moisture content to acceptable levels where mould growth cannot occur, along with adequate storage and transportation facilities. Adequate monitoring of incoming raw materials for mycotoxins is also critical.

Chemical and physical contamination of complementary foods can occur due to their exposure to undesirable chemical substances during storage and processing or the introduction of foreign matter such as dirt, unwanted grains and seeds, insects, pieces of packaging material and metal into the finished product during processing and handling. Strong quality assurance systems are required here as it can be very difficult to detect contamination in finished products by means of conventional inspection driven quality control systems.

Pesticides are typically introduced to complementary foods via raw materials and good control of farming procedures when pesticides are used is essential. The other potential source of pesticide contamination is via the use of poorly controlled internal pest control systems within the manufacturing environment. These need good control.

Typical constituents of a quality monitoring system for complementary foods can be broken up into two categories, namely product specific requirements relating to the quality characteristics of the product itself and broader based requirements relating to food safety, hygiene and good manufacturing practices. These are summarised in tabular format below.

FOOD SAFETY, HYGIENE AND GOOD MANUFACTURING PRACTICE REQUIREMENTS

Acceptability of manufacturing premises and machinery—see table 15 below

Table 15: Acceptability of manufacturing premises and machinery (hygiene, sanitation, pest control, staff working practices, safety, prevention of contamination)

ACTIVITY		HOW			WHO AND TO / BY WHOM		
Indicator	Criteria of success	Where	When (frequency)	Methods	Accountability	Reported to	Actions
Condition of grounds and buildings	Meet GMP standards as expressed by operation of acceptable quality systems, adequate documentation, effective controls and desired level of monitoring and testing	Manufacturing site grounds and buildings	Continuous monitoring by site manufacturing and quality staff + formal internal (3 monthly) and external (annual) audits	Prepare formal checklist for routine monitoring and internal auditing. External auditing will follow standard procedures	Site management (routine monitoring) Quality management staff (internal auditing) Accredited auditor (external auditing)	Site management	Internal actions to remedy issues identified by routine monitoring and internal audit. Issues identified by external auditor require urgent attention by management if site certification approval is be granted / retained
Personal hygiene	Meet GMP standards as expressed by operation of acceptable quality systems, adequate documentation, effective controls and desired level of monitoring and testing	All staff required to achieve required standards after training	Routine checking of personal hygiene standards+ formal internal (3 monthly) and external (annual) audits	Regular training for all staff. Specific training for new staff members Checklist for use by internal auditor. External auditing will follow standard procedures	Site management (routine monitoring) Quality management staff (internal auditing) Accredited auditor (external auditing)	Site management	Internal actions to remedy issues identified by routine monitoring and internal audit. Issues identified by external auditor require urgent attention by management if site certification approval is be granted / retained
Sanitation and House Keeping	Meet GMP standards as expressed by operation of acceptable quality systems, adequate documentation, effective controls and desired level of monitoring and testing	Manufacturing site grounds and buildings	Formal routine (at least weekly) monitoring by site manufacturing and quality staff + formal internal (3 monthly) and external (annual) audits	Prepare formal checklist for routine monitoring and internal auditing. External auditing will follow standard procedures	Site management (routine monitoring) Quality management staff (internal auditing) Accredited auditor (external auditing)	Site management	Internal actions to remedy issues identified by routine monitoring and internal audit. Issues identified by external auditor require urgent attention by management if site certification approval is be granted / retained

ACTIVITY		HOW			WHO AND TO / BY WHOM		
Indicator	Criteria of success	Where	When (frequency)	Methods	Accountability	Reported to	Actions
Pest Control	Meet GMP standards as expressed by operation of acceptable quality systems, adequate documentation, effective controls and desired level of monitoring and testing	Manufacturing site grounds and buildings	Routine implementation of pest control procedures by designated pest control contractor. Formal routine (at least weekly) monitoring by site manufacturing and quality staff + formal internal (3 monthly) and external (annual) audits	Prepare formal checklist for routine monitoring and internal auditing. External auditing will follow standard procedures	Site management (routine monitoring) Quality management staff (internal auditing) Accredited auditor (external auditing)	Site management	Internal actions to remedy issues identified by routine monitoring and internal audit. Issues identified by external auditor require urgent attention by management if site certification approval is be granted / retained
Condition of Machinery	Meet GMP standards as expressed by operation of acceptable quality systems, adequate documentation, effective controls and desired level of monitoring and testing	All machinery on site (i.e. both that used directly in production / movement of ingredients / part processed products / finished products and machinery used for provision of general services)	Formal routine (at least weekly) monitoring by site engineering and manufacturing staff + formal internal (3 monthly) and external (annual) audits	Prepare formal checklist for routine monitoring and internal auditing. External auditing will follow standard procedures	Site engineering management (routine monitoring) Engineering and manufacturing management (internal auditing) Accredited auditor (external auditing)	Site management	Internal actions to remedy issues identified by routine monitoring and internal audit. Issues identified by external auditor require urgent attention by management if site certification approval is be granted / retained
Prevention of Contamination	Absence of physical and chemical contamination in finished products	All machinery on site (i.e. both that used directly in production / movement of ingredients / part processed products / finished products and machinery used for provision of general services). This includes actual services such as water, steam and compressed air quality. This section also includes in-process anti-contamination measures such as screens to remove foreign matter and metal detectors	Formal routine (at least weekly) monitoring by site engineering and manufacturing staff + formal internal (3 monthly) and external (annual) audit. Routine monitoring of quantitative parameters such as water quality and in-process anti-contamination measures (screens, metal detectors etc) to be undertaken by quality management staff.	Prepare formal checklist for routine monitoring and internal auditing. External auditing will follow standard procedures	Site management (routine monitoring) Quality management staff (internal auditing) Accredited auditor (external auditing)	Site management	Internal actions to remedy issues identified by routine monitoring and internal audit. Issues identified by external auditor require urgent attention by management if site certification approval is be granted / retained

Raw and packaging material quality and storage—see table 16 below

Table 16: Raw and packaging material quality and storage

ACTIVITY		HOW			WHO AND TO / BY WHOM		
Indicator	Criteria of success	Where	When (frequency)	Methods	Accountability	Reported to	Actions
Acceptable storage conditions	Storage areas and equipment have acceptable standards of hygiene and sanitation and are appropriate for materials concerned	Storage areas, infrastructure e.g. racking, pallets, materials handling equipment	Storage areas should be included in schedules for routine inspection, internal audits and external audits	Prepare formal checklist for routine monitoring and internal auditing. External auditing will follow standard procedures	Site management (routine monitoring) Quality management staff (internal auditing) Accredited auditor (external auditing)	Site management	Internal actions to remedy issues identified by routine monitoring and internal audit. Issues identified by external auditor require urgent attention by management if site certification approval is granted / retained
Accurate recording of incoming raw & packaging materials	Correctly documented stock records	Stores offices	Ongoing. Records may be subject to broader based financial audit requirements	Suitable formal stock management system	Stores staff (routine) Quality management staff (internal auditing) Accredited auditor (external auditing)	Site management	Internal actions to remedy issues identified by routine monitoring and internal audit. Issues identified by external auditor require urgent attention by management if site certification approval is granted / retained
Correct raw material and packaging specifications	Specifications based on accurate information, agreed by quality and procurement staff and supplier, clearly documented and enforced	Supplier's premises, stores	Specifications drawn up as integral part of procurement process. Procedure for compliance with specifications including sampling of incoming materials	Specifications drawn up in standard format that identifies critical and non-critical attributes. Documented procedure for sampling and where necessary analysis of incoming materials	Procurement and quality staff responsible for specification management. Quality staff responsible for evaluation of incoming materials	Site management and (when applicable) supplier	Acceptance / rejection of incoming materials
Monitoring of stock age and condition and acceptable stock rotation practices	Stock used in chronological order of receipt and within its documented shelf life.	Stores	Ongoing. Stock should be included in schedules for routine inspection, internal audits and external audits	Regular formal inspections of stock age and condition	Stores staff (routine) Quality management staff (internal auditing) Accredited auditor (external auditing)	Site management	Internal actions to remedy issues identified by routine monitoring and internal audit. Issues identified by external auditor require urgent attention by management if site certification approval is granted / retained

