

# Statutory Instrument 1997 No. 2042

## The Processed Cereal-based Foods and Baby Foods for Infants and Young Children Regulations 1997

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### STATUTORY INSTRUMENTS

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**1997 No. 2042**

### **FOOD**

## The Processed Cereal-based Foods and Baby Foods for Infants and Young Children Regulations 1997

<i>Made</i>	<i>21st August 1997</i>
<i>Laid before Parliament</i>	<i>21st August 1997</i>
<i>Coming into force</i>	<i>31st March 1999</i>

The Minister of Agriculture, Fisheries and Food, the Secretary of State for Health and the Secretary of State for Wales, acting jointly, in relation to England and Wales, and the Secretary of State for Scotland in relation to Scotland, in exercise of the powers conferred on them by sections 6(4), 16(1)(a), (e) and (f), 17(1), 26(1)(a) and (3) and 48(1) of the Food Safety Act 1990<sup>[1]</sup> and of all other powers enabling them in that behalf, after consultation in accordance with section 48(4) of that Act with such organisations as appear to them to be representative of interests likely to be substantially affected by the Regulations, hereby make the following Regulations:

### **Title, commencement and interpretation**

**1. - (1) These Regulations may be cited as the Processed Cereal-based Foods and Baby Foods for Infants and Young Children Regulations 1997 and shall come into force on**

**31st March 1999.**

**(2) In these Regulations, unless the context otherwise requires -**

**"the Act" means the Food Safety Act 1990;**

**"baby foods" means foods for particular nutritional use fulfilling the particular requirements of infants and young children in good health and intended for use by infants while they are being weaned, and by young children as a supplement to their diet or for their progressive adaptation to ordinary food other than processed cereal-based foods;**

**"food authority" does not include -**

**(a) the council of a district in a non-metropolitan county in England except where the county functions have been transferred to that council pursuant to a structural change; or**

**(b) the appropriate Treasurer referred to in section 5(1)(c) of the Act (which deals with the Inner and Middle Temple);**

**"processed cereal-based foods" means foods for particular nutritional use within the categories in Part I of Schedule 1 fulfilling the particular requirements of infants and young children in good health and intended for use by infants while they are being weaned, and by young children as a supplement to their diet or for their progressive adaptation to ordinary food; and**

**"sell" includes possess for sale, and offer, expose or advertise for sale and "sale" and "sold" shall be construed accordingly.**

**(3) Other expressions used in these Regulations and in Commission Directive 96/5/EC[2] on processed cereal-based foods and baby foods for infants and young children have, in so far as the context admits, the same meaning as they bear in that Directive.**

**(4) Any reference in these Regulations to a numbered regulation or Schedule shall be construed as a reference to the regulation or Schedule bearing that number in these Regulations and any reference in a Schedule to a numbered Part shall be construed as a reference to the Part of that Schedule bearing that number.**

### **Exemption**

**2. These Regulations shall not apply to any baby food which is a milk intended for young children.**

### **Conditions for the sale of processed cereal-based foods and baby foods**

**3. No person shall sell any processed cereal-based food or baby food unless -**

**(a) it is labelled in accordance with regulation 4; and**

**(b) it complies with the requirements as to manufacture and composition set out in regulation 5.**

### **Labelling**

**4. - (1) Processed cereal-based food and baby food shall be labelled with the following particulars -**

**(a) a statement as to the appropriate age (which shall be not less than four months) from which the food may be used, regard being had to its composition, texture or other particular properties;**

**(b) information as to the presence or absence of gluten if the age stated pursuant to sub-paragraph (a) above is less than six months;**

**(c) the available energy value expressed in kJ and kcal, and the protein, carbohydrate and fat content, expressed in numerical form, per 100 g or 100 ml of the food as sold and, where appropriate, per specified quantity of the food as proposed for consumption;**

**(d) the average quantity, expressed in numerical form, per 100 g or 100 ml of the food as sold and, where appropriate, per specified quantity of the food as proposed for consumption, of each mineral substance and of each vitamin in respect of which a maximum or a minimum compositional requirement is specified in -**

**(i) Part II of Schedule 1 in the case of processed cereal-based foods; and**

**(ii) Schedule 2 in the case of baby foods; and**

**(e) if preparation of the food is necessary, appropriate instructions for preparation and a statement as to the importance of following those instructions.**

