SCHEDULE 5 regulation 4

CONTENTS OF THE STATUTORY STATEMENT (FOR ADDITIVES AND PREMIXTURES NOT CONTAINED IN FEEDING STUFFS)

PART I

ADDITIVES

1. In relation to additives not excluded from application of the Additives Directive by Article 22 thereof, the following particulars shall be contained in the statutory statement (where an authorised additive is sold or otherwise put into circulation by any person) —

(a) in the case of any additive permitted to be contained in material pursuant to paragraph 5(1) of, or referred to in any of Parts I to VIII of, the Table to Schedule 3 or which is otherwise authorised (not being an enzyme, micro-organism, zootechnical additive, an authorised intermediate product or an authorised medicated premix) —

(i) the name of the additive;

(ii) the EC registration number of the additive;

(iii) the name or business name and the address or registered business address of the person within the European Community responsible for the particulars referred to in this Part of this Schedule;

(iv) the net weight, in the case of any non-liquid additive;

(v) either the net weight or the net volume, in the case of any liquid additive; and

(vi) as from 1st April 2001, the approval or registration number allocated, pursuant to Article 5, or, as the case may be, 10 of the Establishments Directive, to the establishment which manufactured the additive, or to the intermediary holding it;

(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 additive permitted to be contained in material pursuant to paragraph 5(1) of, or referred to in any of Parts I to VIII of the Table to Schedule 3 or which is otherwise authorised (not being an enzyme, micro-organism, zootechnical additive, authorised intermediate product or authorised medicated premix), the active substance level;

(e) in the case of any enzyme —

(i) the names of the active constituents according to their enzymatic activities as specified in the authorisation concerned;

(ii) the EC registration number;

(iii) the identification number allotted by the International Union of Biochemistry;

(iv) the name or business name and the address or registered business address of the person within the European Community responsible for the particulars referred to in this Part of this Schedule;

(v) the name or business name and the address or registered business address of the manufacturer, if he is not responsible for the particulars referred to in this Part of this Schedule;

(vi) the activity units(**2**) per gram or per millilitre;

(vii) an indication of the period during which the activity units will remain present;

(viii) the batch reference number and the date of manufacture;

(ix) directions for use, including the recommended dosage or, where appropriate, range of dosages, expressed as a percentage by weight of target feed material per kilogram of feeding stuff, as prescribed in the authorisation concerned;

(x) any safety recommendation as specified in the authorisation concerned;

(xi) the net weight, in the case of any non-liquid enzyme;

(xii) either the net weight or the net volume, in the case of any liquid enzyme;

(xiii) an indication of any significant characteristics of the enzyme arising during manufacture, specified in the authorisation concerned; and

(xiv) as from 1st April 2001, the approval number allocated, pursuant to Article 5 of the Establishments Directive, to the establishment which manufactured the enzyme, or to the intermediary holding it; and

(f) in the case of any micro-organism —

(i) the identification of each strain, in accordance with the authorisation;

(ii) the file number of each strain;

(iii) the number of colony-forming units (expressed as CFU/g);

(iv) the EC registration number;

(v) the name or business name and the address or registered business address of the person within the European Community responsible for the particulars referred to in this Part of this Schedule;

(vi) the number or business name and the address or registered business address of the manufacturer, if he is not responsible for the particulars referred to in this Part of this Schedule;

(vii) as from 1st April 2001, the approval number allocated, pursuant to Article 5 of the Establishments Directive, to the establishment which manufactured the micro-organism, or to the intermediary holding it;

(viii) an indication of the period during which the colony-forming units will remain present;

(ix) the batch reference number and the date of manufacture;

(x) directions for use;

(xi) any safety recommendation specified in the authorisation concerned;

(xii) the net weight, in the case of any non-liquid micro-organism;

(xiii) either the net weight or the net volume, in the case of any liquid micro-organism; and

(xiv) an indication of any significant characteristics of the micro-organism arising during manufacture, specified in the authorisation concerned.

2. In addition to the information required under paragraph 1 above in relation to any additive, the statutory statement may also give —

(**2**) Units of activity expressed as umole of product released per minute per gram of enzymatic preparation.

(a) where the additive is permitted to be contained in material pursuant to paragraph 5(1) of, or referred to in any of Parts I to VIII of the Table to, Schedule 3, or otherwise authorised (and is not a zootechnical additive, an authorised intermediate product or an authorised medicated premix) —

(i) the trade name of the additive;

(ii) any other information, provided that it is clearly separated from the particulars referred to in paragraph 1(a) to (f) above, in paragraph (i) above and in sub-paragraph (b) below; and

(b) where the additive falls within sub-paragraph (a) above and is not an enzyme or micro-organism —

(i) the name or business name, and the address or registered business address, of the manufacturer, if he is not the person responsible for the particulars referred to in this Part of this Schedule;

(ii) directions for use, including any appropriate safety recommendation.

