

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES**

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Appendix 1

PROPOSED DRAFT GUIDELINES FOR READY TO USE THERAPEUTIC FOODS (RUTF)

1. PREAMBLE

Children affected by severe acute malnutrition (SAM) need safe, palatable foods with a high energy content and adequate amounts of vitamins, minerals and other nutrients. Children with SAM need efficacious and timely treatment and RUTF is may be part of the care. RUTF are primarily intended for children with uncomplicated SAM from 6-59 months. Although RUTF may be given to other age groups with various forms of malnutrition at the implementation level, the primary focus for these guidelines is children with SAM from 6-59 months. [Since RUTF are prescribed according to weight, National Authorities may decide to include the provision of RUTF in their national protocols for use by other age groups].

These guidelines provide guidance for the production and labelling of RUTF. The guidelines are intended to facilitate the harmonization of requirements for RUTF at the international level and may provide assistance to governments wishing to establish national regulations. The guidelines are also intended for use as an instrument designed to avoid or remove difficulties which may be created by diverging legal, administrative and technical approaches to RUTF and by varying definitions and nutrient compositions of RUTF. These guidelines should be used in accordance with technical recommendations of that are based on the relevant evidence and related Codex texts/documents by WHO, UNICEF and WFP¹. Governments and other users should ensure adequate provisions are made for competent technical experts for the appropriate use of these guidelines.

¹) A Joint Statement by the World Health Organization, the World Food Programme, the United Nations System Standing Committee on Nutrition and the United Nations Children's Fund. 2007. *Community-Based Management of Severe Acute Malnutrition*; A Joint Statement by the World Health Organization and the United Nations Children's Fund. 2009. *Child growth standards and the identification of severe acute malnutrition in infants and children*, Geneva: World Health Organization; World Health Organisation. 2013. *Guideline: Updates on the management of severe acute malnutrition in infants and children*, Geneva: World Health Organization; World Health Organisation. 2003. *Global Strategy for Infant and Young Child Feeding*, Geneva: World Health Organization; World Health Organisation. [1981. *International code of marketing of breast-milk substitutes*, Geneva: World Health Organization and subsequent relevant WHA Resolutions on infant and young child feeding]; *Code of Ethics for International Trade in Food including Concessional and Food Aid Transactions* (CXC 20-1979); Food and Agriculture Organisation and World Health Organisation. 2016. *FAO/WHO Microbial safety of lipid-based ready-to-use foods for management of moderate acute malnutrition and severe acute malnutrition*, Rome: Food and Agriculture Organisation.

2. PURPOSE OF THE GUIDELINES

To provide guidance on technical and nutritional aspects of the production of Ready to Use Therapeutic Foods for children from the age of 6 to 59 months with severe acute malnutrition, 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 Ready to Use Therapeutic Foods for children from age 6 to 59 months with severe acute malnutrition. Ready-to-Use Supplementary Foods (RUSF), micronutrient supplements², processed cereal based foods³, formulated complementary foods for older infants and young children⁴, canned baby foods⁵ are not covered by these guidelines.

²Guidelines for Vitamin and Mineral Food Supplements (CXG55-2005)

³Standard for Processed Cereal-Based Foods for Infants and Young Children (CXS 74-1981)

⁴Guidelines on Formulated Complementary Foods for Older Infants and Young Children (CXG 8-1991)

⁵Standard for Canned Baby Foods (CXS 73-1981)

4. DESCRIPTION

4.1 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 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. The 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).

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) and the *Standard for Whey Powders* (CXS 289-1995), and other Codex milk and milk product standards as well as other guidelines and Codes of Practice recommended by 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) and the *Code of Hygienic Practices for Low-Moisture Foods* (CXC 75-2015).

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 ~~pulses~~ seeds must be appropriately processed to reduce, as much as possible, the anti-nutritional factors normally present, such as phytate, lectins (haemagglutinins), trypsin, ~~and~~ chymotrypsin inhibitors and phytoestrogens.

[Lectins can be reduced by moist heat treatment. Trypsin inhibitor activity may be reduced to acceptable levels by heating to high temperatures or by prolonged boiling. Phytate can be reduced enzymatically or by soaking or fermentation. Phytoestrogens can be reduced by fermentation. Field beans or Faba 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

All milled cereals 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 anti-nutritional 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 salts of minerals that are insoluble or requiring 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-metabolisable base. The non-metabolizable base can be approximated by the formula: estimated absorbed millimoles (sodium + potassium + calcium + magnesium) - (phosphorus + chloride).]

