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(1) 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 Foods Intended for Use in Energy Restricted Diets for Weight Reduction 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;

“advertise” and “advertising” shall be construed by reference to the definition of “advertisement” in section 53(1) of the Act but shall not relate to any label or wrapper;

“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 Temple and the Middle Temple);

“relevant food” means specially formulated food intended for use in energy-restricted diets for weight reduction, being food which complies with the compositional requirements in Schedule 1 and which, when used as instructed by the manufacturer, replaces—

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(1) 1990 c. 16; “the Ministers” is defined in section 4(1) of the Act. Section 6(4) of the Act was amended by paragraph 6 of Schedule 9 to the Deregulation and Contracting Out Act 1994 (c. 40).
(a) the whole of the total daily diet; or
(b) one or more meals of the total daily diet; and

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

(3) 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.

Name of the food and compositional requirements

2. —(1) No person shall sell any relevant food under any name other than—

(a) “total diet replacement for weight control” in the case of products intended as a replacement for the whole of the daily diet; or

(b) “meal replacement for weight control” in the case of products intended as a replacement for one or more meals of the daily diet.

(2) No person shall sell any food in the labelling of which the name “total diet replacement for weight control” or “meal replacement for weight control” is used unless that food is relevant food.

Labelling requirements

3. No person shall sell any relevant food unless it is labelled with the following particulars—

(a) the available energy value expressed in kJ and kcal, and the content of proteins, carbohydrates and fat, expressed in numerical form, per specified quantity of the product ready for use as proposed for consumption;

(b) the average quantity of each mineral and each vitamin for which compositional requirements are stipulated in paragraph 5 of Schedule 1, expressed in numerical form, per specified quantity of the product ready for use as proposed for consumption and, for products mentioned in regulation 2(1)(b), that average quantity expressed as a percentage of the values as set out in Tables A and B of Part II of Schedule 6 to the Food Labelling Regulations 1996(2);

(c) instructions for appropriate preparation, where necessary and a statement as to the importance of following those instructions;

(d) where a product, when used as instructed by the manufacturer, provides a daily intake of polyols in excess of 20g per day, a statement to the effect that the food may have a laxative effect;

(e) a statement on the importance of maintaining an adequate daily fluid intake;

(f) for products mentioned in regulation 2(1)(a), a statement that the product provides adequate amounts of all essential nutrients for the day and a statement that the product should not be used for more than three weeks without medical advice; and

(g) for products mentioned in regulation 2(1)(b), a statement to the effect that the product is useful for the intended use only as part of an energy-restricted diet and that other food should be a necessary part of such diet.

Labelling, advertising and presentation

4. No person shall sell any relevant food the labelling, advertising or presentation of which refers to the rate or amount of weight loss which may result from its use or to a reduction in the sense of hunger or an increase in the sense of satiety.

(2) S.I.1996/1499.
Packaging

5. No person shall sell any relevant food being a product mentioned in regulation 2(1)(a) unless all individual components making up the product are contained in the same package.

Offences and penalties

6.—(1) If any person contravenes regulation 2, 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 that such food complies with that legislation; and

(b) that the legislation complies with the provisions of Commission Directive 96/8/EC(3) on foods intended for use in energy-restricted diets for weight reduction, 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 Act

9. The following provisions of the Act shall apply for the purposes of these Regulations and, unless the context otherwise requires, any reference in those provisions to the Act or Part thereof shall be construed for the purposes of these Regulations 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) as it applies for the purposes of section 8, 14 or 15;
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);

(3) OJ No. L55, 6.3.96, p. 22.
(4) OJ No. L1, 3.1.94, p. 1.
(5) OJ No. L1, 3.1.94, p. 571.
section 35(1) to (3) (punishment of offences) in so far as it relates to offences under section 33(1) and (2); 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

2nd September 1997

Signed by authority of the Secretary of State for Health

Tessa Jowell
Minister of State for Public Health, Department of Health

4th September 1997

Signed by authority of the Secretary of State for Wales

Win Griffiths
Parliamentary Under Secretary of State, Welsh Office

4th September 1997

Sam Galbraith
Parliamentary Under Secretary of State, Scottish Office

5th September 1997
SCHEDULE 1

ESSENTIAL COMPOSITION OF RELEVANT FOOD

The specifications refer to the products ready for use, sold as such or reconstituted as instructed by the manufacturer.

Energy

1.

1.1. The energy provided by a product mentioned in regulation 2(1)(a) shall not be less than 3360 kJ (800 kcal) and shall not exceed 5040 kJ (1200 kcal) for the total daily ration.

