STATUTORY INSTRUMENTS

1993 No. 3050

The Notification of New Substances Regulations 1993

PART II

NOTIFICATIONS

Full notifications

4. Subject to regulations 6 and 7, a person shall not place a new substance on the market in a total quantity of one tonne or more per year unless he has sent to the competent authority a notification including—

(a) a technical dossier supplying the information necessary for evaluating the foreseeable risk, whether immediate or delayed, which the substance may create for human health and the environment and containing all available relevant data for this purpose and including at least the information and results of the tests referred to in Part A of Schedule 2 together with a detailed and full description of the studies conducted or bibliographic references to them;

(b) a certificate in writing from the body which carried out the tests for the purpose of the technical dossier stating that those tests were carried out in accordance with the principles of good laboratory practice referred to in regulation 14(1);

(c) a declaration concerning the unfavourable effects of the substance in terms of the various foreseeable uses of the substance;

(d) if the substance is a dangerous substance, proposals for the purposes of the Chemicals (Hazard Information and Packaging) Regulations 1993 for—

(i) the classification and labelling of the substance for supply, and

(ii) the safety data sheet referred to in regulation 6 of those Regulations;

(e) in the case of a substance manufactured outside the Communities, where appropriate, a statement by the manufacturer that the notifier has been appointed, for the purpose of submitting a notification of the substance in question, as his sole representative and that he has informed all the importers of the same substance manufactured by him of the name of the sole representative; and

(f) if so desired, a statement that the notifier requests, on reasoned grounds, that the notification be exempted from the provisions of regulation 13 (avoidance of animal testing) for a period which shall not exceed one year from the date of the notification.

Requirements for further testing for substances notified under regulation 4

5.—(1) Any notifier of a substance already notified under regulation 4 shall inform the competent authority—

(a) when the quantity of the substance placed on the market reaches 10 tonnes per year from a single manufacturer or when the total quantity of substance reaches 50 tonnes per manufacturer; the competent authority may then require some or all of the additional tests

or studies or both laid down in Schedule 3 at level 1, to be carried out within the time limit that the competent authority shall determine;

(b) when the quantity of the substance placed on the market reaches 100 tonnes per year from a single manufacturer or when the total quantity of the substance reaches 500 tonnes per manufacturer; the competent authority shall then require the additional tests or studies or both laid down in Schedule 3 at level 1, to be carried out within the time limit that the competent authority shall determine, unless the notifier can give good reason why a given test or study is not appropriate or an alternative test or study would be preferable;

(c) when the quantity of the substance placed on the market reaches 1000 tonnes per year from a single manufacturer or when the total quantity of the substance reaches 5000 tonnes per manufacturer; the competent authority shall then draw up a programme of tests or studies or both according to Schedule 3, level 2 to be carried out by the notifier within the time limit determined by the competent authority.

(2) Where additional testing has been carried out, either in accordance with paragraph (1) or voluntarily, the notifier shall forthwith provide the competent authority with the results of those tests together with a certificate in writing from the person who carried out the tests stating that those tests were carried out in accordance with the principles of good laboratory practice referred to in regulation 14(1).

Reduced notification requirements for substances placed on the market in quantities of less than one tonne per year by a single manufacturer

6.—(1) Subject to the following paragraphs of this regulation and regulation 7, a person responsible for placing a new substance on the market in a total quantity of less than one tonne per year from a single manufacturer shall not place that substance on the market unless he has sent to the competent authority a notification including a summary of—

(a) a technical dossier supplying the information necessary for evaluating the foreseeable risks, whether immediate or delayed, which the substance may create for human health and the environment and containing all available relevant data for this purpose and including at least the information and results of the tests referred to in Part B of Schedule 2; and

(b) all the other information referred to in sub-paragraphs (b) to (f) of regulation 4.

(2) Subject to paragraph (4), where the quantities to be placed on the market are below 100 kg per year from a single manufacturer, the person responsible for placing the substance on the market may restrict the information in the technical dossier referred to in paragraph (1)(a) to that provided for in Part C of Schedule 2, he shall also provide all the other information referred to in paragraph (1)(b) and this information shall be notified to the competent authority in summary form.