**(2) Subject to paragraph (1)(d) above, no person shall label processed cereal-based food or baby food with the average quantity of any nutrient specified in Schedule 4 unless -**

**(a) that average quantity is expressed in numerical form, per 100 g or 100 ml of the food as sold and, where appropriate, per specified quantity of the food as proposed for consumption; and**

**(b) in the case of a mineral substance or vitamin, it is a mineral substance or vitamin other than one referred to in paragraph (1)(d) above.**

**(3) Where, pursuant to paragraph (1)(d) or paragraph (2) above, processed cereal-based food or baby food is labelled with the average quantity, per 100 g or 100 ml of the food as sold, and where appropriate, per specified quantity of the food as proposed for consumption, of any vitamin or mineral which is specified in Schedule 5, the labelling of the food shall not express that average quantity as a percentage of the reference value specified in Schedule 5 in relation to that vitamin or mineral unless the quantity present is equal to 15% or more of the reference value.**

**Manufacture and composition of processed cereal-based foods and baby foods**  
**5. No person shall manufacture any processed cereal-based food or baby food -**

**(a) from any ingredient other than one whose suitability for particular nutritional use by infants and young children has been established by generally accepted scientific data;**

- (b) which does not comply with the compositional requirements specified in Part II of Schedule 1, as read with Schedule 3 in the case of processed cereal-based foods and Schedule 2 in the case of baby foods;**
- (c) which contains any added nutritional substance other than a nutritional substance listed in Schedule 4; or**
- (d) which contains any substance in such quantity as to endanger the health of infants or young children.**

**Offences and penalties**

**6. - (1) If any person contravenes regulation 3, 4 or 5 he shall be guilty of an offence and liable on summary conviction to a fine not exceeding level 5 on the standard scale.**

**(2) Where an offence under these Regulations is committed in Scotland by a Scottish partnership and is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of a partner, he as well as the partnership shall be guilty of the offence and be liable to be proceeded against and punished accordingly.**

**Enforcement**

**7. Each food authority shall enforce and execute these Regulations in its area.**

**Defence in relation to exports**

**8. - (1) In any proceedings for an offence under these Regulations it shall be a defence for the person charged to prove -**

- (a) that the food in respect of which the offence is alleged to have been committed was intended for export to a country which has legislation analogous to these Regulations and it complies with that legislation; and**
- (b) that the legislation complies with the provisions of Commission Directive 96/5/EC[3] on processed cereal-based foods and baby foods for infants and young children, in the case of export to an EEA State.**

**(2) In this regulation -**

**"EEA State" means a state which is a contracting party to the EEA Agreement; and**

**"EEA Agreement" means the Agreement on the European Economic Area[4] signed at Oporto on 2nd May 1992 as adjusted by the Protocol[5] signed at Brussels on 17th March 1993.**

**Application of various sections of the Food Safety Act 1990**

**9. The following provisions of the Act shall apply for the purposes of these Regulations which application shall, in the case of section 21, be as that section applies for the purposes of section 8, 14 or 15 of the Act and unless the context otherwise requires any reference in them to the Act or Part thereof shall be construed as a reference to these Regulations -**

**section 2 (extended meaning of `sale' etc.);**

**section 3 (presumption that food intended for human consumption);**

- section 20 (offences due to fault of another person);**
- section 21 (defence of due diligence);**
- section 22 (defence of publication in the course of a business);**
- section 30(8) (which relates to documentary evidence);**
- section 33 (obstruction etc. of officers);**
- section 36 (offences by bodies corporate); and**
- section 44 (protection of officers acting in good faith).**

*Jeff Rooker*  
**Minister of State, Ministry of Agriculture, Fisheries and Food**  
**24th July 1997**

**Signed by authority of the Secretary of State for Health**

*Baroness Jay*  
**Minister of State for Public Health, Department of Health**  
**7th August 1997**

**Signed by authority of the Secretary of State for Wales**

*Win Griffiths*  
**Parliamentary Under Secretary of State, Welsh Office**  
**25th July 1997**

*Sam Galbraith*  
**Parliamentary Under Secretary of State, Scottish Office**  
**21st August 1997**

