EUROPEAN COMMUNITIES (CLASSIFICATION, PACKAGING AND LABELLING OF PESTICIDES) (AMENDMENT) REGULATIONS 1991

I, MICHAEL O'KENNEDY, Minister for Agriculture and Food, in exercise of the powers conferred on me by section 3 of the European Communities Act, 1972, (No. 27 of 1972), and for the purpose of giving further effect to Council Directive No. 78/631/EEC of 26 June 1978(1), Council Directive 81/187/EEC of 26 March 1981(2), and Commission Directive 84/291/EEC of 18 April 1984(3), hereby make the following Regulations:

REG 1

- (1) These Regulations may be cited as the European Communities (Classification, Packaging and Labelling of Pesticides) (Amendment) Regulations, 1991.
 (2) These Regulations shall come into operation on the 19 day of April, 1991.
- (3) The European Communities (Classification, Packaging and Labelling of Pesticides) Regulations, 1985 to 1989, and these Regulations may be cited together as the European Communities (Classification, Packaging and Labelling of Pesticides) Regulations, 1985 to 1991, and shall be construed together as one.

REG 2

2. In these Regulations—

"the Principal Regulations" means the European Communities (Classification, Packaging and Labelling of Pesticides) Regulations, 1985 (S.I. No. 370 of 1985);

"the Regulations of 1987" means the European Communities (Classification, Packaging and Labelling of Pesticides) (Amendment) Regulations, 1987 (S.I. No. 207 of 1987).

"the Regulations of 1989" means the European Communities (Classification, Packaging and Labelling of Pesticides) (Amendment) Regulations, 1989 (S.I. No. 149 of 1989).

(1)O.J. No. L 206/13 29.7.1978.

(2)O.J. No. L 88/29 2.4.1981.

(3)O.J. No. L 144/1 30.5.1984.

REG 3

3. Regulation 6 of the Principal Regulations is hereby amended by the substitution for Regulation 6 of the following Regulation:
"6. (1) (a) Subject to subparagraph (b) and (c) of this paragraph, in addition to complying with the requirements of Regulation 5 of these Regulations, pesticides to which these Regulations apply shall be classified as to their toxicity, and such classification shall be made in the manner specified in Article 3 of the Directive of 1978, and in making such classification whichever of the reference

- values specified in subparagraph (a), (b) or (c) of paragraph (1) of the said Article 3 is appropriate shall be used, and values shall be determined and tests shall be carried out in accordance with the requirements of that paragraph.
- (b) Subject to subparagraph (d) of this paragraph, where a pesticide to which these regulations apply contains not more than one active substance, it may, with the consent of the Minister, be classified as to its toxicity by means of a calculation in accordance with Annexes V and VI, and where Annex VI does not contain Ld50 figures for particular pesticides, the LD50 figures specified in the WHO Recommended Classification of Pesticides by Hazard and Guidelines to Classification 1990-91 (World Health Organisation WHO/PCS 90.1 REV 1) shall be used.
- (c) Subject to subparagraph (d) of this paragraph, where a pesticide to which these Regulations apply contains more than one active substance, it may, with the consent of the Minister, be classified as to its toxicity by means of a calculation in accordance with Annex VIII and where Annex VIII does not include a class and subclass for particular pesticides, the equivalent class and subclass specified in the WHO Recommended Classification of Pesticides by Hazard and Guidelines to Classification 1990-91 (World Health Organisation WHO/PCS/90.1 REV 1) shall be used.
- (d) A pesticide to which these Regulations apply shall be classified in the manner mentioned in subparagraph (b) or (c) of this paragraph only if—
- (i) it satisfies the requirements of subparagraph (a) or (b) of Article 3 (2) of the Directive of 1978; and
- (ii) the assumption specified in the said Article 3 (2) can be made on the grounds so specified.
- (e) If when making a classification pursuant to the requirements of subparagraphs (b) or (c) of this paragraph, facts appear which leave the correctness of the classification open to doubt, the Minister may require the calculation to be replaced by toxicological tests referred to in Article 3 (4) of the Directive of 1978.
- (2) Notwithstanding paragraph (1) of this Regulation, where the conditions specified in Article 3 (5) of the Directive of 1978 apply, additional toxicological data may be taken into account for the purposes of the classification of pesticides to which these Regulations apply.".

REG 4

- 4. The Principal Regulations are hereby amended by the substitution for Regulation 7 (as amended by the Regulations of 1989) of the following Regulation:
- "7. (1) Where a pesticide is classified in compliance with the requirements of Regulation 6 of these Regulations, the person on whose behalf the classification is made shall send to the Minister for consideration by him three copies of an accurate record of the studies conducted and information used to propose a classification or

classifications and to establish the nature and extent of foreseeable risks which the handling or use of the pesticide entails, together with relevant supporting documentation and materials, as may be specified from time to time by the Minister, together with the particulars of any safety precautions or other recommendations and the conclusions reached as a result of the studies, information and materials.