ACTIVITY		HOW			WHO AND TO / BY WHOM		
Indicator	Criteria of success	Where	When (frequency)	Methods	Accountability	Reported to	Actions
Procedures for disposal of unacceptable materials	Documented disposal procedures (including records of quantities involved and reason for disposal) in place and implemented when required	Stores	Documented system in place for use as required. Documentation available for auditing when required.	Documented procedures to ensure unacceptable materials are fully disposed of in the correct manner and do not constitute a hazard to the public	Stores staff (routine) Quality management staff (internal auditing) Accredited auditor (external auditing)	Site management	Internal actions to remedy issues identified by routine monitoring and internal audit. Issues identified by external auditor require urgent attention by management if site certification approval is granted / retained

Process control—see table 17 below

Table 17: Process control including adherence to required manufacturing procedures for both production and packaging of product

ACTIVITY		HOW			WHO AND TO / BY WHOM		
Indicator	Criteria of Success	Where	When (frequency)	Methods	Accountability	Reported to	Actions
Documented manufacturing procedures including formulations, process details and handling requirements	All procedures documented in Standard Operating Procedure (SOP) format including procedure for making changes when required	Controlled repository of documentation to be held in suitable electronic and / or hard copy format by responsible department	Ongoing including control of changes when required	Agreed document format	Designated persons, usually manufacturing and quality staff. Documentation and procedures for managing same to be reviewed during internal and external audits at agreed intervals	Site management	Internal actions to remedy issues identified by routine monitoring and internal audit. Issues identified by external auditor require urgent attention by management if site certification approval is granted / retained
Formulation control during manufacturing	Required formulations used for all production	Ingredient weighing / dispensing areas and control panels for automatic weighing systems	Ongoing	Recording of quantities used, preferably maintained electronically and reconciled with planned usage and records of bulk receipts of materials	Factory staff responsible for weighing, dispensing of raw materials and supervision of automatic weighing systems	Factory supervisory staff including staff who may be then involved in investigation of discrepancies e.g. quality and stores staff	Any discrepancies in material usage to be investigated by designated persons and remedial action taken as required
Control of process conditions including machine settings	Correct process conditions in place at all times	Process machinery	Ongoing, automatic monitoring where relevant	As required for individual monitoring points	Factory staff responsible for plant operation	Factory supervisory staff including staff who may be then involved in investigation of discrepancies e.g. quality and maintenance staff	Any deviations from required conditions to be investigated as required and remedial action taken

Finished product standards—see table 18 below

Table 18: Finished product standards and safety including compliance with nutritional and organoleptic requirements

ACTIVITY		HOW			WHO AND TO / BY WHOM		
Indicator	Criteria of Success	Where	When (frequency)	Methods	Accountability	Reported to	Actions
Compliance with finished product compositional requirements	Consistent compliance with formal documented and legal requirements	Manufacturing facility	Monitor to agreed frequency, will be more frequent for key parameters	As required for individual attributes using internal or external service providers	Quality department / manufacturing staff as required	Factory supervisory staff including staff who may be then involved in investigation of discrepancies e.g. senior quality and manufacturing staff	Any deviations from required conditions to be investigated as required and remedial action taken
Compliance with finished product nutritional requirements	Consistent compliance with formal documented and legal requirements	Manufacturing facility	Monitor to agreed frequency, will be more frequent for key parameters	As required for individual attributes using internal or external service providers	Quality department / manufacturing staff as required	Factory supervisory staff including staff who may be then involved in investigation of discrepancies e.g. senior quality and manufacturing staff. May also be necessary to involve commercial staff if non-compliance has commercial implications	Any deviations from required specification to be investigated as required and remedial action taken
Compliance with finished product organoleptic requirements	Consistent compliance with agreed sensory attributes	Manufacturing facility	Monitor to agreed frequency	As required using formal sensory evaluation parameters	Quality department / manufacturing staff as required. May be necessary to use trained sensory evaluation staff.	Factory supervisory staff including staff who may be then involved in investigation of discrepancies e.g. senior quality and manufacturing staff. May also be necessary to involve commercial staff if non-compliance has commercial implications	Any deviations from required sensory parameters to be investigated as required and remedial action taken
Compliance with required packaging specification requirements	Consistent compliance with formal documented requirements	Manufacturing facility	Monitor to agreed frequency, will be more frequent for key parameters	As required for individual attributes	Quality department / manufacturing staff as required	Factory supervisory staff including staff who may be then involved in investigation of discrepancies e.g. senior quality and manufacturing staff.	Any deviations from required specification to be investigated as required and remedial action taken
Compliance with required pack size requirements	Consistent compliance with formal documented and legal requirements	Manufacturing facility	Monitor to agreed frequency, will be more frequent for key parameters	As required for individual attributes	Quality department / manufacturing staff as required	Factory supervisory staff including staff who may be then involved in investigation of discrepancies e.g. senior quality and manufacturing staff.	Any deviations from required specification to be investigated as required and remedial action taken

Finished product storage and handling—see table 19 below

Table 19: Finished product storage and handling

ACTIVITY		HOW			WHO AND TO / BY WHOM		
Indicator	Criteria of Success	Where	When (frequency)	Methods	Accountability	Reported to	Actions
Compliance with required packing configurations	Consistent compliance with formal documented requirements	Manufacturing facility	Ongoing	Routine monitoring of packing procedures	Factory staff responsible for plant operation	Factory supervisory staff including staff who may be then involved in investigation of discrepancies e.g. senior quality and manufacturing staff.	Any deviations from required specification to be investigated as required and remedial action taken
Compliance with required transport and storage conditions for finished product	Consistent compliance with formal documented requirements	Distribution locations, including warehouses and trucks	Ongoing	Routine monitoring of finished product storage, handling and transport procedures including conditions such as temperature control, hygiene and sanitation within distribution facilities	Distribution staff and supervisory staff of any outsourced distribution facilities	Distribution supervisory staff including staff who may be then involved in investigation of discrepancies e.g. senior quality and manufacturing / distribution staff.	Any deviations from required specification to be investigated as required and remedial action taken
Compliance with agreed shelf life properties	Product meets shelf life requirements	Distribution chain, retail outlets	Ongoing	Any specific shelf life requirements should be incorporated into initial product parameters as determined by R&D / quality staff and clearly stated at time of development and initial manufacture. Procedures should include system for obtaining and monitoring retention samples from routine production.	R&D / development staff for initial shelf life parameter setting. Sales and warehousing staff to monitor condition of stock and compliance with stock rotation policies	Senior sales and warehouse staff. Involvement by R&D / quality staff required if significant shelf life problems are experienced	Stock rotation problems resulting in over-date stock in the distribution chain is an operational issue and must be dealt with accordingly. Problems with unexpected shelf life issue need urgent attention by technical staff
Compliance with agreed procedures for management of expired or sub-standard stock in distribution chain including formal recall procedures	Consistent compliance with formal documented requirements	Distribution chain, retail outlets	Ongoing	Expired or sub-standard stock to be handled in terms of prescribed procedures with specific regard to ensuring unacceptable stock is fully removed from sale and disposed of in a manner that removes any risk to the public	Distribution, sales / merchandising and warehousing staff with support from quality department when required	Distribution and sales / planning staff	Any deviation from prescribed procedures to be remedied and investigated by staff of responsible functions

