2002 No. 2176

HEALTH AND SAFETY

The Notification of New Substances (Amendment) Regulations 2002

Made - - - - -	*17th August 2002*
Laid Before Parliament	*27th August 2002*
Coming into force - -	*17th September 2002*

The Secretary of State, being the designated(**a**) Minister for the purpose of section 2(2) of the European Communities Act 1972(**b**) in relation to the notification and control of substances, in the exercise of the powers conferred on him by the said section 2(2) and sections 15(1) and (2) and 82(3)(a) of, and paragraph 1(1)(b) and (5) of Schedule 3 to, the Health and Safety at Work etc. Act 1974(**c**) ("the 1974 Act") and of all other powers enabling him in that behalf, for the purpose of giving effect without modifications to proposals submitted to him by the Health and Safety Commission under section 11(2)(d) of the 1974 Act after the carrying out by the said Commission of consultations in accordance with section 50(3) of that Act, hereby makes the following Regulations:

Citation and commencement

1. These Regulations may be cited as the Notification of New Substances (Amendment) Regulations 2002 and shall come into force on 17th September 2002.

Interpretation

2. In these Regulations "the principal Regulations" means the Notification of New Substances Regulations 1993(**d**).

Amendment of the principal Regulations

3.—(1) In Part A of Schedule 2 to the principal Regulations—

(a) before section 0 there shall be added the following—

"For intermediates with limited exposure the provisions under section 7 apply"; and

(b) at the end, there shall be added the following—

"7. REDUCED TEST PACKAGE FOR INTERMEDIATES AT QUANTITIES $\geqslant 1$ TONNE/ANNUM

(**a**) S.I.1981/1536.
(**b**) 1972 c. 68.
(**c**) 1974 c. 37; sections 11(2), 15(1) and 50(3) were amended by the Employment Protection Act 1975 (c. 71), Schedule 15, paragraphs 4, 6 and 16(3) respectively.
(**d**) S.I. 1993/3050, to which there are amendments not relevant to these Regulations.

[DTLR 2374]

7.1 **Definitions**

"intermediate" is a chemical substance that is solely manufactured for and consumed in or used for chemical processing in order to be transformed into another chemical substance(s).

"emission" concerns the release of a substance from a system, for example when a system is breached. To guarantee a maximum level of protection for workers and the environment minimisation of emission through rigorous containment of the process must therefore be the primary aim.

"exposure" is concerned with what happens to a substance after it has been emitted, whether this is into the wider environment or whether the substance can be potentially inhaled or come into contact with the skin of a member of the workforce. If emissions can be anticipated to occur, rigorous exposure control must be achieved by appropriate techniques, noting the need to adopt the precautionary principle in that physicochemical, toxicological or ecotoxicological properties which had not been tested shall be assumed as being hazardous.

"integrated exhaust ventilation system" is an exhaust ventilation system of closed type which is used in combination with locks, enclosures, housings, containers etc. in order to restrict the chemical agents to the inner part of the closed functional unit. Process-related openings must be as small as possible.

The power of extraction and the air ducting must be designed so that there is sufficient under-pressure within the extraction unit to ensure that all of the gases, vapours and/or dusts that occur are fully captured and carried away. Back-flow of the extracted hazardous substances into the working area must be prevented.

This means that hazardous substances are prevented from escaping from the closed functional unit into the working area.

"highly effective exhaust ventilation" is an exhaust ventilation system of open and semi-open type which is dimensioned in such a way that chemical agents remain within the catchment area. This means that the occurrence of chemical agents in the workplace atmosphere can practically be excluded.

"effective exhaust ventilation system" is an exhaust ventilation system of open and semi-open type which is dimensioned in such a way that chemical agents remain within the catchment area, ie, the occurrence of chemical agents in the workplace atmosphere can be largely excluded or proof of adherence to the limit value is furnished.

"other exhaust ventilation system" is an exhaust ventilation system of open and semi-open type which is dimensioned in such a way that the occurrence of chemical agents in the workplace atmosphere cannot be excluded.

"low-emission forms of use" are, for example:

— expendable packaging, ie, the hazardous substance is enclosed in appropriate packaging and, without opening the packaging, is introduced into a reaction system together with this packaging.

— change in consistency, ie, the substance is used, for example, in the form of a paste or a granulate instead of in powder form.

— master batch; this means that the hazardous substance is surrounded by a plastic matrix which prevents direct contact with the hazardous substance.

  The plastic matrix itself is not a hazardous substance. Abrasion of the plastic matrix and therefore of the hazardous substance is, however, possible.

