STATUTORY INSTRUMENTS

1993 No. 2166

DANGEROUS DRUGS

The Controlled Drugs (Substances Useful for Manufacture) (Intra–Community Trade) Regulations 1993

Made - - - -	*4th September 1993*
Laid before Parliament	*13th September 1993*
Coming into force - -	*6th October 1993*

In exercise of the powers conferred upon me by section 2(2) of the European Communities Act 1972(**1**), I hereby make the following Regulations:

1. These Regulations may be cited as the Controlled Drugs (Substances Useful for Manufacture) (Intra–Community Trade) Regulations 1993 and shall come into force on 6th October 1993.

2. In these Regulations–

"the 1990 Act" means the Criminal Justice (International Co–operation) Act 1990(**2**);

"operator" means any person engaged in the manufacture, processing, trade or distribution of scheduled substances in any member State or involved in other related activities such as the brokering and storage of scheduled substances;

"placing on the market" means any supply to a person in any member State, whether against payment or free of charge, of scheduled substances manufactured in a member State or put into free circulation in any member State; and

"scheduled substance", except in so far as the context otherwise requires, means any substance specified in Schedule 1 below, including mixtures containing such substances, but excluding medicinal products or other preparations containing scheduled substances in such a way that such substances cannot be easily used or recovered by readily applicable means.

3. Subject to regulation 7 below, the obligations imposed on operators by regulation 4 below shall be treated as if they were requirements imposed on them by regulations made under section 13(1) of the 1990 Act, and as if the references in regulation 4 to scheduled substances were references to scheduled substances within the meaning of Part II of that Act.

(**1**) 1972 c. 68. The Secretary of State is the designated Minister for the purpose of these Regulations by virtue of S.I. 1981/1536 and 1983/1706.
(**2**) 1990 c. 5.

4.—(1) An operator who is concerned in a transaction leading to the placing on the market of a scheduled substance shall ensure that he has the following documentation, subject to paragraph (2) below–

(a) commercial documents which, taken together, contain sufficient information positively to identify the following matters–

(i) the name of the scheduled substance as given in Schedule 1 below;

(ii) the quantity and weight of the scheduled substance and, where it consists of a mixture, the quantity and weight of the mixture and the quantity and weight or the percentage of any scheduled substance contained in that mixture; and

(iii) the names and addresses of the supplier, distributor and of the consignee; and

(b) a declaration from the customer which shows the specific uses of the scheduled substances.

(2) Paragraph (1) above shall not apply in respect of a transaction concerning a scheduled substance specified in Category 2 of Schedule 1 below where the quantity of that substance does not exceed the quantity relating to that substance, specified in Schedule 2 below.

(3) An operator shall ensure that labels are affixed to scheduled substances before such substances are placed on the market, and that such labels show the names of the substances to which they are affixed as given in Schedule 1 below.

(4) An operator shall keep such detailed records of his activities as are required to comply with his obligations under paragraph (1) above.

(5) An operator shall keep the documentation and records mentioned in paragraphs (1) and (4) above readily available for inspection by the Secretary of State upon request by him, for a period of not less than three years from the end of the year in which the transaction mentioned in paragraph (1) above took place.

(6) In this regulation–

"commercial document" includes invoices, cargo manifests, administrative documents, and transport and other shipping documents; and

"year" means a period of twelve months beginning with 1st January.

5.—(1) No operator shall manufacture or place on the market any of the scheduled substances specified in Category 1 of Schedule 1 below without a licence to do so granted by the Secretary of State in accordance with regulation 6(1) below.

(2) An operator who holds a licence granted under paragraph (1) above shall not supply any of the substances there referred to, except to any of the following persons–

(a) another operator holding such a licence;

(b) an operator who requires any such substance for the manufacture of a medicinal product and in respect of whom a licence is in force to manufacture that product under section 8(2) of the Medicines Act 1968(**3**);

(c) a pharmacist or a person lawfully conducting a retail pharmacy business in accordance with section 69 of the Medicines Act 1968;

(d) a person who is in charge of a laboratory, the recognised activities of which consist in, or include, the conduct of scientific education or research, and which is attached to a university or a hospital in the United Kingdom or to any other institution approved for the purpose by the Secretary of State;

(**3**) 1968 c. 67.

(e) any other person who has been authorised by the Secretary of State to be supplied with such a substance for the purposes of the manufacture of non– medicinal products or other special purposes; or

(f) any other person permitted by a member State other than the United Kingdom to be supplied with, possess or handle such substances in accordance with Article 4(3) of Council Directive 92/109/EEC(**4**).

(3) An operator involved in the manufacture or placing on the market of scheduled substances listed in Category 2 of Schedule 1 below shall register with the Secretary of State the addresses of the premises from which he manufactures or trades in such substances and shall notify him in writing of any change of address.

(4) In this regulation–

"medicinal product" has the meaning assigned to it by section 130(**5**) of the Medicines Act 1968, and "non–medicinal products" shall be construed accordingly; and

"pharmacist" has the meaning assigned to it by section 132(1)(**6**) of that Act.

6.—(1) In considering whether to grant a licence under regulation 5(1) above, the Secretary of State shall take into account in particular the competence and integrity of the applicant for that licence.

(2) A licence granted under regulation 5(1) above may be revoked or suspended by the Secretary of State where there are reasonable grounds for belief that the holder of that licence is no longer a fit and proper person to hold it, or that the conditions under which it was granted are no longer fulfilled.