All added [micronutrients]/[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). Examples of vitamin and 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). [The amount of [micronutrients]/[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 Available Carbohydrates⁶

[Carbohydrates are used to complement other ingredients needed to reach the protein and lipid specifications and to increase palatability of RUTF.] ~~[The palatability of the RUTF can be increased by the addition of available carbohydrates.]~~ Available 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*.

⁶Sucrose, plant starch, maltodextrin, lactose ~~should be~~ are the preferred carbohydrates in RUTF. Fructose, glucose and corn syrup as ingredients should be avoided in RUTF, because of potential adverse effects in SAM children. Only precooked and/or gelatinized starches ~~[gluten-free] by nature~~ may be added. [Any carbohydrate added for sweetness should be used sparingly].

5.2.2 Food Additives and Flavours

[This section will make reference to the *General Standard for Food Additives* (CXS 192-1995)]. ¹

5.3 The Use of other Matrices in RUTF formulation

RUTF may be manufactured with formulations different from the one laid down in these guidelines provided that these formulations comply with Section 3 of the *Standard for Labelling of and Claims for Foods for Special Medical Purposes* (CXS 180-1991), [\[particularly regarding their use that should have been demonstrated, by scientific evidence, to be safe and beneficial in meeting the nutritional requirements of the persons for whom they are intended.\]](#)

6. NUTRITIONAL COMPOSITION AND QUALITY FACTORS

6.1 Energy

The energy density of the formulated RUTF should be between 5.2 - to 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

¹ See recommendation 4 in the report above

Protein should provide 10% - 12% (68.5kcal/100g – 86.67kcal/100g) of the total energy. ["at least 50% of protein is provided by milk products"]

6.3 Lipids

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

The level of linoleic acid should not be less than ~~333~~ 316 mg per 100 kcal and shall not be more than 1115 mg per 100 kcal. The level of alpha-linolenic acid should not be less than 33 mg/100kcal and shall not be more than 280 mg per 100kcal. The level of linoleic acid should ensure a ratio between linoleic acid and alpha-linolenic acid of between ~~5:1~~ 1.1 and 15:1.

6.4 Please see Annex “Nutrition Composition for RUTF”.

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), Maximum Residue Limits (MRLs) and Risk Management Recommendations (RMRs) for Residues of Veterinary Drugs in Foods (CAC/MRL 2-2015) and Codex Maximum Residue Limits for Pesticides].

[Other Contaminants

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. The product covered by the provisions of these Guidelines shall comply with those maximum residue limits and maximum levels established by the Codex Alimentarius Commission]. [~~A maximum of 10 ppb (µg/kg) for aflatoxin is allowed in the RUTF products.~~]

8. PROCESSING TECHNOLOGIES

[Any technologies described below are given as examples of treatment mainly on raw materials. Any technologies used for raw materials for RUTF have to be validated according to *Guidelines for the Validation of Food Safety Control Measures* (CXG 69-2008)]. [In addition to the practices described below, Good Hygiene Practices (*General principles of food hygiene* (CXC 1-1969)) should be implemented to avoid cross contamination during the packing and storage of raw materials.]

8.1 Preliminary Treatment of Raw Materials

Cereals, legumes, pulses and oilseeds should first be treated to obtain wholesome and clean raw materials of good quality. Such treatments include, but are not limited to:

- ~~[Cleaning or washing: to eliminate dirt, damaged grains, foreign grains and noxious seeds, insects and insect excreta and any adhering material.]~~
- **Dehulling:** when necessary, pulses, legumes, oilseeds and certain cereals such as oats, barley, sorghum, millet and teff may be dehulled as completely as is feasible to reduce the fibre content to acceptable levels and to decrease, or if possible, to eliminate phytates, tannins and other phenolic materials, trypsin and chymotrypsin inhibitors which can lower the protein digestibility and amino acid bioavailability and mineral absorption.
- **Degermination:** where necessary and appropriate, degermination of wheat, corn, soy and other crops should be considered in order to reduce the phytate content.

8.2 Milling

- Milling or grinding of suitable raw materials should be carried out in such a way as to minimize the loss of nutritional value and to avoid undesirable changes in the technological properties of the ingredients.
- Dry raw materials may be milled together, if technologically feasible, or mixed after milling or grinding.
- Formulations containing milled cereals, legumes, pulses and/or oilseeds that have not been otherwise processed require adequate boiling to gelatinize the starch portions and/or eliminate anti-nutritional factors present in cereals, legumes and pulses. Boiling improves the digestibility and absorption of nutrients.

