Republic of Latvia

Cabinet
Regulation No. 340
Adopted 6 August 2002

Procedures for Import, Notification and Risk Assessment of New Chemical Substances

Issued pursuant to Section 13, Paragraph three and Paragraph four, Clause 3
of the Chemical Substances and Chemical Products Law

I. General Provisions

1. These Regulations prescribe:

1.1. the procedures for the notification of a new chemical substance and the assessment of risks to the environment and human health; and

1.2. the procedures by which registered consumers, the number of whom is limited, import new chemical substances for precisely formulated purposes of experimental manufacturing in a quantity that does not exceed the quantity required for investigation of the specific process.

2. These Regulations do not apply to:

2.1. new chemical substances utilised as additives in animal feedingstuffs or which are in the composition of animal feedingstuffs in the final stage of preparation thereof;

2.2. new chemical substances utilised as additives in food products;

2.3. chemical substances which are in the composition of waste; and

2.4. new chemical substances that are utilised only as the active substance in the composition of medicinal products (except for intermediate products), biocidal products and plant protection products.

II. Import of New Chemical Substances for Precisely Formulated Purposes of Experimental Manufacturing

3. New chemical substances shall be imported for precisely formulated purposes of experimental manufacturing (hereinafter — experimental manufacturing) in order to:

3.1. determine fields or sectors for utilisation of the relevant substance, as well as the conditions or requirements for utilisation thereof; and

3.2. investigate the relevant substance and adjust it for utilisation in the intended technological equipment and circumstances.

4. New chemical substances that are imported for experimental manufacturing are prohibited:

4.1. to be offered or sold for general use, or to be distributed to consumers which are not included in the list referred to in Sub-Paragraph 5.4 of these Regulations; or

4.2. to be utilised for manufacturing of chemical products which are offered or sold for general use.

5. A legal person who is planning to import a new chemical substance for experimental manufacturing shall submit to the Latvian Environment Agency the following in writing:

5.1. the following information in respect of the relevant legal person:

5.1.1. legal address;

5.1.2. name of the merchant and its registration number in the Enterprise Register, as well as the value added tax payer code; and

5.1.3. information regarding the natural person responsible for the provision of information regarding the new chemical substance — position, given name, surname, telephone and fax number and e-mail address;

5.2. the following information regarding the new chemical substance:

5.2.1. the name of the manufacturer and location of the production site;

5.2.2. the intended types and conditions of use, as well as emission in the work environment and the environment (if known);

5.2.3. the name in accordance with the International Union of Pure and Applied Chemistry (hereinafter — IUPAC) nomenclature, usual name and trade name, as well as the molecular formula, structural formula and composition (degree of purity (%), nature of impurities, all hazardous impurities and the percentage of main impurities);

5.2.4. physico-chemical properties —aggregate condition of the substance at 20°C if the pressure is 101,3 kPA, as well as flash-point and self-ignition temperature;

5.2.5. acute toxicity by inhalation (for gases) or if swallowed if properties, structure or other features of the relevant substance indicate that it can be very toxic, toxic, carcinogenic, toxic for reproduction or mutagenic;

5.2.6. results of biodegradation studies if it is planned to import 100 kg and more per year or the total of 500 kg of the new chemical substance;

5.2.7. the packaging of the new chemical substance;

5.2.8. recommended methods and safety measures when utilising the relevant substance in the intended technological equipment and conditions, storage, transportation, fire safety thereof, emergency medical assistance and measures for accident elimination; and

5.2.9. the total quantity of the new chemical substance to be imported per year;

5.3. information regarding classification and labelling of the new chemical substance in conformity with the regulatory enactments which regulate classification, labelling and packaging of chemical substances and chemical products;

5.4. a list of recipients of the new chemical substance. The list shall specify the following information regarding each recipient of the relevant substance:

5.4.1. legal address;

5.4.2. name and registration number in the Enterprise Register, as well as the value added tax payer code;

5.4.3. information regarding the natural person responsible for activities with the new chemical substance and provision of the relevant information — position, given name, surname, telephone and fax number, as well as the e-mail address;

5.4.4. location of the experimental production site in which it is intended to use the new chemical substance; and

5.4.5. the intended type and conditions of use of the new chemical substance; and

5.5. a plan of investigation measures. The plan shall specify the following information regarding performed or intended investigation by each recipient of the new chemical substance:

5.5.1. the date of commencement of investigation and the planned date of completion;

5.5.2. the main investigation measures; and

5.5.3. the quantity of the new chemical substance required for investigation of the specific process.

6. The Latvian Environment Agency shall register the recipient of the new chemical substance imported for experimental manufacturing, specifying its name, registration number in the Enterprise Register, as well as the official registration number of the new chemical substance intended for experimental manufacturing.

7. A legal person who imports a new chemical substance for experimental manufacturing, not later than within a year shall notify the relevant chemical substance in conformity with the requirements prescribed by these Regulations or submit to the Latvian Environment Agency a request to extend the term for the registration of experimental manufacturing.

III. Notification of New Chemical Substances

8. If it is intended to increase offering or retailing of the new chemical substance on the market, or movement thereof (including importation into the customs territory) which is not a transit operation under customs supervision (hereinafter — trade), the new chemical substance shall be notified:

8.1. by the manufacturer of the substance if it is manufactured within the territory of the relevant state; or

8.2. by the importer of the substance or another performer of the relevant activities who has been authorised by the manufacturer to notify the new chemical substance for offering or retailing on the market (hereinafter — authorised representative of the manufacturer) if the substance is manufactured outside the territory of the relevant state.

9. Each manufacturer of the new chemical substance or the authorised representative of the manufacturer who notifies a new chemical substance (hereinafter — notifier) shall submit to the Latvian Environment Agency a notification in the official language in writing and electronically. The notification shall include the following information:

9.1. the name of the notifier and the registration number thereof in the Enterprise Register, as well as the value added tax payer code;

9.2. the legal address of the notifier;

9.3. information regarding the natural person responsible for activities with the new chemical substance and provision of the relevant information — position, given name, surname, telephone and fax number, as well as the e-mail address;

9.4. technical dossier in accordance with Annex 1 of these Regulations if 10 kg and more, but less than 100 kg of the new chemical substance are manufactured or imported per year and Section 13, Paragraph four, Clause 2 of the Chemical Substances and Chemical Products Law does not apply to the manufacturing or import thereof;

9.5. technical dossier in accordance with Annex 2 of these Regulations if 100 kg and more, but less than one tonne of the new chemical substance are manufactured or imported per year;

9.6. technical dossier in accordance with Annex 3 of these Regulations if one tonne and more of the new chemical substance is manufactured or imported per year;

9.7. technical dossier in accordance with Annex 4 of these Regulations if:

9.7.1. the new chemical substance is an intermediate product (a substance manufactured and used solely for obtaining another chemical substance or substances) and one tonne and more of the new chemical substance is manufactured or imported per year; or

9.7.2. the conditions specified in Paragraph 14 of these Regulations exist; and

9.8. information and documentation in conformity with Paragraph 10 of these Regulations regarding the new chemical substance, its potential effects on the environment and human health, as well as regarding the studies conducted — in conformity with the quantity of the manufactured or imported new chemical substance and previous information as available.

10. The notifier in conformity with Sub-paragraph 9.8 of these Regulations shall submit the following documentation and information:

10.1. descriptions of the analyses, tests, experiments and studies (hereinafter — studies) conducted and of the methods used or a bibliographical reference to the methods used, as well as justification for the use thereof;

10.2. justified proposals regarding classification and labelling of the new chemical substance;

10.3. proposals regarding the content of the chemical substance and chemical product safety data sheet for the new chemical substance if the relevant substance is to be classified as hazardous;

10.4. a statement from the manufacturer that the notifier is the authorised representative of the manufacturer if the new chemical substance is manufactured outside the territory of the state;

10.5. information regarding animal experimentation:

10.5.1. the date of issue, term of validity and essential provisions of the permit for animal experimentation;

10.5.2. information regarding measures which in accordance with Paragraphs 18 and 19 of these Regulations prevent analogous animal experimentation, particularly with vertebrates, by several notifiers of identical new chemical substance;

10.5.3. the submission referred to in Paragraph 20 of these Regulations (at the choice of the notifier);

10.6. certification that the laboratory which conducted studies of the new chemical substance has been examined and operates in accordance with regulatory enactments regulating requirements for work quality and inspection of laboratories;

10.7. a declaration which shall specify:

10.7.1. undesirable consequences or adverse effects caused by the new chemical substance under foreseen conditions of use;

10.7.2. adverse effects and undesirable consequences of the product containing the new chemical substance under foreseen conditions of use if a polymer contains more than 2% or another chemical product contains more than 1% of the new chemical substance; and

10.8. information required to assess risks to the environment and human health and life or the previous risk assessment.

11. The notifier shall only submit the information specified in Annex 1, 2, 3 or 5, Clauses 1 and 2 of these Regulations if the first notification regarding the new chemical substance has been submitted to a competent institution of a European Union Member State at least 10 years before submission of the relevant notification.

12. In order to prevent duplication of information the notifier may submit to the Latvian Environment Agency a copy of the opinion by the competent institution of the European Union Member State and the notification submitted to the institution referred to and a translation thereof into Latvian if the new chemical substance is manufactured or has been notified in a European Union Member State.

