Procedure for Notification of Chemicals

Regulation No. 18 of the Minister of Social Affairs of 22 March 1999

(RTL[1] 1999, 61, 809),

entered into force 7 June 2000,

amended by the following Regulations:

08.05.2003 entered into force 23.05.2003 - RTL 2003, 60, 841;

19.06.2001 entered into force 29.06.2001 - RTL 2001, 77, 1042;

11.04.2001 entered into force 28.04.2001 - RTL 2001, 52, 710.

Pursuant to subsection 20 (3) and § 25 of the Chemicals Act (RT[2] I 1998, 47, 697; 1999, 45, 512; 2002, 53, 336; 61, 375; 63, 387; 2003, 23, 144), I resolve:

1. To approve the Procedure for Notification of Chemicals (annexed).

2. This Regulation enters into force on 7 June 2000 and Part II of the Procedure approved by this Regulation, Procedure for Notification of New Substances, enters into force on 1 May 2004.

(11.04.2001 entered into force 28.04.2001 - RTL 2001, 52, 710; 08.05.2003 entered into force 23.05.2003 - RTL 2003, 60, 841)

Approved by

Regulation No. 18 of the Minister of Social Affairs of 22 March 1999

Procedure for Notification of Chemicals

I. General Part

1. General provisions

1.1. This Procedure sets out the formal and substantive requirements for the notification of new and existing substances and is mandatory for all notifiers.

1.2. A notifier may submit a written application for a portion of information to be classified as a business secret.

1.3. An information centre may classify the personal data of a notifier for up to one year at the written reasoned request of the notifier.

1.4. The working day on which information submitted by a notifier or information supporting a notification is received by the Chemicals Notification Centre is deemed to be the day of registration of the notification.

1.5. An importer is exempt from the duty to notify if an authorised representative of the manufacturer notifies instead of the importer.

1.6. Annexes 1A, 1B, 1C, 1D and 2 to this Procedure and the numeration used in these Annexes are in exact conformity with Annexes VII A, VII B, VII C, VII D and VIII to Council Directive 92/32 EEC and the numeration used in those Annexes.

2. Definitions

2.1. In this Regulation, the following definitions are used:

- “polymer” means a substance consisting of molecules characterised by the sequence of at least three monomer units of one or more types which are covalently bound to at least one other monomer unit or other reactant and consists of less than a simple weight majority of molecules of the same molecular weight. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. In the context of this definition, a “monomer unit” means the reacted form of a monomer in a polymer;

- “existing substance” means a substance which is registered in the European Inventory of Existing Commercial Substances (EINECS);

- “scientific research and development” means scientific experimentation, analysis or research carried out under controlled conditions. It includes the determination of intrinsic properties, performance and efficacy of chemicals as well as scientific investigation related to product characteristics and product development;

- “process-orientated research and development” means the further development of the production technology of a substance in the course of which the production process is studied and pilot plant or production trials are used to test the fields of application of the substance;

- “placing on the market” means the making available of chemicals to third parties;

- “notifier” means an undertaking manufacturing a substance, a representative authorised by the manufacturer, or the importer;

- “notification” means the submission of information formalised pursuant to the requirements of this Procedure on a chemical subject to notification to the Chemicals Notification Centre;

- an average quantity of chemicals is 10 to 1000 tonnes;

- a large quantity of chemicals exceeds 1000 tonnes.

(11.04.2001 entered into force 28.04.2001 - RTL 2001, 52, 710)

2.2. Additional explanations are provided for definitions set out in § 2 of the Chemicals Act:

- “substance” means a chemical element and its compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the product and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;

- “preparation” means a mixture or solution composed of two or more substances.

II. Procedure for Notification of New Substances

3. General requirements

3.1. Before a substance is placed on the market, the manufacturer, the authorised representative of the manufacturer if the manufacturer is located outside Estonia, or the importer shall notify the Chemicals Notification Centre of the new substance, even if the substance is contained in a preparation or is contained in a product if the substance may be emitted during the use of the product.

3.2. A notifier shall submit the following information in writing (which may be duplicated by other data media):

3.2.1. a technical dossier supplying the information necessary for evaluating the risks which the substance may entail, pursuant to Annexes 1A, 1B, 1C, 1D or 2 to this Procedure;

3.2.2. a declaration concerning the unfavourable effects of the substance in terms of the various foreseeable uses;

3.2.3. the proposed classification and labelling of the substance;

3.2.4. a proposal for the safety data sheet in the case of dangerous substances;

3.2.5. if the manufacturer of the chemical is located outside Estonia and the notifier is the authorised representative of the manufacturer in Estonia, a documentary statement thereon from the manufacturer.

3.3. The following are not subject to notification as new substances:

3.3.1. substances which appear on the European Inventory of Existing Commercial Substances (EINECS);

3.3.2. additives and substances for exclusive use in animal feedingstuffs;

3.3.3. substances used exclusively as additives in foodstuffs and substances used exclusively as flavourings in foodstuffs;

3.3.4. substances which are placed on the market exclusively as cosmetic products or as ingredients in cosmetic products;

3.3.5. substances which are placed on the market exclusively as medicinal products or for exclusive use as active ingredients in medicinal products. This does not include chemical intermediates;

3.3.6. explosives, radioactive substances, narcotic substances and plant protection products;

3.3.7. substances which are classified as waste;

3.3.8. substances which are placed on the market for use in other product sectors and regarding which notification is given pursuant to other legislation or which are exempt from the duty of notification pursuant to other legislation.

3.4. Substances which are transported or stored under a customs transit procedure are not subject to notification if they are under the supervision of the customs authorities and if the substances are not handled in a manner which may result in their properties changing.

3.5. The transport of dangerous substances by rail, road, inland water body, sea and air is not subject to notification.

4. Specifications

4.1. In this Procedure, the following are considered as having been notified:

4.1.1. polymers, with the exception of those which contain in combined form 2 per cent or more of any new substance;

4.1.2. substances placed on the market in quantities of less than 10 kilograms per year per manufacturer, provided that the manufacturer or importer satisfies all the requirements set by the Chemicals Notification Centre. The requirements set by the Chemicals Notification Centre shall not exceed the requirements of clauses 1 and 2 of Annex 1C to this Procedure;

4.1.3. substances placed on the market in quantities of less than 100 kilograms per year per manufacturer, provided that the substances are intended solely for purposes of scientific research and development carried out under controlled conditions. In such case, each manufacturer or importer shall hold information necessary for the identification and labelling of the substances and information on the handlers of the substances and the quantities delivered to them and shall, if necessary, make such information available to the Chemicals Notification Centre;

4.1.4. substances which are marketed to registered handlers for the purposes of process-orientated research and development in quantities and which are limited to these purposes. These

substances shall qualify for an exemption for a period of one year provided that the manufacturer or importer submits the information necessary for the identification and labelling of the substances, the quantity of the marketed substances together with the justification therefor, a list of handlers and the research and development programme for the implementation of which the substances are needed to the Chemicals Notification Centre. At the same time, a notifier shall comply with precepts issued by the Chemicals Notification Centre which shall not require more information than required by the reduced notification provided for in this Procedure. The manufacturer or importer shall also give an assurance that the substance or the preparation in which it is incorporated will be handled only by customers' staff in controlled conditions and will not be made available to the general public in any manner.

