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GUIDELINES FOR READY-TO-USE THERAPEUTIC FOODS
(CXG 95-2022)

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GUIDELINES FOR READY-TO-USE THERAPEUTIC FOODS

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1. Preamble

Children affected by severe acute malnutrition (SAM) need efficacious and timely intervention including safe, palatable foods with a high-energy content and adequate amounts of vitamins, minerals and other nutrients within an appropriately designed programme that promotes continuation of breastfeeding, appropriate transition to nutritious family food and psycho-social support for recovery. In accordance with the Joint Statement[1] by the World Health Organization (WHO), the World Food Programme (WFP), the United Nations System Standing Committee on Nutrition (UNSCN) and the United Nations Children's Fund (UNICEF) (2007) and taking note of other relevant documents by WHO and FAO, ready-to-use therapeutic food (RUTF) is a WHO recommended option for the dietary management of children aged from 6 to 59 months with SAM without medical complications. However, this does not preclude other dietary options including the use of locally-based foods. RUTF is not for general retail sale.

2. Purpose of the guidelines

To provide guidance on technical and nutritional aspects of the production of RUTF for children from the age of 6 to 59 months with SAM, including:

i. **nutritional composition**
ii. **raw materials and ingredients**
iii. **good manufacturing practices**
iv. **microbiological and chemical contaminant criteria**
v. **methods of analysis and sampling**
vi. **provisions for packaging and labelling**

3. Scope

The provisions of these guidelines apply to RUTF for children aged from 6 to 59 months with SAM. Ready-to-use supplementary foods (RUSF), micronutrient supplements,[2] processed cereal-based foods,[3] formulated complementary foods for older infants and young children,[4] canned baby foods[5] are not covered by these guidelines.

4. Description

4.1 Ready-to-use therapeutic foods (RUTF)

Ready-to-use therapeutic foods (RUTF) are foods for special medical purposes and are high energy and contain adequate protein and other essential nutrients for the dietary management of children from 6 to 59 months with severe acute malnutrition without medical complications with appetite. These foods should be soft or crushable and should be easy for children to eat without any prior preparation.

4.2 Severe acute malnutrition (SAM)

Severe acute malnutrition (SAM) is defined by weight for height (or length) less than –3 Z-score of the median WHO growth standards, or by mid upper arm circumference (MUAC) <11.5 cm, or by the presence of bilateral oedema.

5. Suitable raw materials and ingredients

RUTF are made of ingredients embedded in a lipid-rich matrix e.g. paste or biscuit, resulting in an energy and nutrient-dense food. The following raw materials, many of which can be sourced locally, are suitable ingredients for the production of RUTF under the specified conditions given below. Any formulation of RUTF shall comply with Section 3 of the *Standard for the Labelling of and Claims for Foods for Special Medical Purposes* (CXS 180-1991)[6] including the specification that their use should have been demonstrated, by scientific evidence, to be safe and beneficial in meeting the nutritional requirements of the persons for whom they are intended.

5.1 Basic raw materials and ingredients

5.1.1 Milk and other dairy products

Milk and other dairy products used in the manufacturing of RUTF must comply with the *Standard for Milk Powders and Cream Powder* (CXS 207-1999)[7] and the *Standard for Whey Powders* (CXS 289-1995),[8] and other Codex milk and milk product standards as well as other guidelines and codes of practice recommended by the Codex Alimentarius Commission, which are relevant to these products. Relevant codes of practice include the *Code of Hygienic Practice for Milk and Milk Products* (CXC 57-2004)[9] and the *Code of Hygienic Practices for Low-Moisture Foods* (CXC 75-2015).[10]

5.1.2 Legumes and seeds

Legumes and seeds such as soybeans, lentils, chickpeas, cowpeas, beans, peanut, sesame and other types of legumes and seeds must comply with the relevant Codex Alimentarius texts when used in the manufacturing of RUTF.

Legumes and seeds must be appropriately processed to reduce, as much as possible, the antinutritional factors normally present, such as phytate, lectins (haemagglutenins), trypsin, chymotrypsin inhibitors and phytoestrogens.