"emission-free forms of use" are, for example, master batches without abrasion, ie, the plastic matrix is so resistant to abrasion that no hazardous substance can be released.

"technically leakproof" is applied to a sub-unit if a leak is not discernible during testing, monitoring or checking for leakproofness, eg, using foaming agents or leak searching/indicating equipment performed for the particular use. Systems, sub-systems and functional elements are technically leakproof if the rate of leakage is < 0.00001 mbar/l/s.

7.2 For intermediates, the notifier may request the competent authority to grant permission to apply a reduced test package (RTP). This RTP represents a minimum data set designed to produce a first preliminary risk assessment for any chemical intermediate to be placed on the market. Any additional test results might be required, in accordance with article 16.1 of the Directive, based on the outcome of the risk assessment.

7.3 **Conditions for the application of a reduced test package**

The notifier must demonstrate to the satisfaction of the competent authority where the substance is notified that the following conditions are fulfilled:

(a) the substance is solely manufactured for and consumed in or used for chemical processing. Monomers are excluded. When processed the substance is transformed into chemically different molecules, not being polymers.

(b) the substance is restricted to a maximum number of 2 users' sites. For example, it may be manufactured by one company and then transported to 1 or 2 others for processing. Note that if supply is intended to progress to more than 2 users' sites, the conditions for a RTP are no longer met and the dossier must be upgraded to the appropriate level.

(c) the supply to the enterprise which uses the intermediate for further processing must be directly from the notifier and not through an intermediate supplier.

(d) the substance must be rigorously contained by technical means during its whole lifecycle. This includes production, transportation, purification, cleaning and maintenance, sampling, analysis, loading and unloading of equipment/vessels, waste disposal/purification and storage. In general, an appropriate process would have all functional elements of the plant such as filling ports, emptying equipment etc. either of a closed construction type with assured leakproofness or of a closed construction type with integrated exhaust ventilation.

(e) where there is the potential for exposure, procedural and control technologies must be used which minimise emission and the resulting exposure.

(f) in case of cleaning and maintenance works special procedures such as purging and washing must be applied before the system is opened or entered.

(g) transport operations will be in compliance with the requirements of the Carriage of Dangerous Goods by Road Regulations 1996(**a**).

(h) in case of accident and where waste is generated following purification or cleaning and maintenance procedures, environmental exposure may occur. In either case, procedural and/or control technologies are used which minimise emissions and the resulting exposures.

(i) a management system must exist which identifies the roles of the individuals in the organisation.

(j) the packaging of the substance will be labelled according to the Chemicals (Hazard Information and Packaging for Supply) Regulations 2002(**b**) and additionally with the following sentence: "Caution—substance not yet fully tested".

(k) the notifier must operate a system of product stewardship and must monitor the users (a maximum of 2) to ensure compliance with the conditions listed above.

7.4 **Technical dossier to be supplied for a reduced test package**

A notifier requesting a RTP for a substance must supply the following technical dossier to the competent authority for all production and user sites:

(a) a statement that the notifier and each user accepts the conditions listed in section 7.3.

(b) a description of the technical measures by which rigorous containment of the

(**a**) S.I. 1996/2095, to which there are amendments not relevant to these Regulations.
(**b**) S.I. 2002/1689.

substance is achieved(**a**) including procedures for charging, sampling, transfer and cleaning. It is not necessary to provide details of the integrity of every seal or efficiency of integrated exhaust ventilation. However, whatever means are used to achieve rigorous containment of the process it is important that the information is available, if needed, to verify that the assertions made for achievement of control are true.

(c) if the criteria for the assessment of closed systems during handling of chemical agents detailed in section 7.5 are not fulfilled, the notifier must submit exposure data based on representative monitoring data and/or reliable model calculations to enable the competent authority to make a decision whether to accept an RTP request or not.

(d) a detailed description of the processes at all sites involved in production and use. In particular, it must be stated whether production and/or processing wastes are discharged to waste-water, liquid or solid waste is to be incinerated, and how the cleaning and maintenance of all equipment is made.

(e) a detailed assessment of the possible emissions and possible exposure to man and the environment during the whole life cycle, including details of the various chemical reactions involved in the process and the ways in which residues are dealt with.

Where emissions may lead to exposure, the means by which these are controlled must be described in sufficient detail to enable the competent authority to make a decision whether to accept the statement or to calculate an emission rate according to the EU Technical Guidance Document.

(f) changes which might affect exposure to man or the environment must be notified in advance, eg any change in the functional elements of the plant, new user or site.