13. For polymers which contain in a bound form 2% and more of the new chemical substance, the technical dossier provided in accordance with Annex 1, 2 or 3 of these Regulations shall be supplemented with the information specified in Annex 5 of these Regulations, as well as contain a description of the methods used or a bibliographic reference to the methods used. A polymer is a high molecular weight compound consisting of chain links characterised by the sequence of one or more types of monomer units and excess weight of monomer molecules. A polymer molecule consists of at least three monomer units, which are covalently bound to at least one other monomer unit or other reactant, and the smallest part of weight of the polymer consists of molecules of the same molecular weight. Monomer unit is the form of a monomer in a polymer after polymerisation reaction.

14. The notifier shall submit a technical dossier in accordance with Annex 4 of these Regulations if the following conditions exist:

14.1. the new chemical substance is manufactured and utilised only in the chemical technology process;

14.2. the relevant substance is not a monomer;

14.3. during the chemical technology process another substance with a different molecular composition is obtained from the relevant substance (except for polymers);

14.4. the relevant substance is utilised in not more than two places;

14.5. the notifier delivers the relevant substance without intermediaries to the merchant who utilises the intermediate product in the chemical technology process to manufacture another substance;

14.6. the notifier ensures that during the whole circulation cycle of the relevant substance (in manufacturing, transporting, processing, taking of samples, conducting of analyses, storing of waste, performing maintenance of equipment and premises or storing of the relevant substance) technical measures are taken which prevent the possibility of the substance to escape from the packaging, means of transport, research or technological equipment or closed system:

14.6.1. the measures referred to are taken in respect of all functional elements of the equipment, including closed devices which guarantee leak-tightness or which have integrated exhaust ventilation; and

14.6.2. the relevant substance is so used as not to cause emissions or to reduce the possibility of emission, for example, packaging of the substance is mechanically durable, non-reusable and together with the substance is input in the technological equipment or the substance is used in the form of paste or granules;

14.7. the notifier ensures supervision of the control system of the technological process and safety of the technological process, as well as measures for prevention of emission of the relevant substance or reduction of the harmful effects thereof;

14.8. the notifier ensures specific precautionary and technological process safety measures in the course of technical maintenance depending on the nature or quantity of the relevant activities, for example, before opening, cleaning or entering of each equipment empties and washes the relevant equipment;

14.9. the notifier ensures measures to prevent emission of the relevant substance or reduction of the harmful effects thereof during technical maintenance or accidents, for example, equipment which contains the spread of the accident, spillage or waste collection equipment and reservoirs, pollution detection equipment, equipment, facilities and measures intended for human safety and protection of the environment;

14.10. merchant's work organisation and management system specifies duties of the employees, particularly in respect of control and reduction of the emission and effects on the environment and human health of the new chemical substance;

14.11. the new chemical substance, taking into account the investigated hazardous properties thereof, has been classified in accordance with regulatory enactments regulating classification, labelling and packaging of chemical substances and chemical products, and the label bears a warning "Uzmanību! Šī viela vēl nav pilnīgi pārbaudīta!" ["Caution! This substance not yet fully tested!];

14.12. in performing activities with the new substance the precautionary principle is observed: if physical, chemical, toxic or ecotoxic properties have not been tested or have not been determined but specific signs attest thereto (for example, properties or structure of the substance), the relevant substance shall be deemed to be hazardous;

14.13. if the new chemical substance needs to be transported outside the territory of the merchant, taking into account the investigated hazardous properties of the relevant substance, it is classified, labelled, packaged, as well as the relevant provisions in accordance with regulatory enactments regulating procedures for carriage of hazardous goods are observed;

14.14. the notifier informs the employees and the responsible State institutions in good time regarding changes, which may cause adverse effects on the environment or human organism;

14.15. the notifier in conformity with the concluded contract supervises whether the users of the relevant intermediate product (not more than two) ensure management of the new chemical substance in accordance with the requirements set out in Sub-paragraphs 14.1, 14.2,

14.3, 14.4, 14.5, 14.6, 14.7, 14.8, 14.9, 14.10, 14.11, 14.12, 14.13 and 14.14 of these Regulations;

14.16. the notifier has submitted the following information to the Latvian Environment Agency:

14.16.1. a description of technical measures which during the entire circulation cycle of the new chemical substance prevent the possibility of a substance to escape from the packaging, means of transport, research or technological equipment or other closed system;

14.16.2. results of evaluation of the used technology and measures for reducing the risks caused by the new chemical substance to human health and the environment;

14.16.3. confirmation that in evaluating functional elements of the technological equipment the criteria specified in Annex 4 of these Regulations have been observed;

14.16.4. assessment of the effect of the new chemical substance on the environment and human health, taking into account justified monitoring data or results of technical simulation assessment if the assessment criteria specified in Annex 4 of these Regulations have not been complied with;

14.16.5. a detailed description of the technological process (including chemical process) of all those undertakings or production sites in which the new chemical substance is manufactured and used. The description shall specify the intended measures for industrial wastewater treatment, incineration or another management of liquid and solid waste, repeated use of waste or wastewater, as well as specify how cleaning and maintenance of all equipment is performed;

14.16.6. a detailed assessment of the possible emission or accidental spillage of the new chemical substance and the possible harmful effect thereof on the environment and human health during the whole circulation cycle of the substance (when manufacturing, transporting, processing, disposing waste or storing the relevant substance), as well as information regarding chemical reactions during technological processes and residues and waste of technological processes;

14.16.7. information regarding the necessary restrictions, prohibitions or other risk reduction measures if emission or accidental spillage may adversely affect humans or the environment; and

14.16.8. a statement that the notifier undertakes to comply with the requirements specified in Sub-paragraphs 14.1, 14.2, 14.3, 14.4, 14.5, 14.6, 14.7, 14.8, 14.9, 14.10, 14.11, 14.12, 14.13 and 14.14 of these Regulations; and

14.17. the Latvian Environment Agency, on the basis of the information submitted by the notifier has recognised that manufacture and management of the new chemical substance is intended in accordance with the requirements specified in Sub-paragraph 14.16 of these Regulations and the notifier has submitted the technical dossier in accordance with Annex 4 of these Regulations.

15. The notifier who has submitted the technical dossier in accordance with Annex 4 of these Regulations shall supplement and submit the technical dossier in accordance with Annex 3 of these Regulations and information and documentation in accordance with Paragraph 10 of these Regulations if:

15.1. the notifier or users of the production of the notifier have not complied with:

15.1.1. the requirements specified in Paragraph 14 of these Regulations; or

15.1.2. the assessment criteria specified in Annex 4 of these Regulations; and

15.2. the Latvian Environment Agency, on the basis of the information submitted by the notifier regarding the effect of the new chemical substance on the environment and human health, has announced in writing that the notifier cannot guarantee minimum effect of the relevant substance.

16. The notifier, taking into account the investigated hazardous properties of the new chemical substance, shall:

16.1. classify, package and label the new chemical substance in accordance with regulatory enactments regulating the classification, labelling and packaging of chemical substances and chemical products; and

16.2. specify on the label a warning "Uzmanību! Šī viela vēl nav pilnīgi pārbaudīta!" ["Caution! – This substance not yet fully tested"] if:

16.2.1. any physical, chemical, toxic or ecotoxic property of the substance has not been tested in conformity with the requirements of these Regulations but there are signs which attest that the substance has the relevant hazardous property; or

16.2.2. it is or it may be necessary to perform further or additional studies.

17. In order to prevent duplication of chemical properties tests or toxicological or ecotoxicological studies, the subsequent notifier of the new chemical substance may refer to the testing or studies results submitted to the Latvian Environment Agency by the first notifier if:

17.1. the subsequent notifier may prove that:

17.1.1. the notified new chemical substance is identical with the chemical substance already notified (with the same degree of purity and the nature of impurities); and

17.1.2. it is necessary to conduct analogous studies or tests; and

17.2. the first notifier has agreed in writing that the results of the studies he or she has submitted are being utilised.

18. In order to prevent analogous experiments with animals, particularly vertebrate animals, the notifier shall ensure acquisition of information and taking of measures:

18.1. at least two months before notification of the new chemical substance the notifier shall submit to the Latvian Environment Agency a request to ascertain whether identical new chemical substance has been notified. The request shall specify the name, molecular formula, structural formula of the chemical substance and information regarding the quantity of the substance that is intended to be manufactured or imported;

18.2. the Latvian Environment Agency shall within a week inform the submitter of the request in writing of the previous notifier (if any) and indicate its the name and address (if the previous notifier has permitted the release of the data referred to), as well as inform the previous notifier of the subsequent notifier and specify its the name and address;

18.3. if possible, the previous and the subsequent notifier shall co-operate and provide one another with information in order to prevent the performance of analogous experiments with animals, particularly vertebrates; and

18.4. the previous and the subsequent notifier of identical new chemical substance shall agree on further co-operation if:

18.4.1. additional experiments with animals, particularly vertebrates, are necessary; or

18.4.2. the previous and the subsequent notifier have co-operated in conducting experiments with animals.

19. If the previous and the subsequent notifier have not agreed on co-operation regarding experiments with animals, they shall inform the Latvian Environment Agency in writing of the reasons why agreement has not taken place. The Latvian Environment Agency shall instruct the previous and the subsequent notifier in writing to perform exchange of information in order to prevent duplication of experiments with animals, specifying:

19.1. the conditions to be observed in performing exchange of information (including the purpose for which it is permitted to use the relevant information); and

19.2. the procedures by which exchange of the relevant information shall be performed.