Example of a quality control / assurance schedule for a typical cereal based complementary food

Let us assume we have a complementary food containing maize, soy beans, sugar, skimmed milk powder and a vitamin / mineral fortification premix produced using a roast / grind / dry mix process as discussed above and summarised in Figure 10 below. The product is packed in high barrier flexible packaging in 500g quantities and then in corrugated cases in a 24 x 500g packing configuration.

What are our key quality requirements?

- Product must be safe to consume
- Product must meet required nutritional specifications
- Product must be free of unwanted contaminants
- Product must meet any other non-nutritional specifications required

Where do we need controls?

- Incoming raw and packing materials
- Process control
- Finished product

We can therefore set up a theoretical quality control / assurance system as follows in Table 21 below using typical specifications for a product of this type. N.B. actual specifications will be determined on a case-by case basis

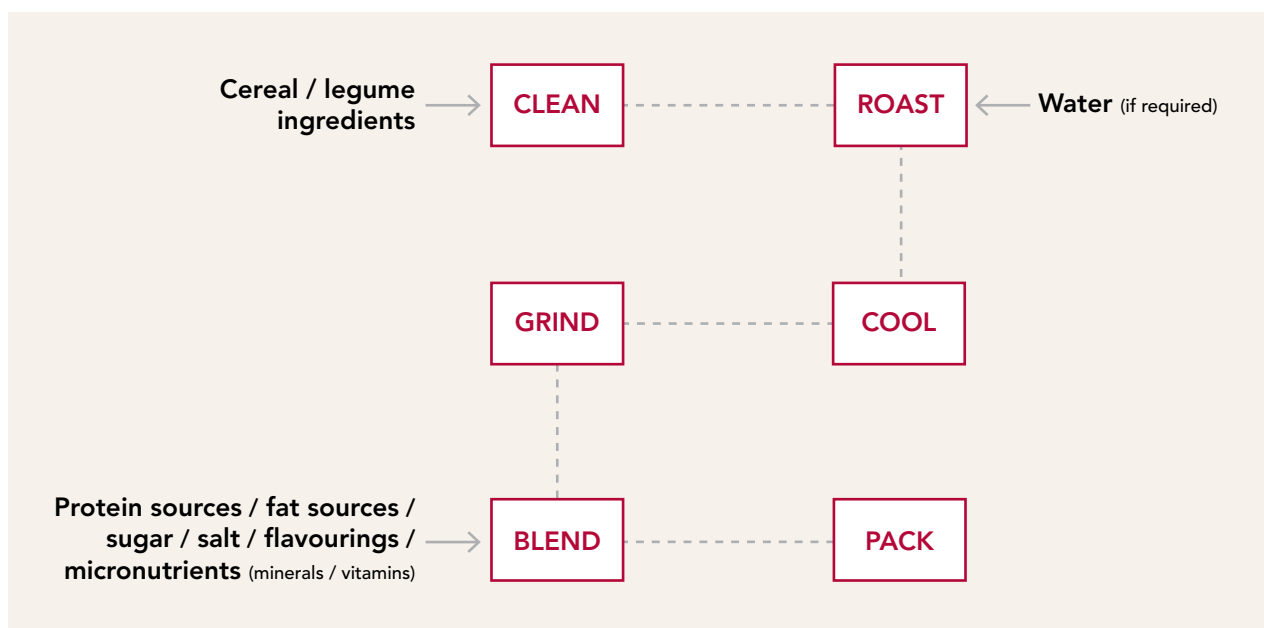


Figure 10: Roasting / grinding / dry mixing process for complementary foods

Table 20—Practical Quality Control System for a Complementary Food

Stage	Item	Parameter	Typical specification	How assessed	Frequency	Corrective action	Comments
Raw materials	Whole maize	Moisture content	<14%	Laboratory analysis	Each consignment received	Reject consignment	
		Protein content	>9%	Laboratory analysis	1 per week	Monitor results and review quality of maize if consistently out of specification	Build up history by supplier / source
		Appearance / Cleanliness	Free from gross contamination and foreign matter	Visual	Each consignment	Reject consignment	May also use quantitative specs e.g. maximum loose dirt / dust
		Aflatoxin	As per local standard	Laboratory analysis	Each consignment	Reject consignment	
	Whole soya beans	Moisture content	<14%	Laboratory analysis	Each consignment received	Reject consignment	
		Protein content	>34%	Laboratory analysis	1 per week	Monitor results and review quality of maize if consistently out of specification	Build up history by supplier / source
		Appearance / Cleanliness	Free from gross contamination and foreign matter	Visual	Each consignment	Reject consignment	May also use quantitative specs e.g. maximum loose dirt / dust
		Aflatoxin	As per local standard	Laboratory analysis	Each consignment	Reject consignment	
	Sugar	Appearance / cleanliness	Free from caking and physical contamination	Visual	Each consignment	Reject consignment	
	Skim milk powder	Moisture content	<4%	Laboratory analysis	Each consignment	Reject consignment or work away sub-standard material at low levels	Decision to reject will be based on degree of non-compliance
		Protein content	>35%	Laboratory analysis	Each consignment	Reject consignment or work away sub-standard material at low levels	Decision to reject will be based on degree of non-compliance
		Appearance / Cleanliness	Free from caking and physical contamination	Visual	Each consignment	Reject consignment or work away sub-standard material at low levels	Decision to reject will be based on degree of non-compliance
	Fortification premix	Appearance / cleanliness	Free from caking and physical contamination	Visual	Each consignment	Reject consignment or work away sub-standard material at low levels	Decision to reject will be based on degree of non-compliance
	Nutritional composition	As per certificate of analysis / specification	Select 1 or 2 micro-nutrients and conduct laboratory analysis	Initial consignment then as required depending on supplier history	Reject consignment or place on hold pending confirmatory testing	Not feasible to analyse for all micronutrients hence conduct selective analysis	