After one year, notification shall be given of these substances as new substances pursuant to the general procedure.

According to their competence, the Health Protection Inspectorate, the Labour Inspectorate and the Environmental Inspectorate have the right to restrict the use of all products containing the new substances which were produced during the process-orientated research and development if use may result in an unacceptable risk to health and the environment.

The Minister of Social Affairs may extend the one-year exemption period referred to above for a further year if the notifier makes an application therefor which is justified and submitted at the correct time.

4.2. Substances which are considered as having been notified shall, in so far as the manufacturer is aware of their dangerous properties, be packaged and labelled pursuant to the Procedure for Identification, Classification, Packaging and Labelling of Dangerous Chemicals approved by Regulation No. 64 of the Minister of Social Affairs of 11 December 1998 (RTL 1998, 372/373, 1610). If the results of the tests provided for in Annex 1A to this Procedure are not all available, the label shall additionally bear the warning *"Ettevaatust – aine ei ole veel täielikult testitud"* ["Caution – substance not yet fully tested"].

Where a substance is very toxic, toxic, carcinogenic, toxic for reproduction or mutagenic, the manufacturer or importer shall transmit to the Chemicals Notification Centre any appropriate information as regards subclauses 2.3, 2.4 and 2.5 of Annex 1A to this Procedure. Acute toxicity data shall be given immediately where available.

5. Methods of testing and analysis

The physical and chemical properties and health and environmental hazards of new substances shall be determined using generally recognised methods, and good laboratory practice shall be applied*. The needless torture of laboratory animals shall be avoided and the number of tests on laboratory animals shall be reduced to the minimum which enables reliable results to be obtained.

6. Full notification

6.1. A new substance is subject to full notification if it is planned to place the substance on the market in quantities of at least 1 tonne per year per manufacturer.

6.2. A full notification dossier shall contain at least the information set out in Annex 1A to this Procedure together with a detailed and full description of the studies conducted and of the methods of analysis used or a bibliographical reference to the professional publications used.

6.3. Information set out in subclauses 3.2.2-3.2.5 of this Procedure and, if necessary, a written application from the notifier for classification of the connection of the notifier with notification of the given substance and an application for classification of the information as a business secret shall be appended to a technical dossier. Additionally, the notifier may present the opinion thereof on the actual or potential health and environmental hazards arising from the substance.

6.4. A notifier is required to notify the Chemicals Notification Centre before the quantity of a substance placed on the market and regarding which notification has already been given reaches:

- 10 tonnes per year per manufacturer or the total quantity reaches 50 tonnes per manufacturer. The Chemicals Notification Centre may require some or all of the additional studies laid down in level 1 of Annex 2 to this Procedure to be carried out;

-100 tonnes per year per manufacturer or the total quantity reaches 500 tonnes per manufacturer. The results of additional studies laid down in level 1 of Annex 2 to this Procedure shall be submitted to the Chemicals Notification Centre unless the notifier can give good reason why the given studies are not appropriate and agreement is reached with the Chemicals Notification Centre beforehand on conducting more appropriate alternative research;

-1000 tonnes per year per manufacturer or the total quantity reaches 5000 tonnes per manufacturer. The results of additional studies laid down in level 2 of Annex 2 to this Procedure shall be submitted to the Chemicals Notification Centre.

6.5. The results of additional studies shall be submitted to the Chemicals Notification Centre within a term designated by the latter.

7. Reduced notification

7.1. A new substance is subject to reduced notification if it is planned to place the substance on the market in quantities of less than 1 tonne per year per manufacturer. A reduced notification dossier shall contain the information set out in Annex 1B to this Procedure together with a detailed and full description of the studies conducted and of the methods of analysis used or a bibliographical reference to the professional publications used.

7.2. Information set out in subclauses 3.2.2-3.2.5 of this Procedure and, if necessary, a written application from the notifier for classification of the connection of the notifier with notification of the given substance and an application for classification of the information as a business secret shall be appended to a technical dossier. Additionally, the notifier may present the opinion thereof on the actual or potential health and environmental hazards arising from the substance.

7.3. When the quantities of the substance to be placed on the market are below 100 kg per year per manufacturer, the technical dossier may contain the information set out in Annex 1C to this Procedure.

7.4. In the case of a notifier who has submitted a reduced notification dossier in conformity with clause 7.3 of this Procedure, the notifier shall, before the quantity of the substance placed on the market reaches 100 kg per year per manufacturer or before the total quantity placed on the market reaches 500 kg per manufacturer, provide the additional information necessary to complete the technical dossier to the level of Annex 1B to this Procedure.

7.5. In the case of a notifier who has submitted a reduced notification dossier in conformity with clause 7.4 of this Procedure, the notifier shall submit a full notification before the quantity of the substance placed on the market reaches 1 tonne per year per manufacturer or before the total quantity placed on the market reaches 5 tonnes per manufacturer.

7.6. Substances of which reduced notification is given shall, in so far as the handler is aware of their dangerous properties, be packaged and labelled pursuant to the Procedure approved by the Minister of Social Affairs (RTL 1998, 372/373, 1610). If the results of all the tests provided for in Annex 1A are not all available, the label shall additionally bear the warning *"Ettevaatust – aine ei ole veel täielikult testitud"* ["Caution – substance not yet fully tested"].

8. Notification of polymers

Upon notification of a new substance which is a polymer, a technical dossier which conforms to the requirements of Annex 1D to this Procedure shall be submitted.

9. Substances already notified (10-year rule)

In the case of substances which were first notified at least 10 years previously, it is sufficient to submit the information set out in clauses 1 and 2 of Annexes 1A, 1B, 1C or 1D respectively.

10. New substances manufactured outside Estonia

Where more than one notification exists for a substance manufactured by the same manufacturer which is located outside Estonia, the cumulative yearly quantity of the substance placed on the market shall be determined on the basis of information obtained from notifiers and the obligation to carry out supplementary testing set out in clause 6.4 of this Procedure falls collectively on all notifiers.

11. Renotification of same substance and avoidance of duplicating testing on laboratory animals

11.1. The Chemicals Notification Centre may agree that a prospective notifier of a substance already notified may refer to the results of the tests and analyses forwarded by the first notifier in the information and testing results part in accordance with clauses 3, 4 and 5 of Annexes 1A and 1B and clauses 3 and 4 of Annex 1C to this Procedure. Reference is permitted only with the written consent of the first notifier. The prospective notifier shall provide evidence that the

substance notified thereby is the same substance as the one previously notified, including the degree of purity and the nature of impurities.

