STATUTORY RULES OF NORTHERN IRELAND

2003 No. 36

HEALTH AND SAFETY

Notification of New Substances (Amendment) Regulations (Northern Ireland) 2003

Made - - - -	*24th January 2003*
Coming into operation	*28th February 2003*

The Department of Enterprise, Trade and Investment(**1**), being the Department designated(**2**) for the purpose of section 2(2) of the European Communities Act 1972(**3**) in relation to the notification and control of substances, in exercise of the powers conferred on it by the said section 2(2) and, being the Department concerned(**4**), in exercise of the powers conferred by Articles 17(1), (2), (3) and (4) and 55(2) of, and paragraph 1(1) and (5), 14(1) and 15 of Schedule 3 to, the Health and Safety at Work (Northern Ireland) Order 1978(**5**) ("the 1978 Order") and of every other power enabling it in that behalf, and for the purpose of giving effect without modifications to proposals submitted to it by the Health and Safety Executive for Northern Ireland under Article 13(1A) of that Order(**6**) after the carrying out by the said Executive of consultations in accordance with Article 46(3)(**7**) of that Order, hereby makes the following Regulations:

Citation and commencement

1. These Regulations may be cited as the Notification of New Substances (Amendment) Regulations (Northern Ireland) 2003 and shall come into operation on 28th February 2003.

Interpretation

2.—(1) In these Regulations "the principal Regulations" means the Notification of New Substances Regulations (Northern Ireland) 1994(**8**).

(2) The Interpretation Act (Northern Ireland) 1954(**9**) shall apply to these Regulations as it applies to an Act of the Northern Ireland Assembly.

(**1**) Formerly the Department of Economic Development: *see*S.I. 1999/283, Article 3(5)
(**2**) S.I. 1981/1536
(**3**) 1972 c. 68
(**4**) *See* Article 2(2) of S.I. 1978/1039 (N.I. 9)
(**5**) S.I. 1978/1039 (N.I. 9)
(**6**) Article 13(1) was substituted by S.I. 1998/2795 (N.I. 18), Article 4
(**7**) Article 46(3) was amended by S.I. 1998/2795 (N.I. 18), Article 6(1) and Schedule 1, paragraphs 8 and 18
(**8**) S.R. 1994 No. 6, amended by S.R. 1995 No. 60, S.R. 1996 No. 159, S.R. 1997 No. 234, S.R. 1998 No. 125, S.R. 1999 No. 150, S.R. 2000 No. 375 and S.R. 2001 No. 422
(**9**) 1954 c. 33 (N.I.)

Amendment of the principal Regulations

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

(a) immediately before paragraph 0 there shall be inserted the following paragraph–

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

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

"**7.** REDUCED TEST PACKAGE FOR INTERMEDIATES AT QUANTITIES ≥ 1 TONNE/ANNUM

Definitions

7.1. For the purposes of the following paragraphs–

"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 underpressure 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, i.e., 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, i.e., 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, i.e., 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, i.e., 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, e.g., 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.

Conditions for the application of a reduced test package

7.3. 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 (Northern Ireland) 1997(**10**).

(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 (Northern Ireland) 2002(**11**) 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.

Technical dossier to be supplied for a reduced test package

7.4. 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 substance is achieved(**12**), 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.

(**10**) S.R. 1997 No. 248, amended by S.R. 1998 No. 448, S.R. 1999 No. 150 and S.R. 2000 No. 119

(**11**) S.R. 2002 No. 301

(**12**) The type of construction and the technical specifications (e.g. 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

(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 a 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, e.g. 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).

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

7.5.