- ~~[The bulkiness of foods from food formulations containing dry ingredients obtained by milling of the raw materials can be reduced by adding, during the formulation, adequate amounts of enzymes such as alpha-amylase which, during the slow heating to boiling, predigest partially the starch and reduce the amount of water needed for the preparation of the food.]~~

8.3 Toasting

- Toasting (dry heating) enhances the flavour and the taste of the food through dextrinization of starch. It also improves digestibility. ~~[and contributes to reducing the bulkiness of the formulated food. Moreover, it reduces microorganisms and enzyme activity and destroys insects, thus improving keeping qualities.]~~
- Protein damage due to the Maillard reaction may occur in the presence of reducing carbohydrates. The toasting process should therefore be carefully controlled.
- Pulses as well as oilseeds such as soya beans, groundnuts and sesame seeds can be toasted as whole grains directly or after soaking.
- Toasted raw materials can be milled or ground for use as ingredients.
- [The use of appropriate enzymes may be considered to decrease anti-nutrients in ingredients.]

[8.4 Sprouting, Malting and Fermentation

- ~~Cereals and pulses can be induced to germinate by soaking or humidifying. It is necessary, however, to ensure that growth of mycotoxin-producing microorganisms does not occur. The action of natural amylases contained in the grains results in the pre-digestion of the starchy portion of the grain (dextrinization) thus reducing the bulk of the food when prepared for feeding and, ultimately, increasing the nutrient density of the food. Sprouting, malting and fermentation can induce hydrolysis of phytates and decrease its inhibitory effect on mineral absorption, and may improve B vitamin content.~~
- ~~During the germination process, the seed coat of the grain splits and can be removed by washing. The malted raw material is milled or ground after drying.]~~

8.5 Other Processing Technologies

Whenever feasible, 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 or their raw materials include both thermal (e.g. roasting, steam treatment followed by a drying step) and non-thermal (e.g. antimicrobial fumigation) control measures. [These practices should be in accordance with the *Guidelines for the Validation of Food Safety Control Measures* (CXG 69-2008) and *Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)* (CXG 63-2007)]. ~~should be adhered to.]~~

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), and *Code of Hygienic Practice for Low-Moisture Foods* (CXC 75-2015).

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) and Annex 1 of *Code of Hygienic Practice for Low-Moisture Foods* (CXC 75-2015).

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), *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995), *The Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997), *Code of Hygienic Practice for Low Moisture Foods* (CXC 75-2015), and other relevant Codex Alimentarius texts. When needed, specific methods of analysis should be developed in accordance with appropriate *Guidelines on Measurement Uncertainty* (CXG 54-2004), *Protocol for the Design, Conduct and Interpretation of Method Performance Studies* (CXG 64-1995), and Harmonized IUPAC.

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 be in accordance with the *Standard for the Labelling of and Claims for Foods for Special Medical Purposes* (CXS 180-991), ~~*Codex General Standard for the Labelling of Pre-packaged Foods* (CODEX STAN 1-1985)~~, the *General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses* (CXS 146-1985), [~~*Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997)~~] and *Guidelines on Nutrition Labelling* (CXG 2- 1985).

The Name of the Food

The name of the food to be declared on the label shall indicate that the food is a Ready-To-Use Therapeutic Food for Children from 6 to 59 months. 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.

List of Ingredients

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

Additional Mandatory Labelling Requirements

The following statements shall appear on the label of RUTF:

- "USE UNDER MEDICAL SUPERVISION" shall appear on the label in bold letters in an area separated from the written, printed, or graphic information.
- "For the dietary management of severe acute malnutrition" shall appear on the label.
- A prominent warning statement consisting of an explanatory statement in bold letters indicating that RUTF are for special medical purposes and may pose a health hazard when consumed by individuals who do not have the disease(s), disorder(s) or medical condition(s) for which the food is intended.
- The product is not to be used for parenteral, rectal or Nasogastric Tube (NG tube) administration.
- A statement indicating whether the product is or is not intended as the sole source of nutrition.
- A statement indicating that RUTF are not breastmilk substitutes and shall not be presented as such.
- [Exclusive breastfeeding is recommended for the first 6 months of life, and continued breastfeeding is recommended for at least 24 months.]