11.2. Before carrying out testing on laboratory animals, a notifier shall enquire of the Chemicals Notification Centre as to

- whether or not the substance has already been notified;

- the name and address of the first notifier

and the notifier shall confirm the intention thereof to place the new substance on the market and the quantities intended to be placed on the market.

11.3. If the Chemicals Notification Centre finds that

- the substance has been notified previously;

- the connection of the first notifier with notification of the given substance is not temporarily classified;

- the quantities intended to be placed on the market are adaptable to the first notification,

the Chemicals Notification Centre shall provide the prospective notifier with the name and address of the first notifier and shall inform the first notifier of the name and address of the prospective notifier.

11.4. The first notifier and the prospective notifier shall take all reasonable steps to reach an agreement on the sharing of information so as to avoid the duplication of testing on laboratory animals.

11.5. Notifiers who have agreed to share information relating to Annexes 1A, 1B and 1C to this Procedure shall also take all necessary steps to reach an agreement on the sharing of information derived from testing on laboratory animals required in Annex 2 to this Procedure.

12. Creation of right to place new substances on market

12.1. Substances of which full notification is given may be placed on the market no sooner than 60 days after the day of registration of the notification unless the Chemicals Notification Centre advises before these 60 days pass that the notification is not in conformity with the requirements established by this Procedure or requests additional information.

12.2. If the Chemicals Notification Centre advises in writing that the notification is not in conformity with the requirements established by this Procedure or requests additional information within 60 days, the 60-day period shall begin as of the day when the information required to supplement the notification is registered in the Chemicals Notification Centre.

12.3. Substances subject to reduced notification may be placed on the market no sooner than 30 days after the day of registration of the notification unless the Chemicals Notification Centre advises before these 30 days pass that the notification is not in conformity with the requirements of this Procedure or requests additional information.

12.4. If the Chemicals Notification Centre advises in writing that the notification is not in conformity with the requirements established by this Procedure or requests additional information within 30 days, the 30-day period shall begin as of the day when the information required to supplement the notification is registered in the Chemicals Notification Centre.

12.5. Additional information shall be required until the notification conforms to the requirements set out in this Procedure.

12.6. If the Chemicals Notification Centre has informed a notifier in writing that the information is in conformity with the requirements established in this Procedure, the substance may, in the case of reduced notification and as an exception, be placed on the market 15 days after the day of registration of the notification.

12.7. The Chemicals Notification Centre shall inform notifiers of the registration of notifications in writing.

12.8. If the Chemicals Notification Centre approves the submitted information, the Chemicals Notification Centre shall communicate a registration number to the notifier in writing within 60 days in the case of full notification or within 30 days in the case of reduced notification as of the receipt by the Chemicals Notification Centre of information or additional information which is in conformity with the requirements.

13. Notification of changes

13.1. Any notifier is required to inform the Chemicals Notification Centre in writing of the following:

13.1.1. changes in the quantities of substances placed on the market (annual and total quantities);

13.1.2. new knowledge of the effects of a substance on humans and the environment;

13.1.3. new uses of a substance;

13.1.4. any change in the composition of a substance on the basis of the provisions of clause 1.3 of Annexes 1A, 1B or 1C to this Procedure;

13.1.5. any change in the status thereof as a manufacturer or importer.

13.2. Any importer of a substance which is produced by a manufacturer located outside Estonia and regarding which an authorised representative of the manufacturer in Estonia has given

notification previously shall promptly communicate information on any changes in the quantity of the substance placed on the market to the authorised representative of the manufacturer.

III. Procedure for Notification of Existing Substances

14. Notification of chemicals with high or lower volume production

14.1. Each notifier who at least once during the time that this Procedure is in force manufactures or imports a chemical substance which appears in the European Inventory of Existing Commercial Chemical Substances (EINECS) either as a substance or as a preparation in quantities which exceed 1000 tonnes per year shall inform the Chemicals Notification Centre of the information set out in Annex 3 to this Procedure concerning the previous year by 7 June every year.

14.2. A notifier is required to obtain the information set out in clauses 2-5 of Annex 3 to this Procedure from among the existing available information. If there is no such information, the notifier is not required to carry out testing on laboratory animals in order to obtain such absent information.

14.3. Each notifier who at least once during the time that this Procedure is in force manufactures or imports a chemical substance which appears in the European Inventory of Existing Commercial Chemical Substances (EINECS) either as a substance or as a preparation in quantities which exceed 10 tonnes but do not exceed 1000 tonnes a year shall inform the Chemicals Notification Centre of the information set out in clauses 1.1-1.17 of Annex 3 to this Procedure concerning the previous year by 7 June every year.

(08.05.2003 entered into force 23.05.2003 - RTL 2003, 60, 841)

* Good laboratory practice (GLP) means the principles which are provided for in European Union directives 87/18/EEC, 88/320/EEC and 89/569/EEC and which concern the verification of studies and analyses carried out to test chemicals and of the results obtained.

Annex 1A

to the Procedure for Notification of Chemicals

Information set out in subclause 6.2 of this Procedure to be submitted to the Chemicals Notification Centre

The agencies responsible for carrying out the studies shall be mentioned upon notification.

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 Chemicals Notification Centre.

This Annex is in conformity with Annex VII A of Council Directive 92/32/EEC.

Technical dossier

0. Identity of manufacturer and the identity of the notifier: location of the production site

For substances manufactured outside Estonia and for which the notifier has been designated as the authorised representative of the manufacturer, the identity and the addresses of the importers shall be indicated.

1. Identity of the substance

1.1. Name

1.1.1. Names in the IUPAC nomenclature

1.1.2. Other names (usual name, trade name, abbreviation);

1.1.3. CAS number and CAS name (if available).

1.2. Molecular and structural formula

1.3. Composition of the substance

1.3.1. Degree of purity (%);

1.3.2. Nature of impurities, including isomers and by-products;

1.3.3. Percentage of significant impurities;

1.3.4. If the substance contains a stabilising agent or an inhibitor or other additives, specify their nature and order of magnitude: ..... ppm, ... %;

1.3.5. Spectral data (UV, IR, NMR or mass spectrum);

1.3.6. High-performance liquid chromatography and gas chromatography data.

1.4. Methods of detection and determination

A full description of the methods used or the appropriate bibliographical references. Apart from methods of detection and determination, information shall be given on analytical methods which are known to the notifier and allow detection of the substance and its transformation products after discharge into the environment as well as determination of the direct exposure of humans.

2. Information on the substance

2.0. Production

Information shall be sufficient to allow an approximate but realistic estimation of human and environmental exposure associated with the production process of the substances. Precise details of the production process, particularly those of a commercially sensitive nature, are not required.

2.0.1. Technological process used in production;

2.0.2. Exposure estimates related to production:

- in working environment;
- in natural and human environment.

2.1. Proposed uses

Information shall be sufficient to allow an approximate but realistic estimation of human and environmental exposure associated with the expected uses of the substances.