1.2. The energy provided by a product mentioned in regulation 2(1)(b) shall not be less than 840 kJ (200 kcal) and shall not exceed 1680 kJ (400 kcal) per meal.

Protein

2.

2.1. The protein contained in products mentioned in regulation 2(1)(a) and (b) shall provide not less than 25% and not more than 50% of the total energy of the product. In any case the amount of protein of products mentioned in regulation 2(1)(a) shall not exceed 125 g.

2.2. The above-mentioned provisions on protein refer to a protein the chemical index of which is equal to that of the FAO/WHO (1985) reference protein given in Schedule 2. If the chemical index is lower than 100% of the reference protein, the minimum protein levels shall be correspondingly increased. In any case the chemical index of the protein shall at least be equal to 80% of that of the reference protein.

2.3. The ‘chemical index’ shall mean the lowest of the ratios between the quantity of each essential amino acid of the test protein in and the quantity of each corresponding amino acid of the reference protein.

2.4. In all cases, the addition of amino acids is permitted solely for the purpose of improving the nutritional value of the proteins, and only in the proportions necessary for that purpose.

Fat

3.

3.1. The energy derived from fat shall not exceed 30% of the total available energy of the product.

3.2. For products mentioned in regulation 2(1)(a), the linoleic acid (in the form of glycerides) shall not be less than 4.5 g.

3.3. For products mentioned in regulation 2(1)(b), the linoleic acid (in the form of glycerides) shall not be less than 1 g.

Dietary fibre

4. The dietary fibre content of products mentioned in regulation 2(1)(a) shall not be less than 10 g and shall not exceed 30 g for the daily ration.

Vitamins and minerals

5.
5.1. The products mentioned in regulation 2(1)(a) shall provide for the whole of the daily diet at least 100% of the amounts of vitamins and minerals specified in the Table below.

5.2. The products mentioned in regulation 2(1)(b) shall provide at least 30% of the amounts of vitamins and minerals specified in the Table below per meal; however, the amount of potassium per meal provided by these products shall be at least 500 mg.

<table>
<thead>
<tr>
<th>Vitamin</th>
<th>Amount (μg RE, mg-TE, mg-NE, μg)</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin A</td>
<td>700</td>
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</tr>
<tr>
<td>Vitamin D</td>
<td>5</td>
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</tr>
<tr>
<td>Vitamin E</td>
<td>10</td>
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<tr>
<td>Vitamin C</td>
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<tr>
<td>Thiamin</td>
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</tr>
<tr>
<td>Riboflavin</td>
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<tr>
<td>Niacin</td>
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</tr>
<tr>
<td>Vitamin B6</td>
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</tr>
<tr>
<td>Folate</td>
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</tr>
<tr>
<td>Vitamin B12</td>
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<tr>
<td>Biotin</td>
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</tr>
<tr>
<td>Pantothenic acid</td>
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</tr>
<tr>
<td>Calcium</td>
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<tr>
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<tr>
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<tr>
<td>Manganese</td>
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### SCHEDULE 2

AMINO ACID REQUIREMENT PATTERN

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<tbody>
<tr>
<td>Cystine+methionine</td>
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<tr>
<td>Histidine</td>
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<tr>
<td>Isoleucine</td>
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<tr>
<td>Leucine</td>
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</tr>
<tr>
<td>Lysine</td>
<td>1.6</td>
</tr>
<tr>
<td>Phenylalanine+tyrosine</td>
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<tr>
<td>Threonine</td>
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</tr>
<tr>
<td>Tryptophan</td>
<td>0.5</td>
</tr>
<tr>
<td>Valine</td>
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</tr>
</tbody>
</table>


### EXPLANATORY NOTE

(This note is not part of the Regulations)


The Regulations—

(a) prohibit the sale, under any name other than either of those specified, of food intended for use in energy-restricted diets for weight reduction which complies with the compositional requirements in Schedule 1 ("relevant food") (regulation 2(1));

(b) prohibit the sale of any food under either specified name unless it is relevant food (regulation 2(2));

(c) prohibit the sale of relevant food unless labelled with specified particulars (regulation 3);

(d) prohibit the sale of relevant food if reference is made in the labelling, advertising or presentation to the rate or amount of weight loss which may result from its use or to a reduction in the sense of hunger or an increase in the sense of satiety (regulation 4);

(e) prohibit the sale of relevant food intended as a replacement for the whole of the daily diet unless all the components are contained in the same package (regulation 5);

(f) create offences and prescribe penalties (regulation 6);

(g) specify the enforcement authorities (regulation 7);
(h) 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

(i) 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.