Field beans or fava beans (*Vicia faba* L.) should not be used in the formulation of RUTF because of the danger of favism.

5.1.3 Fats and oils

Fats and oils used in the manufacturing of RUTF must comply with the relevant Codex Alimentarius texts. Fats and oils are incorporated as technologically feasible for the purpose of achieving the energy density and providing essential fatty acids. Care must be taken to avoid oxidized fat which will adversely affect nutrition, flavour, and shelf life.

Partially hydrogenated fats and oils should not be used in RUTF.

5.1.4 Cereals, roots and tubers and their derived products

All milled cereals, roots and tubers and their derived products suitable for human consumption may be used provided that they are processed in such a way that the fibre content is reduced, when necessary, and that the effects of antinutritional factors such as phytates, tannins or other phenolic materials, lectins, trypsin, and chymotrypsin inhibitors which can lower the protein quality and digestibility, amino acid bioavailability and mineral absorption are removed or reduced, whilst retaining maximum nutrient value.

5.1.5 Vitamins and minerals

Vitamin and mineral forms used must be soluble and easily absorbed by patients with SAM. Children with SAM have low or absent gastric acid which means that they should not be given inorganic mineral salts that are insoluble or require an acid gastric environment for absorption, in order to avoid metabolic acidosis. It is important that RUTF should have a mineral composition that leads to a moderate excess of non-metabolizable buffer base. The non-metabolizable buffer base can be approximated by the formula: estimated absorbed millimoles (sodium + potassium + calcium + magnesium) - (phosphorus + chloride).

All added vitamins and minerals must be in accordance with the *Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children* (CXG 10-1979).[11] Examples of mineral forms for RUTF formulation can be found in the *WHO Management of severe malnutrition: A manual for physicians and other senior health workers (1999).*[12] The amount of vitamins and minerals added to achieve the target level must be adjusted based on the chemical form, interaction, and impaired absorption with other nutrients and non-nutrients and scientific evidence showing adequate stability and bioavailability in the finished product.

5.2 Other ingredients

5.2.1 Carbohydrates

Carbohydrates are used to achieve energy requirements in balance with proteins and lipids. Plant starch, lactose, maltodextrin and sucrose are the preferred carbohydrates in RUTF. Free sugars should be limited and should not exceed 20 percent of total energy. Only precooked and/or gelatinized starches may be added. Glucose and fructose should not be used. Carbohydrates must adhere to the relevant Codex Alimentarius texts.

Honey should not be used in RUTF due to the risk of infant botulism from *Clostridium botulinum*.

5.2.2 Food additives

Only the food additives listed in this Section (Table A: Food additives in RUTF formulation) or in the *Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children* (CXG 10-1979)[11] may be present in the foods described in Section 4.1 of these guidelines. Other than by direct addition, an additive may be present in RUTF as a result of carry-over from a raw material or other ingredient (including food additive) used to produce the food, subject to the following conditions:

a) The additive is acceptable for use in the raw materials or other ingredients (including food additives) according to the *General Standard for Food Additives* (CXS 192-1995);[13]

b) The amount of the additive in the raw materials or other ingredients (including food additives) does not exceed the maximum use level specified in the *General Standard for Food Additives* (CXS 192-1995);[13] and

c) The food into which the additive is carried over does not contain the additive in greater quantity than would be introduced by the use of the raw materials or ingredients under proper technological conditions or good manufacturing practice, consistent with the provisions on carryover in the Preamble of the *General Standard for Food Additives* (CXS 192-1995).[13]

Table A

Food additives in RUTF formulation

Functional class	Food additive	International numbering system (INS)	Maximum use level
Emulsifier	Mono- and di-glycerides of fatty acids	471	4 000 mg/kg
	Citric and fatty acid esters of glycerol	472c	9 000 mg/kg
	Lecithin	322(i)	5 000 mg/kg
Antioxidant	Ascorbyl palmitate	304	10 mg/kg
	Tocopherol concentrate, mixed	307b	10 mg/kg
	Ascorbic acid, L-	300	GMP
Acidity regulator	Citric acid	330	GMP
Packaging gas	Nitrogen	941	GMP
	Carbon dioxide	290	GMP
Carrier	Silicon dioxide, amorphous	551	10 mg/kg

6. Nutritional composition and quality factors

The nutritional composition of RUTF shall comply with the requirements set out in the table in the annex. Furthermore, the following requirements shall be complied with.