2.1.1. Types of use: description and desired effects:

2.1.1.1. Technological processes related to the use of the substance (where known);

2.1.1.2. Exposure estimate(s) related to use (where known):
- in working environment;
- in natural and human environment;

2.1.1.3. Form under which the substance is marketed: substance, preparation, product;

2.1.1.4. Concentration of the substance in marketed preparations and products (where known).

2.1.2. Fields of application with approximate breakdown:
- industries;
- farmers and other skilled trades;
- use by the public at large.

2.1.3. Identity of the recipients of the substance (where known and where appropriate);

2.1.4. Waste quantities and composition of waste resulting from the proposed uses (where known).

2.2. Estimated production and/or imports for each of the anticipated uses or fields of application

2.2.1. Overall production and/or imports (in tonnes per year):
- the first calendar year;
- the following calendar years.

For substances manufactured outside Estonia and for which the notifier has been designated as the authorised representative of the manufacturer, this information shall be given for each of the importers identified in clause 0 of this Annex;

2.2.2. Production and/or imports, broken down in accordance with clauses 2.1.1 and 2.1.2 of this Annex and expressed as a percentage:
- the first calendar year;
- the following calendar years.

2.3. Recommended methods and precautions concerning:

2.3.1. Handling;

2.3.2. Storage;

2.3.3. Transport;

2.3.4. Fire (nature of combustion gases or pyrolysis, where proposed uses justify this);

2.3.5. Other dangers, particularly chemical reaction with water;

2.3.6. Information concerning the susceptibility of the substance to explode when presented in the form of a dust (if relevant).

2.4. Emergency measures in the case of accidental spillage.

2.5. Emergency measures in the case of injury to persons (e.g. poisoning).

2.6. Packaging

3. Physico-chemical properties of the substance

3.0. State of the substance at 20°C and 101.3kPa

3.1. Melting-point
3.2. Boiling-point
3.3. Relative density
3.4. Vapour pressure
3.5. Surface tension
3.6. Water solubility
3.8. Partition coefficient n/octanol/water
3.9. Flash-point
3.10. Flammability
3.11. Explosive properties
3.12. Self-ignition temperature
3.13. Oxidising properties
3.15. Granulometry

For those substances which may be marketed in a form which gives rise to the danger of exposure by the inhalatory route, the particle size distribution of the substance as it will be marketed shall be determined.

4. Toxicological studies
4.1. Acute toxicity

For tests set out in subclauses 4.1.1-4.1.3 of this Annex, substances other than gases shall be administered via at least two routes, one of which should be the oral route. The choice of the second route will depend on the nature of the substance and the likely route of human exposure. Gases and volatile liquids shall be administered by the inhalation route.

4.1.1. Administered orally;
4.1.2. Administered by inhalation;
4.1.3. Administered cutaneously;
4.1.5. Skin irritation;
4.1.6. Eye irritation;
4.1.7. Skin sensitisation.
4.2. Repeated dose

The route of administration shall be the most appropriate having regard to the likely route of human exposure, the acute toxicity and the nature of the substance. In the absence of contra-indications, the oral route is usually the preferred one.

4.2.1. Repeated dose toxicity (28 days).
4.3. Other effects
4.3.1. Mutagenicity;

The mutagenicity of a substance shall be examined in two tests:

- a bacteriological reverse mutation test, with and without metabolic activation;

- a non-bacteriological test to detect chromosome aberrations or other damage.

In the absence of contra-indications, this test shall be conducted *in vitro*,

both with and without metabolic activation. In the event of a positive result in either test, further testing according to the strategy approved by the Chemicals Notification Centre shall be carried out;

4.3.2. Screening for toxicity related to reproduction;

4.3.3. Assessment of the toxicokinetic behaviour of a substance to the extent that can be derived from the information indicated here and other relevant information.

5. Ecotoxicological studies

5.1. Effects on living organisms

5.1.1. Acute toxicity for fish;

5.1.2. Acute toxicity for water fleas (Daphnia);

5.1.3. Growth-inhibitor test on algae;

5.1.6. Bacterial inhibition.

Where biodegradation may be affected by the inhibitory effect of a substance on the bacteria, a test for bacterial inhibition shall be carried out prior to undertaking the biodegradation.

5.2. Degradation:

- biotic;
- antibiotic;

If the substance is not readily biodegradable, then consideration shall be given to the need to carry out the following tests: hydrolysis as a function of pH.

5.3. Absorption/desorption screening test

6. Possibility of rendering the substance harmless

6.1. For industry / skilled trades

6.1.1. Possibility of recycling;

6.1.2. Possibility of neutralisation of unfavourable effects;

6.1.3. Possibility of destruction:

- controlled discharge into the environment;
- incineration;
- water purification station;
- others;

6.2. For the public at large

6.2.1. Possibility of recycling;

6.2.2. Possibility of neutralisation of unfavourable effects;

6.2.3. Possibility of destruction:

- controlled discharge into the environment;
- incineration;
- water purification station;
- others.

Annex 1B

to the Procedure for Notification of Chemicals

Information set out in clause 7.1 of this Procedure to be submitted to the Chemicals Notification Centre

The agencies responsible for carrying out the studies shall be mentioned upon notification.

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 Chemicals Notification Centre.

This Annex is in conformity with Annex VII B of Council Directive 92/32/EEC.

Technical dossier

In addition to the information required below and if the Chemicals Notification Centre considers it necessary for the risk assessment, the following information shall be provided:

- vapour pressure;

- acute toxicity for water fleas (*Daphnia*).

0.	Identity of manufacturer and the identity of the notifier: location of the production site For substances manufactured outside Estonia and for which the notifier has been designated as the authorised representative of the manufacturer, the identity and the addresses of the importers shall be indicated.
1.	Identity of the substance
1.1.	Name
1.1.1.	Name in the IUPAC nomenclature;
1.1.2.	Other names (usual name, trade name, abbreviation);
1.1.3.	CAS number and CAS name (if available).
1.2.	Molecular and structural formula
1.3.	Composition of the substance
1.3.1.	Degree of purity (%);
1.3.2.	Nature of impurities, including isomers and by-products;
1.3.3.	Percentage of significant impurities;
1.3.4.	If the substance contains a stabilising agent or an inhibitor or other additives, specify their nature and order of magnitude: ..... ppm, ... %;
1.3.5.	Spectral data (UV, IR, NMR or mass spectrum);
1.3.6.	High-performance liquid chromatography and gas chromatography data.
1.4.	Methods of detection and determination

A full description of the methods used or the appropriate bibliographical references.

Apart from methods of detection and determination, information shall be given on analytical methods which are known to the notifier and allow detection of the substance and its transformation products after discharge into the environment as well as determination of the direct exposure of humans.

2. Information on the substance

2.0. Production

The given information shall be sufficient to allow an approximate but realistic estimation of human and environmental exposure associated with the production process of the substances.

Details of the production process, particularly those of a commercially sensitive nature, are not required.