(3) At the request of the competent authority, the person responsible for placing the substance on the market shall provide it with the full information referred to in paragraph (1) or (2), as appropriate, together with a detailed and full description of the studies conducted or bibliographic references to them.

(4) Subject to paragraph (5) and the conditions set out below, the following new substances shall be treated as having been notified under these Regulations—

(a) polymers except those containing in combined form 2 per cent or more of a new substance;

(b) subject to paragraph (6), substances placed on the market in quantities of less than 10 kg per year per manufacturer;

(c) substances placed on the market in quantities of less than 100 kg per year per manufacturer and intended solely for the purposes of scientific research and development on condition that the person placing the substance on the market maintains a record of the identity of the substance, labelling data and a list of customers in member States;

(d) substances placed on the market for the purposes of process-orientated research and development with a limited number of registered customers in quantities that are limited to those purposes, subject to the following conditions—

(i) the substance is duly notified within one year of its first having been placed on the market unless on reasoned grounds provided by the person responsible for placing the substance on the market the competent authority approves an extension for up to a further year,

(ii) the person responsible for placing the substance on the market has notified to the competent authority the following information about the substance, namely, identity, labelling data, a justification for the quantity placed on the market,

(iii) the person responsible for placing the substance on the market has provided a list of the customers,

(iv) the person responsible for placing the substance on the market has provided an assurance that the substance or a preparation in which it is incorporated will only be handled by the customer's staff in controlled conditions and will not be made available to the general public at any time, and

(v) the person responsible for placing the substance on the market satisfies any condition imposed by the competent authority, which shall be limited to requiring the information provided for in paragraph (1).

(5) In the case of any substance to which paragraph (4) applies and which on the basis of the information available might reasonably be expected to be very toxic, toxic, carcinogenic, toxic for reproduction or mutagenic, the person responsible for placing the substance on the market shall forthwith notify to the competent authority any appropriate information relating to paragraphs 2.3, 2.4 and 2.5 of Part A of Schedule 2, and, where available, any acute toxicity data.

(6) In the case of a substance to which paragraph (4)(b) applies, which on the basis of the information available might reasonably be expected to be dangerous for the environment and which is intended to be used outside physical containment, the person responsible for placing the substance on the market shall forthwith notify to the competent authority any appropriate information relating to paragraph 2.3 of Part C of Schedule 2.

(7) Substances to which paragraphs (1), (2) and (4) apply shall be packaged and labelled in accordance with the requirements of the Chemicals (Hazard Information and Packaging) Regulations 1993 insofar as the notifier may reasonably be expected to be aware of their dangerous properties, and if it is not reasonably practicable to label the substances completely on the basis of tests carried out in accordance with Schedule 2, Part A, in addition to the label deriving from such tests, the label shall carry the warning "Caution-substance not yet fully tested".

(8) In the case of a notifier who has submitted a reduced notification dossier in conformity with paragraph (2), he shall before the quantity of the substance reaches 100 kg per year from a single manufacturer or a total quantity of 500 kg per manufacturer, provide the competent authority with the information necessary to complete the dossier to the level of Part B Schedule 2.

(9) In the case of a notifier who has submitted a reduced notification dossier in conformity with paragraph (1), he shall before the quantity of the substance reaches 1 tonne per year from a single manufacturer or a total quantity of 5 tonnes per manufacturer, submit to the competent authority a full notification in conformity with regulation 4.

Notifications relating to polymers

7. Subject to regulation 6(4)(a), for polymers the specific provisions relating to the technical dossiers contained in notifications under regulation 4 or 6(1) or (2) shall be those in Part D of Schedule 2.

Placing of notified substances on the market

8.—(1) Substances notified in accordance with regulation 4 may, in the absence of any objection by the competent authority, be placed on the market no sooner than 60 days after receipt of a notification which is in conformity with the requirements of that regulation.

