

S.I. No. 463/1999 — European Communities (Classification, Packaging and Labelling of Pesticides) (Amendment) Regulations, 1999

STATUTORY INSTRUMENTS.

S.I. No. 463 of 1999.

EUROPEAN COMMUNITIES (CLASSIFICATION, PACKAGING AND
LABELLING OF PESTICIDES) (AMENDMENT) REGULATIONS, 1999

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LABELLING OF PESTICIDES) (AMENDMENT) REGULATIONS, 1999

I, JOE WALSH, Minister for Agriculture, Food and Rural Development, 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, 1978¹, hereby make the following Regulations:

1. (1) These Regulations may be cited as the European Communities (Classification, Packaging and Labelling of Pesticides) (Amendment) Regulations, 1999.

(2) The European Communities (Classification, Packaging and Labelling of Pesticides) Regulations, 1994 and these Regulations may be cited together as the European Communities (Classification, Packaging and Labelling of Pesticides) Regulations, 1994 and 1999 and shall be construed together as one.

(3) These Regulations shall come into operation on the first day of January, 2000.

Interpretation

2. (1) In these Regulations—

“the principal Regulations” means the European Communities (Classification, Packaging and Labelling of Pesticides) Regulations, 1994;

“permission to market” means a permission to market a pesticide granted by the Minister pursuant to subparagraph (2)(c) of Regulation 6 of the Principal Regulations.

(2) In these Regulations, unless otherwise indicated—

(a) a reference to a Regulation is a reference to a Regulation of these Regulations,

(b) a reference to a paragraph or subparagraph is a reference to a paragraph or subparagraph of the provision in which the reference occurs,

(c) a reference to the Fourth Schedule is a reference to the Fourth Schedule of the Principal Regulations as amended by these Regulations.

(3) The phrase “designated chemist” and the interpretation of the phrase that follows it, included in paragraph (1) of Regulation 2 of the Principal Regulations, is hereby replaced by the following:

““designated analyst” means any appropriately qualified officer of the Minister who is authorized in writing by the Minister for the purposes of these Regulations.”

(4) The phrase “State Chemist” and the interpretation of the phrase that follows it, included in paragraph (1) of Regulation 2 of the principal Regulations, is hereby replaced by the following:

““State Chemist” means the Head of the State Laboratory or a member of the staff of the State Laboratory authorized by the State Chemist in writing to perform functions assigned to the State Chemist under Regulation 24”.

(5) A word or expression that is used in any Council Directive of the European Communities mentioned in these Regulations has, unless the contrary intention appears, the meaning in these Regulations that it has in the Directive concerned.

Amendments

3. Regulation 9 of the Principal Regulations is hereby revoked and is replaced by the following:—

“9. The Provisions of Regulations 7 and 8 are in addition to, and not in substitution for, the provisions of the European Communities (Aerosol Dispensers) Regulations, 1977 (S.I. No. 144 of 1977), the European Communities (Aerosol Dispensers) (Amendment) Regulations, 1995 (S.I. No. 127 of 1995) and the Packaged Goods (Quantity Control) Regulations, 1981 (S.I. No. 39 of 1981).”

4. Regulation 12 of the Principal Regulations is hereby revoked and is replaced by the following:

“12. (1) Subject to paragraph (7) an authorised officer may at any reasonable time enter—

- (a) any place or premises in which he/she has reasonable grounds for believing that a pesticide is being manufactured, placed on the market, stored or used,
- (b) any railway wagon, vehicle, ship, vessel, aircraft, container or other thing in which he/she has reasonable grounds for believing that a pesticide is being either transported, stored or used,
- (c) any premises in which he/she has reasonable grounds for believing that there are any books, documents or records relating to any business whose activities consist of or include the manufacture, placing on the market, storage, transport or use of a pesticide,