(g) The information prescribed for the RTP is the following:

Part B of this Schedule plus the following tests from this Part:

— vapour pressure (3.4)
— explosive properties (3.11)
— self-ignition temperature (3.12)
— oxidising properties (3.13)
— granulometry (3.15)
— acute toxicity for daphnia (5.1.2)

The notifier must also include other relevant information to enable the competent authority to make an informed decision and to enable proper controls to be put in place by the user at the intermediate processing site. For example, if supplementary physicochemical and/or toxicological information and/or information about the environmental behaviour is available this data must also be submitted. Additionally, the notifier must review the available toxicity and ecotoxicity data on substances having a close structural relationship to the notified substance. If relevant data are available, especially on chronic and reproductive toxicity and carcinogenicity, then a summary of these data must be provided.

(h) identities of the notifier, producer and the user(s).

7.5 **Criteria for the assessment of closed systems during the handling of chemical agents**

7.5.1 Use

An assessment index is used in the assessment of the plant. The assessment index classifies the handling of the substance and the resultant process-related exposure potential. The notifier shall examine the plant or plant unit in order to determine the assessment index. Each individual functional element must be assessed.

(**a**) The type of construction and the technical specifications (eg leakproofness) of the closed functional element determines the effectiveness of the containment. To enable the competent authority to make a decision as to whether rigorous containment is achieved or not, it is essential that the notifier includes details on these aspects. The technical measures must normally fulfil the conditions of the "Criteria for the assessment of closed systems during handling of chemical agents" which are included for guidance in section 7.5 and in table 1 of Annex VIIA of the Directive. This must be stated by the notifier, however it is not necessary to address every type of closed functional element in the description provided of the technical measures. Any deviation from the conditions of the Criteria must be fully described, with justification.

Systems are regarded as closed if the assessment of all the available functional elements corresponds to the assessment index 0.5 and if only functional elements are involved which are of closed type with assured leakproofness and/or equipped with integrated exhaust ventilation. In addition, direct skin contact must be excluded.

In the collection of examples in Table 1 in Annex VIIA of the Directive relevant functional elements are indicated by 0.5 in bold type.

Functional elements of partially open type with highly effective exhaust ventilation (also indicated by the assessment index 0.5, but in normal type) are not regarded as closed according to the meaning of this rule.

In the case of functional elements assigned the assessment index 1, the safe adherence to the limit value on a permanent basis is not always assured/ Such functional elements are:

1 —closed type, leakproofness not assured

1 —partially open type with effective exhaust ventilation

In the case of functional elements assigned the assessment indices 2 and 4 adherence to the limit values is not always assured. Such functional elements are:

2 —of a partially open type, opening as intended with simple exhaust ventilation

2 —open with simple exhaust ventilation

4 —open type or partially open type

4 —natural ventilation

The catalogue of examples in Table 1 of Annex VIIA to the Directive facilitates classification of the functional elements. Functional elements which are not included in the collection of examples can be classified by means of conclusions drawn by analogy. The plant or plant unit is then classified using the index value of the functional element which has received the highest assessment index.

7.5.2 Checking

Use of this criterion requires adherence to the process parameters which have been laid down as well as performance of the checks cited in the collection of examples (eg inspection and maintenance).

7.6 **Application of a reduced test package**

If the competent authority accepts the notifier's application for a RTP, information from the tests and/or studies set out in section 7.4 shall be required for the technical dossier referred to in article 7 of the Directive. Note that for quantities below 1 tonne/annum the usual testing requirements in Parts B and C of this Schedule apply.".

(2) For Schedule 3 to the principal Regulations, there shall be inserted the following Schedule—

"SCHEDULE 3 Regulation 5

(This Schedule substantially reproduces Annex VIII to the Directive)

ADDITIONAL INFORMATION AND TESTS REQUIRED UNDER REGULATION 5

Tests under this Part shall be according to methods recognized and recommended by the competent international bodies where such recommendations exist.

If it is not technically possible or if it does not appear scientifically necessary to give information, the reasons shall be clearly stated and be subject to acceptance by the competent authority.

The name of the body or bodies responsible for carrying out the studies shall be indicated.

LEVEL 1

Where, in accordance with the provisions of Part A of Schedule 2 related to intermediates, the relevant competent authority has authorised the application of a reduced test package to a chemical substance, the requirements of this section shall be reduced as follows.

When the quantity of the substance placed on the market reaches 10 tonnes per year per manufacturer or when the total quantity of the substance placed on the market reaches 50 tonnes per manufacturer; in this case the relevant competent authority shall require all those tests and studies laid down in sections 3 to 6 of Part A of Schedule 2 (excepting those already performed); in addition, the relevant competent authority may require those Level l tests and studies related to aquatic organisms.