(2) If, within 60 days from receipt of the notification, the competent authority decides the notification is not in conformity with regulation 4, it shall inform the notifier in writing forthwith, and the substance shall only be placed on the market 60 days after receipt by the competent authority of the information necessary to bring the notification into conformity with that regulation.

(3) Substances notified in accordance with regulation 6(1) or (2) may, in the absence of any objection by the competent authority, be placed on the market no sooner than 30 days after receipt of a notification which is in conformity with the requirements of the relevant paragraph of regulation 6.

(4) If, within 30 days from receipt of the notification referred to in paragraph (3), the competent authority decides the notification is not in conformity with the relevant paragraph of regulation 6, it shall inform the notifier in writing forthwith, and the substance shall only be placed on the market 30 days after receipt by the competent authority of the information necessary to bring the notification into conformity with that paragraph.

(5) In the case of a notification made under regulation 6, if the competent authority has informed the notifier in writing that the notification has been accepted as in conformity with that regulation, the substance may be placed on the market no sooner than 15 days after receipt of the summary of the dossier by the competent authority.

(6) If a notification under regulation 4 or 6 has been accepted as conforming to the requirements of these Regulations, the competent authority shall forthwith advise the notifier of the official notification number that has been allocated to the notification.

Requirements for further information

9.—(1) Subject to paragraph (2), in relation to a substance already notified, the competent authority may in writing require further information, verification or confirmation tests concerning the substance or its transformation products within the time limit which it may specify.

(2) The competent authority may only require further information in accordance with paragraph (1) if—

(a) it is satisfied that the further information is reasonably required to evaluate the risks created by the substance to human health or the environment; or

(b) it is acting in accordance with a decision of the European Commission under Articles 18(2) of the Directive.

(3) When further information has been obtained by the notifier in pursuance of paragraph (1), the notifier shall forthwith provide the competent authority with that information in writing.

(4) The information required under paragraph (1) may include requiring the information referred to in Schedule 3 earlier than required under regulation 5.

Follow up information

10.—(1) The notifier of a substance already notified in accordance with regulation 4 or 6 shall inform the competent authority of—

(a) changes in the annual or total quantity of the substance placed on the Communities' market, by him or in the case of a substance manufactured outside the Communities for which the notifier has been designated as the sole representative of the manufacturer, by him and other importers whom he represents;

(b) new knowledge of which he may be aware of the effects of the substance on human health or the environment or both;

(c) new uses of which he may be aware for the substance;

(d) any change in the composition of the substance as given in paragraph 1.3 of Schedule 2, Part A, B, or C as appropriate; and

(e) any change in his status as manufacturer, importer or sole representative.

(2) Any importer of a new substance manufactured outside the Communities who imports that substance under a notification made by a sole representative shall ensure that the sole representative is provided with up-to-date information on the quantity of the substance placed on the Communities' market by that importer.

Notification of substances previously notified

11. In the case of a new substance which had originally been notified at least 10 years previously, a subsequent notifier need not provide the information included in Schedule 2, Part A, B or C with the exception of that specified in paragraphs 1 and 2 of the relevant Part.

Substances manufactured outside the Communities

12.—(1) Subject to paragraph (2), where for a substance manufactured outside the Communities—

(a) more than one notification exists for the same substance manufactured by the same manufacturer (whether to one or more competent authorities of member States); and

(b) the cumulative annual tonnage or the cumulative total tonnage determined by the European Commission and the competent authorities of the member States, on the basis of information notified underArticles 7(1), 8(1) and 14 of the Directive, exceeds for the first time any of the limits specified in regulation 5, each notifier established in Great Britain shall carry out the additional testing required under paragraph (1) of regulation 5 and shall provide the competent authority with the results of those tests in accordance with paragraph (2) of that regulation.

(2) Where the manufacturer has appointed a sole representative, the obligation to comply with paragraph (1) shall not apply to previous notifiers other than the sole representative, and only to the sole representative if he is established in Great Britain.