Stage	Item	Parameter	Typical specification	How assessed	Frequency	Corrective action	Comments
Packing materials	Flexible packaging film	Appearance	Free from damage and physical contamination	Visual	Each consignment	Reject consignment or faulty portion of consignment	Physical damage may be limited to part of consignment
		Gauge / dimensions	As per suppliers specification	Measure width / determine grams per m ²	Each consignment	Will depend on degree of non-compliance.	Reject if material unsuitable for running on packaging machines or barrier properties have been adversely affected
	Corrugated cases	Appearance / cleanliness	Free from damage and physical contamination	Visual	Each consignment	Reject consignment or faulty portion of consignment	Physical damage may be limited to part of consignment
		Dimensions	As per specification	Measurement	Each consignment	Reject consignment	
Process control	Maize & soya after cleaning	Appearance / cleanliness	Minimal residues of foreign matter / dirt	Visual	Hourly	Recycle material for additional cleaning	
	Roasting of soya and maize	Roasting temperature	As per specification	Thermometer	Each batch	Hold defective batches and re-cycle if feasible	
		Roasting time	As per specification	Clock / automated timer	Each batch	Hold defective batches and re-cycle if feasible	
	Cooling of soya & maize	Maximum temperature before grinding	As per specification	Thermometer	Each batch	Hold defective batches and re-cycle if feasible	
	De-hulling of soya	Appearance / residual husk	Minimal levels of residual husk / absence of burnt particles	Visual using reference standards / photographs	Each batch	Hold defective batches and re-cycle if feasible	
	Grinding of maize	Particle size	As per specification	Sieve test	Hourly	Hold defective batches and re-cycle if feasible	
	Grinding of soya	Particle size	As per specification	Sieve test	Hourly	Hold defective batches and re-cycle if feasible	
	Dry mixing	Recipe compliance	As per prescribed recipe	Checklist by operators / ingredient dispensers	Each batch	Hold defective batches and re-cycle if feasible	Degree of non-compliance may only be possible to determine by analysis and / or sensory evaluation. If in doubt, defective batches should be destroyed
		Mixing time	As per specification	Clock / automated timer	Each batch	Hold defective batches and re-cycle if feasible	

Stage	Item	Parameter	Typical specification	How assessed	Frequency	Corrective action	Comments
Finished product	Finished product before packing	Moisture	As per specification, typically <7%	Laboratory analysis	2 per day, may differ depending on nature of process	Hold defective batches and re-cycle if feasible	May be necessary to determine % moisture for each batch, depending on quality of process control
		Flavour	As per reference sample	Sensory evaluation	Each batch	Hold defective batches and re-cycle if feasible	Good practice where practical to taste each batch before release for packaging
		Micronutrient check	Addition as per specification	Reconciliation of premix usage vs quantity of product mixed	Each shift	Check each batch for tracer micronutrient	Preferable to use reconciliation method due to impracticality of analysing all individual batches for micronutrient content
	Packaging	Weight	500g	Check weighing	Either continuous check weighing or manual checking at 10' intervals	Hold defective product and re-pack if required	Corrective action will depend on degree of non-compliance including provisions under local metrology regulations
		Seal quality	Full seals, free from leaks	Visual	Every 10' or as required	Hold defective product and re-pack if required	Checking frequency will depend on performance of packing machinery
		Units per case	24 or as specified	Count	Hourly	Re-pack into cases with correct count of packs	
		Case integrity	Rigid with no potential for crushing and minimal headspace	Visual	Hourly	Re-pack as required	
		Case stacking	Correct configuration for both pallet and free stacking	Visual	Hourly	Re-stack and/ or re-pack as required	
	Packed product	Moisture content	As per specification, typically <7%	Laboratory analysis	Weekly or as required for internal or external audit	Check retention samples and hold as required	
		Protein content	As per specification, typically >16%	Laboratory analysis	Weekly or as required for internal or external audit	Check retention samples and hold as required	
		Fat content	As per specification, typically >9%	Laboratory analysis	Weekly or as required for internal or external audit	Check retention samples and hold as required	

Stage	Item	Parameter	Typical specification	How assessed	Frequency	Corrective action	Comments
Finished product		Aflatoxin	As per local specification	Laboratory analysis	Daily or as required for internal or external audit	Check retention samples and hold as required	
		Micronutrient content	As per specification	Laboratory analysis of selected micronutrient(s)	Weekly or as required for internal or external audit	Check further batches for tracer micronutrient	Assessment of potentially defective product to be conducted in conjunction with premix usage reconciliation figures due to unrepresentative nature of single sample analysis
		Microbiological acceptability	Typically: TPC <10000/g Coliforms <10/g E.coli absent in 1g Salmonella absent in 25g Yeast & moulds <100/g	Microbiological analysis	As required, daily for high risk products	Hold affected product and re-assess further samples	
		Any other parameters required by customers	As required	As required	As required	As required	As required



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13 | Regulatory requirements for complementary foods

Global trends in complementary food regulation

Complementary foods are, along with foods for infants, probably the most highly regulated foodstuffs due to their very specific nutritional requirements and their consumption by a vulnerable age group who require suitable protection against foods produced in an unsafe manner or foods of poor nutritional quality

While all countries have locally enforced regulations and standards, there are a number of global standards for various aspects of these products that have been prepared by Codex Alimentarius, the central body falling under the auspices of WHO and FAO whose mandate is to assist in achieving the maximum possible standardisation of global food legislation. Codex Standards and Guidelines are not legally binding but it is customary practice, particularly in countries with limited technical and legal capacity to develop their own regulations, to adopt Codex Standards and Guidelines for local use, either in their entirety or as key components of local regulatory requirements for food. They have the additional advantage of being based on very sound scientific principles and after extensive consultation with globally recognised bodies and individuals in the area concerned. While the often lengthy time taken to finalise Codex Standards and Guidelines

is sometimes criticised, countries adopting them can be confident that they have been produced in a manner that ensures their scientific credibility.

A number of Codex Standards and Guidelines are specifically applicable to complementary foods:

- Codex Stan 74-1981, last amended in 2017: Standard for processed cereal-based foods for infants and young children
- Codex CAC/GL 8-1991, last amended in 2017: Guidelines on formulated complementary foods for older infants and young children
- CAC/GL 10-1979, last amended in 2015: Advisory lists of nutrient compounds for use in foods for special dietary uses intended for infants and young children
- Codex Stan 1-1985, last amended in 2018: General standard for the labelling of pre-packaged foods
- CAC/GL 2-1985, last amended in 2017: Guidelines on nutrition labelling

Copies of all the above documents are supplied with this manual. Key features of the various standards and guidelines are:

- Recommendations on suitable ingredients including cereals, legumes and pulses, oilseed flours and oilseed protein products, animal source foods, fats and oils, fruits and vegetables, food additives and flavourings.
- Recommendations on processing requirements including cleaning and dehulling, milling, heat treatment, extrusion and use of enzymes to improve carbohydrate digestibility.
- Recommendations on nutritional composition and serving sizes.
- Recommendations on energy density, protein quality, fatty acid composition, carbohydrate quality and selection of micronutrients for fortification purposes.
- Recommendations on procedures for avoiding product contamination.
- Recommendations for hygienic practices during manufacture.
- Recommendations for packaging.
- Recommendations for information to be provided on product labels, including product names, ingredient statements, nutritional information and instructions for use.

However, each country has their own specific regulations and standards and these are the legally binding requirements. It is only possible to use Codex as a clear reference point if local regulatory requirements do not exist for a particular regulatory matter and even then Codex is not legally binding.



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14 | Regulatory requirements for complementary foods in Kenya

The regulatory provisions for complementary foods in Kenya fall under the Kenya Standards Bureau (KEBS).

In many instances KEBS standards are aligned with or identical to standards derived for the East Africa region (East African Standards / EAS) that are applicable in Burundi, Kenya, Rwanda Tanzania and Uganda.