2.0.1. Technological process used in production;

2.0.2. Exposure estimates related to production:
- in working environment;
- in natural and human environment.

2.1. Proposed uses

Information shall be sufficient to allow an approximate but realistic estimation of human and environmental exposure associated with the expected uses of the substances.

2.1.1. Types of use: description and desired effects;

2.1.1.1. Technological processes related to the use of the substance (where known);

2.1.1.2. Exposure estimate(s) related to use (where known):
- in working environment;
- in natural and human environment;

2.1.1.3. Form under which the substance is marketed: substance, preparation, product;

2.1.1.4. Concentration of the substance in marketed preparations and products (where known).

2.1.2. Fields of application with approximate breakdown:
- industries;
- farmers and other skilled trades;
- use by the public at large.

2.1.3. Identity of the recipients of the substance (where known and where appropriate);

2.1.4. Waste quantities and composition of waste resulting from the proposed uses (where known).

2.2. Estimated production and/or imports for each of the anticipated uses or fields of application

2.2.1. Annual overall production and/or imports (in tonnes per year):
- the first calendar year;
- the following calendar years.
For substances manufactured outside Estonia and for which the notifier has been designated as the authorised representative of the manufacturer, this information shall be given for each of the importers identified in clause 0 of this Annex.

2.2.2. Production and/or imports, broken down in accordance with clauses 2.1.1 and 2.1.2 of this Annex and expressed as a percentage:
- the first calendar year;
- the following calendar years.

2.3. Recommended methods and precautions concerning:

2.3.1. Handling;

2.3.2. Storage;

2.3.3. Transport;

2.3.4. Fire (nature of combustion gases or pyrolysis, where proposed uses justify this);

2.3.5. Other dangers, particularly chemical reaction with water.

2.4. Emergency measures in the case of accidental spillage

2.5. Emergency measures in the case of injury to persons (e.g. poisoning)

2.6. Packaging

3. Physico-chemical properties of the substance

3.0. State of substance at 20°C and a pressure of 101.3kPa

3.1. Melting-point

3.2. Boiling-point

3.6. Water solubility

3.8. Partition coefficient n-octanol/water

3.9. Flash-point

3.10. Flammability

4. Toxicological studies

4.1. Acute toxicity

For tests set out in subclauses 4.1.1 and 4.1.2 of this Annex, one route of administration is sufficient. Gases shall be tested by inhalation and substances other than gases shall be tested by oral administration.

4.1.1. Administered orally;

4.1.2. Administered by inhalation;

4.1.5. Skin irritation;

4.1.6. Eye irritation;

4.1.7. Skin sensitisation;

4.3. Other effects

4.3.1. Mutagenicity;

The mutagenicity of a substance shall be examined in a bacteriological reverse mutation test with and without metabolic activation.

5. Ecotoxicological studies

5.2. Degradation:
- biotic.

Annex 1C

to the Procedure for Notification of Chemicals

Information set out in clause 7.3 of this Procedure to be submitted to the Chemicals Notification Centre

The agencies responsible for carrying out the studies shall be mentioned upon notification.

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 Chemicals Notification Centre.

This Annex is in conformity with Annex VII C of the Council Directive 92/32/EEC.

Technical dossier

0. Identity of manufacturer and the identity of the notifier: location of the production site
For substances manufactured outside Estonia and for which the notifier has been designated as the authorised representative of the manufacturer, the identity and the addresses of the importers shall be indicated.

1. Identity of the substance

1.1. Name

1.1.1. Name in the IUPAC nomenclature;

1.1.2. Other names (usual name, trade name, abbreviation);

1.1.3. CAS number and CAS name (if available).

1.2. Molecular and structural formula

1.3. Composition of the substance

1.3.1. Degree of purity (%);

1.3.2. Nature of impurities, including isomers and by-products;

1.3.3. Percentage of significant impurities;

1.3.4. If the substance contains a stabilising agent or an inhibitor or other additives, specify their nature and order of magnitude: ppm, %;

1.3.5. Spectral data (UV, IR, NMR or mass spectrum);

1.3.6. High-performance liquid chromatography and gas chromatography data.

1.4. Methods of detection and determination
A full description of the methods used or the appropriate bibliographical

references. Apart from methods of detection and determination, information shall be given on analytical methods which are known to the notifier and allow detection of the substance and its transformation products after discharge into the environment as well as determination of the direct exposure of humans.

2. Information on the substance

2.0. Production

Information shall be sufficient to allow an approximate but realistic estimation of human and environmental exposure associated with the production process of the substances. Details of the production process, particularly those of a commercially sensitive nature, are not required.

2.0.1. Technological process used in production;

2.0.2. Exposure estimates related to production:
- in working environment;
- in natural and human environment.

2.1. Proposed uses

Information shall be sufficient to allow an approximate but realistic estimation of human and environmental exposure associated with the expected uses of the substances.

2.1.1. Types of use: description and desired effects;

2.1.1.1. Technological processes related to the use of the substance (where known);

2.1.1.2. Exposure estimate(s) related to use (where known):
- in working environment;
- in natural and human environment;

2.1.1.3. Form under which the substance is marketed: substance, preparation, product;

2.1.1.4. Concentration of the substance in marketed preparations and products (where known).

2.1.2. Fields of application with approximate breakdown:
- industries;
- farmers and other skilled trades;
- use by the public at large.

2.1.3. Identity of the recipients of the substance (where known and where appropriate).

2.2. Estimated production and/or imports for each of the anticipated uses or fields of application

2.2.1. Annual overall production and/or imports (in tonnes per year):
- the first calendar year;
- the following calendar years.

For substances manufactured outside Estonia and for which the notifier has been designated as the authorised representative of the manufacturer, this

information shall be given for each of the importers identified in clause 0 of this Annex.

2.2.2. Production and/or imports, broken down in accordance with clauses 2.1.1 and 2.1.2. of this Annex and expressed as a percentage:
- the first calendar year;
- the following calendar years.

2.3. Recommended methods and precautions concerning:

2.3.1. Handling;

2.3.2. Storage;

2.3.3. Transport;

2.3.4. Fire (nature of combustion gases or pyrolysis, where proposed uses justify this);

2.3.5. Other dangers, particularly chemical reaction with water.

2.4. Emergency measures in the case of accidental spillage

2.5. Emergency measures in the case of injury to persons (e.g. poisoning)

2.6. Packaging

3. Physico-chemical properties of the substance

3.0. State of the substance at 20°C and a pressure of 101.3kPa

3.9. Flash-point

3.10. Flammability

4. Toxicological studies

4.1. Acute toxicity

One route of administration is sufficient. Substances other than gases shall be tested by oral administration. Gases shall be tested by inhalation.