20. The Latvian Environment Agency, taking into account a motivated submission by the notifier, has the right to permit the notifier to not perform information exchange regarding experiments with animals (for a period not longer than one year) if it is restricted access information or a commercial secret.

21. The notifier shall submit additional information to the Latvian Environment Agency if:

21.1. the information provided in the notification or the previous risk assessment does not comply with the requirements of these Regulations;

21.2. the notifier, in accordance with the requirements of these Regulations within the time periods specified by the Latvian Environment Agency, has to conduct additional studies in order to determine the effect of the new chemical substance on the environment and human health;

21.3. it is intended to increase trade in the new chemical substance in conformity with Paragraphs 22, 23 or 25 of these Regulations;

21.4. the changes referred to in Paragraph 24 of these Regulations are intended;

21.5. information provided does not ensure commencement, performance of the risk assessment or taking of a decision regarding trade in the new chemical substance; or

21.6. the notifier before increasing the volume of trade in the new chemical substance has to conduct additional studies in conformity with Annex 6 of these Regulations within the time periods set by the Latvian Environment Agency.

22. The notifier who has submitted the technical dossier in accordance with Sub-paragraph 9.4 of these Regulations, before the total volume of trade reaches 100 kg per year per manufacturer or 500 kg in total, shall submit additional information which ensures compliance of the technical dossier with Sub-paragraph 9.5 and Paragraph 10 of these Regulations.

23. The notifier who has submitted the technical dossier in accordance with Sub-paragraph 9.5 of these Regulations, before the total volume of trade reaches one tonne per year per manufacturer or five tonnes in total, shall submit additional information which ensures compliance of the technical dossier with Sub-paragraph 9.6 and Paragraph 10 of these Regulations.

24. Each notifier of the new chemical substance already notified shall inform the Latvian Environment Agency in writing:

24.1. of the effect of the substance on humans or the environment which was not known when submitting the notification and precautionary measures to be taken to reduce the newly discovered adverse effect;

24.2. if in offering or retailing the substance such types of use have been intended as were not specified in the notification;

24.3. of any changes in the composition and manufacturing of the substance in conformity with Annexes 1, 2, 3, 4 and 5 of these Regulations; and

24.4. of any changes in the status of the manufacturer of the substance, authorised representative of the manufacturer or importer.

25. The notifier shall inform the Latvian Environment Agency of the changes in the trade volume of the chemical substance already notified in writing and specify the quantity of the new chemical substance which the notifier or another manufacturer whose authorised representative acts as notifier offers or sells if the quantity of the new chemical substance offered or sold is:

25.1. up to 10 tonnes per year or the total trade volume — up to 50 tonnes per manufacturer;

25.2. up to 100 tonnes per year or the total trade volume — up to 500 tonnes per manufacturer; or

25.3. up to 1000 tonnes per year or the total trade volume — up to 5000 tonnes per manufacturer.

26. If the notified new chemical substance is manufactured outside Latvia, each importer shall guarantee that the authorised representatives of the manufacturer in Latvia have correct information regarding the total quantity of the substance imported into Latvia.

27. If more than one notification has been submitted regarding the new chemical substance manufactured in foreign states by one and the same manufacturer, the Latvian Environment Agency shall:

27.1. determine the total trade volume in the state on the basis of notifications by the previous and the subsequent notifier and information submitted in accordance with Paragraph 25 of these Regulations; and

27.2. verify whether the notifier has complied with the requirements prescribed by Paragraph 25 of these Regulations.

28. The Latvian Environment Agency:

28.1. may instruct the notifier to conduct some or all additional studies (specifying the time periods for conducting of the studies) in accordance with Annex 6 of these Regulations (except for the studies specified in Annex 6, Paragraph 5) if the quantity of the chemical substance notified by the notifier has increased up to the quantity specified in Sub-paragraph 25.1 of these Regulations;

28.2. shall instruct the notifier to conduct all additional studies (specifying the time periods for conducting of the studies) in accordance with Annex 6 of these Regulations (except for the studies specified in Annex 6, Paragraph 5) if the quantity of the chemical substance notified by the notifier has increased up to the quantity specified in Sub-paragraph 25.2 of these

Regulations. The Latvian Environment Agency may abstain from requiring that the notifier conduct some studies or may permit the specified studies to be replaced with other if the notifier proves that the specified studies are not useful or that alternative studies are more suitable to ascertain the properties of the relevant substance or the effect thereof on the environment and humans; and

28.3. shall develop a programme which specifies the additional studies to be conducted by the notifier in accordance with Annex 6, Paragraph 5 of these Regulations (specifying the time periods for conducting of the studies) if the trade volume of the notified chemical substance has increased up to the quantity specified in Sub-paragraph 25.3 of these Regulations.

29. The Latvian Environment Agency shall inform the following of the changes in the trade volume of the notified chemical substance:

29.1. the first notifier — of the subsequent notifiers who have notified identical chemical substance; and

29.2. subsequent notifiers of identical chemical substance:

29.2.1. of the fact that trade in the new chemical substance has reached the quantity specified in Paragraph 25 of these Regulations; and

29.2.2. of the fact that the subsequent notifiers are jointly responsible with the first notifier for conducting of additional studies in accordance with Paragraph 28 of these Regulations.

30. The first and the subsequent notifiers shall mutually co-ordinate what additional studies in conformity with Paragraph 28 of these Regulations shall be conducted by each notifier, particularly, to prevent duplication of experiments with animals.

31. The notifier who has conducted additional studies shall submit to the Latvian Environment Agency a final report regarding the additional studies conducted. The report shall specify the methods utilised, their results and conclusions. The report shall be submitted:

31.1. regarding studies conducted in accordance with Paragraph 28 of these Regulations — within the time periods set by the Latvian Environment Agency; and

31.2. regarding voluntarily conducted studies (if necessary).

IV. Procedures for Assessing Notifications of New Chemical Substances and Risks to the Environment and Human Health

32. The director of the Latvian Environment Agency shall set up a commission for evaluation of notifications and risk assessment to the environment and human health. In the composition of the commission there shall be at least one representative from the Latvian Environment Agency and Public Health Agency, as well as toxicology and ecotoxicology experts.

33. In evaluating notifications and assessing risks to the environment and human health the commission shall:

33.1. examine whether the notification has been drawn up in conformity with the requirements specified by these Regulations and assess whether the information submitted provides a possibility to evaluate the effect of the new chemical substance on human health and the environment;

33.2. if necessary, invite relevant experts for provision of professional consultations and expert-examinations for determination of the properties of the new chemical substance and assessment of different hazardous properties, as well as for classification, labelling and packaging of the substance, drawing up of safety data sheets and restriction of use;

33.3. verify whether laboratory methods approved by the Minister for Environmental Protection and Regional Development (hereinafter — approved methods), standardised or generally recognised methods have been utilised, and analyse whether the most appropriate analyses, experimental and study methods have been utilised;

33.4. verify whether proposals regarding classification of the new chemical substance or a product containing the new chemical substance conforms to the determined hazardous properties of the relevant substance;

33.5. verify whether proposals regarding labelling of the new chemical substance or a product containing the new chemical substance conform with the classification of the relevant substance or product;

33.6. assess whether the notifier has proposed all necessary measures in order to reduce undesirable consequences caused by the new chemical substance or adverse effects on the environment and human health and has provided for restrictions of use of the relevant substance;

33.7. assess risks to the environment and human health or life or evaluate the previous risk assessment submitted by the notifier;

33.8. if necessary, in preparing the opinion of the commission use the opinion of the competent institution of a European Union Member State and the notification submitted thereto;

33.9. request additional information from the notifier or propose performance of an analysis of the relevant data during evaluation of the notification and environmental and human health risks;

33.10. prepare proposals regarding additional evaluation of the new chemical substance;

33.11. prepare proposals regarding additional measures necessary in order to reduce undesirable consequences caused by the new chemical substance or adverse effects on the environment and human health;

33.12. prepare a written opinion regarding conformity of the notification with the requirements specified in these Regulations and regarding effects of the new chemical substance and risks to the environment and human health:

33.12.1. a representative of the Public Health Agency and an expert in toxicology shall prepare the part of the opinion regarding the effect of the new chemical substance and the environmental and human health risks; and

33.12.2. a representative of the Latvian Environment Agency and an expert in ecotoxicology shall prepare the part of the opinion regarding the effect and risk to the environment caused by the new chemical substance, including effects on the organisms living in the environment, as well as the identity, physical and chemical properties of the substance, foreseen conditions of use and emission, movement, transformation or degradation in the environment; and

33.13. in the opinion of the commission regarding conformity with the requirements specified by these Regulations and effects and risks to human health and the environment of the new chemical substance specify the criteria used, methods, risk assessment results, substantiated conclusions, as well as proposals regarding the necessary additional measures and proposals or recommendations to the Latvian Environment Agency for taking of a decision.

34. The commission, on the basis of the information provided in the notification or additional information, utilising generally recognised risk assessment methods and technical recommendations in respect of the new chemical substance and risk assessment of the existing substances, shall assess the following risks of the new chemical substance:

34.1. risks to human health caused by physical and chemical properties;

34.2. risks to human health caused by irritating, corrosive, sensitising, mutagenic, carcinogenic and toxic effects; and

34.3. risk to the environment.