**SCHEDULE 1**

**Regulation 1, 4(1)(d)(i) and 5(b)**

**PROCESSED CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN**

**PART I**

**categories of processed cereal-based foods for infants and young children**

- 1. Simple cereals which are or have to be reconstituted with milk or other appropriate nutritious liquids.**
- 2. Cereals with an added high protein food which are or have to be reconstituted with water or other protein-free liquid.**
- 3. Pastas which are to be used after cooking in boiling water or other appropriate liquids.**
- 4. Rusks and biscuits which are to be used either directly or after pulverisation with the addition of water, milk or other suitable liquids.**

**PART II**

**essential composition of processed cereal-based foods for infants and young children**

**The requirements concerning nutrients refer to the products ready for use, marketed as such or reconstituted as instructed by the manufacturer.**

**1. Cereal content**

**Processed cereal-based foods are prepared primarily from one or more milled cereals and/or starchy root products.**

**The amount of cereal and/or starchy root shall not be less than 25% of the final mixture on a dry weight for weight basis.**

**2. Protein**

**2.1. For products mentioned in paragraph 2 and 4 of Part I the protein content shall not exceed 1.3 g/100 kJ (5.5 g/100 kcal).**

**2.2. For products mentioned in paragraph 2 of Part I the added protein shall not be less than 0.48 g/100 kJ (2 g/100 kcal).**

**2.3. For biscuits mentioned in paragraph 4 of Part I made with the addition of a high protein food, and presented as such, the added protein shall not be less than 0.36 g/100 kJ (1.5 g/100 kcal).**

**2.4. The chemical index of the added protein shall be equal to at least 80% of that of the reference protein (casein as defined in Schedule 3), or the protein efficiency ratio (PER) of the protein in the mixture shall be equal to at least 70% of that of the reference protein. In all cases, the addition of amino acids is permitted solely for the purpose of improving the nutritional value of the protein mixture, and only in the proportions necessary for that purpose.**

**3. Carbohydrates**

**3.1. If sucrose, fructose, glucose, glucose syrups or honey are added to products mentioned in paragraphs 1 and 4 of Part I:**

- the amount of added carbohydrates from these sources shall not exceed 1.8 g/100 kJ (7.5 g/100 kcal),
- the amount of added fructose shall not exceed 0.9 g/100 kJ (3.75 g/100 kcal).

**3.2. If sucrose, fructose, glucose syrups or honey are added to products mentioned in paragraph 2 of Part I:**

- the amount of added carbohydrates from these sources shall not exceed 1.2 g/100 kJ (5 g/100 kcal),
- the amount of added fructose shall not exceed 0.6 g/100 kJ (2.5 g/100 kcal).

#### **4. Fat**

**4.1. For products mentioned in paragraphs 1 and 4 of Part I the fat content shall not exceed 0.8 g/100 kJ (3.3 g/100 kcal).**

**4.2. For products mentioned in paragraph 2 of Part I the fat content shall not exceed 1.1 g/100 kJ (4.5 g/100 kcal). If the fat content exceeds 0.8 g/100 kJ (3.3 g/100 kcal):**

- (a) the amount of lauric acid shall not exceed 15% of the total fat content;**
- (b) the amount of myristic acid shall not exceed 15% of the total fat content;**
- (c) the amount of linoleic acid (in the form of glycerides=linoleates) shall not be less than 70 mg/100 kJ (300 mg/100 kcal) and shall not exceed 285 mg/100 kJ (1200 mg/100 kcal).**

#### **5. Minerals**

##### **5.1. Sodium**

- sodium salts may only be added to processed cereal-based foods for technological purposes,
- the sodium content of processed cereal-based foods shall not exceed 25 mg/100 kJ (100 mg/100 kcal).