and there or at any other place—

- (i) make such examinations, tests and inspections, and
- (ii) take samples in accordance with the methods described in the manual on the development and use of FAO specifications for plant protection products (Food and Agriculture Organization of the United Nations, FAO Plant Production and Protection Paper 128, Fourth Edition), as updated from time to time, of any pesticide which he/she finds in the course of his/her inspection and which he/she believes is or may be a pesticide to which these Regulations apply, and
- (iii) take samples in accordance with Commission Directive 79/700/EEC of 24 July 1979², or the Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission, recommended method of sampling for the determination of Pesticide Residues (Volume 2, Codex Alimentarius, Food and Agriculture Organisation of the United Nations, World Health Organization, Rome, 1993), where relevant, and in accordance with other internationally accepted procedures in other cases, of any plant, plant product, soil, compost, or take samples from or of any other thing, which he/she finds in the course of an inspection and which he/she believes may have been treated or contaminated with a pesticide to which the Regulations apply,

as he/she may consider appropriate and provided the quantity which a sample taken pursuant to this Regulation comprises is reasonable.

(2) A person who has in any place, on any premises or in any railway wagon, vehicle, ship, vessel, aircraft container or other thing a pesticide to which these Regulations apply shall at all reasonable times—

- (a) afford to an authorised officer such facilities and assistance as are reasonably necessary for an inspection and taking of samples pursuant to this

Regulation,

- (b) give an authorised officer any information which he/she may reasonably require regarding the purchase, importation, sale or use of any such pesticide and which is within the person's knowledge or procurement, and
 - (c) produce to an authorised officer any document relating to the raw materials used in the formulation of any pesticide which the authorised officer may reasonably require and when produced permit the officer to inspect and take extracts from the document.
- (3) In addition to the foregoing any person who carries on the business of manufacturing, formulating, packaging, processing or marketing a pesticide for the purposes of the Directive of 1978 shall—
- (a) keep records of all transactions regarding the pesticide.
 - (b) produce at the request of an authorised officer any records, books or other documents relating to such business which are in his/her possession or under his/her control,
 - (c) permit such an officer to inspect and take extracts from such records, books or other documents and give to the officer any information which is within his/her knowledge or under his control and which such officer may reasonably require in relation to any entries therein,
 - (d) afford to any such an officer such facilities and assistance as are reasonably necessary for inspecting the stock of any pesticide on any premises on which such person carries on such a business, and
 - (e) give to such an officer any information he/she may reasonably require in relation to such transactions, including, in particular, information which he/she may reasonably require regarding any pesticide specified by him/her.
- (4) Where a sample is taken pursuant to this Regulation, the authorised officer concerned shall—
- (a) divide the sample into three or more parts, each of which he/she shall seal and mark,
 - (b) give one part thereof to a designated analyst for analysis in accordance with paragraph (5),
 - (c) leave with, deliver to, or send by registered post to, the defendant or his/her agent, a second part thereof,
 - (d) where there is more than one defendant, leave with, deliver to, or send by registered post to such defendant, a further part thereof, and
 - (e) give the remaining part thereof to the State Chemist for analysis in

accordance with Regulation 16.

- (5) Where a designated analyst or the State Chemist receives a sample from an authorized officer in pursuance of these Regulations he/she shall make analyses thereof using validated analytical methods.
- (6) (a) In any proceedings for an offence under these Regulations, the result of any test, examination or analysis of, or any report on, a sample taken pursuant to this Regulation shall not be adduced unless, before the proceedings were instituted, one of the parts into which the sample was divided (as required by paragraph (4)) was left with, delivered to or sent by registered post to, the defendant or his/her agent.
- (b) In any proceedings for an offence under these Regulations, evidence of the presence of a residue of a pesticide to which the Regulations apply, in or on agricultural produce, in soil or compost or in or on surfaces or other materials which may have been treated with or exposed to the pesticide, shall be evidence, until the contrary is proved, of the use of the pesticide by the owner, occupier or person in possession, as the case may be.
- (c) In any proceedings for an offence under these Regulations, a certificate in the form set out in the Second or Third Schedule showing the results of an analysis shall, until the contrary is shown, be sufficient evidence of the facts certified to therein in relation to the presence in a pesticide of any pesticidal substance, impurity or formulating ingredient, and the level such presence and document purporting to be such a certificate shall be deemed, until the contrary is shown, to be such a certificate.
- (d) In any proceedings for an offence under these Regulations, each of the documents referred to in subparagraphs (1) (ii) and (iii) may be proved by a production of a copy thereof purporting to have been published in the Official Journal of European Communities, by the Food and Agriculture Organization of the United Nations, by the World Health Organization, as appropriate.
- (e) For the purpose of these Regulations, the presence of a pesticide, to which these Regulations apply, on any premises (including any stores), shall, until the contrary is shown, be sufficient evidence that the pesticide in question is or was being placed on the market by the owner and by the occupier of such premises.
- (7) An authorised officer shall be furnished with a certificate of his/her appointment as an authorised officer and when exercising any power conferred on him/her by these Regulations, shall if requested by any person affected, produce the certificate to that person.
- (8) A designated analyst shall be furnished with a warrant of his/her appointment by the Minister to carry out analyses as required by these Regulations.”