(3) Where in accordance with paragraph (1), the obligation to carry out further testing falls upon one or more notifiers established in Great Britain, the competent authority shall inform each such notifier of the identities of other notifiers within the Communities and draw attention to the collective responsibilities of notifiers under Article 11 of the Directive.

Further notification of the same substance and avoidance of duplication of testing on vertebrate animals

13.—(1) In the case of a substance that has already been notified under regulation 4 or 6(1) or (2), the competent authority may agree that a subsequent notifier of that substance may, for the purposes of paragraphs 3, 4, and 5 of Part A or B of Schedule 2 or paragraphs 3 and 4 of Part C of Schedule 2, refer to the results of tests or studies or both included in the technical dossier forwarded by the previous notifier if—

(a) the subsequent notifier can provide evidence that the substance intended to be notified is the same as the one previously notified, including the degree of purity and the nature of the impurities; and

(b) the previous notifier has given his consent in writing that such reference may be made.

(2) Without prejudice to paragraph (1), where a prospective notifier intends to notify a new substance to the competent authority under regulation 4 or 6(1) or (2), he shall enquire of the competent authority as to—

(a) whether or not the substance that he intends to notify has already been notified to a competent authority of a member State; and

(b) the name and address of the previous notifier.

(3) Any enquiry made in accordance with paragraph (2) shall be supported by evidence that the prospective notifier has the intention to place the substance on the market and of the quantities involved.

(4) Where—

(a) the competent authority is satisfied that the prospective notifier intends to place the substance on the market in the quantities stated;

(b) the substance had been notified previously; and

(c) the first notifier had not requested in accordance with regulation 4(f) a temporary exemption from the provisions of this regulation to which the competent authority has agreed, after informing the previous notifier of its intention, the competent authority shall provide the prospective notifier with the name and address of the previous notifier.

(5) In a case in which the competent authority has given the prospective notifier the name and address of the previous notifier in accordance with paragraph (4), those notifiers shall take all reasonable steps to reach an agreement to share information in accordance with paragraph (1) so as to avoid the duplication of testing on vertebrate animals.

(6) Where, notwithstanding the requirements of paragraph (5), the prospective notifier has failed to reach an agreement with the first notifier, he shall forthwith inform the competent authority in writing and shall not commence testing on vertebrate animals within 30 days of the receipt of that information by the competent authority.

(7) Where, in accordance with paragraph (5), notifiers have agreed to share information to avoid the duplication of testing on vertebrate animals, and additional testing is required under regulation 5, they shall take all reasonable steps to reach agreement to share the information required by that regulation.

Tests under these Regulations to conform to the principles of good laboratory practice

14.—(1) Where a notifier requires tests to be carried out for the purposes of making a notification under regulation 4, 5 or 6, he shall take all reasonable steps to ensure that those tests are carried out in accordance with the principles of good laboratory practice referred to in Article 1 of Council Directive No.87/18/EEC(**1**) on the application of the principles of good laboratory practice and the verification of their application for tests on chemical substances.

(2) Where the tests are carried out at a laboratory not under the control of the notifier, before the tests are commenced the notifier shall inform the person having control of that laboratory that the tests are required for the purposes of these Regulations.

(3) A person having control of a laboratory in which tests are carried out for the purposes of these Regulations shall, if it be the case, provide the notifier at his request with a certificate in writing that the tests were conducted in accordance with the principles of good laboratory practice.

(4) The principles of good laboratory practice referred to in paragraph (1) are set out in Annex B of Commission Directive 90/18/EEC(**2**) adapting to technical progress the Annex to Council Directive 88/320/EEC(**3**) on the inspection and verification of Good Laboratory Practice.

(**1**) OJ No. L15, 17.1.87, p. 29.
(**2**) OJ No. L11, 12.1.90, p. 37.

Notifications and reports to be in English

15. Notifications and reports required under these Regulations shall be in English.

(**3**) OJ No. L145, 11.6.88, p. 35.