7. Where a person is convicted of an offence contrary to section 13(5) of the 1990 Act as a result of the application of regulation 3 above, section 13(5)(a) of the Act shall have effect as if for the words "6 months" there were substituted the words "3 months".

8.—(1) A person who fails to comply with any provision of regulation 5 above is guilty of an offence and liable–

(a) on summary conviction, to imprisonment for a term not exceeding 3 months or a fine not exceeding the statutory maximum or both;

(b) on conviction on indictment, to imprisonment for a term not exceeding two years or a fine or both.

(2) The powers conferred by subsection (1) of section 23 of the Misuse of Drugs Act 1971(**7**) shall be exercisable also for the purposes of the execution of regulation 5 above and subsection (3) of that section (excluding paragraph (a)) shall apply also to the offence under paragraph (1) above, taking references in those subsections to controlled drugs as references to scheduled substances.

(3) The reference in paragraph (1) above to a person who fails to comply with any provision in regulation 5 above includes a person, who in purported compliance with any such provision–

(a) furnishes information which he knows to be false in a material particular; or

(b) recklessly furnishes information which is false in a material particular.

(**4**) OJNo. L370, 19.12.92, p.76, as amended by Commission Directive 93/46/EEC (OJ No. L159, 1.7.93. p.134).
(**5**) Section 130 was amended by sections 13(2) and 16 of, and paragraph 3 of Schedule 1 and Schedule 2 to, the Animal Health and Welfare Act 1984 (c. 40).
(**6**) The definition in section 132(1) was amended by paragraph 7 of Schedule 5 to the Pharmacy (Northern Ireland) Order 1976 (S.I. 1976/1213 (N.I. 22)).
(**7**) 1971 c. 38. Section 23 of the 1971 Act was amended by the insertion of subsection (3A), by section 23(4) of the Criminal Justice (International Co–operation) Act 1990 (c. 5).

Michael Howard
One of Her Majesty's Principal Secretaries of State

Home Office
4th September 1993

SCHEDULE 1

Regulation 2

SCHEDULED SUBSTANCES

CATEGORY 1

Ephedrine

Ergometrine

Ergotamine

Isosafrole

Lysergic acid

3, 4 methylenedioxyphenyl propan – 2 – one

N– acetylanthranilic acid

1 – phenyl – 2 – propanone

Piperonal

Pseudoephedrine

Safrole

The salts of the substances listed in this Category whenever the existence of such salts is possible.

CATEGORY 2

Acetic anhydride

Anthranilic acid

Phenylacetic acid

Piperidine

The salts of the substances listed in this Category whenever the existence of such salts is possible.

SCHEDULE 2

Regulation 4

SPECIFIED QUANTITIES OF SCHEDULED SUBSTANCES IN CATEGORY 2 OF SCHEDULE 1

Substance	Quantity
Acetic Anhydride	20 litres
Anthranilic acid and its salts	1 kilogramme
Phenylacetic acid and its salts	1 kilogramme
Piperidine and its salts	500 grammes

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations implement Council Directive 92/109/EEC (on the manufacture and the placing on the market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances) "the Community Directive").

The Community Directive provides, in Article 2, for the documentation and labelling of scheduled substances (substances useful for the manufacture of controlled drugs). Article 4 of the Community Directive requires that each member State ensures that those who manufacture certain scheduled substances or place them on the market within the European Community obtain licences to do so, and that such substances are supplied only to those specifically authorised to be supplied with them. Article 6 of the Community Directive requires member States to adopt within the framework of their domestic law the measures necessary to enable the competent authorities in each such State to obtain information on any orders for or operations involving scheduled substances and to enter operators' business premises to obtain evidence of irregularities. This is in order to ensure the correct application of Articles 2 and 4. Article 8 of the Community Directive requires member States to determine the penalties to be applied for infringement of the provisions of the Community Directive.

The Community Directive applies only to manufacture and trade in scheduled substances which occurs within the European Community. It is therefore complementary to Council Regulation (EEC) 3677/90 ("the Council Regulation") which deals principally with the exportation of such substances from, and their importation to, the Community. The Council Regulation was implemented by the Controlled Drugs (Substances Useful for Manufacture) Regulations 1991 (S.I.1991/1285, amended by S.I. 1992/2914).

These Regulations treat the provisions in the Community Directive on the documentation and labelling of scheduled substances as if they were requirements of regulations made under section 13(1) of the Criminal Justice (International Co– operation) Act 1990 ("the 1990 Act"). Section 23 of the 1990 Act provides for rights of entry and search of premises in order to investigate suspected breaches of regulations made under section 13(1) of that Act. The 1990 Act also provides for breaches of such regulations, although the penalties for breaches of these Regulations are in certain respects lower than those provided for under the 1990 Act.

These Regulations also provide for the grant of licences in accordance with the Community Directive. A person who manufactures a scheduled substance listed in Category 1 of Schedule 1 to these Regulations, or places it on the market within the European Community, without a licence to do so is subject to the same enforcement powers and penalties as those outlined above. The same applies to a person who supplies such a substance to a person not authorised to be supplied with it.

The list of scheduled substances in Schedule 1 to these Regulations does not include a number of the substances listed in the Annex to the Council Regulation (and in Schedule 2 to the Criminal Justice (International Co–operation) Act 1990, as modified by S.I. 1992/ 2873, under which certain statutory controls are imposed). This is because these Regulations do not impose controls on those substances.