4.1.1. Administered orally;

4.1.2. Administered by inhalation.

Annex 1D

to the Procedure for Notification of Chemicals

Additional requirements for technical dossiers upon notification of polymers

A. Definitions

“Homopolymer” is a polymer consisting of only one kind of monomer unit;

“Copolymer” is a polymer consisting of more than one kind of monomer unit;

“Family of polymers” is a group of homopolymers or copolymers with different number-average molecular weights or different compositions resulting from different ratios of monomer units. The difference in the number-average molecular weight or in the composition is determined not

by unintentional process-related fluctuations but by deliberate alterations to the process conditions, the process itself remaining the same;

"M_n" is the number-average molecular weight;

"M" is the molecular weight.

B. Family approach

In order to avoid unnecessary testing, polymers shall be grouped into families. Representative members of a polymer family shall be tested.

Homopolymers of the same family differ from each other only in terms of the number-average molecular weight.

Copolymers of the same family differ from each other in terms of the number-average molecular weight and the ratios of monomer units.

In cases where there are dissimilarities in the effects seen in the representative members of the studied polymers depending on the M_n- or composition-range, additional testing of other polymers of the same family shall be required.

C. Information required upon notification of polymers

Appropriate available information on the properties of the monomers may be taken into account in the part of the technical dossier which concerns the notification of the polymer and pertains to the assessment of the properties of the polymer.

The necessary tests shall be conducted according to methods recognised and recommended by the competent international bodies where such methods exist.

The agencies responsible for carrying out the studies shall be mentioned upon notification.

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 Chemicals Notification Centre.

C.1. Polymers with standard test package

C.1.1. Polymers placed on the market in quantities of >= 1 tonne per year or total quantities of >= 5 tonnes.

In addition to the information required in Annex 1A to this Procedure, the following polymer-specific information is required:

1. Identity of the substance

1.2.1. Number-average molecular weight;

1.2.2. Molecular weight distribution;

1.2.3. Identity and concentration of starting monomer(s) and starting substance(s)

which will be bound in the polymer;

1.2.4. Identification of end groups and frequency and identity of reactive functional groups;

1.3.2.1. Identity of non-reacted monomers;

1.3.3.1. Percentage of non-reacted monomers.

2. Information on the substance

2.1.1.5. Statement, with relevant information, if the polymer has been developed to be environmentally degradable.

3. Physico-chemical properties of the substance

3.6.1. Water extractivity

Further tests may be required additionally (the list is not exhaustive):

- light-stability if the polymer is not specifically light-stabilised;

- long-term extractivity (leachate test); depending on the results of this test, appropriate tests on the leachate may be requested on a case by case basis.

C.1.2. Polymers placed on the market in quantities of < 1 tonne per year or total quantities of < 5 tonnes, but >= 100 kilograms per year or total quantities >= 500 kilograms.

In addition to the information required in Annex 1B to this Procedure, the following polymer-specific information is required:

1. Identity of the substance

1.2.1. Number-average molecular weight;

1.2.2. Molecular weight distribution;

1.2.3. Identity and concentration of starting monomer(s) and starting substance(s) which will be bound in the polymer;zx

1.2.4. Identification of end groups and frequency and identity of reactive functional groups;

1.3.2.1. Identity of non-reacted monomers;

1.3.3.1. Percentage of non-reacted monomers.

2. Information on the substance

2.1.1.5. Statement, with relevant information, if the polymer has been developed to be environmentally degradable.

3. Physico-chemical properties of the polymer

3.6.1. Water extractivity

C.1.3. Polymers placed on the market in quantities of < 100 kilograms per year or total quantities of < 500 kilograms.

In addition to the information required in Annex 1C to this Procedure, the following polymer-specific information is required:

1. Identity of the substance

1.2.1. Number-average molecular weight;

1.2.2. Molecular weight distribution;

1.2.3. Identity and concentration of starting monomer(s) and starting substance(s) which will be bound in the polymer;

1.2.4. Identification of end groups and frequency and identity of reactive functional

groups;

1.3.2.1. Identity of non-reacted monomers;

1.3.3.1. Percentage of non-reacted monomers.

2. Information on the substance

2.1.1.5. Statement, with relevant information, if the polymer has been developed to be environmentally degradable.

C.2. Polymers for which a reduced test package is acceptable

Under certain conditions the base set test package can be reduced.

Polymers with a high number-average molecular weight, a low content of low molecular weight species and a low solubility or extractivity may be regarded as being non-bioavailable (non-readily degradable). The following criteria shall be used to make a decision on the use of a reduced test package on a case by case basis.

For non-readily degradable polymers placed on the market in quantities of >= 1 tonne per year or total quantities of >= 5 tonnes, the following criteria define those polymers for which a reduced test package is acceptable:

I High number-average molecular weight (M_n); (shall be decided on a case by case basis by the Chemicals Notification Centre);

II Extractivity in water (see 3.6.1); < 10 mg/l excluding any contribution from additives and impurities;

III Less than 1% with M < 1000; the percentage refers only to molecules directly derived from and including monomer(s), excluding other components e.g. additives or impurities.

If all criteria are fulfilled, the polymer is regarded as a polymer for which a reduced test package is acceptable.

In the case of non-readily degradable polymers placed on the market in quantities of < 1 tonne per year or total quantities of < 5 tonnes, it is sufficient that criteria I and II are fulfilled for the polymer to be considered a polymer for which a reduced test package is acceptable.

If it is not possible to prove the criteria with the assigned tests, the notifier shall demonstrate compliance with the criteria by other means.

Under certain circumstances, toxicological and ecotoxicological tests may be required.

C.2.1. Polymers placed on the market in quantities of >= 1 tonne per year or total quantities of >= 5 tonnes.

0 Identity of manufacturer and the identity of the notifier: location of the production site

For polymers manufactured outside Estonia and for which the notifier has been designated as the authorised representative of the manufacturer, the identity and the addresses of the importers of the polymers shall be indicated.

1. Identity of the substance

1.1. Name

1.1.1. Name in the IUPAC nomenclature;
1.1.2. Other names (usual name, trade name, abbreviation);
1.1.3. CAS number and CAS name (if available).
1.2. Molecular and structural formula
1.2.1. Number-average molecular weight;
1.2.2. Molecular weight(s) distribution;
1.2.3. Identity and concentration of starting monomer(s) and starting substance(s) which will be bound in the polymer;
1.2.4. Identification of end groups and frequency and identity of reactive functional groups.
1.3. Composition of the substance
1.3.1. Degree of purity (%);
1.3.2. Nature of impurities, including by-products;
1.3.2.1. Identity of non-reacted monomer(s);
1.3.3. Percentage of significant impurities;
1.3.3.1. Percentage of non-reacted monomer(s);
1.3.4. If the substance contains a stabilising agent or an inhibitor or other additives, specify their nature and order of magnitude: ..... ppm, ... %;
1.3.5. Spectral data (UV, IR, NMR or mass spectrum);
1.3.6.1. Gel permeation chromatography (GPC).
1.4. Methods of detection and determination

A full description of the methods used or the appropriate bibliographical references. Apart from methods of detection and determination, information shall be given on analytical methods which are known to the notifier and allow detection of the substance and its transformation products after discharge into the environment as well as determination of the direct exposure of humans.