The key standards applicable to complementary foods in Kenya are:

KS 2515:2014 Formulated complementary foods for older infants and young children—Guidelines

KS EAS 72:2013 Processed cereal based foods for infants and young children—Specification

KS 2775:2018 Labelling of complementary foods and designated products—Requirements

KS 429:2003 Code of marketing for breast milk substitutes

Summary of regulatory requirements

The key KS / EAS Standards listed above cover a wide range of parameters and requirements for complementary foods. They can be summarised as follows:

All standards:

- Scope and purpose
- References to other relevant Standards
- Definitions of key terms

KS 2515:2014 Formulated complementary foods for older infants and young children—Guidelines. Based on Codex Standard 08:1991 revised in 2013

- Recommended preliminary treatment of raw materials
- Quality requirements including compositional requirements
- Serving sizes
- Specific prohibitions for certain ingredients
- Permitted food additives
- Contaminants including pesticides, aflatoxin and anti-nutrient factors
- Hygiene and microbiological standards
- Packaging, labelling and sampling procedures

KS EAS 72:2013 Processed cereal based foods for infants and young children—Specification

- Product categories
- Ingredient, compositional and process requirements and prohibitions
- Permitted food additives
- Contaminants including pesticides and mycotoxins
- Hygiene and microbiological standards
- Packaging, labelling and sampling requirements

KS 2775:2018 Labelling of complementary foods and designated products—Requirements

- General requirements regarding acceptable labelling procedures
- Specific requirements for language, naming, supplier details
- Ingredient statements
- Nutritional information
- Quantity declarations
- Date marking, storage and usage instructions
- Specific requirements for infant and young child feeding

KS 429:2003 Code of marketing for breast milk substitutes

- General principles specifically in regard to encouragement of breastfeeding
- Persons & organisations to whom the Code shall be applicable
- Ethics and professional standards for consumer and professional information and advisory services
- Product information
- Restrictions on advertising and promotional practices
- Relationships with health professionals

General comments on Kenyan regulatory requirements

- All the Standards are very much aligned with Codex Guidelines and Standards and as such are aligned with global best practice.
- The requirements are both comprehensive and stringent and place a considerable burden on manufacturers.
- It is therefore essential that would-be manufacturers of complementary foods factor in the relevant regulatory requirements at an early stage of their development process.
- A 'checklist' approach where the compliance requirements of every aspect of the manufacturing process is systematically checked is highly recommended.
- While this manual provides the basic components of the regulatory requirements, it is strongly recommended that manufacturers lacking a comprehensive knowledge of the legal requirements for food and for complementary food in particular obtain expert advice in order to avoid regulatory difficulties that could potentially jeopardise either a new product launch or the ability to sell existing complementary food products.
- Manufacturers should in any case obtain copies of the relevant documents from KEBS and retain these for reference.



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15 | Principles for developing complementary food formulations and processing

INTRODUCTION

The development and manufacture of complementary foods can in fundamental terms be treated in the same manner as is applicable for that of any food product for which the following are key drivers:

- Consumer acceptance
- Cost
- Availability of suitable raw materials
- Availability of suitable manufacturing capability
- Safety
- Regulatory compliance

However complementary foods and in particular those required in low-income countries, have additional requirements over and above these, namely:

- Nutritional requirements which may be highly specific and / or legally enforceable
- Need for low cost due to limited purchasing power of target consumers
- Fluctuating availability and quality of key raw materials
- Limited availability of specialist raw and packaging materials
- Lack of sophisticated manufacturing infrastructure

The development of complementary foods in the countries in which this manual is to be used thus involves a complex matrix of parameters and some degree of potential compromise between conflicting requirements.

WHERE TO BEGIN?

A food manufacturer or entrepreneur wishing to start development of a complementary food is faced with many questions around how best to pull together all the above general and complementary-food-specific requirements and it can seem to be a daunting task -where should I initially start? The following is intended as a suggested procedure.

Step 1—Identify the nutritional requirements

It is important to understand that nutritional requirements should be the first priority.

How do we obtain information on the critical nutritional requirements in the country concerned? There are several options:

- Government nutrition policies, particularly those relating to the 6-36 month age group, which highlight both general nutritional requirements and the need to address specific nutritional deficiencies within the country.
- Specific regulatory requirements for complementary foods in the country.
- Global guidelines for nutritional composition of complementary foods, such as those from WHO or Codex Alimentarius.

Step 2—Identify key consumer preferences

The following may be helpful here:

- Formal or informal discussions and observations on eating habits among local consumers
- Market research information, ideally on complementary foods themselves but also on general food preferences among the target population and how consumers interpret these in the context of feeding children in the 6-36 month age group.
- Discussions with local community health workers tasked with providing guidance on food choices to the public.
- Review of either existing complementary food products or foods with similar characteristics to complementary foods in local retail outlets.

Step 3—What raw materials are available?

Key considerations are:

- What are the key staple foods in the country concerned?
- What are the key crops (cereals and legumes) grown in the country concerned?
- Which of the key crops may be potentially useable in complementary foods—refer to the tables in section VI if necessary
- If the key crops grown are not among those typically suggested for use in complementary foods, how can we get advice as to their potential suitability?

- What is the general availability of the key crops in terms of seasonality and out-of-harvest-season stock management?
- What quality issues are experienced for the key crops?
- Are there existing local suppliers of part-processed cereal & legume ingredients such as flours?
- What is the availability of typical non-cereal / legume ingredients? Are any of them locally produced?
- If importation of ingredients is required, how do we find suitable suppliers?
- What are the regulatory and customs requirements for importation of food ingredients?
- Are there any import concessions for ingredients intended for use in products aimed at public health improvement?

TURNING THE BASICS INTO PRACTICAL FORMULATIONS

Clearly we need to start turning all the available information into actual product formulations. This can initially be done as a theoretical desk exercise where we calculate the nutritional content of potential formulations. The best way to do this is by using nutritional calculation spreadsheets.

A suitable calculation spreadsheet has been devised for this purpose and is enclosed with this manual as a simple Excel file.

In this approach:

- Suitable raw materials with known nutritional composition are selected from a pre-compiled list, usually based on their local availability and consumer acceptability. The list of raw materials is quite large to cater for the needs of different countries.
- There is provision in the spreadsheet for new raw materials and their nutritional characteristics to be added to the list. The spreadsheet can accommodate a total of up to 100 different raw materials.
- The quantities of each raw material in the proposed formulation are inserted into the spreadsheet.

- The spreadsheet automatically calculates the nutritional composition of the theoretical formulation and provides it as a table.
- The calculated nutritional composition is compared with that required, as determined from an existing specification or client request
- The formulation can be manipulated by means of altering the quantities of the various raw materials or by removal or introduction of different raw materials.

It should be noted that the spreadsheet that has been provided is a simplified version of a far more comprehensive calculation spreadsheet caters for more complex requirements such as protein quality and integration of complementary foods into broader based diets. This is available on request but requires considerable expertise in its use and in interpretation of the results.