5. Regulation 15 of the Principal Regulations is hereby revoked and is replaced by the following:

“15. (1) An offence under these Regulations may be prosecuted by the Minister.

(2) In proceedings for an offence under Regulation 14(1), evidence that claims have been made that a substance or preparation—

- (a) destroys organisms harmful to plants or to plant products or protects plants and plant products from such organisms,
- (b) improves or regulates plant production, with the exception of fertilizers and soil conditioners,
- (c) preserves plant products,
- (d) destroys undesired plants,
- (e) destroys parts of plants, checks or prevents undesired growth of plants or
- (f) renders harmless or destroys, or gives protection against, harmful organisms which do not attack plants, and undesired organisms,

shall, until the contrary is shown, be sufficient evidence that it is a pesticide to which these Regulations apply.”

6. The phrase “designated chemist” included in paragraph (2) of Regulation 16 of the principal Regulations, is hereby replaced by the phrase “designated analyst”.

7. Regulation 18 of the Principal Regulations is hereby revoked and is replaced by the following:

“18 (1) Every application for approval of documentation and materials and for clearance of a pesticide shall be subject to the payment of the following fees, that is to say—

- (a) for each active substance contained in the pesticide, the fee set out in column (2) of Part 1A of the Fourth Schedule payable to the Minister in respect of the appropriate type of clearance in relation to a category set out in column (1) of the said Part 1A;
- (b) in relation to each preparation, the fee set out in column (2) of Part 1B of the Fourth Schedule payable to the Minister in respect of the appropriate type of clearance in relation to a category set out in column (1) of the said Part 1B;
- (c) a fee of £150 shall be payable in each case where an application is made for minor amendments to the packaging and labelling or to the documentation and materials submitted in accordance with Regulations 6(2)(a) or 6(2)(b), where it is considered that an evaluation of the risks arising for man, animals or the environment is not involved or required.

(d) a fee of £1,000 shall be payable in each case where an application is made

for a permission to market in accordance with Regulation 6(2)(c).

- (2) (a) Every grant of a clearance of a pesticide or of a permission to market a pesticide shall be for 12 months from the date of such grant and shall be renewable at the discretion of the Minister for further periods of 12 months on an application being made in that behalf to the Minister and shall be accompanied by the appropriate annual fee set out in Part 2 of the Fourth Schedule and on a request being made to him in that behalf. In the event of a failure to pay the annual fee set out in Part 2 of the Fourth Schedule, within 30 days of the annual fee falling due, renewal of clearance or permission to market, as appropriate, may be granted where application is made more than 30 days but not more than 60 days after the annual fee fell due, on payment to the Minister of the late annual fee set out in Part 3 of the Fourth Schedule.
- (b) Pesticides notified as being on the market on or before the second of December 1985, in accordance with the provisions of the Principal Regulations, may continue to be placed on the market and used if the annual fee set out in Part 2 of the Fourth Schedule has been paid to the Minister, within 30 days of the fee falling due. Where for a particular pesticide, the annual fee has not been paid by the date due, the notification concerned shall be revoked, but renewal of the notification may be granted where application is made more than 30 days but not more than 60 days after the annual fee fell due, on payment to the Minister of the late annual fee set out in Part 3 of the Fourth Schedule.
- (c) Notwithstanding the periods for which clearances or permissions are granted are valid, one half of the annual fees payable in accordance with subparagraph, (a) shall be paid by 1 April of each year, the balance by 1 September of each year. One half of the annual fees payable in accordance with subparagraph (b) shall be paid by 1 April of each year, the balance by 1 September of each year.
- (d) In the case of a pesticide already on the market for a period of one year or more prior to the calendar year for which the annual fee is payable, the Minister may reduce the level of the annual fee payable to the Minister in accordance with this paragraph for particular pesticides, where, on the basis of an auditor's certificate furnished to him, he is satisfied that the wholesale sales of the pesticide during the previous calendar year did not exceed—
- (i) in the case of pesticides for household, home garden or other amateur use, £5,000, and
- (ii) in the case of other pesticides, £15,000.