35. In assessing risks of the new chemical substance the commission shall determine:

35.1. undesirable consequences or adverse effects on human health or the environment, which the new chemical substance causes or may cause due to the hazardous properties characteristic thereto (hazard identification). In performing hazard identification the commission shall evaluate the conformity, usefulness and effectiveness of the used study methods in determining hazardous properties of the new chemical substance;

35.2. effects of the new chemical substance on human health and the environment and response reactions caused by the substance or severity or frequency of the consequences (if possible) caused by the substance depending on:

35.2.1. the dose of the substance; and

35.2.2. the concentration of the substance;

35.3. emission, pathways, speed, transformation or degradation in the environment of the new chemical substance, as well as concentration or dose and manner in which the new chemical substance affects or may affect groups of people and the environment (hereinafter — exposure assessment);

35.4. spread, frequency and severity of the potential adverse effects or undesirable consequences caused during the actual or predicted exposure to the new chemical substance (hereinafter — risk characterisation). If necessary, in determining risk characterisation risk estimation shall be carried out, numerically assessing the risk probability;

35.5. whether risk reduction measures proposed by the notifier are appropriate, useful and effective and prevent or reduce environmental and human health risks. If the measures proposed by the notifier are not appropriate, useful and effective, the commission shall provide the notifier with recommendations regarding additional measures for risk reduction;

35.6. recommendations to be observed by the notifier or other performers of the relevant activities in order to reduce risk:

35.6.1. to change classification or labelling of the new chemical substance (if possible specifying the correct classification or labelling of the chemical substance);

35.6.2. to provide for the packaging of the relevant chemical substance which conforms with its hazardous properties and prevents the possibility of the substance to escape from the packaging and endanger the environment, human life and health;

35.6.3. to adjust or supplement the safety data sheet (if necessary specifying the issues to be adjusted or supplemented); and

35.6.4. to adjust or supplement precautionary, urgent or emergency measures, as well as proposed means and methods how to render the hazardous chemical substance harmless (neutralise) (if possible or necessary specifying what adjustments or supplements are necessary); and

35.7. recommendations to State institutions in respect of risk control and reduction (including recommendations regarding restrictions of trade or use of the new chemical substance), precautionary, urgent or emergency measures, as means and methods how to render the hazardous chemical substance harmless.

36. If due to specific undesirable consequences or adverse effects it is impossible to assess risk in accordance with Paragraph 35 of these Regulations, the risk assessment method shall be selected in each case individually, taking into account the physical, chemical, toxicological and ecotoxicological properties of the new chemical substance, its features and conditions for performance of activities with the relevant substance.

37. In cases specified in Paragraph 36 of these Regulations the commission shall substantiate the choice of the risk assessment method and assumptions and prepare a full description of the risk assessment, as well as specify reasons why risk assessment has not been performed in accordance with Paragraph 35 of these Regulations.

38. In assessing human health risks caused by the physical and chemical properties of the new chemical substance:

38.1. the following types of hazard of the substance shall be assessed:

38.1.1. explosiveness;

38.1.2. flammability;

38.1.3. oxidising potential; and

38.1.4. other hazards if results of studies attest thereto, structure of the substance or other features;

38.2. the following groups of people shall be taken into account which are or may be exposed to the new chemical substance:

38.2.1. employees;

38.2.2. consumers; and

38.2.3. people liable to indirect exposure via environment.

39. In assessing human health risk caused by physical and chemical properties of the new chemical substance:

39.1. in identifying hazard of the new chemical substance, the following shall be specified:

39.1.1. the substance is to be classified as hazardous on the basis of the results of such studies, which have been conducted with the most appropriate approved study method or any other standardised method (the determined hazard shall be described);

39.1.2. the substance is not to be classified as hazardous on the basis of the results of such studies which have been conducted by the most appropriate approved study method or any other standardised method;

39.1.3. for determination of the hazardous properties of the substance no approved method or any other standardised or generally recognised method exists;

39.2. in performing exposure assessment of the new chemical substance the intended conditions of use for each reasonably foreseeable type or field of use of the substance shall be taken into account, or those types, conditions and circumstances of use of the substance as

specified in the notification if the new chemical substance is not to be classified as hazardous or its hazard cannot be determined;

39.3. in the risk characterisation the following shall be specified:

39.3.1. possible adverse effects and undesirable consequences of the new chemical substance which may arise under intended conditions of use for each reasonably foreseeable type or field of use of the substance to every group of people referred to in Sub-paragraph 38.2 of these Regulations which is or may be exposed to the new chemical substance;

39.3.2. hazardous properties of the new chemical substance which cannot be determined but to which specific signs attest, for example properties or structure of the substance; and

39.3.3. no hazardous properties of the new chemical substance have been determined and under the foreseen conditions of use there is not and there may not arise adverse effects and hazardous consequences;

39.4. if it is specified in the risk characterisation that the new chemical substance may cause adverse effects or undesirable consequences to the relevant group of people, the recommendations shall specify how to reduce the risk to each group of people referred to in Sub-paragraph 38.2 of these Regulations; and

39.5. the summary shall specify conclusions regarding adverse effects or undesirable consequences of the new chemical substance and evaluation and integration of risk reduction recommendations (particularly if conclusions and recommendations are contradictory or different) in respect of:

39.5.1. different groups of people; and

39.5.2. reduction of several undesirable consequences or risks.

40. In assessing human health risks caused by irritating, corrosive, sensitising, mutagenic, carcinogenic and toxic properties of the new chemical substance:

40.1. the following effects shall be evaluated:

40.1.1. acute toxicity;

40.1.2. irritating effects;

40.1.3. corrosivity;

40.1.4. sensitising effects;

40.1.5. repeated dose toxicity;

40.1.6. mutagenic effects;

40.1.7. carcinogenic effects;

40.1.8. toxicity for reproduction; and

40.1.9. specific toxic effects if study results, properties or structure of the new chemical substance or other signs attest thereto; and

40.2. the following groups of people shall be taken into account which are or may be exposed to the effects of the new chemical substance:

40.2.1. employees;

40.2.2. consumers; and

40.2.3. people liable to indirect exposure of the new chemical substance via environment.

41. In assessing human health risks caused by irritating, corrosive, sensitising, mutagenic, carcinogenic and toxic properties of the new chemical substance:

41.1. in identifying hazard of the new chemical substance the following shall be specified:

41.1.1. the substance is to be classified as hazardous on the basis of the results of such studies, which have been conducted with the most appropriate approved study method or any other standardised method (the determined hazard shall be described);

41.1.2. the substance is not to be classified as hazardous on the basis of the results of such studies which have been conducted by the most appropriate approved study method or any other standardised method; and

41.1.3. for determination of the hazardous properties of the substance no approved method or any other standardised or generally recognised method exists;

41.2. dependence of adverse effects or undesirable consequences of the new chemical substance on the concentration and the dose shall be determined for each effect referred to in Sub-paragraph 40.1 of these Regulations (if such has been determined);

41.3. in order to determine reproductive toxicity or repeated dose toxicity of the new chemical substance, as well as dependence of the consequences or effects on the concentration of the substance, the greatest dose or concentration of the new chemical substance shall be determined which does not cause undesirable consequences or adverse effects (hereinafter — no observed adverse effect level) or the lowest dose or concentration which causes undesirable consequences or adverse effects (hereinafter — lowest observed adverse effect level);

41.4. in order to evaluate dependence of the adverse effects or undesirable consequences of acute toxicity, corrosivity or irritation of the new chemical substance on the concentration and dose, the following shall be determined:

41.4.1. the not observed adverse effect level or the lowest observed adverse effect level if such may be determined by using approved methods;

41.4.2. for acute toxicity — the lethal dose (LD50, mg/kg), lethal concentration (LC50, mg/l) or if a fixed dose method is used in determining acute toxicity — the characteristic discriminating dose; and

41.4.3. for corrosivity or irritation — whether the substance has properties, which cause or may cause the effects referred to;

41.5. in order to evaluate dependence of the adverse effects or undesirable consequences of mutagenicity and carcinogenity of the new chemical substance on the concentration and dose, the following shall be determined:

41.5.1. the no observed adverse effect level or the lowest observed adverse effect level if the substance is carcinogenic but is non-genotoxic; and

41.5.2. whether the substance has properties, which cause or may cause such effects;

41.6. for skin or respiratory sensitisation:

41.6.1. dependence of adverse effects or undesirable consequences of the new chemical substance on the concentration and dose shall not be determined if there is no approved method or other standardised generally recognised method to determine dependence on the dose or the relevant effect level; and

41.6.2. whether the substance has properties, which cause or may cause skin or respiratory sensitisation;

41.7. in evaluating the type of exposure of the new chemical substance or the way in which the substance works or may work (for example, by inhalation, oral ingestion, contact with skin) different duration, frequency, quantity and spread of exposure or effect shall be taken into account. Exposure assessment shall be performed to each group of people referred to in Sub-paragraph 40.2 of these Regulations, which may come into contact with the relevant substance under its intended conditions of use:

41.7.1. the dose or concentration and the way in which the new chemical substance works or may work shall be characterised or quantitatively determined;

41.7.2. the information which characterises exposure shall be analysed, particularly observation and measurement results, the quantity of the substance, physical and chemical properties and state of aggregation of the substance, whether the substance is in the composition of a product, the quantity of the substance in the product, the intended fields of use, pathways, transformation and degradation in the environment and potential for absorption of the substance;

41.7.3. for exposure forecast the assessment and measurement data regarding substances with analogous utilisation and effect shall be used if exposure observations and measurements of the new chemical substance have not been performed and if the relevant data are available;