Once a theoretical formulation has been obtained that meets the required nutritional specification and use ingredients that can be readily sourced by the manufacturer, it then needs to be critically scrutinised for:

- Potential palatability and consumer acceptance
- Cost
- Ease of manufacturing

Palatability and consumer acceptance

Clearly the product needs to have a palatable flavour and texture and these will be determined by the ingredients and mode of processing. A few points that are worth considering are the following:

- The core cereals are generally fairly bland in flavour but some form of heat treatment during their processing is essential to remove raw flavour notes.
- Protein and fat sources vary widely in terms of palatability. Full fat soya can be a major challenge in terms of raw flavour and 'green' flavour notes resulting from oxidation of its fat components and it is not realistic to incorporate it at levels much above 20%, even when roasting or other heat treatments are used. Other soya derivatives are much blander due largely to the removal of the fat.
- Other non-animal protein sources can also have raw flavours and will typically require significant heat treatment to render them palatable.

- Milk ingredients always improve the flavour of the product in which they are incorporated.
- Addition of free oils and fats can affect the mouthfeel of the product, not always in a desirable manner. Soy oil should not be added at a level of more than 5% and should undergo minimal heat treatment during processing.
- While addition of sugar is not desirable from a nutritional perspective, it will significantly improve palatability. At least 5% is needed to have a significant effect on flavour.
- A small amount of salt can also be beneficial. Again this is not desirable from a nutritional perspective but even a small quantity can help in improving flavour in many formulations.
- Most complementary foods are consumed as porridges and their texture and mouthfeel are defined by factors such as particle size of the ingredients, degree of starch cooking achieved during processing (which will in turn be affected by cook time and temperature during both processing and preparation by the consumer) and amount of moisture added during processing.
- Colour of typical complementary food formulations is unlikely to be a problem, however excessively high temperatures can result in unacceptable browning of the product due to reactions between the protein and carbohydrate components. This is also potentially an indicator of loss of nutritional quality.

Cost

Any proposed theoretical formulations that have been assessed for nutritional composition as per the procedure outlined above can readily be costed by means of a further spreadsheet. Note the following:

- The required raw material costs need to be available.
- Imported raw material costs can fluctuate considerably due to exchange rates. Realistic exchange rates should be used and a clear idea of other key factors such as transport costs and import duties must be obtained.
- Provision needs to be made for a certain amount of product loss during processing. The amount of loss will be dependent on the process used and the efficiency of the plant but should not exceed 4% and should ideally be less than 2%.

Ease of Manufacturing

The various processes available for the manufacture of complementary foods have already been explained and compared in section VIII above. For an existing manufacturer with established plant and processes, it will obviously be solely a matter of ensuring that these can accommodate the proposed formulation. For a start-up operation where the choice of process and related decisions on purchase of processing machinery can potentially be impacted by the nature of the product concerned, an extensive evaluation of the available options will be required. The comparison table in section VIII which evaluates the advantages and disadvantages of the three potential processes, namely roast / grind / mix, extrusion and drum drying will be of assistance here. Certain fundamental principles can however influence process choice:

- Drum drying is unlikely to be the optimum process, unless a product with the specific attributes of a drum-dried product is required.
- Any product that can be produced on a drum dryer can normally be produced by means of either of the other two processes and deliver a product with comparable nutritional properties, albeit with slightly different finished product physical characteristics.
- The decision between the roast / grind / mix and extrusion processes will be driven largely by issues of capital cost, capacity requirements (both initial and future) and ease of operation. These are discussed in section VIII.

NEXT STEPS

The development process will then follow established product development principles which may include:

- Adjustments may have to be made to the proposed theoretical formulations in order to accommodate some or all of the above issues.
- The revised formulations will then have to be assessed for compliance with required specifications and further adjustments made.
- Initial prototypes are produced, either on an existing facility or by using suitable experimental facilities such as small scale pilot plants belonging to the manufacturer, independent research bodies such as research institutes or university research facilities or machinery manufacturers.
- The prototypes are assessed for consumer acceptance and shelf life
- Nutritional composition then needs to be determined by laboratory analysis and the results compared with theoretical values and the required nutritional specifications
- The final prototypes need to be re-checked for financial viability

Providing all requirements have been met, commercialisation of the product, including where appropriate the establishment of new or modified manufacturing facilities, can then proceed.



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16 | Commercial aspects of complementary food manufacture

While the primary purpose of the manual is to address the more technical aspects of complementary food manufacture, it is desirable in conclusion to discuss briefly certain issues relating to the commercial sale and marketing of complementary food products.

Complementary foods are typically marketed through 3 channels:

- Government agencies where they are supplied via the public health system or are provided as part of disaster relief.
- Non-governmental and United Nations organisations where they are usually supplied as part of nutritional improvement programs for targeted populations or are provided as part of disaster relief.
- Commercially distributed and sold via formal or informal retail channels.

Irrespective of which of the above channels is used, it must be recognised that complementary foods are a highly sensitive area in regard to acceptable sales and marketing practices, due to the vulnerable age group for which they are intended. While regulatory requirements for complementary foods

are considerably more stringent than those for foods in general, considerations relating to ethical practices also need to be considered.

It cannot be too strongly emphasised that complementary foods are exactly what their name implies, namely a constituent and not the sole component of the diet of an older infant or young child. It is particularly important that complementary foods are not allowed to supplant breast feeding and that breast milk continues to be a significant part of the child's diet after the initial 6 month period of breast feeding is complete. The progressive phasing down of breast feeding needs to be conducted in a suitably controlled manner over the following 18 months by means of suitable advice from qualified health professionals. Under no circumstances should any commercial practices by suppliers of complementary foods be seen to discourage breast feeding, irrespective of the age of the child.

The above principles form the basis for the International Code of Marketing of Breast-milk Substitutes, first published by the WHO in 1981 and which in turn resulted from a resolution from the World Health Assembly. While some of the Code deals with practices within healthcare systems, significant portions of it also deal with commercial marketing practices. It is fair to say

that, rightly or wrongly, there is a strong feeling in global public health circles that the food industry has in the past been guilty of unacceptable marketing practices in regard to the potential substitution of breast milk with commercially manufactured products such as infant formula and to some extent complementary foods. Progress in implementation of the Code was formally reviewed in 2018 by a joint working group from the WHO, UNICEF and the International Baby Food Action Network (IBFAN). The working group focussed on assessing the extent to which the provisions of the Code had been converted into formal regulatory requirements and concluded that insufficient progress had been made in many countries.

To this end, much of the regulation relating to complementary foods deals not only with compositional and food safety issues but also with marketing practices. There are comprehensive legal prohibitions in many countries on marketing practices such as product sampling in retail outlets, provision of samples to government and other health facilities dealing with child care and distribution of feeding products such as bottles and spoons by companies.

Manufacturers of complementary foods not only need to comply with any relevant regulatory requirements in this area but also need to be aware of any broader requirements from the International Code. While these may not always be legally binding in some countries, manufacturers have a clear ethical duty to meet the highest possible standards of commercial behaviour in this sensitive area. Any marketing or sales activities for complementary foods should be reviewed beforehand in terms of both the formal regulatory requirements and also the broader principles of the International Code. In the case of complementary foods supplied via government, UN or other NGO channels, compliance with the International Code is likely to be incorporated directly or indirectly in the contractual conditions of supply for the product.