##### **5.2. Calcium**

**5.2.1. For products mentioned in paragraph 2 of Part I the amount of calcium shall not be less than 20 mg/100 kJ (80 mg/100 kcal).**

**5.2.2. For products mentioned in paragraph 4 of Part I manufactured with the addition of milk (milk biscuits) and presented as such, the amount of calcium shall not be less than 12 mg/100 kJ (50 mg/100 kcal).**

#### **6. Vitamins**

**6.1. For processed cereal-based foods the amount of thiamin shall not be less than 25 µg/100 kJ (100 µg/100 kcal).**

**6.2. For products mentioned in paragraph 2 of Part I:**

	<i>Per 100 KJ</i>		<i>Per 100 kcal</i>	
	<i>Minimum</i>	<i>Maximum</i>	<i>Minimum</i>	<i>Maximum</i>
Vitamin A (µg RE)(1)	14	43	60	180
Vitamin D (µg)(2)	0.25	0.75	1	3

**(1) REµ all trans retinol equivalents**

**(2)In the form of cholecalciferol, of which 10 µg=400 i.u. of vitamin D**

**These limits are also applicable if vitamins A and D are added to other processed cereal-based foods.**

**SCHEDULE 2**

**Regulation 4(1)(d)(i)(ii) and 5(b)**

**ESSENTIAL COMPOSITION OF BABY FOODS FOR INFANTS AND YOUNG CHILDREN**

**The requirements concerning nutrients refer to the products ready for use, marketed as such or reconstituted as instructed by the manufacturer.**

**1. Protein**

**1.1. If meat, poultry, fish, offal or other traditional source of protein are the only ingredients mentioned in the name of the product, then:**

- the named meat, poultry, fish, offal or other traditional protein source, in total, shall constitute not less than 40% by weight of the total product,**
- each named meat, poultry, fish, offal or other traditional source of protein shall constitute not less than 25%, by weight, of total named protein sources,**
- the total protein from the named sources shall not be less than 1.7 g/100 kJ (7 g/100 kcal).**

**1.2. If meat, poultry, fish, offal or other traditional source of protein, singularly or in combination, are mentioned first in the name of the product, whether or not the product is presented as a meal, then:**



- the named poultry, fish, offal or other traditional protein source, in total, shall constitute not less than 10% by weight of the total product,

- each named meat, poultry, fish, offal or other traditional source of protein shall constitute not less than 25%, by weight, of total named protein sources,

- the protein from the named sources shall not be less than 1 g/100 kJ (4 g/100 kcal).

**1.3. If meat, poultry, fish, offal or other traditional source of protein, singularly or in combination are mentioned, but not first, in the name of the product, whether or not the product is presented as a meal, then:**

- the named meat, poultry, fish, offal or other traditional protein source, in total, shall constitute not less than 8% by weight of the total product,

- each named meat, poultry, fish, offal or other traditional source of protein shall constitute not less than 25%, by weight, of total named protein sources,

- the total protein from the named sources shall not be less than 0.5 g/100 kJ (2.2 g/100 kcal),

- the total protein in the product from all sources shall not be less than 0.7 g/100 kJ (3 g/100 kcal).

**1.4. If the product is designated on the label as a meal, but does not mention meat, poultry, fish, offal or other traditional source of protein in the name of the product, the total protein in the product from all sources shall not be less than 0.7 g/100 kJ (3 g/100 kcal).**

**1.5. The addition of amino acids is permitted solely for the purpose of improving the nutritional value of the protein present, and only in the proportions necessary for that purpose.**

## **2. Carbohydrates**

**The quantities of total carbohydrates present in fruit and vegetable juices and nectars, fruit-only dishes, and desserts or puddings shall not exceed:**

- 10 g/100 ml for vegetable juices and drinks based on them,

- 15 g/100 ml for fruit juices and nectars and drinks based on them,
- 20 g/100 g for fruit-only dishes,
- 25 g/100 g for desserts and puddings,
- 5 g/100 g for other non-milk-based drinks.

**3. Fat**

**3.1. For products referred to in paragraph 1.1. of this Schedule if meat or cheese are the only ingredients or are mentioned first in the name of a product the total fat in the product from all sources shall not exceed 1.4 g/100 kJ (6 g/100 kcal).**

**3.2. For all other products the total fat in the product from all sources shall not exceed 1.1 g/100 kJ (4.5 g/100 kcal).**

**4. Sodium**

**4.1. The final sodium content in the product shall be either not more than 48 mg/100 kJ (200 mg/100 kcal) or not more than 200 mg per 100 g. However if cheese is the only ingredient mentioned in the name of the product, the final sodium content in the product shall not be more than 70 mg/100 kJ (300 mg/100 kcal).**