In all such cases, the minimum fee payable for each such pesticide shall be £50.

- (e) In the case of a pesticide on the market for less than one year prior to the calendar year for which an annual fee is payable, the Minister may refund part of the annual fee payable in accordance with this paragraph, on a request being made to him in that behalf, where, on the basis of an

auditor's certificate furnished to him, he is satisfied that the wholesale sales of the pesticide during the year for which the annual fee was paid, did not exceed—

(i) in the case of pesticides for household, home garden or other amateur use, £5,000, and

(ii) in the case of other pesticides, £15,000.

In all such cases, any refund made shall be such that for each such pesticide, the minimum annual fee payable shall be £50.

(3) In the case of a pesticide already on the market for a period of three years or more prior to the calendar year in which the fee is payable and which is placed on the market exclusively for a specialized use or specialized uses, the fee or fees payable in accordance with paragraph (1)(a), (b) and (d) shall be reduced by the amount specified in column (2) of Part 1C of the Fourth Schedule, on a request being made to the Minister in that behalf, where, on the basis of an auditor's certificate furnished to him, he is satisfied that the wholesale sales of the pesticide during each of the three calendar years immediately prior to the year in which the fee or fees are payable, did not exceed the amounts specified in column (1) of the said Part 1C.

(4) In the case of a pesticide on the market for a period of less than three years prior to the calendar year in which the fee is payable and which is placed on the market exclusively for a specialized use or specialized uses, the fee or fees payable in accordance with paragraph (1)(a), (b) and (d) shall be reduced by the amount specified in column (2) of Part 1D of the Fourth Schedule, on a request being made to the Minister in that behalf, where, on the basis of a market survey report provided by the applicant, he is satisfied that the potential annual wholesale sales of the pesticide do not exceed the amounts specified in column (1) of the said Part 1D. In cases, where the pesticide has been on the market for one or two years immediately prior to the calendar year in which the fee is payable, any application made for a reduction in fees must be supported by an auditor's certificate relating to the wholesale sales of the pesticide during each such year.

(5) Each clearance of a pesticide and each permission to market a pesticide granted and each notification accepted for a pesticide in accordance with the requirements of these Regulations shall be withdrawn if, in each case where such a pesticide continues to be placed on the market, there is a failure to pay the annual renewal fee set out in Part 2 of the Fourth Schedule within 30 days of the fee falling due but an application for a renewal of clearance of a pesticide, or of a permission to market a pesticide or of a notification for a pesticide, as appropriate, may be made more than 30 but not more than 60 days after the renewal fee fell due on payment to the Minister of the late annual renewal fee set out in Part 3 of the Fourth Schedule.

(6) In the case of an application to alter the type of clearance where a clearance has been approved, the fee, or fees, payable in respect of any subsequent clearance shall be reduced by the amount already paid in accordance with paragraph (1)(a) and (b).

(7) A fee payable under these Regulations may be recovered by the Minister as a simple contract debt in any court of competent jurisdiction.”

8. The Second Schedule of the Principal Regulations is hereby revoked and is replaced by the following:

Regulation 12(6)(d).