- (2) (a) In the case of a pesticide which is placed on the market on or before the commencement of these Regulations, the pesticide shall no longer be placed on the market or used unless the record of the studies conducted and the information, documentation and materials to which it relates are submitted for approval at a time to be specified by the Minister and are approved by him.
- (b) In the case of a pesticide which is not placed on the market on or before the commencement of these Regulations, the pesticide shall not be cleared and placed on the market or used unless the record of the studies conducted and the information, documentation and materials to which it relates have been approved by the Minister.
- (c) In the case of a pesticide referred to in subparagraph (b) of this paragraph and notwithstanding the provisions of that subparagraph or of paragraph (1), where the pesticide is similar to and considered by the Minister to involve no greater risk for man or for the environment than a pesticide referred to in subparagraph (a) of this paragraph, and for which a date has not yet been specified as the date by which the studies conducted and the supporting information, documentation and materials are to be submitted, permission may be granted by the Minister on approval of an accurate record of a limited number of studies, information supporting documentation and materials, as specified from time to time by the Minister, to market such a pesticide.
- (d) In the case of a pesticide in relation to which the record of the studies conducted and the information, documentation and materials have neither been approved nor submitted for approval by the Minister under subparagraph (a) or (b) of this paragraph, notwithstanding non-compliance with the provisions of this Regulation, an authorised officer acting on behalf of the Minister, where there is no apparent risk to man or to the environment through the placing on the market or use of such a pesticide, may, by a notice in writing given to the owner or person in apparent charge or control, permit the controlled placing on the market or use of existing stocks of the pesticide subject to specified conditions.
- (e) The Minister may, on a request being made to him in that behalf by a person who had been granted clearance in respect of a pesticide under this paragraph, withdraw his approval in respect of that pesticide.".

- 5. Regulation 17 (inserted by the Regulations of 1987) of the Principal Regulations is hereby amended—
- (1) (a) By the insertion in paragraph (1) (inserted by the Regulations of 1989) after subparagraph (d) of the following subparagraph:
- "(e) a fee of £300 shall be payable in each case where an application is made for permission to market under Regulation 7 (2)
- (c) of these Regulations. This fee shall not be offset against the fees mentioned in subparagraph (a) and (b) of this paragraph.", and
- (b) by the substitution for paragraph (2) of the following paragraph.
- "(2) (a) Every grant of an approval of documentation and materials and for clearance of pesticides shall be for 12 months from the date of such grant and shall be renewable at the discretion of the Minister for a maximum of 9 further periods of 12 months on an application being made in that behalf to the Minister and shall be accompanied by the appropriate fee set out in Part 2 of the Second Schedule to these Regulations and on a request being made to him in that behalf.
- (b) The Minister may reduce the fee payable under this paragraph where he is satisfied that the wholesale sales of a pesticide during the previous 12 month period did not exceed 50 times the fee payable under this paragraph to the Minister.".

REG 6

- 6. Regulation 2 of the Principal Regulations is hereby amended by the insertion after the definition of "Annex VII" of the following definition:
- "'Annex VIII' (which is set out in the Schedule hereto) means Annex II to the Directive of 1978 as amended by Council Directive 81/187/EEC of 26 March 1981 and Commission Directive 84/291/EEC of 18 April 1984;"

REG 7

7. The Schedule to the Principal Regulations is hereby amended by the insertion after Annex VII of the following Annex:
"Annex VIII

(Annex II to Council Directive 78/631/EEC as amended by Council Directive 81/187/EEC and adapted by Commission Directive 84/291/EEC). Classification by calculation of pesticides containing more than one

active substance (See Article 3 (3))

1. For the purpose of applying the method of calculation for the

classification of pesticides which contain more than one active substance, the dangerous substances used in their preparation are divided into categories and sub-categories in accordance with the list in point 5.

2. The following formula shall be used for the classification of a pesticide:

S ä(P x I)

Where:

P = the percentage by weight of each dangerous substance present in the pesticide;

I = the distinguishing index of the sub-category to which each substance belongs. It is assigned for every percentage unit of the substance in question present in the pesticide.

In particular, I breaks down into the following:

I1: for classifying solid pesticides as toxic or harmful;

I2: for classifying liquid or gaseous pesticides as toxic or harmful.