6.1 Energy

The energy density of the formulated RUTF should be between 5.2–5.5 kcal per gram. The energy density of RUTF can be achieved during manufacturing by the addition of energy containing ingredients (i.e. fats and oils and/or digestible carbohydrates) and/or processing the basic raw materials and ingredients as indicated in Section 8.

6.2 Proteins

Protein should provide 10 percent to 12 percent of the total energy.

Protein quality should be determined using protein digestibility corrected amino acid score (PDCAAS), calculated according to the reference amino acid requirement and scoring patterns related to catch-up growth of 10 g/kg per day in the target population for RUTF which is children with SAM aged from 6 to 59 months.

For all RUTF formulations, the PDCAAS shall not be less than 0.9. The PDCAAS shall be calculated using appropriate digestibility values and the reference amino acid pattern as stipulated in the *Report of the FAO Expert Working Group: Protein quality assessment in follow-up formula for young children and ready-to-use therapeutic foods (2018).*[14]

High quality protein will be achieved with RUTF formulations containing a minimum of 50 percent of protein from milk products.

In formulations with lower PDCAAS scores, the quality and/or quantity of protein should be adjusted to achieve the desired value. The addition of limiting amino acids, solely in the L-form, shall be permitted only in amounts necessary to improve the protein quality of the RUTF.

6.3 Lipids

Lipids should provide 45 percent to 60 percent of the total energy.

6.4 Vitamins and minerals

RUTF should contain the vitamins and minerals presented in the annex: Nutritional composition of RUTF. RUTF should comply with the minimum and maximum or guidance upper levels in the annex.

6.5 Water activity

RUTF is a low-moisture food with a water activity of 0.6 or below.

7. Contaminants

It is recommended that the products covered by the provisions of these guidelines and the ingredients used in such products comply with the *General Standard for Contaminants and Toxins in Food and Feed* (CXS 193-1995),[15] *Maximum Residue Limits (MRLs) and Risk Management Recommendations (RMRs) for Residues of Veterinary Drugs in Foods* (CX/MRL 2-2021)[16] and Codex Maximum Residue Limits for Pesticides.[17]

Further guidance is given by Codex codes of practice and should be adhered to.

The product should not contain contaminants or other undesirable substances (e.g. biologically active substances, metal fragments) in amounts which may represent a risk to the health of children.

8. Processing technologies

Processing technologies used for RUTF and their ingredients shall be validated to prove that they do not alter the nutritional value of RUTF and that they allow the reduction of antinutritional factors. Milling or grinding, roasting, toasting are examples of processing technologies that can be used on ingredients.

Any technologies used should take into consideration the target group and any impact on the integrity of the nutrient content of the products. In addition to the practices described above, good hygiene practices should be implemented for manufacturing of RUTF, according to the *General Principles of Food Hygiene* (CXC 1-1969)[18] and the *Code of Hygienic Practices for Low-Moisture Foods* (CXC 75-2015)[10] to avoid cross contamination during the storage of raw materials and the manufacturing process.

RUTF and/or their raw materials should be treated with a validated microbial reduction treatment in order to inactivate pathogens such as *Salmonella*, noting that some pathogens have increased heat resistance characteristics at reduced water activities in food matrices. Commonly used microbial reduction treatments that could be applied to RUTF and/or their raw materials include both thermal and non-thermal control measures.

For additional information on validation of control measures, refer to the *Guidelines for the Validation of Food Safety Control Measures* (CXG 69-2008).[19] Additionally, refer to the *Principles and Guidelines for the Conduct of Microbiological Risk Management* (MRM) (CXG 63-2007).[20]

9. Good manufacturing practices and good hygiene practices

It is recommended that the products covered by the provisions of these guidelines be prepared and handled in accordance with the appropriate sections of the *General Principles of Food Hygiene* (CXC 1-1969),18 and *Code of Hygienic Practice for Low-Moisture Foods* (CXC 75-2015),10 and other relevant Codex texts.