Lack of compliance with regulatory requirements clearly constitute an offence by the manufacturer and will be treated as such by the authorities. However lack of compliance with provisions that may not necessarily be legally enforceable but are still considered to be desirable and ethical practice may also have negative implications for the manufacturer. Not only will this be regarded as undesirable by the authorities but activist groups such as IBFAN may intervene. They carry considerable influence and, while their activities are sometimes driven by ideological as well purely scientific and legal considerations, they are in a position to cause considerable adverse publicity and bad public relations for the company concerned.

Acceptable marketing practices should thus be a major priority for complementary food manufacturers. A link to the International Code of Marketing of Breast-milk Substitutes is supplied along with this manual and it should be noted that a specific Kenya Standard, already discussed in the regulatory section above, comprises a code of marketing of breast milk substitutes.



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17 | Technical resources

The following may be useful additional sources of information and some of them have already been quoted in the manual.

WHO guiding principles for complementary feeding: https://www.who.int/nutrition/publications/guiding_principles_compfeeding_breastfed.pdf

https://www.who.int/nutrition/topics/complementary_feeding/en/

<https://www.who.int/nutrition/publications/infantfeeding/924154614X/en/>

Lutter CK & Dewey KG: 'Proposed Nutrient Composition for Fortified Complementary Foods—Journal of Nutrition 2003 Sep; 133(9): 3022S-20S <https://www.ncbi.nlm.nih.gov/pubmed/12949402>

Formulations for fortified complementary foods and supplements: Review of successful products for improving the nutritional status of infants and young children—Food and Nutrition Bulletin vol 30 no2 2009 <http://journals.sagepub.com/doi/pdf/10.1177/15648265090302S209>

Kenya Demographic and Health Survey 2014 <https://dhsprogram.com/pubs/pdf/FR308/FR308.pdf>

The Kenya National Micronutrient Survey 2011 <http://www.nutritionhealth.or.ke/wp-content/uploads/Downloads/The%20Kenya%20National%20Micronutrient%20Survey%202011.pdf>

FAO crop statistics for Kenya <http://www.fao.org/faostat/en/#data/QC>

Buhler Ltd—Extrusion Technology <https://www.buhlergroup.com/global/en/industry-solutions/processed-food/cereals.htm>

CFAM Technologies—Extrusion Technology <https://cfam.co.za/>

Andritz Gouda—drum drying technology http://www.andritzgouda.com/en/index.php/machine/category/Drum_Dryer/Drum_Dryer

DSM—Development of Micronutrient Fortification Premixes <https://www.dsm.com/markets/human-nutrition/en/customized-services/customized-premixes.html>

FAO—Food Quality and Safety Systems—A Training Manual on Food Hygiene and the Hazard Analysis and Critical Control Point (HACCP) System <http://www.fao.org/3/a-w8088e.pdf>

Theurich et al, Food Safety Issues for Complementary Foods <https://academic.oup.com/nutritionreviews/article/77/5/350/5366312>

Codex Alimentarius <http://www.fao.org/fao-who-codexalimentarius/en/>

International Code of Marketing of Breast Milk Substitutes https://www.who.int/nutrition/publications/code_english.pdf



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Annexes

ANNEX I—AN INTRODUCTION TO NUTRITION AND HEALTH

Nutrition can best be defined as the study of the influence of food intake on our health and wellbeing. A satisfactory intake of appropriate nutrients is essential at all times in our lives if we are to maintain our health.

Nutrients can be divided into two types namely macronutrients and micronutrients. Macronutrients are those typically constituting the bulk of our food such as protein, carbohydrate and fat, along with energy which in turn is derived from these. Micronutrients are those occurring in much smaller quantities in our food but whose consumption is critical to many of our body's functions.

We should also not forget that water can be considered as a nutrient as it is also critical in maintaining our bodies.

The following information derived from sources such as the Food and Agriculture Organisation of the United Nations and the British Nutrition Foundation provides a useful overview of the different nutrients.

Energy

- Energy is needed by the body for a number of functions.
- Energy is provided by the diet (food and drinks) in the form of carbohydrate, proteins, fats and alcohol.
- Energy can be measured in either joules (J) or calories (cal). One calorie is equivalent to 4.184 joules or one kilocalorie (kcal) is 4.184 kilojoules (KJ).
- The amount of energy made available to the body by carbohydrates, proteins, fats varies: per gram of carbohydrate (starch and sugar) provides 16KJ (3.75 kcal), per gram of protein provides 17KJ (4 kcal) and per gram of fat provides 37KJ (9kcal). Summary provided below

Amount of energy made available by different sources of energy

Energy source (per gram)	Kilojoules (kJ)	Kilocalories (kcal)
Carbohydrate	16	3.75
Protein	17	4
Fat	37	9

- Energy balance occurs when energy intake (food and drinks consumed) equals energy expenditure. An individual in energy balance will maintain their weight. Increases in energy intake/decreases in energy expenditure will lead to weight gain and decreases in energy intake/increases in energy expenditure will lead to weight loss.
- Energy expenditure is primarily determined by body size, body composition and physical activity.
- The actual amount of energy needed will vary from person to person and depends on their basal metabolic rate (BMR) and their level of activity.
- Energy requirements increase by approximately 800 KJ/day in the last trimester of pregnancy, and by about 2100 KJ/day during full lactation.
- At least half the energy in our diets should come from carbohydrate, mostly as starchy carbohydrates.
- Frequent consumption of food and drinks containing non-milk extrinsic sugars can increase risk of tooth decay.

Carbohydrate

- Carbohydrate is needed by the body's tissues for energy.
- There are two main types of carbohydrates: sugars and starch. Both sugars and starch provide energy.
- Sugars can be subdivided into intrinsic and extrinsic. Intrinsic sugars are those that are part of the cellular structure of foods e.g. sugars in fruits and vegetables. Extrinsic sugars are those that are not part of a cellular structure e.g. lactose in dairy products, or honey, fruit juices and confectionary (also known as non-milk extrinsic sugars).
- Complex carbohydrates include starch and non-starch polysaccharides. Starch is found in potatoes, bread, rice and pasta and non-starch polysaccharides are found in fruits, vegetables, legumes and whole-grain cereals.
- Fibre is a type of carbohydrate found only in plants. Fibre cannot be digested so it does not provide energy but is needed for a healthy digestive system.
- **Protein**
- Protein is needed by the body for growth and repair and is able to provide energy when the diet is low in carbohydrate.
- Protein is found in animal and plant cells in a variety of foods e.g. meat, fish, eggs, dairy, cereals, nuts and pulses.
- Proteins are made up of amino acids. There are approximately 20 different amino acids found in foods.
- Amino acids are broken down into 2 groups: essential and non-essential.
- **Essential amino acids** are those that must be supplied by the diet: Leucine, Isoleucine, Valine, Threonine, Methionine, Phenylalanine, Tryptophan, and Lysine. Histidine is an essential amino acid for children (not adults) because children are unable to produce enough to meet their needs.
- **Non-essential amino acids** are those that the human body is able to make itself (by breaking down amino acids in protein that are eaten and absorbing them to make other proteins in the body).
- Different foods contain different amounts and combinations of amino acids.
- Vegans and vegetarians can get all the protein they need by combining different plant sources of protein, e.g. pulses and cereals.