The values of the indices I1 and I2 are given in the table below: Table of Classification Indices

Category to which the

substance belongsPesticide classification indicesSolidLiquid or gaseousI1 (=conc.%)I2 (=conc.%)Category II/a500(= 1%)500(= 1%)I/b100(= 5%)125(= 4%)I/c 15(= 33%) 25(= 20%)Category IIII/a 5(=100%) 10(= 50%)II/b 2(=100%) 4(=100%)II/c 1(=100%) 2(=100%)II/d 0.5(=100%) 1(=100%)

- 3. Pesticides containing one or more of the substances listed in point 5 are regarded as toxic if the sum of the products obtained by multiplying the percentage by weight P of the various substances present in the pesticide by the respective indices I1 or I2 is greater than 500, i.e.:
- —for solid pesticides: $å(P \times I1) > 500$;
- —for liquid or gaseous pesticides: $å(P \times I2) > 500$;
- 4. Pesticides containing one or more of the substances listed in point 5 are regarded as harmful if the sum of the products referred to in point 3 is 500 or less but greater than 25 for solid pesticides, or 500 or less but greater than 40 for liquid or gaseous pesticides, i.e.:
- —for solid pesticides: 25 < å (P x I1) < 500;
- —for liquid or gaseous pesticides: 40 < å (P x I2) < 500.

When the result of this calculation is 25 or less for a solid pesticide or 40 or less for a liquid or gaseous one, the pesticide is not classified.

5. List of active substances, divided into classes and subclasses. The substances bearing the indication (NT) cannot be transferred into other classes.

Class I/a

No. in Directive 67/548/EECNomenclature according to Directive 67/548/EEC006-008-00-0Antu(NT)015-056-00-1Azinphos-ethyl015-039-00-9Azinphos-methyl006-029-00-5Dioxacarb006-026-00-9Carbofuran015-071-00-3Chlorfenvinphos606-014-00-

9Chlorophacinone(NT)015-038-00-3Coumaphos607-059-00-7Coumatetralyl613-004-00-8Crimidine(NT)015-070-00-8Cyanthoate(NT)Cycloheximide(NT)015-028-00-9Demeton-O(NT)015-029-00-4Demeton-S(NT)015-088-00-6Dialifos015-073-00-4Dicrotophos015-061-00-9Dimefox(NT)015-063-00-XDioxathion609-020-00-XDNOC015-060-00-3Disulfoton(NT)602-051-00-XEndrin015-036-00-2EPNEthoprophos015-090-00-7Fensulfothion(NT)607-078-00-0Fluenetil(NT)616-002-00-5Fluoroacetamide015-091-00-2Fonofos602-053-00-0Isobenzan(NT)006-009-00-6Isolan015-094-00-9Mephosfolan015-095-00-4Methamidophos015-069-00-2MethidathionMethomylMevinphos(NT)015-072-00-9Monocrotophos614-001-00-4Nicotine650-004-00-7Norbormide(NT)015-034-00-1Parathion(NT)015-035-00-7Parathion-methyl(NT)015-033-00-6Phorate(NT)Phospholan015-022-00-6PhosphamidonPromurit(NT)015-032-00-0Prothoate015-026-00-8Schradan614-003-00-5Strychnine015-027-00-3Sulfotep(NT)015-025-00-2TEPP(NT)Thionazin(NT)015-024-00-7Triamiphos015-098-00-0Trichloronate607-056-00-0Warfarin(NT)602-049-00-9Dieldrin604-002-00-8Pentachlorophenol602-008-00-5Tetrachloromethane(NT)602-002-00-3Bromomethane(NT)006-003-00-3Carbon disulphide(NT)015-004-00-8Aluminium phosphide(NT)015-006-00-9Zinc phosphide(NT)602-010-00-61, 2-Dibromoethane(NT)603-023-00-XEthylene oxide(NT) Class I/b

No. in Directive 67/548/EECNomenclature according to Direction 67/548/EEC605-008-00-32-Propenal

(Acrolein) 602-048-00-3 Aldrin 603-015-00-62-Propen-1-ol006-018-00-5 Aminocarb 015-064-00-5 Bromophos-ethyl Crotoxyphos 015-044-00-6 Carbophenothion 015-086-00-5 Coumithoate 015-031-00-5 Demeton-S-methyl 015-078-00-1 Demeton-S-methyl sulphone 015-019-00-X Dichlorvos 006-040-00-5 Dimetilan 609-025-00-7 Dinose b 609-026-00-2 Salts

and esters of dinoseb609-030-00-4Dinoterb609-031-00-XSalts and esters of dinoterb607-055-00-5Endothal-sodium015-049-00-3Endothion611-003-00-7Fenaminosulf015-045-00-1Mecarbam015-066-00-6OmethoateHeptachlor epoxide

No. in Directive 67/548/EECNomenclature according to Direction 67/548/EEC006-023-00-2006-023-00-2Methiocarb006-037-00-9Promecarb Class I/c

