
STATUTORY INSTRUMENTS

1993 No. 3050

The Notification of New Substances Regulations 1993

PART II

NOTIFICATIONS

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

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

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.