PART II

PREMIXTURES

1. This Part of this Schedule applies to premixtures containing only such additives as are of any type regulated by Part I of this Schedule.

2. In relation to premixtures not excluded from application of the Additives Directive by Article 22 thereof, the following particulars shall be contained in the statutory statement —

(a) in the case of any premixture —

(i) the description "premixture";

(ii) directions for use, including any appropriate safety recommendation;

(iii) the species or category of animal for which the premixture is intended;

(iv) the name or business name, and the address or registered business address, of the person within the European Community responsible for the particulars referred to in this Part of this Schedule;

(v) the net weight of any non-liquid premixture;

(vi) either the net weight or the net volume of any liquid premixture; and

(vii) from 1st April 2001, the approval or registration number allocated, pursuant to Article 5 or, as the case may be, 10 of the Establishments Directive, to the establishment which produced or manufactured the premixture, or to the intermediary holding it;

(b) in the case of any antioxidant, colourant (including pigment), trace element or preservative, in a premixture, for which a maximum content in a complete feeding stuff is prescribed in the appropriate Part of the Table to Schedule 3, or in another authorisation —

(i) the name of the additive; and

(ii) the active substance level;

(c) in the case of vitamin E in a premixture —

(i) the name of the additive;

(ii) the alpha-tocopherol level as acetate; and

(iii) an indication of the period during which that level will remain present;

(d) subject to paragraph (4) below, in the case of any vitamin other than vitamin E, or any provitamin or substance having a similar effect, in a premixture —

(i) the name of the additive;

(ii) the active substance level; and

(iii) an indication of the period during which that level will remain present;

(e) in the case of any enzyme in a premixture —

(i) the names of the active constituents according to their enzymatic activities, as specified in the authorisation concerned;

(ii) the EC registration number;

(iii) the identification number allotted by the International Union of Biochemistry;

(iv) the activity units (expressed as activity units per gram or activity units per millilitre);

(v) an indication of the period during which the activity units will remain present;

(vi) the batch reference number and the date of manufacture;

(vii) the name or business name and address or registered business address of the manufacturer, if he is not responsible for the particulars referred to in this Part of this Schedule;

(viii) an indication of any significant characteristics of the enzyme arising during manufacture, as specified in the authorisation concerned; and

(ix) the recommended dosage or, where appropriate, range of dosages, expressed as a percentage by weight of target feed material per kilogram of the feeding stuff, as prescribed in the authorisation concerned;

(f) in the case of any micro-organism in a premixture —

(i) the identification of each strain, in accordance with the authorisation;

(ii) the file number of each strain;

(iii) the number of colony-forming units (expressed as CFU/g);

(iv) the EC registration number;

(v) the name or business name and the address or registered business address of the manufacturer, if he is not responsible for the particulars referred to in this Part of this Schedule;

(vi) an indication of the period during which the colony-forming units will remain present; and

(vii) an indication of any significant characteristics of the micro-organism arising during manufacture, specified in the authorisation concerned;

(g) in the case of any additive in a premixture —

(i) which is an additive of a type referred to in any of Parts I to VIII of Schedule 3, or which is otherwise authorised (other than any additive of a type referred to in sub-paragraphs (b) to (f) above), or which is an additive of a type referred to in any of those Parts, or in another authorisation, and in those sub-paragraphs, in respect of which no maximum level is laid down;

(ii) which fulfils a function in the feeding stuff as such; and

(iii) in respect of which the amount which is present in the premixture can be determined by using one of the methods of analysis specified in Annex I to Part II of Schedule 2

to the Feeding Stuffs (Sampling and Analysis) Regulations 1999(**1**) or by some other valid scientific method, the name of the additive, and the active substance level.

3. In relation to an additive permitted to be contained in material pursuant to paragraph 5(1) of, or referred to in any of Parts I to VIII of the Table to, Schedule 3, or which is otherwise authorised, in a premixture, in addition to the information required under paragraph 2 above, the statutory statement may give —

(a) the trade name of the additive;

(b) in the case of any additive not being an enzyme or a micro-organism, its EC registration number;

(c) any other information, provided that it is clearly separated from the particulars referred to in paragraph 2 above, and in the foregoing provisions of this paragraph.

4. In the case of a premixture containing more than one vitamin (other than vitamin E), provitamin or substance having a similar effect, the requirement in paragraph 2(d)(iii) above shall apply only to whichever of those additives has the shortest such period.

(**1**) S.I. 1999/1663, to which there is an amendment not relevant to these Regulations.