“SECOND SCHEDULE

CERTIFICATE OF RESULT OF ANALYSIS

Laboratory Reference Number.....

Sample of.....
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received by the designated analyst on.....
.....

from.....
.....

Methods of analysis used.....
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This is to certify that the above mentioned sample, which was duly fastened and sealed, has been analyzed under the provisions of the European Communities (Classification, Packaging and Labelling of Pesticides) Regulations, 1994 to 1999 and that the results of the analysis are as follows:—

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This certificate is issued under the European Communities (Classification, Packaging and Labelling of Pesticides) Regulations, 1994 to 1999

Date

Signed

Designated Analyst

.....

Designated Analyst

.....

Designated Analyst”

9. The Fourth Schedule of the Principal Regulations is hereby revoked and is replaced by the following:

Regulation 18.

“FOURTH SCHEDULE

PART I

Fees for clearance of pesticides

A. Each active substance contained in the pesticide

Column (1)

Column (2)

Type of clearance and fee payable

Category	Trial	Limited	Provisional	Restricted or Commercial
	£	£	£	£
I	150	2,000	4,000	4,500

B. Each preparation

Column (1)	Column (2)			
	Type of clearance and fee payable			
Category	Trial	Limited	Provisional	Restricted or Commercial
	£	£	£	£
I	100	400	1,000	1,500
II	75	200	400	600

In this Schedule—

“Category I”

means a pesticide containing one or more active ingredients of particular specification not previously cleared and for which approval of classification, packaging and labelling in accordance with Regulation 4 of the Principal Regulations, is sought;

or

means a pesticide for which clearance and approval of classification, packaging and labelling in accordance with Regulation 4 of the Principal Regulations, for a major new area of use or a major formulation change, is sought;

“Category II”

means a pesticide for which clearance and approval of classification, packaging and labelling in accordance with Regulation 4 of the Principal Regulations, for a minor extension in use or a minor formulation changes, is sought;

“Commercial clearance”

means clearance for commercial sale and use of a pesticide;

“Limited clearance”

means clearance for commercial sale and use of a pesticide, in limited quantities or for a limited period or both, subject to specified restrictions or conditions;

“Provisional clearance”

means clearance for commercial sale and use of a pesticide, sometimes for a limited period, subject to specified restrictions or conditions;

“Restricted clearance”

means clearance for commercial sale and use of a pesticide subject to restriction(s) imposed by other statutory provisions or subject to special restrictions;

“Trial clearance” means clearance for experimental use of a pesticide subject to specified restrictions or conditions.

C. Reduced fees payable for pesticides for specialized use or uses already on the market for 3 calendar years

Column (1)	Column (2)
Wholesale sales in each of three calendar years immediately prior to the year in which the fee is payable	Percentage of the fee payable
	%
less than £5,000	10
£5,000 to £9,999	25
£10,000 to £19,999	50

D. Reduced fees payable for pesticides for specialized use or uses, on the market for less than 3 calendar years

Column (1)	Column (2)
Estimated potential annual wholesale sales	Percentage of the fee payable
	%
less than £10,000	10
£10,000 to £19,999	25
£20,000 to £39,999	50

PART 2

Type of Clearance	Amount
Annual Fee for a Limited, Provisional, Commercial, or Restricted Clearance, for 2 Permission to Market and for Notified Pesticides:	£200
Trial Clearance	£ 50

PART 3

Type of Clearance	Amount
Late Annual Renewal Fee for a Limited, Provisional, Commercial, or Restricted Clearance, for a Permission to Market and for Notified Pesticides:	£300

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GIVEN under my Official Seal, this 16th day of December, 1999.

JOE WALSH

Minister for Agriculture, Food and Rural Development.

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation.)

The amendments specify revision to the monitoring and control arrangements under the Regulations and to fees for applications for the clearance of pesticides. The Regulations also provide for evidence for prosecution under the Regulations and for the application of an annual fee.

¹ O.J. No. L206/13 29/7/1978.

² O.J. No. L207/26 15/8/1979