41.7.4. information characterising the groups of people exposed to the substance shall be analysed, specifying the number of people, their age, sex and composition of the group (employees, consumers, people liable to indirect exposure of the new chemical substance via environment); and

41.7.5. all possible exposures of chemical products shall be taken into account if, in accordance with regulatory enactments which regulate classification, labelling and packaging of chemical substances and chemical products, the relevant products are to be classified as hazardous and if they contain the new chemical substance which has irritating, corrosive, sensitising, carcinogenic, mutagenic, toxic for reproduction, as well as very toxic, toxic or harmful properties. If chemical products, taking into account their irritating, corrosive, sensitising, carcinogenic, mutagenic, toxic for reproduction, very toxic, toxic or harmful properties, are not to be classified as hazardous, exposures of the relevant products shall not be taken into account if there is no justified reason to believe that the chemical product has the hazardous properties referred to;

41.8. the risk characterisation shall specify the following:

41.8.1. hazardous properties of the new chemical substance cannot be identified, it does not have and under the foreseen conditions of use there may not arise adverse effects and undesirable consequences;

41.8.2. hazardous properties of the new chemical substance cannot be identified but there is a justified reason to believe that the substance may have some toxic property to which attest, for example, the properties of the relevant substance, potential toxicity signs related to the structure of the substance, positive results in laboratory studies (*in vitro*), as well as conclusions of the exposure assessment;

41.8.3. the possible adverse effects or undesirable consequences of the new chemical substance under the foreseen conditions of use for each reasonably foreseeable type of field of use of the substance;

41.8.4. for each group of people which is or may be exposed to the effect of the new chemical substance — comparison of doses or concentration of the effect of the

substance with the relevant no observed adverse effect level or lowest observed adverse effect level for the types of effect referred to in Sub-paragraph 40.1 of these Regulations. If the exposure assessment is numerical, the comparison shall be specified numerically; and

41.8.5. if for the types of effect referred to in Sub-paragraph 40.1 of these Regulations it is impossible to determine not observed adverse effect level, lowest observed adverse effect level or any other numerical characterisation of exposure, the relative severity, spread and probability of adverse effects or undesirable consequences shall be specified for the relevant group of people;

41.9. recommendations shall specify how to reduce risk to each group of people referred to in Sub-paragraph 40.2 of these Regulations if the risk characterisation shows that the new chemical substance may cause adverse effects or undesirable consequences for the relevant group of people;

41.10. the summary shall specify:

41.10.1. conclusions regarding all adverse effects or undesirable consequences of the new chemical substances to each group of people;

41.10.2. risk reduction recommendations regarding all adverse effects or undesirable consequences to each group of people;

41.10.3. evaluation and integration of risk reduction recommendations, particularly if for reduction of risks caused by different hazardous properties of the new chemical substance to different groups of people contradictory or different recommendations have been provided; and

41.10.4. integrated conclusions and common recommendations for risk reduction in respect of general toxicity of the new chemical substance; and

41.11. in preparing the opinion, recommendations and proposals, the following shall be taken into account:

41.11.1. reliability of the results of studies conducted by the notifier, possible inaccuracy and uncertainty (for example, variability in the experimental data and differences between species and individuals of one species);

41.11.2. type, severity, spread and frequency of adverse effects or undesirable consequences, as well as dependence on the concentration or dose of the substance; and

41.11.3. groups of people which are or may be exposed to the relevant adverse effects.

42. In the environmental risk assessment:

42.1. in identifying hazard of the new chemical substance it shall be determined whether there are justified reasons or information for drawing up an environmental risk characterisation (no studies regarding environmental hazard of the new chemical substance have been conducted or the information is insufficient to classify the relevant substance as hazardous for the environment), including:

42.1.1. signs attesting to the possible bioaccumulation potential of the substance;

42.1.2. results of ecotoxicity studies — relationship of the determined toxic effect and time (the shape of the “toxicity/time” curve);

42.1.3. on the basis of toxicity studies the substance has been classified as very toxic, toxic or mutagenic, as well as harmful with the characterisation of the effect of the

substance “Danger of serious damage to health by prolonged exposure” or “Possible risk of irreversible effects”; and

42.1.4. information regarding substances with similar structure;

42.2. if no studies regarding environmental hazard of the new chemical substance have been conducted but there are justified reasons to draw up an environmental risk characterisation, in identifying hazard of the new chemical substance the necessary additional information shall be specified — depending on the signs attesting to the possible hazard;

42.3. in evaluating reaction caused by the new chemical substance in the environment, its environmental effects or undesirable consequences for the environment, on the basis of the notification or additional information regarding the results of the conducted ecotoxicological studies, the concentration of the new chemical substance shall be determined below which adverse effects are not caused or no effect on water, air, terrestrial ecosystems or other environmental spheres is observed (hereinafter — predicted no effect concentration);

42.4. in calculating the predicted no effect concentration the following doses or concentrations obtained in ecotoxicologial studies shall be used:

42.4.1. the highest dose or concentration which does not cause adverse consequences or effect on the environment (hereinafter — no observed effect level or concentration);

42.4.2. the smallest dose or concentration which causes adverse consequences or effect on the environment (hereinafter — lowest observed effect level or concentration);

42.4.3. lethal dose (normally determined LD50, mg/kg);

42.4.4. lethal concentration (normally determined LC50, mg/l);

42.4.5. effective concentration (EC50); and

42.4.6. concentration causing prevention of the development of specific functions, parameters or properties of the investigated organisms (normally inhibiting concentration is determined (IC50));

42.5. in calculating the predicted no effect concentration the uncertainty assessment factor shall be taken into account. The uncertainty assessment factor shall be used in order to extrapolate results of the studies conducted with one or several species and to predict the effect of the new chemical substance on the environment;

42.6. in determining numerical value of the uncertainty assessment factor the parameters characteristic to the relevant environmental sphere, the number of species studied, duration, reliability, possible inaccuracy or uncertainty of the studies conducted, as well as other available information shall be taken into account. If concentration LC50 or EC50 has been obtained in acute toxicity studies, normally the uncertainty assessment factor 1000 shall be used;

42.7. in evaluating exposure of the new chemical substance:

42.7.1. the trade volume, intended fields, types and conditions of use of the new chemical substance shall be taken into account (for example, whether the substance is in the composition of a product, the quantity of the substance in the product), as well as physical and chemical properties of the substance — melting or boiling point, vapour pressure, surface tension, water solubility, partition coefficient (n-octanol solubility of the relevant substance in relation to water solubility) or other properties;

42.7.2. information regarding the technological process of the manufacturing and emission of the new chemical substance, pathways, transformation or degradation in the environment, potential for absorption, frequency and duration of exposure of the new chemical substance shall be taken into account;

42.7.3. environmental spheres where emission of the substance is foreseen or spread, transformation or degradation thereof is predicted shall be determined, as well as environmental spheres with which the substance may come into direct contact when manufacturing, storing or performing other activities with the new chemical substance shall be determined;

42.7.4. if possible the concentration of the substance which is or may be in the relevant environmental sphere shall be determined (hereinafter — predicted environmental pollution concentration);

42.7.5. exposure characterisation for each environmental sphere shall be drawn up for which it is not possible to determine the predicted environmental pollution concentration; and

42.7.6. if the total trade volume of the substance is less than 10 tonnes per year or less than 50 tonnes, the predicted environmental pollution concentration or exposure characterisation shall only be determined to the species, generation or local environment which is affected or may be affected by the relevant substance;

42.8. the risk characterisation shall specify:

42.8.1. comparison of the predicted environmental pollution concentration with the predicted no effect concentration in each environmental sphere, including the calculated ratio of the predicted environmental pollution concentration against the predicted no effect concentration;

42.8.2. if the ratio of the predicted environmental pollution concentration and predicted no effect concentration is one or less than one, it shall be specified that no additional risk reduction measures or additional information are required so long as the trade volume is not increased or changes in conformity with Paragraph 24 of these Regulations are not performed;

42.8.3. if it is not possible to calculate the predicted environmental pollution concentration and predicted no effect concentration ratio, the possibility shall be evaluated that under the predicted exposure or under the foreseen exposure conditions adverse effects on the environment or undesirable consequences may occur; and

42.8.4. recommendations and proposals what additional risk reduction measures and additional information is required if the predicted environmental pollution concentration and predicted no effect concentration ratio is greater than one or it is possible that under the predicted exposure or under the foreseen exposure conditions adverse effects on the environment or undesirable consequences may occur;

42.9. recommendations shall specify how in accordance with the risk characterisation to reduce risks caused by the new chemical substance to each environmental sphere;

42.10. the summary shall specify:

42.10.1. conclusions regarding adverse effects of the new chemical substance on each environmental sphere and all undesirable consequences of the effects of the substance, as well as specify conclusions regarding the general ecotoxicity of the new chemical substance and adverse effects on the environment or undesirable consequences; and

42.10.2. recommendations how to reduce adverse effects of the new chemical substance on each environmental sphere and undesirable consequences, as well as evaluation and integration of the recommendations referred to, particularly, if contradictory or different recommendations for risk reduction to different environmental

spheres have been provided or for reduction of risks caused by different hazardous properties of the new chemical substance; and

42.11. in preparing the opinion, recommendations and proposals, the following shall be taken into account:

42.11.1. the probable inaccuracy, uncertainty and interpretation of the results of the studies conducted by the notifier, including the variability in the experimental data and differences between species and individuals of one species;

42.11.2. the type, severity, spread and frequency of the adverse effects on the environments and undesirable consequences; and

42.11.3. the environmental sphere which is or may be exposed to the adverse effects or undesirable consequences.