The product should comply with any microbiological criteria established in accordance with the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997).[21]

The ingredients and final product should be prepared, packed, and held under sanitary conditions and should comply with relevant Codex texts.

10. Methods of analysis and sampling

It is recommended that methods of analysis and sampling of RUTF be in accordance with the *Recommended Methods of Analysis and Sampling* (CXS 234-1999).[22]

11. Packaging

It is recommended that RUTF be packaged in such a way to safeguard the hygienic and other qualities, including nutritional properties of the food, for the duration of its defined shelf life.

The packaging materials shall be made only of substances which are safe and suitable for their intended uses. Where the Codex Alimentarius Commission has established a standard for any such substance used as packaging materials, that standard shall apply.

12. Labelling

It is recommended that the labelling of RUTF for children from 6 to 59 months with SAM be in accordance with the *Standard for the Labelling of and Claims for Foods for Special Medical Purposes* (CXS 180-1991),[6] the *General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses* (CXS 146-1985),[23] and the *Guidelines on Nutrition Labelling* (CXG 2-1985).[24] Nutrition and health claims shall not be permitted for RUTF.

12.1 The name of the food

The name of the food to be declared on the label shall indicate that the food is a RUTF for children from 6 to 59 months with SAM. The appropriate designation indicating the true nature of the food should be in accordance with national legislation. The age from which the product is recommended for use shall appear in close proximity to the name of the food.

12.2 List of ingredients

The list of ingredients shall be declared in accordance with Section 4.2 of the *General Standard for the Labelling of Pre-packaged Foods (*CXS 1-1985).[25]

12.3 Additional mandatory labelling requirements

Provisions of Sections 4.4 and 4.5 of the *Standard for the Labelling of and Claims for Food for Special Medical Purposes* (CXS 180-1991)6 shall apply.

12.4 The following additional statements shall appear on the label of RUTF:

- The product is not to be used for nasogastric tube (NG tube) administration.
- The product should be used in conjunction with breastfeeding.
- Exclusive breastfeeding is recommended for the first 6 months of life, and continued breastfeeding is recommended for up to 2 years or beyond.

12.5 Instructions for use

- The label should indicate clearly from which age the product is recommended for use. This age shall not be less than 6 months for any product.
- Feeding instructions shall be given; preferably accompanied by graphical presentations.
- The time within which the product should be consumed after opening should be clearly indicated.

Annex

Table

Nutritional composition of RUTF

	Unit	Minimum	Maximum	GUL
Energy	kcal/100 g	520	550	-
Protein	g/100 kcal	2.5	3.0	-
Lipids	g/100 kcal	5	7	-
n-6 Fatty acids	mg/100 kcal	330	780	-
n-3 Fatty acids	mg/100 kcal	110	280	-
Vitamin A	µg RE/100 kcal *	145	308	-
Vitamin D	µg100 kcal **	2.7	4.2	-
Vitamin E	mg α-TE /100 kcal ***	3.6	-	-
Vitamin K	µg/100 kcal	2.7	6	-
Vitamin B1	mg/100 kcal	0.09	-	-
Vitamin B2	mg/100 kcal	0.29	-	-
Vitamin C	mg/100 kcal	9	-	-
Vitamin B6	mg/100 kcal	0.11	-	-
Vitamin B12	µg/100 kcal	0.29	-	-
Folic Acid	µg/100 kcal ****	36	-	-
Niacin	mg/100 kcal	0.91	-	-
Pantothenic Acid	mg/100 kcal	0.55	-	-
Biotin	µg/100 kcal	11	-	-
Minerals				
Sodium	mg/100 kcal	-	56	-
Potassium	mg/100 kcal	200	308	-
Calcium	mg/100 kcal	55	151	-
Phosphorus	mg/100 kcal	55	151	-
Magnesium	mg/100 kcal	15	45	-
Iron	mg/100 kcal	1.8	2.7	-
Zinc	mg/100 kcal	2	2.7	-
Copper	mg/100 kcal	0.25	0.35	-
Selenium	µg/100 kcal	3.6	8	-
Iodine	µg/100 kcal	13	27	-

* 1 µg RE = 3.33 IU Vitamin A = 1 µg trans retinol. Retinol contents shall be provided by preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration of vitamin A activity.