Fat

- Fat is needed by the body for energy, for providing essential fatty acids, and for carrying and absorbing fat-soluble vitamins (A, D, E and K).
- Fat is found in meat/meat products, dairy products, fish, eggs, fruit, vegetables, nuts, cereals and cereal products (including cakes and biscuits), savoury snacks and oils.
- Fats are described as either **saturated** or **unsaturated** depending on the proportions of fatty acids present. Butter is described as a saturated fat because it has more saturated fatty acids than unsaturated fatty acids. Olive oil is described as an unsaturated fat because it has more mono- and polyunsaturated fatty acids than saturated.
- Saturated fats are usually found in animal products and unsaturated fats in vegetable sources. There are exceptions to this rule. Unsaturated fats may be converted into saturated fatty acids by hydrogenation.
- Essential fatty acids (EFAs) are those that must be supplied in the diet because the body is unable to make them. There are two essential fatty acids: alpha linolenic acid (*n-3*) and linoleic acid (*n-6*). The body is able to synthesise other fatty acids from these two essential fatty acids.
- Fat should not exceed more than one third of a human being's energy intake and a high intake of saturated fat can have adverse effects on health.

Vitamins

- Vitamins are nutrients that are needed by the body in very small amounts for a variety of functions carried out by the body e.g. co-factors in enzyme activity and antioxidants. They are complex organic molecules based on carbon, hydrogen and oxygen atoms although some of them also contain other elements such as nitrogen and phosphorus.
- Different foods supply different amounts of vitamins.
- Vitamins needed by the body include: vitamin A, D, E, K (fat soluble vitamins), C, B1, B2, Niacin, B6, B12, Folate (water soluble vitamins).
- Vitamins, except vitamin D, have to be provided by the diet because the body is unable to make them.

- Vitamin D can be produced by the action of sunlight on the skin.
- Each vitamin is required in different amounts for a number of different processes in the human body.
- The amount of each vitamin needed by the body changes during a person's lifetime.

Minerals

- Minerals are single element nutrients that are needed by the body for a variety of functions e.g. formation of bones and teeth, as an essential constituent of body fluids and tissues, for nerve function and components of enzyme systems.
- Different foods supply different amounts of minerals.
- Minerals needed by the body include: calcium, magnesium, phosphorus, sodium, potassium, chloride, iron, zinc, iodine, fluoride, selenium, copper, chromium and manganese. They are rarely consumed as the pure elements but are normally consumed in the form of mineral salts. For example, calcium and phosphorus can be consumed as one or more of the various calcium phosphates and iron can be consumed as ferrous sulphate or ferrous fumarate. Direct dietary intake of minerals can come from a wide variety of often complex salts of the various minerals concerned.
- Each mineral is required in different amounts for a number of different processes in the human body. Some minerals are needed in large amounts (e.g. calcium, phosphorus, magnesium, sodium, potassium and chloride) and others in smaller amounts (e.g. iron, zinc, iodine, fluoride, selenium and copper).
- The efficacy of absorption of a mineral into the body is measured in terms of the bioavailability of the mineral source concerned. As a rule of thumb, the more water-soluble the mineral source is, the higher the bioavailability will be, as a solubilised vitamin is more easily absorbed through the walls of the digestive system.
- The amount of each mineral needed by the body changes during a person's lifetime.

Water

- Over half the human body consists of water, and regular fluid intake is essential for the correct functioning of the body. For example, it acts as a lubricant for joints and eyes, helps for swallowing, provides a medium in which most reactions in the body occur, helps eliminate waste, helps regulate body temperature.
- The amount of fluid needed varies between people and according to age, time of year, climatic conditions, diet and levels of physical activity.
- Water can be obtained from the direct consumption of water and other drinks (e.g. squash, tea, coffee) and through the consumption of food (e.g. fruits and vegetables).

ANNEX II—KEY QUALITY CONTROL PROCEDURES

Rapid testing for mycotoxins

As indicated in Table 21 in Section XI, a key component of quality systems for complementary foods is monitoring of both raw materials and finished products for mycotoxins and in particular for aflatoxin. Monitoring needs to be done on incoming consignments of cereal and oilseed ingredients and this in turn requires rapid methods for quantitative determination.

A number of companies supply test kits for the quantitative determination of aflatoxin and other mycotoxins. The kits enable a result to be obtained in as short a time as 5 minutes of the test being conducted, in turn enabling rapid decisions to be made as to the acceptability or otherwise of a particular consignment. Suppliers of test kits include Vicam, Neogen, Creative Diagnostics and Biosystems. Procedures vary slightly but generally involve:

- A simple sample preparation process where the material to be tested is ground to a fine powder
- The ground material is then extracted with water, organic solvent or a mixture of both
- The liquid extract is centrifuged to separate it from the solid material
- The extract is added to the test kit which is normally based on paper strips impregnated with specialised reagents for identifying the mycotoxin concerned

- The test kit is allowed to stand and the level of mycotoxin can be determined within a short period and is normally assessed by means of colour development, the extent of which can be quantified to determine the amount of mycotoxin present.

Iron spot test

It is common practice when conducting quality control of fortified products containing micronutrient premixes such as complementary foods to establish the level of a limited number of micronutrients in the finished fortified product and use the results for these in conjunction with the certificate of analysis for the premix to confirm that the correct quantities of all micronutrients are present. This is known as using a tracer micronutrient.

Tracer micronutrients are typically selected for use on the basis of ease of analysis. The most commonly selected micronutrient is iron, which is commonly incorporated in premixes and is thus well suited for this purpose.

The iron content of products of this sort is commonly determined by means of the iron spot test which uses a very simple procedure involving simple laboratory glassware and a limited number of readily obtained laboratory reagents. Typical procedure is shown below:

Semi-quantitative spot test for iron as ferrous sulphate, ferrous fumarate, or electrolytic iron:

- Reagents:

Hydrochloric acid, HCl, 37% Merck 317
Hydrogen peroxide, H₂O₂, 30%, Merck 7209
Potassium thiocyanate, KSCN, Merck 5124 or 5125

- Solutions:

KSCN—10%: Dissolve 10 g of KSCN in 100 ml distilled water. HCl - 2M: To a 500 ml beaker, add 100 ml distilled water, then 17 ml concentrated HCl and, finally 83 ml distilled water. H₂O₂ - 3%: Add 9 ml concentrated H₂O₂ (30%) to 81 ml distilled water.

Reagent 1:

Immediately before using, mix equal amounts of 10% KSCN and 2M HCl. Mark the levels of 20 and 40 ml on a flask, using a pipette. Add 2M

HCl up to the 1st mark and then add 10% KSCN up to the 2nd mark. This is reagent 1. Use within 1 day. Discard the remaining

Reagent 2:

3% H₂O₂. Discard remaining solution at the end of the day

- Materials: Watch glass Droppers

- Procedure:

1. Take a sample of 100 g of flour and place it on the watch glass. With the lower part of another watch glass, press on the flour sample so that it forms a flat surface.

2. Add 5 drops of reagent 1 with the dropper so that it covers an area of 4x4 cm (1.5x1.5 inches). Let stand for 15-30 seconds.

3. Add 5 drops of reagent 2 on the surface covered by reagent 1. Let stand for 1-2 minutes.

- Interpretation:

The appearance of red coloured spots indicates the presence of iron. The number of spots is a broad estimation of the amount and homogeneity of iron in the sample. If a more accurate estimation is required, testing with known concentrations of iron (30, 60, and 90 ppm) is recommended in order to compare results of these samples with those of the flour being tested.



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