2. Information on the substance
2.0. Production

The given information shall be sufficient to allow an approximate but realistic estimation of human and environmental exposure associated with the production process of the substances.

Precise details of the production process, particularly those of a commercially sensitive nature, are not required.

2.0.1. Technological process used in production;
2.0.2. Exposure estimates related to production:
- in working environment;
- in natural and human environment.
2.1. Proposed uses

Information shall be sufficient to allow an approximate but realistic estimation of human and environmental exposure associated with the expected uses of the substances.

2.1.1. Types of use: description and desired effects;
2.1.1.1. Technological processes related to the use of the polymer (where known);

2.1.1.2. Exposure estimate(s) related to use (where known):
- in working environment;
- in natural and human environment.

2.1.1.3. Form under which the substance is marketed: substance, preparation, product;

2.1.1.4. Concentration of the polymer in marketing preparations and products (where known).

2.1.2. Fields of application with approximate breakdown:
- industries;
- farmers and other skilled trades;
- use by the public at large.

2.1.3. Identity of the recipients of the substance (where known and where appropriate);

2.1.4. Waste quantities and composition of waste resulting from the proposed uses (where known).

2.2. Estimated production and/or imports for each of the anticipated uses or fields of application

2.2.1. Annual overall production and/or imports (in tonnes per year):
- the first calendar year;
- the following calendar years.

For substances manufactured outside Estonia and for which the notifier has been designated as the authorised representative of the manufacturer, this information shall be given for each of the importers identified in clause 0 of this Annex.

2.2.2. Production and/or imports, broken down in accordance with clauses 2.1.1 and 2.1.2 of this Annex and expressed as a percentage:
- the first calendar year;
- the following calendar years.

2.3. Recommended methods and precautions concerning:

2.3.1. Handling;

2.3.2. Storage;

2.3.3. Transport;

2.3.4. Fire (nature of combustion gases or pyrolysis, where proposed uses justify this);

2.3.5. Other dangers, particularly chemical reaction with water;

2.3.6. Information concerning the susceptibility of the substance to explode when presented in the form of a dust (if relevant).

2.4. Emergency measures in the case of accidental spillage

2.5. Emergency measures in the case of injury to persons (e.g. poisoning)

2.6. Packaging

3. Physico-chemical properties of the substance

3.0. State of the substance at 20ºC and 101.3kPa

3.1. Melting range (e.g. from the thermal stability test)

3.3. Relative density

3.6.1. Water extractivity.

3.10. Flammability

3.11. Explosive properties

3.12. Self-ignition temperature

3.15. Particle size

For those polymers which my be marketed in a form which gives rise to the danger of exposure by the inhalatory route, the particle size distribution of the substance as it will be marketed shall be determined.

3.16. Thermal stability

3.17. Extractivity with:

- water at 37°C (at pH 2 and pH 9);
- cyclohexane.

4. Toxicological studies

On a case by case basis and without delaying the registration of the polymer, the Chemicals Notification Centre may, on the basis of the presence of reactive groups, structural or physical characteristics, knowledge concerning the properties of low molecular weight components of the polymer or exposure potential, require certain tests to be carried out. In particular tests for inhalation toxicity shall be carried out (see subclauses 4.1.2 or 4.2.1 of Annex 1A to this Procedure) if exposure by the inhalatory route is considered possible.

5. Ecotoxicological studies

On a case by case basis and without delaying the review of the notification concerning the polymer, the Chemicals Notification Centre may, on the basis of the presence of reactive groups, structural or physical characteristics, knowledge concerning the properties of low molecular weight components of the polymer or exposure potential, require additional tests to be carried out. In particular, the following additional tests shall be carried out:

- light-stability of the polymer, if the polymer is not specifically light-stabilised;
- long-term extractivity (leachate test).

Depending on the results of this test, appropriate tests on the leachate may be requested on a case by case basis.

6. Possibility of rendering the substance harmless

6.1. For industry or other skilled trades

6.1.1. Possibility of recycling;

6.1.2. Possibility of neutralisation of unfavourable effects;

6.1.3. Possibility of destruction (degradation):

- controlled discharge into the environment;
- incineration;
- water purification station;
- others.

6.2. For the public at large

6.2.1. Possibility of recycling;

6.2.2. Possibility of neutralisation of unfavourable effects;

6.2.3. Possibility of destruction (degradation):
- controlled discharge into the environment;
- incineration;
- water purification station;
- others.

C.2.2. Polymers placed on the market in quantities of < 1 tonne per year or total quantities of < 5 tonnes.

0. Identity of manufacturer and the identity of the notifier.
Location of the production site

For polymers manufactured outside Estonia and for which the notifier has been designated as the sole representative of the manufacturer, the identity and the addresses of the importers of the polymers shall be indicated.

1. Identity of the substance

1.1. Name

1.1.1. Name in the IUPAC nomenclature;

1.1.2. Other names (usual name, trade name, abbreviation);

1.1.3. CAS number and CAS name (if available).

1.2. Molecular and structural formula

1.2.1. Number-average molecular weight;

1.2.2. Molecular weight distribution;

1.2.3. Identity and concentration of starting monomers and starting substances which will be bound in the polymer;

1.2.4. Identification of end groups and frequency and identity of reactive functional groups.

1.3. Composition of the substance

1.3.1. Degree of purity (%);

1.3.2. Nature of impurities, including by-products;

1.3.2.1. Identity of non-reacted monomer(s);

1.3.3. Percentage of significant impurities;

1.3.3.1. Percentage of non-reacted monomer(s);

1.3.4. If the substance contains a stabilising agent or an inhibitor, specify their nature and order of magnitude: ..... ppm, ... %;

1.3.5. Spectral data (UV, IR, NMR or mass spectrum);

1.3.6.1. Gel permeation chromatography (GPC).

1.4. Methods of detection and determination

A full description of the methods used or the appropriate bibliographical references. Apart from methods of detection and determination, information shall be given on analytical methods which are known to the notifier and allow detection of the substance and its transformation products after discharge into the environment as well as determination of the direct exposure of humans.

2. Information on the substance

2.0. Production

Information shall be sufficient to allow an approximate but realistic estimation of human and environmental exposure associated with the production process of the substances. Precise details of the production process, particularly those of a commercially sensitive nature, are not required.

2.0.1. Technological process used in production;

2.0.2. Exposure estimates related to production:
- in working environment;
- in natural and human environment.

2.1. Proposed uses

Information shall be sufficient to allow an approximate but realistic estimation of human and environmental exposure associated with the expected uses of the substances.

2.1.1. Types of use: description and desired effects;

2.1.1.1. Technological processes related to the use of the polymer (where known);

2.1.1.2. Exposure estimate(s) related to use (where known):
- in working environment;
- in natural and human environment;

2.1.1.3. Form under which the substance is marketed: substance, preparation, product;

2.1.1.4. Concentration of the polymer in marketing preparations and products (where known).

2.1.2. Fields of application with approximate breakdown:
- industries;
- farmers and other skilled trades;
- use by the public at large.