** 1 µg calciferol = 40 IU vitamin D. Two forms of vitamin D allowed in RUTF formulation are cholecalciferol (D3) and ergocalciferol (D2).

*** 1 mg α-tocopherol = 1 mg RRR-α-tocopherol (d-α-tocopherol) 41 mg RRR-α-tocopherol =2.00 mg *all-rac*-α-tocopherol (dl- α-tocopherol)

**** 1 µg of folic acid = 1.7 µg of dietary folate equivalents (DFE)

Notes

1 World Health Organization (WHO), UNICEF and the World Food Programme (WFP). 2007. Joint statement on the community-based management of severe acute malnutrition. Geneva.

2 FAO, WHO. 2005. *Guidelines for Vitamin and Mineral Food Supplements.* Codex Guideline, No. CXG 55-2005. Codex Alimentarius Commission. Rome.

3 FAO, WHO. 1981. *Standard for Processed Cereal-Based Foods for Infants and Young Children.* Codex Standard, No. CXS 74-1981. Codex Alimentarius Commission. Rome.

4 FAO, WHO. 1991. *Guidelines on Formulated Complementary Foods for Older Infants and Young Children.* Codex Guideline, No. CXG 8-1991. Codex Alimentarius Commission. Rome.

5 FAO, WHO. 1981. *Standard for Canned Baby Foods.* Codex Standard, No. CXS 73-1981. Codex Alimentarius Commission. Rome.

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8 FAO, WHO. 1995. *Standard for Whey Powders.* Codex Standard, No. CXS 289-1995. Codex Alimentarius Commission. Rome.

9 FAO, WHO. 2004. *Code of Hygienic Practice for Milk and Milk Products*. Codex Code of Practice, No. CXC 57-2004. Codex Alimentarius Commission. Rome.

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13 FAO, WHO. 1995.*General Standard for Food Additives*. Codex Standard, No. CXS 192-1995. Codex Alimentarius Commission. Rome.

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16 FAO, WHO. 20212021. *Maximum Residue Limits (MRLs) and Risk Management Recommendations (RMRs) for Residues of Veterinary Drugs in Foods*. Codex Guideline, No. CXM 2-2021. Codex Alimentarius Commission. Rome.

17 FAO, WHO. 2022. Codex Pesticides Residues in Food Online Database. In: *Codex Alimentarius* [online]. Rome. https://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/pt

18 FAO, WHO. 1969. *General Principles of Food Hygiene*. Codex Code of Practice, No. CXC 1-1969. Codex Alimentarius Commission. Rome.

19 FAO, WHO. 2008. *Guidelines for the Validation of Food Safety Control Measures.* Codex Guideline, No. CXG 69-2008. Codex Alimentarius Commission. Rome.

20 FAO, WHO. 2007. *Principles and Guidelines for the Conduct of Microbiological Risk Management* (MRM). Codex Guideline, No. CXG 63-2007. Codex Alimentarius Commission. Rome.