Instructions for use

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

Table: Nutritional Composition for RUTF

Energy			
Unit	Minimum	Maximum	GUL
g/100g	5.2	5.5	-
g/100kcal	520	550	-
Protein			
Unit	Minimum	Maximum	GUL
g/100g	42.8 13	46.2 16.5	-
g/100kcal	2.3 2.4	3.4 3.2	-
Lipids			
Unit	Minimum	Maximum	GUL
g/100g	26 25.8	37 36.3	-
g/100kcal	5 4.7	6.7 7	-
n-6 Fatty acids			
Unit	Minimum	Maximum	GUL
	3	10	-
mg/100g	3 1731.6	40 6111	-
mg/100kcal	576.9 316	1818.2 1114	-
n-3 Fatty acids			
Unit	Minimum	Maximum	GUL
Kcal/100kcal	0.3	2.5	-
mg/100g	0.3 172	2.5 1529	-
mg/100kcal	57.69 33	454.5 278	-
Vitamin A			
Unit	Minimum	Maximum	GUL
mg RE/100g	0.8	[1.1] OR [1.2]	-
mg/ RE/100kcal	0.15	[0.2] OR [0.22]	-
² µg RE/100kcal	150	[200] OR [220]	-
² 1µg 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.			
Vitamin D			
Unit	Minimum	Maximum	GUL

³ µg/100 g	15	[20] OR [22]	[30]
³ µg/100 kcal	2.7	[3.6] OR [4]	-

³ 1 µg cholecalciferol = 40 IU vitamin D. [Two forms of Vitamin D allowed in RUTF formulation are cholecalciferol (D3) and ergocalciferol (D2).]

Vitamin E

Unit	Minimum	Maximum	GUL
⁴ mg/100 g	20	-	-
⁴ mg α-TE /100 kcal	4- 3.84	-	-
⁴ 1 mg α-tocopherol = 1 mg RRR-α-tocopherol (d-α-tocopherol)			
⁴ 1 mg RRR-α-tocopherol = 2.00 mg <i>all-rac</i> -α-tocopherol (di- α-tocopherol)			

Vitamin K

Unit	Minimum	Maximum	GUL
µg/100 g	15	30	-
µg/100 kcal	2.9	5.5	-

Vitamin B1

Unit	Minimum	Maximum	GUL
mg/100 g	0.5	-	-
mg/100 kcal	0.1	-	-

Vitamin B2

Unit	Minimum	Maximum	GUL
mg/100 g	1.6	-	-
mg/100 kcal	0.3	-	-

Vitamin C

Unit	Minimum	Maximum	GUL
mg/100 g	50	-	-
mg/100 kcal	9.6	-	-

Vitamin B6

Unit	Minimum	Maximum	GUL
mg/100 g	0.6	-	-
mg/100 kcal	0.12	-	-

Vitamin B12

Unit	Minimum	Maximum	GUL
µg/100 g	1.6	-	-
µg/100 kcal	0.3	-	-

Folic Acid

Unit	Minimum	Maximum	GUL
⁵ µg/100 g	200	-	-
⁵ µg/100 kcal	38.5	-	-

⁵ 1 µg of folic acid = 1.7 µg of Dietary Folate Equivalents (DFE)

Niacin

Unit	Minimum	Maximum	GUL
mg/100 g	5	-	-
mg/100 kcal	0.96 1	-	-

Pantothenic Acid

Unit	Minimum	Maximum	GUL
mg/100 g	3	-	-
mg/100 kcal	0.6	-	-

Biotin

Unit	Minimum	Maximum	GUL
µg/100 g	60	-	-
µg/100 kcal	11.5	-	-

Sodium

Unit	Minimum	Maximum	GUL
mg/100 g	-	290	-
mg/100 kcal	-	53	-

Potassium

Unit	Minimum	Maximum	GUL
mg/100 g	1,100	1,400	-
mg/100 kcal	212	255	-

Calcium

Unit	Minimum	Maximum	GUL
mg/100 g	300	[600] or [785]	-
mg/100 kcal	58	[109] or [143]	-

Phosphorus

Unit	Minimum	Maximum	GUL
mg/100 g	300	[600] or [785]	-
mg/100 kcal	58 57.6	[109] or [143]	-

Magnesium

Unit	Minimum	Maximum	GUL
mg/100 g	80	[140] or [235]	-
mg/100 kcal	15.4	[26] [25.4] or [43] [42.7]	-

Iron

Unit	Minimum	Maximum	GUL
mg/100 g	10	14	-
mg/100 kcal	1.9	2.6	-

Zinc

Unit	Minimum	Maximum	GUL
mg/100 g	11	14	-
mg/100 kcal	2	2.6 2.5	-

Copper

Unit	Minimum	Maximum	GUL
mg/100 g	1.4	1.8	-
mg/100 kcal	0.27	0.33	-

Selenium

Unit	Minimum	Maximum	GUL
µg /100 g	20	40	-
µg /100 kcal	4- 3.84	7 7.3	-

Iodine

Unit	Minimum	Maximum	GUL
µg /100 g	70	140	-
µg /100 kcal	13.46 13.5	25.5	-

Moisture Content

Unit	Minimum	Maximum	GUL
[Water activity (aW)]	0.2	2.5 0.45	-