43. If the notifier has submitted additional information in accordance with Paragraphs 21, 22, 23, 24, 25, 28 or 31 of these Regulations, the commission shall repeatedly assess risk, clarify or supplement the risk assessment and prepare a written opinion.

44. Costs related to the services of experts for evaluation of the notification or to the environmental or human health risk assessment shall be covered by the notifier.

V. Taking and Notification of Decisions

45. The Latvian Environment Agency, on the basis of the evaluation of the notification, risk assessment results and conclusions, as well as the written opinion of the commission shall take a relevant decision:

45.1. the new chemical substance is not to be classified as hazardous and further risk assessment, additional risk reduction measures or additional information is not required so long as the trade volume is not increased or changes in conformity with Paragraph 24 of these Regulations are not carried out — if the commission has concluded that the new chemical substance is not hazardous and may not present risk in relation to the new chemical substance's:

45.1.1. physical and chemical properties;

45.1.2. irritating, corrosive, sensitising, mutagenic, carcinogenic and toxic effects on human health; and

45.1.3. effect on the environment;

45.2. the new chemical substance may present risk to human health or the environment and prior to increasing the trade volume or carrying out changes in conformity with Paragraph 24 of these Regulations additional information is required in order to determine the type, severity, spread and frequency of adverse effects or undesirable consequences;

45.3. the new chemical substance shall probably present risk to human health or the environment and prior to commencement of trade or until the time period set by the Latvian Environment Agency additional information is necessary in order to determine the type, severity, spread and frequency of adverse effects or undesirable consequences; or

45.4. the new chemical substance will definitely present risk to human health or the environment and prior to commencement of trade or until the time period set by the Latvian Environment Agency additional risk reduction measures are necessary.

46. The Latvian Environment Agency shall evaluate the measures required to reduce adverse effects and undesirable consequences of the new chemical substance in respect of each group of people or each environmental sphere, taking into account that some appropriate measures in respect of one group of people or environmental sphere may increase risks to another group of people or environmental sphere. On the basis of the relevant evaluation the Latvian Environment Agency shall specify such required risk reduction measures so that risk to all groups of people or environmental spheres is minimal.

47. If the decision referred to in Sub-paragraph 45.3 or 45.4 of these Regulations is taken, the Latvian Environment Agency shall provide the notifier with a possibility to submit explanations or additional information before preparation of the opinion.

48. The Latvian Environment Agency, on the basis of a written opinion of the commission and the decision taken, shall prepare a written opinion (in two originals). The opinion shall include the following information:

48.1. the decision taken in conformity with Paragraph 45 of these Regulations, risk assessment conclusions, a description of the risk reduction measures intended by the notifier, as well as instructions to State institutions regarding control and risk reduction measures;

48.2. if in respect of the new chemical substance the decision referred to in Sub-paragraph 45.2 or 45.3 of these Regulations is taken — a description regarding the additional studies or information required regarding each adverse effect or undesirable consequences in respect of each environmental sphere or group of people, as well as justification why such studies or information are required;

48.3. if in respect of a new chemical substance the decision referred to in Sub-paragraph 45.4 of these Regulations is taken — a description regarding additional studies, information or risk reduction measures required regarding each adverse effect or undesirable consequences in respect of each environmental sphere or group of people, as well as justification why such studies, information or measures are required;

48.4. time periods within which the measures referred to in Sub-paragraphs 48.2 and 48.3 of these Regulations are to be taken or information provided;

48.5. integration of the additional information or explanations of the notifier; and

48.6. risk characterisation, particularly the quantity, severity, spread and frequency of the possible adverse effects or undesirable consequences caused by the new chemical substance depending on the predicted quantity of exposure, specifying uncertainty assessment factors and justifying the assessment or calculation method or model used.

49. The Latvian Environment Agency shall:

49.1. inform the notifier in writing of the conformity of the notification or supplemented notification with the requirements set out by these Regulations:

49.1.1. regarding the official registration number of the new chemical substance if the information provided in the notification or supplemented notification is sufficient and conforms to the requirements set out by these Regulations;

49.1.2. regarding the official registration number of the new chemical substance and instructions regarding additional evaluation thereof if the information provided in the notification, supplemented or corrected notification conforms to the requirements set out by these Regulations but is insufficient for full evaluation of specific types of effect risks

to human health or the environment (if risk assessment results do not affect taking of the decision);

49.1.3. regarding the necessary additional evaluation of the chemical substance, information or amendments to the notification if the information submitted is not sufficient or does not conform to the requirements set out by these Regulations; or

49.1.4. regarding the fact when or on what conditions the opinion regarding the risk assessment results shall be provided if the opinion referred to is not provided together with the information regarding conformity of the notification or supplemented notification; and

49.2. send the opinion regarding the performed risk assessment, repeatedly performed risk assessment or required additions and clarifications in the risk assessment:

49.2.1. to the notifier — the original of the opinion;

49.2.2. to the Public Health Agency, the State Sanitary Inspection and the State Environment Inspection — a copy of the opinion; and

49.2.3. to the Commission of the European Communities — the opinion drawn up in conformity with its requirements. The opinion shall specify the decision taken and the essential information provided in the notification.

50. The Latvian Environment Agency shall inform the notifier in writing of the conformity of the notification or supplemented notification with the requirements set out by these Regulations within the following time periods:

50.1. within 60 days after receipt of the notification if:

50.1.1. the technical dossier has been submitted in accordance with Sub-paragraph 9.6 of these Regulations;

50.1.2. the technical dossier has been submitted in accordance with Sub-paragraph 9.7 of these Regulations; or

50.1.3. the technical dossier has been submitted in accordance with Sub-paragraph 9.6 and Paragraph 13 of these Regulations; and

50.2. within 30 days after receipt of the notification if:

50.2.1. the technical dossier has been submitted in accordance with Sub-paragraph 9.4 of these Regulations;

50.2.2. the technical dossier has been submitted in accordance with Sub-paragraph 9.4 and Paragraph 13 of these Regulations;

50.2.3. the technical dossier has been submitted in accordance with Sub-paragraph 9.5 of these Regulations; or

50.2.4. the technical dossier has been submitted in accordance with Sub-paragraph 9.5 and Paragraph 13 of these Regulations.

51. If the notifier has received a positive reply from the Latvian Environment Agency regarding the conformity of the notification with the requirements set out by these Regulations or the Latvian Environment Agency has failed to provide a reply within the time period specified in Paragraph 50 of these Regulations, the notifier has the right to commence trade in the new chemical substance or chemical product, or polymer which contains the new chemical substance not earlier than 60 days after the Latvian Environment Agency has received the notification if:

51.1. the technical dossier has been submitted in accordance with Sub-paragraph 9.6 of these Regulations;

51.2. the technical dossier has been submitted in accordance with Sub-paragraph 9.7 of these Regulations; or

51.3. the technical dossier has been submitted in accordance with Sub-paragraph 9.6 and Paragraph 13 of these Regulations.

52. If the notifier has received a positive reply from the Latvian Environment Agency regarding the conformity of the notification with the requirements set out by these Regulations, the notifier has the right to commence trade in the new chemical substance or chemical product, or polymer which contains the new chemical substance not earlier than 15 days after the Latvian Environment Agency has received the notification if:

52.1. the technical dossier has been submitted in accordance with Sub-paragraph 9.4 of these Regulations;

52.2. the technical dossier has been submitted in accordance with Sub-paragraph 9.4 and Paragraph 13 of these Regulations;

52.3. the technical dossier has been submitted in accordance with Sub-paragraph 9.5 of these Regulations; or

52.4. the technical dossier has been submitted in accordance with Sub-paragraph 9.5 and Paragraph 13 of these Regulations.

53. If the Latvian Environment Agency has not provided a reply regarding the conformity of the notification with the requirements of these Regulations within the time period specified in Paragraph 50 of these Regulations, the notifier has the right to commence trade in the new chemical substance or chemical product, or polymer which contains the new chemical substance not earlier than 30 days after the Latvian Environment Agency has received the notification if:

53.1. the technical dossier has been submitted in accordance with Sub-paragraph 9.4 of these Regulations;

53.2. the technical dossier has been submitted in accordance with Sub-paragraph 9.4 and Paragraph 13 of these Regulations;

53.3. the technical dossier has been submitted in accordance with Sub-paragraph 9.5 of these Regulations; or

53.4. the technical dossier has been submitted in accordance with Sub-paragraph 9.5 and Paragraph 13 of these Regulations.

54. If the notifier has received a positive reply from the Latvian Environment Agency regarding the conformity of the supplemented notification with the requirements set out by these Regulations or the Latvian Environment Agency has failed to provide a reply within the time period specified in Paragraph 50 of these Regulations, the notifier has the right to commence trade in the new chemical substance or chemical product, or polymer which contains the new chemical substance not earlier than 60 days after the Latvian Environment Agency has received the supplemented notification if:

54.1. the technical dossier has been submitted in accordance with Sub-paragraph 9.6 of these Regulations;

54.2. the technical dossier has been submitted in accordance with Sub-paragraph 9.7 of these Regulations; or

54.3. the technical dossier has been submitted in accordance with Sub-paragraph 9.6 and Paragraph 13 of these Regulations.