No. in Directive 67/548/EECNomenclature according to Directive 67/548/EEC608-006-00-0Bromoxynil602-044-00-1Camphechlor606-019-00-6Chlordecone015-085-00-XChlorphonium015-084-00-4Chlorpyrifos613-013-00-7Cyanazine602-045-00-7DDT015-030-00-XDemeton-O-methyl602-021-00-61, 2-Dibromo-3-chloropropane006-010-00-1Dimetan006-028-00-XDinobuton006-029-00-5Dioxacarb650-008-00-9Drazoxolon602-052-00-5endosulfan015-047-00-2Ethion015-048-00-8Fenthion050-003-00-6Fentin acetate050-004-00-1Fentin

hydroxide 602-046-00-2 Heptachlor 608-007-00-6 Ioxynil 602-043-00-6 Lindane 615-002-00-2 Methyl

isothiocyanate 015-099-00-6Pirimiphos-ethyl
006-016-00-4Propoxur 015-050-00-9Thiometon 015-059-00-8Vamid
othion Class II/a

No. in Directive 67/548/EECNomenclature according to Directive

67/548/EEC612-052-00-72-Aminobutane006-011-00-7Carbaryl650-007-00-3Chlordimeform607-039-00-82,

4-D006-019-00-0 Di-allate 015-068-00-7 Dichlofen thion 015-089-00-1 Ethoate-methyl 613-015-00-8 Fenaza flor 015-057-00-7 Formothion 607-079-00-6 Kelevan 080-003-00-1 Mercurous chloride 613-018-00-4 Morfamquat, and

salts006-014-00-3Nabam015-097-00-5Phenthoate015-101-00-5015-040-00-4Phosmet Diazinon Ioxynil octanoate

Class II/b

No. in Directive 67/548/EECNomenclature according to Directive 67/548/EEC015-080-00-2Amidithion602-047-00-8Chlordane607-074-00-9Chlorfenac015-087-00-0Cyanophos050-002-00-0Cyhexatin613-008-00-XDazomet613-021-00-0Dithianon015-054-00-0Fenitrothion605-005-00-7Metaldehyde015-055-00-6Naled607-041-00-92,

4, 5-T607-042-00-4Salts and esters of 2, 4,

5-T006-005-00-4Thiram015-021-00-0Trichlorphon609-024-00-1Binapacryl015-051-00-4Dimethoate

Class II/c

No. in Directive 67/548/EECNomenclature according to Directive 67/548/EEC015-079-00-7Acephate006-025-00-3Allethrin616-004-00-6AllidochlorBarium carbonate015-083-00-9Bensulide603-049-00-1Chlorfenethol616-005-00-1Chlorthiamid607-057-00-6Coumachlor015-074-00-XCrufomate607-083-00-82, 4-DB602-012-00-71,

2-Dichloroethane607-045-00-0Dichlorprop603-044-00-4Dicofol607-047-00-1FenopropMalathion containing more than 1.8% isomalation607-051-00-3MCPA607-052-00-9Salts and esters of MCPA607-053-00-4MCPB607-054-00-XSalts and esters of MCPB607-049-00-2Mecoprop006-038-00-4SulfallateMolinate613-020-00-5Tridemorph

Class II/d

No. in Directive 67/548/EECNomenclature according to Directive 67/548/EECAlachlor613-010-00-0Ametryne006-020-00-6Barban613-012-00-1Bentazone006-036-00-3Benzthiazuron609-032-00-5BromofenoximBromophos607-075-00-4Chlorfenprop-methyl613-007-00-4Desmetryne606-018-00-0Dichlone609-023-00-6Dinocap616-007-00-2Diphenamid607-076-00-XDodine006-030-00-0EPTC607-077-00-5Erbon015-052-00-XFenchlorphos613-017-00-98-Hydroxyquinoline sulphateHexachloroacetone006-032-00-1MonolinuronMonuron006-034-00-2Pebulate616-009-00-3PropanilPropargite2,

 $3, 6\text{-}TBATrifenmorph006-039-00-XTrial late Malathion containing } 1.8\% isomalathion or$

less006-012-00-2Ziram613-011-00-6Aminotriazole015-100-00-XPhoxim
No. in Directive 67/548/EECNomenclature according to Directive
67/548/EEC016-010-00-3Sodium Polysulphides(1)016-007-00-7Potassium
polysulphides(1)016-008-00-2Ammonium polysulphides(1)016-005-00-6Calcium
polysulphides(1)016-003-00-5Barium
polysulphides(1)616-006-00-7Dichlofuanid(1)
(1)Conventional LD50 and LC50 values have not been given to these
substances because of their corrosive/irritant properties

GIVEN under my Official Seal, this 12 day of April, 1991. M. O'KENNEDY, Minister for Agriculture and Food.

EXPLANATORY NOTE.

These Regulations amend existing Regulations on pesticides (i) to allow for the classification, by calculation, of pesticides which contain more than one active substance and are intended solely for marketing in Ireland, (ii) to provide for permissions to market a pesticide which is similar to a notified pesticide and to prescribe the fee for such clearance, and (iii) to provide for renewal of clearances at the discretion of the Minister.