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(2), 18(1)(a) and (b), 26(1)(a) and (3) and 48(1) of the Food Safety Act 1990 and 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 and commencement

1. These Regulations may be cited as the Novel Foods and Novel Food Ingredients Regulations 1997 and shall come into force on 16th June 1997.

Interpretation

2.—(1) In these Regulations—
“the Act” means the Food Safety Act 1990;
“food authority” has the same meaning as set out in section 5(1), (1A), (2) and (3) of the Act save that it 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);
“novel food” and “novel food ingredients” have the meaning set out in Article 1(2) of Regulation (EC) No. 258/97(3)

(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).
(2) Section 5 of the Act was amended by paragraph 16(1) of Schedule 9 to the Local Government (Wales) Act 1994 (c. 19).
“Regulation (EC) No. 258/97” means Regulation (EC) No. 258/97 of the European Parliament and of the Council concerning novel foods and novel food ingredients; and “specified Community provision” means a provision of Regulation (EC) No. 258/97 specified in column 1, and described in column 2, of the Schedule to these Regulations.

(2) Other expressions used in these Regulations have, insofar as the context admits, the same meanings as in Regulation (EC) No. 258/97 and in these Regulations any reference to a numbered article is a reference to the article so numbered in Regulation (EC) No. 258/97.

Requests relating to Novel Foods and Novel Food Ingredients

3. Any request made pursuant to Article 4.1. shall be submitted for processing to the Minister of Agriculture, Fisheries and Food, who shall act jointly with the Secretary of State for Health as the food assessment body in Great Britain for the purposes of that Regulation.

Enforcement

4. Each food authority shall, within its area, enforce and execute the provisions of Regulation (EC) No. 258/97 and these Regulations.

Offences and penalties

5.—(1) Any person who contravenes or fails to comply with any of the specified Community provisions 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 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 liable to be proceeded against and punished accordingly.

Application of various provisions of the Act

6. The following provisions of the Act shall apply for the purposes of these Regulations as they apply for the purposes of sections 8, 14 or 15 of the Act and unless the context otherwise requires any reference in them to the Act shall be construed as a reference to these Regulations—

<table>
<thead>
<tr>
<th>(a)</th>
<th>(b)</th>
<th>(c)</th>
<th>(d)</th>
<th>(e)</th>
<th>(f)</th>
<th>(g)</th>
<th>(h)</th>
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<tbody>
<tr>
<td>(a) section 2</td>
<td>(b) section 3</td>
<td>(c) section 20</td>
<td>(d) section 21</td>
<td>(e) section 30(8)</td>
<td>(f) section 35(1) to (3)</td>
<td>(g) section 36</td>
<td>(h) section 44</td>
</tr>
<tr>
<td>(extended meaning of “sale” etc.);</td>
<td>(presumption that food is intended for human consumption);</td>
<td>(offences due to fault of another person);</td>
<td>(defence of due diligence);</td>
<td>(which relates to documentary evidence);</td>
<td>(punishment of offences) insofar as it relates to offences under section 33(1) and (2);</td>
<td>(offences by bodies corporate); and</td>
<td>(protection of officers acting in good faith).</td>
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</tbody>
</table>
Powers of Entry

7. Sections 32 and 33 of the Act (powers of entry; obstruction etc. of officers) shall apply for the purposes of these Regulations, as they apply for the purposes of the Act and any reference in subsection (1) of that section to the Act shall be construed for the purposes of these Regulations as including a reference to the specified Community provision.

Jeff Rooker
Minister of State, Ministry of Agriculture,
Fisheries and Food
21st May 1997

Signed by authority of the Secretary of State for Health

Tessa Jowell
Minister of State, for Public Health
20th May 1997

Signed by authority of the Secretary of State for Wales

Win Griffiths
Parliamentary Under Secretary of State, Welsh Office
19th May 1997

Sewel
Parliamentary Under Secretary of State, Scottish Office
21st May 1997
THE SCHEDULE

SPECIFIED COMMUNITY PROVISIONS

<table>
<thead>
<tr>
<th>Provision of Regulation (EC) No. 258/97</th>
<th>Subject Matter</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Article 3.1</td>
<td>Requirement that foods and food ingredients falling within the scope of the Regulation must not be dangerous, misleading or differ from the foods or food ingredients they are intended to replace so as to be nutritionally disadvantageous.</td>
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<tr>
<td>2. Article 3.2</td>
<td>Requirement that, subject to Article 3.3, specified procedures shall apply for the purposes of placing on the market the foods and food ingredients falling within the scope of the Regulation.</td>
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<tr>
<td>3. Article 4.1</td>
<td>Requirement that the person responsible for placing on the Community market (“the applicant”) submit a request to the Member State in which the product is to be first marketed and at the same time transmit a copy of the request to the Commission.</td>
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<tr>
<td>4. Article 5</td>
<td>Requirement that in the case of foods or food ingredients referred to in Article 3(4) the applicant notify the Commission of the placing on the market when he does so.</td>
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<tr>
<td>5. Article 6.1</td>
<td>Requirement that the request referred to in Article 4.1 contain specified information and be accompanied by specified documentation.</td>
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<tr>
<td>6. Article 6.4</td>
<td>Requirement that the applicant provide a copy of specified information if requested by a Member State.</td>
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<tr>
<td>7. Article 8.1</td>
<td>Requirement that labelling inform the final consumer of any characteristic or food property which renders a novel food or food ingredient no longer equivalent to an existing food or food ingredient. Specific labelling requirements to ensure that in such a case, the labelling indicates the characteristics or properties modified and the method by which these were obtained. Requirement that labelling inform the final consumer of the presence in the novel food or food ingredient of material which is not present in an existing equivalent foodstuff and which may have implications for the health of certain sections of the population or gives rise to ethical concerns.</td>
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<tr>
<td>Provision of Regulation (EC) No. 258/97</td>
<td>Subject Matter</td>
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<td>Requirement that labelling inform the final consumer of the presence of a genetically modified organism.</td>
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<tr>
<td><strong>8. Article 9.1</strong></td>
<td>Requirement that the information required in the request for placing on the market mentioned in Article 6.1 be accompanied by specified information and documentation where a food or food ingredient falling within the scope of the Regulations contains or consists of a genetically modified organism.</td>
</tr>
</tbody>
</table>

**EXPLANATORY NOTE**

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


In particular these Regulations—

(a) Designate the Minister of Agriculture, Fisheries and Food and the Secretary of State for Health to act jointly as the food assessment body in Great Britain for the purposes of Regulation (EC) No. 258/97 (Regulation 3);

(b) Appoint food authorities to enforce and execute the provisions of Regulation (EC) No. 258/97 and of these Regulations (Regulation 4);

(c) Specify certain provisions of Regulation (EC) No. 258/97 and establish penalties for contravening those provisions (Regulation 5 and the Schedule).

A Compliance Cost Assessment has been prepared and a copy has been placed in the library of each House of Parliament. Copies can be obtained from Room 239c, Ergon House, c/o Nobel House, 17 Smith Square, London SW1P 3JR.

These Regulations come into force on 16th June 1997.