55. If the notifier has received a positive reply from the Latvian Environment Agency regarding the conformity of the supplemented notification with the requirements set out by these Regulations, the notifier has the right to commence trade in the new chemical substance or chemical product, or polymer which contains the new chemical substance not earlier than 15 days after the Latvian Environment Agency has received the supplemented notification if:

55.1. the technical dossier has been submitted in accordance with Sub-paragraph 9.4 of these Regulations;

55.2. the technical dossier has been submitted in accordance with Sub-paragraph 9.4 and Paragraph 13 of these Regulations;

55.3. the technical dossier has been submitted in accordance with Sub-paragraph 9.5 of these Regulations; or

55.4. the technical dossier has been submitted in accordance with Sub-paragraph 9.5 and Paragraph 13 of these Regulations.

56. If the Latvian Environment Agency has failed to provide a reply regarding the conformity of the notification with the requirements set out by these Regulations within the time period specified in Paragraph 50 of these Regulations, the notifier has the right to commence trade in the new chemical substance or chemical product, or polymer which contains the new chemical substance not earlier than 30 days after the Latvian Environment Agency has received the supplemented notification if:

56.1. the technical dossier has been submitted in accordance with Sub-paragraph 9.4 of these Regulations;

56.2. the technical dossier has been submitted in accordance with Sub-paragraph 9.4 and Paragraph 13 of these Regulations;

56.3. the technical dossier has been submitted in accordance with Sub-paragraph 9.5 of these Regulations; or

56.4. the technical dossier has been submitted in accordance with Sub-paragraph 9.5 and Paragraph 13 of these Regulations.

57. It is prohibited to commence trade in the new chemical substance if the Latvian Environment Agency has recognised that the information provided in the notification or supplemented notification is not sufficient or does not conform to the requirements set out by these Regulations.

VI. Rights and Duties of Notifier of New Chemical Substances, Importer for Experimental Manufacturing, State Institutions and Experts

58. The notifier of the new chemical substance and the importer importing the new chemical substance for experimental manufacturing shall ensure:

58.1. the acquisition of information regarding the new chemical substance (including determining of physical and chemical properties and studies of the effects of the substance on the environment and human health), using the most appropriate approved, standardised or generally recognised methods;

58.2. creation of the trade the name of the new chemical substance in accordance with the Chemical Substances and Chemical Products Law and regulatory enactments regulating

classification, labelling and packaging of chemical substances and chemical products if the name of the relevant substance is restricted access information or a commercial secret;

58.3. correctness, completeness and accuracy of the information provided in accordance with the requirements prescribed by these Regulations;

58.4. taking of the necessary observation, monitoring and risk reduction measures in order to prevent harm to the environment, human life, health and property when manufacturing the new chemical substance or performing other activities with the new chemical substance or polymer, or other chemical product which contains the new chemical substance;

58.5. performance of measures to prevent duplication of experiments with animals;

58.6. provision of information to other performers of the relevant activities or consumers regarding classification, labelling of the new chemical substance, polymer or chemical product which contains the new chemical substance and the properties thereof in respect of risk, hazard and safety, specifying measures to be taken in order to ensure protection of the environment and human life and health; and

58.7. compliance with the provisions or requirements and performance deadlines thereof provided for in the notification or specified in the opinion of the Latvian Environment Agency.

59. Employees and experts of State institutions — members of the commission established by the Latvian Environment Agency — have the right to obtain restricted access information or information which is a commercial secret and is related to the studies conducted by the notifier, or to obtain information regarding the new chemical substance and refer to it in the relevant conclusions or opinions.

60. State institutions and members of the commission shall ensure that restricted access information or information which is a commercial secret is not available and is not disclosed to third persons except for the cases provided for in regulatory enactments.

61. If necessary for evaluation of the notification or risk assessment the Latvian Environment Agency and the Public Health Agency have the right:

61.1. to take control samples of the new chemical substance; and

61.2. to specify for the notifier the quantity of the new chemical substance to be delivered for performance of the evaluation.

62. The Latvian Environment Agency shall perform recording of the control samples of the new chemical substance and keep them for the entire period of validity or for at least 10 years.

63. State control institutions have the right to request that the manufacturer or importer of the new chemical substance take all the necessary measures for safe use, manufacturing or importation of the new chemical substance and observe the provisions or requirements and their performance deadlines provided for in the notification or specified in the opinion of the Latvian Environment Agency.

64. The Latvian Environment Agency:

64.1. shall perform recording and registration of the new chemical substance in writing and electronically, specifying the following:

64.1.1. information regarding the notifier;

64.1.2. the date of submission of the notification;

64.1.3. the name of the new chemical substance;

64.1.4. information regarding conformity of the notification or supplemented notification with the requirements set out by these Regulations and the decision of the Latvian Environment Agency in accordance with Paragraph 45 of these Regulations;

64.1.5. the official registration number of the new chemical substance intended for experimental manufacturing and of the new chemical substance; and

64.1.6. classification and labelling of the new chemical substance;

64.2. shall keep the notification and the risk assessment for 10 years.

65. Classification, labelling and safety data sheets of a new chemical substance, as well as the fact whether activities with new chemical substances are not performed without notifying the relevant substances shall be controlled:

65.1. at sales points — by the State Sanitary Inspection; and

65.2. in undertakings and other locations where the relevant activities are performed other than sales points — by the State Environment Inspection.

VII. Closing Provisions

66. These Regulations shall come into force on 1 January 2003.

67. If the trade in the new chemical substance has been commenced until 1 January 2003, the manufacturer or the importer shall:

67.1. by 1 March 2003 submit to the Latvian Environment Agency the following information:

67.1.1. the legal address and location of the manufacturer or the importer;

67.1.2. the name of the manufacturer and the importer and the registration number in the Enterprise Register, as well as the value added tax payer code;

67.1.3. information on the natural person who is responsible for provision of information regarding the new chemical substance — position, given name, surname, telephone and fax number, as well as e-mail address;

67.1.4. the location of the production site and the name of the manufacturer if the substance is imported;

67.1.5. the name of the substance in the IUPAC nomenclature, usual the name, trade the name, abbreviation of the name, molecular formula and structural formula, composition (degree of purity (%), nature of impurities, all hazardous impurities and the content of the main impurities (%));

67.1.6. types and conditions of use of the new chemical substance and the initial emission exposure assessment in the work environment and the environment (if known); and

67.1.7. the total quantity of the new chemical substance imported or manufactured per year;

67.2. by 1 March 2003 co-ordinate with the Latvian Environment Agency a time schedule for submission of the notification; and

67.3. by 1 January 2004 submit a notification to the Latvian Environment Agency.

68. Clause 49.2.3 of these Regulations shall come into force by means of separate Cabinet Regulations.

Informative Reference to European Union Directives

These Regulations contain legal norms which follow from Directive 67/584/EEC and its amendments, particularly Directive 92/32/EEC and 2001/59/EC, as well as Directive 93/67/EEC.

Prime Minister A. Bērziņš

Acting for the Minister for Environmental Protection and Regional Development — Minister for Transport A. Gorbunovs

Annex 1
Cabinet Regulation No. 340
6 August 2002

Content of the Technical Dossier if 10 kg or More but Less than 100 kg of the New Chemical Substance are Manufactured or Imported per Year

1. Identity of the new chemical substance:
    1.1. the name in the IUPAC nomenclature;
    1.2. usual the name, trade the name, abbreviations and other the names;
    1.3. registration number in the chemical reference journal *Chemical Abstracts* (hereinafter — CAS number) (if available);
    1.4. molecular formula and structural formula;
    1.5. composition:
        1.5.1. degree of purity (%);
        1.5.2. nature of impurities, including isomers and by-products;
        1.5.3. percentage of main impurities;
        1.5.4. nature and content of stabilising agents, inhibitors and other impurities contained by the chemical substance (ppm and %);
        1.5.5. spectral analyses data (ultraviolet (UV), infrared (IR), nuclear magnetic resonance (NMR) spectrometry or mass spectrometry); and
        1.5.6. high-performance liquid chromatography (HPLC), gas chromatography;
    1.6. methods (including information regarding analytical methods) which allow detection of the new chemical substance and its transformation products after discharge into the environment, as well as determination of the direct effect on humans.

