SCHEDULE 3

PROVISIONS FOR CLASSIFYING DANGEROUS PREPARATIONS

PART I

GENERAL PROVISIONS

Classification of preparations by health effects

4.—(1) The health effects of a preparation shall be assessed by one or more of the following methods—

(a) by the conventional method described in paragraphs 7 to 15 using concentration limits; or

(b) by the criteria set out in the approved classification and labelling guide in relation to the preparation for an appropriate classification and label.

(2) Any one or more of the health effects of the preparation which are not assessed by the method set out in sub-paragraph (1)(b) shall be assessed in accordance with the conventional method.

(3) Where the health effects have been established by both methods, the results of the method referred to in sub-paragraph (1)(b) shall be used for classifying the preparation except in the case of carcinogenic and mutagenic effects and toxic effects for reproduction, when the conventional method referred to in sub-paragraph (1)(a) shall always be used.

(4) Where it can be demonstrated—

(a) by epidemiological studies, by scientifically valid case studies as specified in the approved classification and labelling guide or by statistically backed experience (such as the assessment of data from poison information units or concerning occupational diseases) that toxicological effects on man differ from those suggested by the application of the methods set out in paragraph (1), then the preparation shall be classified according to its effects on man;

(b) that owing to effects such as potentiation, a conventional assessment would underestimate the toxicological hazard, those effects shall be taken into account in classifying the preparation; or

(c) that owing to effects such as antagonism, a conventional assessment would overestimate the toxicological hazard, those effects shall be taken into account in classifying the preparation.

(5) Subject to sub-paragraph (6), for preparations of a known composition, with the exception of plant protection products, classified in accordance with the method referred to in sub-paragraph (1)(b), a new health effect assessment shall be performed either by the method referred to in sub-paragraph (1)(a) or (1)(b) whenever—

(a) changes of composition of the initial concentration, as a weight/weight or volume/volume percentage, of one or more of the dangerous constituents are introduced by the manufacturer which exceed the permitted variations set out in the following table—

Initial concentration range of the constituent		*Permitted variation in actual concentration of the constituent*
	≤ 2.5%	± 30%
> 2.5	≤ 10%	± 20%

Initial concentration range of the constituent		*Permitted variation in actual concentration of the constituent*
> 10	≤ 25%	± 10%
> 25	≤ 100%	± 5%

or,

(b) changes of composition involving the substitution or addition of one or more constituents, which may or may not be dangerous within the definitions in Schedule 1, are introduced by the manufacturer.

(6) The revised assessment required by sub-paragraph (5) shall not be required where there is a valid scientific justification for considering that a re-evaluation of the hazard will not result in a change of classification.