2.1.3. Identity of the recipients of the substance (where known and where appropriate);

2.1.4. Waste quantities and composition of waste resulting from the proposed uses (where known).

2.2. Estimated production and/or imports for each of the anticipated uses or fields of application

2.2.1. Annual overall production and/or imports (in tonnes per year):
- the first calendar year;
- the following calendar years.

For substances manufactured outside Estonia and for which the notifier has been designated as the authorised representative of the manufacturer, this information shall be given for each of the importers identified in clause 0 of this Annex.

2.2.2. Production and/or imports, broken down pursuant to clause 2.1.2 of this Annex and expressed as a percentage:
- the first calendar year;
- the following calendar years.

2.3. Recommended methods and precautions concerning:

2.3.1. Handling;

2.3.2. Storage;
2.3.3. Transport;
2.3.4. Fire (nature of combustion gases or pyrolysis, based on the proposed uses);
2.3.5. Other dangers, particularly chemical reaction with water;
2.3.6. Information concerning the susceptibility of the substance to explode when presented in the form of a dust (if relevant).
2.4. Emergency measures in the case of accidental spillage
2.5. Emergency measures in the case of injury to persons (e.g. poisoning)
2.6. Packaging
3. Physico-chemical properties of the polymer
3.0. State of the polymer at 20ºC and a pressure of 101.3kPa
3.1. Melting range (e.g. from the thermal stability test)
3.6.1. Water extractivity
3.10. Flammability

Annex 2

to the Procedure for Notification of Chemicals

Additional information and tests to be submitted to the Chemicals Notification Centre pursuant to the requirements set out in subclause 6.4 of this Procedure

The agencies responsible for carrying out the studies shall be mentioned upon notification.

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 Chemicals Notification Centre.

Level 1

Physico-chemical studies

Further studies on physico-chemical properties depend on the results of studies obtained pursuant to Annex 1 to this Procedure. Further studies could include for example the development of analytical methods which make it possible to detect a substance or its transformation products and studies on thermal decomposition products.

Toxicological studies

Fertility study (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, one generation, male and female, most appropriate route of administration) shall be required if the results of the repeated-dose study pursuant to Annex 1A to this Procedure or other relevant information demonstrate the need for further investigation.

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

(a) serious or irreversible lesions;

(b) a very low or absence of a “no effect” level;

(c) a clear relationship in structure between the substance being studied and other substances which have been proved dangerous.

- Additional mutagenesis studies and/or screening studies for carcinogenesis shall be carried out using the method approved by the Minister of Social Affairs.

When both tests in the base set provided for in Annex 1 to this Procedure are negative, further tests shall be conducted according to the specific properties and the purposed use of the substance.

When a test or both tests were positive in the base set provided for in Annex 1 to this Procedure, a supplementary study should include the same or different end points in other *in vivo* test methods.

- Basic toxicokinetic information.

Ecotoxicity studies

- Prolonged (long-term) (cumulative) toxicity study with *Daphnia magna* (21 days);

- Test on plants;

- Test on earthworms;

- Further toxicity studies with fish;

- Tests for species accumulation; one species, preferably fish;

- Supplementary degradation studies if sufficient degradation has not been proved by the degradation studies conducted pursuant to Annex 1 to this Procedure;

- Further studies on absorption/desorption dependent on the results of the studies conducted pursuant to Annex 1 to this Procedure.

Level 2

Toxicological studies

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

- Chronic toxicity study;

- Carcinogenicity study;

- Fertility study (including three-generation study) only if an effect on fertility has been established by studies required at level 1 of this Procedure;

- Developmental toxicity study on peri- and postnatal effects;

- Teratology study (species not employed in studies required at level 1 of this Procedure);

- Additional toxicokinetic studies which cover biotransformation and pharmacokinetics;

- Additional tests to investigate organ toxicity 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.

Annex 3

to the Procedure for Notification of Chemicals

Information required upon notification of existing substances

1. General information
1.1. Name of substance;

1.2. EINECS number;
1.3. CAS number;
1.4. Synonyms;
1.5. Degree of purity (%);
1.6. Impurities;
1.7. Molecular formula;
1.8. Structural formula;
1.9. Type of substance;
1.10. Physical state;
1.11. Indicate origin of information (notifier);
1.12. Quantity. May be classified pursuant to clause 1.2 of this Procedure;
1.13. Indicate if the substance has been produced during the last 12 months;
1.14. Indicate if the substance has been imported during the last 12 months;
1.15. Classification and labelling;
1.16. Use pattern;
1.17. Has the complete data set already been submitted by another manufacturer or importer (other relevant information shall be submitted upon notification pursuant to clause 1.3 of this Procedure);
1.18. Specify if the notifier is acting on behalf of another manufacturer or importer;
1.19. Other information (for example options for disposal).
2. Physico-chemical properties
2.1. Melting-point;
2.2. Boiling-point;
2.3. Density;
2.4. Vapour pressure;
2.5. Partition coefficient n-octanol/water ($\log_{10} P_{ow}$);
2.6. Water solubility;
2.7. Flash-point;
2.8. Self-ignition temperature;
2.9. Flammability;
2.10. Explosive properties;
2.11. Oxidising properties;
2.12. Other information.
3. Environmental fate and pathways
3.1. Stability:
3.1.1. Photodegradation;
3.1.2. Stability in water;
3.1.3. Stability in soil;
3.2. Environmental monitoring data;
3.3. Transport and distribution between environmental compartments including estimated environmental concentrations and distribution pathways;

3.3.1. Transport;
3.3.2. Distribution between environmental compartments;
3.4. Biodegradation;
3.5. Bioaccumulation;
3.6. Other information.
4. Ecotoxicity
4.1. Toxicity to fish;
4.2. Toxicity to *Daphnia magna* and other aquatic invertebrates;
4.3. Toxicity to algae;
4.4. Toxicity to bacteria;
4.5. Toxicity to terrestrial organisms;
4.6. Toxicity to soil dwelling organisms;
4.7. Other information.
5. Toxicity
5.1. Acute toxicity;
5.1.1. Acute oral toxicity;
5.1.2. Acute inhalation toxicity;
5.1.3. Acute dermal toxicity;
5.1.4. Acute toxicity (other routes of administration);
5.2. Corrosiveness and irritation;
5.2.1. Skin irritation;
5.2.2. Eye irritation;
5.3. Sensitisation;
5.4. Repeated dose toxicity;
5.5. Genetic toxicity *in vitro;*
5.6. Genetic toxicity *in vivo;*
5.7. Carcinogenicity;
5.8. Toxicity to reproduction;
5.9. Other relevant information;
5.10. Experience with human exposure.
6. List of professional publications and other sources of information

[1] RTL = *Riigi Teataja Lisa = Appendix to the State Gazette*

[2] RT = *Riigi Teataja = State Gazette*