SCHEDULE 8

LABELLING AND MARKING OF ADDITIVES AND PREMIXTURES

PART I

ADDITIVES

- 1. The label or mark shall give—
 - (a) in the case of an additive referred to in paragraph 6(1) of, or in the Table to, Schedule 4 (other than an enzyme);
 - (i) the name of the additive;
 - (ii) the name or business name and the address or registered business address of the person responsible within the European Community for the particulars referred to in this Part of this Schedule;
 - (iii) the net weight of any non-liquid additive; and
 - (iv) either the net weight or the net volume of any liquid additive;
 - (b) in the case of vitamin E,
 - (i) the alpha-tocopherol level as acetate; and
 - (ii) an indication of the period during which that level will remain present;
 - (c) in the case of any vitamin other than vitamin E, or any added provitamin or substance having a similar effect,
 - (i) the active substance level; and
 - (ii) an indication of the period during which that level will remain present;
 - (d) in the case of any trace element, colourant (including pigment), preservative or other additive referred to in the Table to Schedule 4 but not specified above (other than an enzyme), the active substance level;
 - (e) in the case of any enzyme (whether or not contained in a preparation where the enzyme is not of a type referred to in Part X of the Table to Schedule 4):
 - (i) the names of the active constituents according to their enzymatic activities (in the case of an enzyme of a type referred to in Part X of the Table to Schedule 4, as specified in column 3 of that Part);
 - (ii) the identification number allotted by the International Union of Biochemistry;
 - (iii) the name or business name and the address or registered business address of the person responsible for the particulars referred to in this sub-paragraph;
 - (iv) the name or business name and the address or registered business address of the manufacturer if he is not responsible for the particulars in the label or mark;
 - (v) the activity units(1) (expressed as activity units per gram or activity units per millilitre);
 - (vi) an indication of the period during which the activity units will remain present;
 - (vii) the batch reference number and the date of manufacture;

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⁽¹⁾ Units of activity expressed as µmole of product released per minute per gram of enzymatic preparation.

- (viii) directions for use, including any safety recommendation (in the case of an enzyme of a type referred to in Part X of the Table to Schedule 4, as specified in column 3 of that Part);
- (ix) the net weight for any non-liquid additive;
- (x) either the net weight or the net volume of any liquid additive; and
- (xi) in the case of an enzyme of a type referred to in Part X of the Table to Schedule 4, an indication of any significant characteristics of the enzyme arising during manufacture, specified in column 8 of that Part;
- (f) in the case of any micro-organism (whether or not contained in a preparation);
 - (i) the identification of the strain(s) according to a recognised international code of nomenclature;
 - (ii) the deposit number of the strain(s);
 - (iii) the number of colony-forming units (expressed as CFU/g);
 - (iv) the name or business name and address or registered business address of the person responsible for the particulars referred to in this sub-paragraph;
 - (v) the name or business name and address or registered business address of the manufacturer if he is not responsible for the particulars in the label or mark;
 - (vii) the batch reference number and the date of manufacture;
 - (viii) directions for use, including any safety recommendation;
 - (ix) the net weight of any non-liquid additive;
 - (x) either the net weight or the net volume of any liquid additive; and
 - (xi) an indication of any significant characteristics of the micro-organism arising during manufacture.
- **2.** The label or mark may give, in addition to the name used in relation to any additive referred to in paragraph 6(1) of, or in the Table to, Schedule 4—
 - (a) the trade name of the additive and its EEC number;
 - (b) the name or business name and the address or registered business address of the manufacturer;
 - (c) directions for use, including any appropriate safety recommendation;
 - (d) any other information, provided that it is clearly separated from the particulars referred to in paragraph 1(a)–(d) above and in the foregoing provisions of this paragraph, and from the relevant particulars referred to in paragraph 1(e) above.
- **3.** In the case of any enzyme (other than of a type referred to in Part X of the Table to Schedule 4) or micro-organism, whether or not the enzyme or micro-organism is contained in a preparation, the label or mark may give any other information, provided that it is clearly separated from the relevant particulars referred to in paragraph 1(e) and (f) above.