**4.2. Sodium salts may not be added to products based on fruit, nor to desserts, puddings except for technological purposes.**

**5. Vitamins**

**Vitamin C -**

**In a fruit juice, nectar, or vegetable juice the final content of vitamin C in the product shall be either not less than 6 mg/100 kJ (25 mg/100 kcal) or not less than 25 mg per 100 g.**

**Vitamin A -**

**In vegetable juices, the final content of vitamin A in the product shall be not less than 25 µg RE/100 kJ (100 µg RE/100 kcal) and, for the purposes of this paragraph, RE=all trans retinol equivalents.**

**Vitamin A shall not be added to other baby foods.**

**Vitamin D**

-

**Vitamin D shall not be added to baby foods.**

SCHEDULE 3

Regulation 5(b) and paragraph 2.4. of Schedule 1

AMINO ACID COMPOSITION OF CASEIN

<i>Amino Acid</i>	<i>(g per 100 g of protein)</i>
Arginine	3.7
Cystine	0.3
Histidine	2.9
Isoleucine	5.4
Leucine	9.5
Lysine	8.1
Methionine	2.8
Phenylalanine	5.2
Threonine	4.7
Tryptophan	1.6
Tyrosine	5.8
Valine	6.7

SCHEDULE 4

Regulation 4(2) and 5(c)

NUTRITIONAL SUBSTANCES

1. Vitamins

**Vitamin A**

**Retinol**  
**Retinyl acetate**  
**Retinyl palmitate**  
**Betacarotene**

**Vitamin D**

**Vitamin D<sub>2</sub> (=ergocalciferol)**  
**Vitamin D<sub>3</sub> (=cholecalciferol)**

**Vitamin B<sub>1</sub>**

**Thiamin hydrochloride**  
**Thiamin mononitrate**

**Vitamin B<sub>2</sub>**

**Riboflavin****Riboflavin-5'-phosphate, sodium**

**Niacin**

**Nicotinamide**  
**Nicotinic acid**

**Vitamin B<sub>6</sub>**

**Pyridoxine hydrochloride**  
**Pyridoxine-5-phosphate**  
**Pyridoxine dipalmitate**

**Pantothenic acid**

**D-pantothenate, calcium**  
**D-pantothenate, sodium**  
**Dexpanthenol**

**Folate**

**Folic acid**

**Vitamin B<sub>12</sub>**

**Cyanocobalamin**  
**Hydroxocobalamin**

**Biotin**

**D-biotin**

**Vitamin C**

**L-ascorbic acid**  
**Sodium L-ascorbate**  
**Calcium L-ascorbate**  
**6-palmityl-L-ascorbic acid (ascorbyl palmitate)**  
**Potassium ascorbate**

**Vitamin K**

**Phylloquinone (phytomenadione)**

**Vitamin E**

**D-alpha tocopherol**

**DL-alpha tocopherol**

**D-alpha tocopherol acetate**

**DL-alpha tocopherol acetate**

**2. Amino acids**

L-arginine	)
L-cystine	)
L-histidine	)
L-isoleucine	)and their hydrochlorides
L-leucine	)
L-lysine	)
L-cysteine	)

**L-methionine**

**L-phenylalanine**

**L-threonine**

**L-tryptophan**

**L-tyrosine**

**L-valine**

**3. Others**

**Choline**

**Choline chloride**

**Choline citrate**

**Choline bitartrate**

**Inositol**

**L-carnitine**

**L-carnitine hydrochloride**

**4. Salts of minerals and trace elements**

**Calcium**

**Calcium carbonate**

**Calcium chloride**

**Calcium salts of citric acid**

**Calcium gluconate**

**Calcium glycerophosphate**

**Calcium lactate**

**Calcium oxide**

**Calcium hydroxide**

**Calcium salts of orthophosphoric acid**

**Magnesium**

**Magnesium carbonate**

**Magnesium chloride**

**Magnesium salts of citric acid**  
**Magnesium gluconate**  
**Magnesium oxide**  
**Magnesium hydroxide**  
**Magnesium salts of orthophosphoric acid**  
**Magnesium sulphate**  
**Magnesium lactate**  
**Magnesium glycerophosphate**