When the quantity of the substance placed on the market reaches 100 tonnes per year per manufacturer or when the total quantity of the substance placed on the market reaches 500 tonnes per manufacturer; in this case the relevant competent authority shall require the Level 1 tests or studies related to reproductive toxicity. The relevant competent authority may decide that the classification of the substance as an intermediate qualifying for a reduced test package constitutes a good reason why one or more tests or studies, except those related to reproductive toxicity, are not appropriate.

Physicochemical studies

Further studies on physicochemical properties are dependent upon the results of the studies laid down in Schedule 2. Such further studies could include for example the development of analytical methods which make it possible to observe and detect a substance or its transformation products and studies on thermal decomposition products.

Toxicological studies

Fertility studies (one species, one generation, male and female, most appropriate route of administration).

If there are equivocal findings in the first generation, study of a second generation is required.

Depending upon the dosing schedule it may be possible in this study to obtain an indication of teratogenicity. A positive indication should be examined in a formal teratology study.

- Teratology study (one species, most appropriate route of administration).

  This study is required if teratogenicity has not been examined in the fertility study.
- Sub-chronic and/or chronic toxicity study, including special studies (one species, male and female, most appropriate route of administration) shall be required if the results of the repeated-dose study in Schedule 2 or other relevant information demonstrate the need for further appropriate investigation.

  The effects which would indicate the need for such a study could include for example:

  (a) serious or irreversible lesions;

  (b) a very low or absence of a "no-effect" level;

  (c) a clear relationship in chemical structure between the substance being studied and other substances which have been proved dangerous.
- Additional mutagenesis studies and/or screening study(ies) for carcinogenesis as prescribed in the testing strategy described in Annex V of the Directive.

  When both tests in the base set are negative, further tests shall be conducted according to the specific properties and the proposed use of the substance.

  When a test or both tests were positive in the base set, a supplementary study should include the same or different end points in other *in vivo* test methods.
- Basic toxicokinetic information.

Ecotoxicity studies

- Prolonged toxicity study with Daphnia magna (21 days).
- Tests on higher plants.
- Tests on earthworms.
- Further toxicity studies with fish.
- Tests for species accumulation: one species, preferably fish.
- Supplementary degradation study(ies), if sufficient degradation has not been proved by the studies laid down in Schedule 2.
- Further studies on absorption/desorption dependent upon the results of the investigations laid down in Schedule 2.

LEVEL 2

When the quantity of the substance placed on the market reaches 1,000 tonnes per year per manufacturer or when the total quantity of the substance placed on the market reaches 5,000 tonnes per manufacturer; additional studies mentioned in Level l or 2 would not normally be required. The relevant competent authority should however, consider additional tests and may require additional tests including the tests laid down in Levels 1 and 2 of this Schedule.

Toxicological studies

The test programme shall cover the following aspects unless there are strong reasons to the contrary, supported by evidence, that it should not be followed:

— Chronic toxicity study.
— Carcinogenicity study.
— Fertility study (eg three-generation study): only if an effect on fertility has been established at level 1.
— Developmental toxicity study on perinatal and postnatal effects.
— Teratology study (species not employed in the respective level 1).
— Additional toxicokinetic studies which cover biotransformation, pharmokinetics.
— Additional tests to investigate organ or system toxicity.

Ecotoxicological studies

— Additional tests for accumulation, degradation, mobility and absorption/desorption.
— Further toxicity studies with fish.
— Toxicity studies with birds.
— Additional toxicity studies with other organisms.".

Signed by authority of the Secretary of State

Ian McCartney
Minister of State,
Department for Work and Pensions

17th August 2002

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Notification of New Substances Regulations 1993 (S.I. 1993/3050) by amending Schedules 2 and 3 to incorporate a reduced test method for chemical intermediates thereby implementing paragraphs 7 and 8 of article 1 of Commission Directive 2001/59/EC (OJ No. L 225, 21.8.2001, p.1) adapting to technical progress for the 28th time Council Directive 67/548/EEC (OJ No. 196, 16.8.1967, p.1) (OJ/SE 1967 p.234) on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

A copy of the regulatory impact assessment prepared in respect of these Regulations can be obtained from the Health and Safety Executive, Economic Advisers Unit, Rose Court, 2 Southwark Bridge, London SE1 9HS. A copy of the transposition note in relation to implementation of Commission Directive 2001/59/EC can be obtained from the Health and Safety Executive, International Branch at the same address. Copies of both these documents have been placed in the Library of each House of Parliament.

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