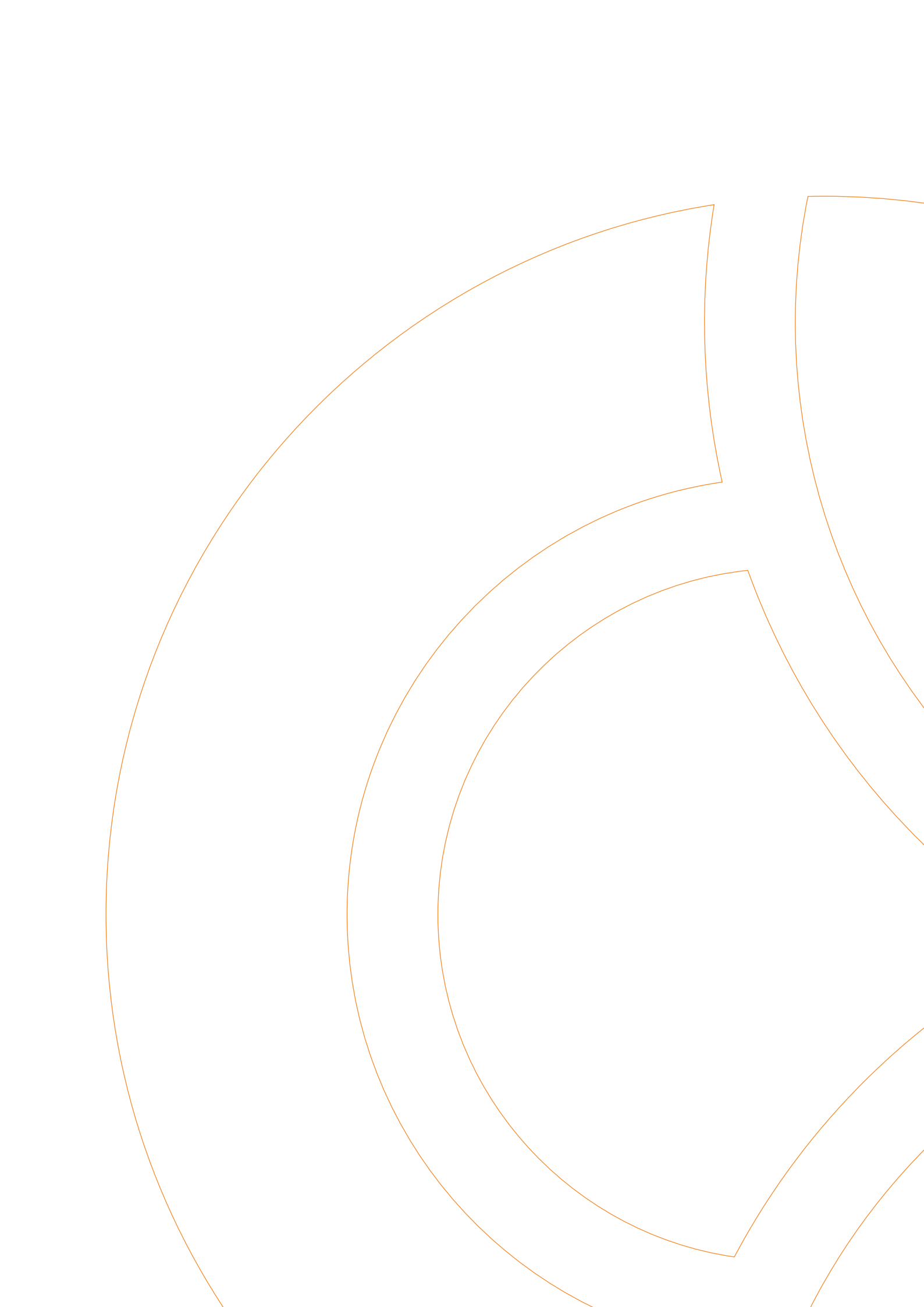
21 FAO, WHO. 1997. *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods.* Codex Guideline, No. CXG 21-1997. Codex Alimentarius Commission. Rome.

22 FAO, WHO. 1999. *Recommended Methods of Analysis and Sampling.* Codex Standard, No. CXS 234-1999. Codex Alimentarius Commission. Rome.

23 FAO, WHO. 1985. *General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses.* Codex Standard, No. CXS 146-1985. Codex Alimentarius Commission. Rome.

24 FAO, WHO. 1985. *Guidelines on Nutrition Labelling.* Codex Guideline, No. CXG 2-1985. Codex Alimentarius Commission. Rome.

25 FAO, WHO. 1985. *General Standard for the Labelling of Pre-packaged Foods.* Codex Standard, No. CXS 1-1985. Codex Alimentarius Commission. Rome.



Contacts

codex@fao.org

codexalimentarius.org

twitter.com/FAOWHOCodex

youtube.com/user/CodexAlim

Food and Agriculture Organization of the United Nations
Rome, Italy

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