**Potassium**

**Potassium chloride**  
**Potassium salts of citric acid**  
**Potassium gluconate**  
**Potassium lactate**  
**Potassium glycerophosphate**

**Iron**

**Ferrous citrate**  
**Ferric ammonium citrate**  
**Ferrous gluconate**  
**Ferrous lactate**  
**Ferrous sulphate**  
**Ferrous fumarate**  
**Ferric diphosphate (ferric pyrophosphate)**  
**Elemental iron (carbonyl+electrolytic+hydrogen-reduced)**  
**Ferric saccharate**  
**Sodium ferric diphosphate**  
**Ferrous carbonate**

**Copper**

**Copper-lysine complex**  
**Cupric carbonate**  
**Cupric citrate**  
**Cupric gluconate**  
**Cupric sulphate**

**Zinc**

**Zinc acetate**  
**Zinc citrate**  
**Zinc lactate**  
**Zinc sulphate**  
**Zinc oxide**  
**Zinc gluconate**

**Manganese**

**Manganese carbonate**  
**Manganese chloride**  
**Manganese citrate**  
**Manganese gluconate**  
**Manganese sulphate**  
**Manganese glycerophosphate**

**Iodine**

Sodium iodide  
Potassium iodide  
Potassium iodate  
Sodium iodate.

SCHEDULE 5

Regulation 4(3)

REFERENCE VALUES FOR NUTRITION LABELLING FOR FOODS INTENDED FOR INFANTS AND YOUNG CHILDREN

<i>Nutrient</i>	<i>Labelling reference value</i>
Vitamin A	(µg) 400
Vitamin D	(µg) 10
Vitamin C	(mg) 25
Thiamin	(mg) 0.5
Riboflavin	(mg) 0.8
Niacin equivalents	(mg) 9
Vitamin B <sub>6</sub>	(mg) 0.7
Folate	(µg) 100
Vitamin B <sub>12</sub>	(µg) 0.7
Calcium	(mg) 400
Iron	(mg) 6
Zinc	(mg) 4
Iodine	(µg) 70
Selenium	(µg) 10
Copper	(mg) 0.4

EXPLANATORY NOTE

*(This note is not part of the Regulations)*

**These Regulations, which come into force on 31st March 1999, apply to Great Britain and implement Commission Directive 96/5/EC (OJ No. L49, 28.2.96, p. 17) on processed cereal-based foods and baby foods for infants and young children.**

**The Regulations -**

- (a) exempt from their application any baby food which is a milk intended for young children (regulation 2);**
- (b) prohibit the sale of any processed cereal-based food or baby food unless it complies with the labelling requirements in regulation 4 and the manufacturing and compositional requirements in regulation 5 (regulation 3);**
- (c) prescribe labelling requirements (regulation 4 and Schedule 5);**
- (d) prescribe manufacturing and compositional requirements (regulation 5 and Schedules 1, 2, 3 and 4);**
- (e) create offences and prescribe penalties (regulation 6);**
- (f) specify the enforcement authorities (regulation 7);**
- (g) provide a defence in relation to exports in accordance with Articles 2 and 3 of, as read with the ninth recital to, Council Directive 89/397/EEC (OJ No. L186, 30.6.89, p. 23) on the official control of foodstuffs (regulation 8); and**
- (h) apply various sections of the Food Safety Act 1990 (regulation 9) including those relating to enforcement and defences.**

**A compliance cost assessment of the effect that these Regulations would have on the cost of business is available from the Food Labelling and Standards Division, Branch A, of the Ministry of Agriculture, Fisheries and Food, Ergon House, 17, Smith Square, London SW1P 3JR.**

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***Notes:***

**[1] 1990 c.16; "the Ministers" is defined in section 4(1) of the Act. Section 6(4)(a) of the Act was amended by paragraph 6 of Schedule 9 to the Deregulation and Contracting Out Act 1994 (c.40).[back](#)**

**[2] OJ No. L49, 28.2.96, p. 17.[back](#)**

**[3] OJ No. L49, 28.2.96, p. 17.[back](#)**

**[4] OJ No. L1, 3.1.94, p.1.[back](#)**

**[5] OJ No. L1, 3.1.94, p.571.[back](#)**

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