2. Information regarding manufacturing or import of the new chemical substance:
    2.1. the name, the legal address and location of the manufacturer;
    2.2. the name and the legal address of the importer;
    2.3. the name of the performer of tests and studies;
    2.4. the location of the production site;
    2.5. information regarding the manufacturing process and effects of the substance related to the manufacturing process on humans and the environment (without specifying precise details of the manufacturing process, particularly those which are a commercial secret):
        2.5.1. technological process of manufacturing;
        2.5.2. an estimate of the effect related to manufacturing in the work environment;
        2.5.3. an estimate of the effect related to manufacturing in the environment;
    2.6. information regarding the intended use of the substance and the effect of the substance related thereto on humans and the environment:
        2.6.1. the intended types of use of the substance;
        2.6.2. technological process during which the substance is manufactured, used or treated (if known);
        2.6.3. an assessment of the effects of the substance on the work environment (if known);
        2.6.4. an assessment of the effects of the substance on the environment (if known);

2.6.5. information whether the substance is offered or sold as a chemical substance or in the composition of a chemical product;

2.6.6. the concentration of the substance in the relevant chemical product (if known);

2.6.7. the fields or sectors in which the substance is intended to be used (for example, industry, agriculture, crafts); and

2.6.8. the recipients of the substance (if known and if they can be identified);

2.7. manufacturing and import an estimate in each type of use of the substance:

2.7.1. the total quantity of production or imports in the first calendar year (tonnes per year);

2.7.2. the total quantity of production or imports in the following calendar years (tonnes per year);

2.7.3. the total quantity of production or imports of the substance broken down according to the types of use thereof expressed as percentage (in the first and following calendar years); and

2.7.4. the total quantity of production or imports of the substance broken down according to the fields or sectors of use thereof expressed as percentage (in the first and following calendar years);

2.8. recommended methods and safety measures in respect of:

2.8.1. activities with the substance;

2.8.2. storage of the substance;

2.8.3. transportation of the substance;

2.8.4. fire safety of the substance; and

2.8.5. other potential danger of the substance, particularly chemical reaction with water;

2.9. measures to eliminate accidents if spillage of the substance has occurred;

2.10. emergency medical assistance in the case of injury or poisoning of a person; and

2.11. packaging of the substance.

3. Physical and chemical properties of the new chemical substance:

3.1. state of aggregation if the temperature is 20°C and the pressure — 101,3 kPa;

3.2. flash point; and

3.3. flammability.

4. Toxicological studies in respect of acute toxicity which may be caused by the new chemical substance if it is administered orally (substances other than gases) or inhaled (substances which are gases or volatile liquids).

Acting for the Minister for Environmental
Protection and Regional Development —
Minister for Transport A. Gorbunovs

Annex 2
Cabinet Regulation No. 340
6 August 2002

Content of the Technical Dossier if 100 kg and More but Less than One Tonne of the New Chemical Substance is Manufactured or Imported per Year

1. Identity of the new chemical substance:
    1.1. the name in the IUPAC nomenclature;
    1.2. usual the name, trade the name, abbreviations and other the names;
    1.3. CAS number (if available);
    1.4. molecular formula and structural formula;
    1.5. composition:
        1.5.1. degree of purity (%);
        1.5.2. nature of impurities, including isomers and by-products;
        1.5.3. percentage of main impurities;
        1.5.4. nature and content of stabilising agents, inhibitors and other impurities contained by the chemical substance (ppm and %);
        1.5.5. spectral analyses data (ultraviolet (UV), infrared (IR), nuclear magnetic resonance (NMR) spectrometry or mass spectrometry); and
        1.5.6. high-performance liquid chromatography (HPLC), gas chromatography;
    1.6. methods (including information regarding analytical methods) which allow detection of the new chemical substance and its transformation products after discharge into the environment, as well as determination of the direct effect on humans.

2. Information regarding manufacturing or import of the new chemical substance:
    2.1. the name, the legal address and the location of the manufacturer;
    2.2. the name and the legal address of the importer;
    2.3. the name of the performer of tests and studies;
    2.4. the location of the production site;
    2.5. information regarding the manufacturing process and effects of the substance related to the manufacturing process on humans and the environment (without specifying precise details of the manufacturing process, particularly those which are a commercial secret):
        2.5.1. technological process of manufacturing;
        2.5.2. an estimate of the effect related to manufacturing in the work environment; and
        2.5.3. an estimate of the effect related to manufacturing in the environment;
    2.6. information regarding the intended use of the substance and the effect of the substance associated thereto on humans and the environment:
        2.6.1. the intended types of use of the substance;
        2.6.2. technological process during which the new chemical substance is manufactured, used or treated (if known);
        2.6.3. an assessment of the effects of the substance on the work environment (if known);

2.6.4. an assessment of the effects of the substance on the environment (if known);

2.6.5. information whether the substance is offered or sold as a chemical substance or in the composition of a chemical product;

2.6.6. the concentration of the substance in the relevant chemical product (if known);

2.6.7. the fields or sectors where the substance is intended to be used (for example, industry, agriculture, crafts); and

2.6.8. recipients (if known and if they can be identified);

2.7. manufacturing and import an estimate in each type of use of the substance:

2.7.1. the total quantity of production or imports in the first calendar year (tonnes per year);

2.7.2. the total quantity of production or imports in the following calendar years (tonnes per year);

2.7.3. the total quantity of production or imports of the substance broken down according to the types of use thereof expressed as percentage (in the first and following calendar years); and

2.7.4. the total quantity of production or imports of the substance broken down according to the fields or sectors of use thereof expressed as percentage (in the first and following calendar years);

2.8. recommended methods and safety measures in respect of:

2.8.1. activities with the substance;

2.8.2. storage of the substance;

2.8.3. transportation of the substance;

2.8.4. fire safety of the substance; and

2.8.5. other potential danger of the substance, particularly chemical reaction with water;

2.9. measures to eliminate accidents if spillage of the substance has occurred;

2.10. emergency medical assistance in the case of injury or poisoning of a person; and

2.11. packaging of the substance.

3. Physical and chemical properties of the new chemical substance:

3.1. state of aggregation if the temperature is 20°C and the pressure — 101,3 kPa;

3.2. melting point;

3.3. boiling point;

3.4. water solubility;

3.5. partition coefficient — n-octanol solubility of the substance in relation to water solubility;

3.6. flash point; and

3.7. flammability.

4. Toxicological studies in respect of acute toxicity which may be caused by the new chemical substance if it is administered orally (substances other than gases) or inhaled (substances which are gases or volatile liquids), as well as if it comes into contact with skin — skin irritation, eye irritation and skin sensitisation shall be determined.

5. Other toxicological studies. Mutagenicity of the new chemical substance shall be determined by using the bacteriological (reverse mutation) method with and without metabolic activation.

6. Ecotoxicological studies. Testing of biodegradation.

7. Other information if necessary for risk an assessment (submitted in accordance with the requirements set out in Sub-paragraphs 33.9, 49.2, 49.3, Clause 50.1.2 or 50.1.3 of these Regulations):

7.1. vapour pressure; and

7.2. acute toxicity tests with daphnia (*Daphnia magna*).

Acting for the Minister for Environmental
Protection and Regional Development —
Minister for Transport A. Gorbunovs

Annex 3
Cabinet Regulation No. 340
6 August 2002

Content of the Technical Dossier if One Tonne and More of the New Chemical Substance is Manufactured or Imported per Year

1. Identity of the new chemical substance:
    1.1. the name in the IUPAC nomenclature;
    1.2. usual the name, trade the name, abbreviations or other the names;
    1.3. CAS number (if available);
    1.4. molecular formula and structural formula;
    1.5. composition of the substance:
        1.5.1. degree of purity (%);
        1.5.2. nature of impurities, including isomers and by-products;
        1.5.3. percentage of main impurities;
        1.5.4. nature and content of stabilising agents, inhibitors or other impurities contained by the chemical substance (ppm and %);
        1.5.5. spectral analyses data (ultraviolet (UV), infrared (IR), nuclear magnetic resonance (NMR) spectrometry or mass spectrometry); and
        1.5.6. high-performance liquid chromatography (HPLC), gas chromatography;
    1.6. methods (including information regarding analytical methods) which allow detection of the new chemical substance and its transformation products after discharge into the environment, as well as determination of the direct effect on humans.

2. Information regarding manufacturing or import of the new chemical substance:
    2.1. the name, the legal address and the location of the manufacturer;
    2.2. the name and the legal address of the importer;
    2.3. the name of the performer of tests and studies;
    2.4. the location of the production site;
    2.5. information regarding the manufacturing process and effects of the substance related to the manufacturing process on humans and the environment (without specifying precise details of the manufacturing process, particularly those which are a commercial secret):
        □□□□□□□technological process of manufacturing;
        2.5.2. an estimate of the effect related to manufacturing in the work environment; and
        2.5.3. an estimate of the effect related to manufacturing in the environment;
    2.6. intended use of the substance and the effect of the substance related thereto on humans and the environment:
        2.6.1. the intended types of use of the substance;
        2.6.2. technological process during which the substance is manufactured, used or treated (if known);
        2.6.3. an assessment of the effects of the substance on the work environment (if known);

2.6.4. an assessment of the effects of the substance on the environment (if known);

2.6.5. information whether the substance is offered or sold as a chemical substance or in the composition of a chemical product;

2.6.6. the concentration of the substance in products (if known);

2.6.7. the fields or sectors where the substance is intended to be used (for example, industry, agriculture, crafts);

2.6.8. the recipients of the substance (if known and if they can be identified); and

2.6.9. the quantity and composition of waste resulting from the intended use of the substance (if known);

2.7. manufacturing and import an estimate in each type of use of the substance:

2.7.1. the total quantity of production or imports in the first calendar year (tonnes);

2.7.2. the total quantity of production or imports in the following calendar years (tonnes per year);

2.7.3. the total quantity of production or imports of the substance broken down according to the types of use thereof expressed as percentage (in the first and following calendar years); and

2.7.4. the total quantity of production or imports of the substance broken down according to the fields or sectors of use thereof expressed as percentage (in the first and following calendar years);

2.8. recommended methods and safety measures in respect of:

2.8.1. activities with the substance;

2.8.2. storage of the substance;

2.8.3. transportation of the substance;

2.8.4. fire safety of the substance;

2.8.5. other potential danger of the substance, particularly chemical reaction with water; and

2.8.6. potential explosion of the substance if it is in the form of a dust (specify if necessary);

2.9. measures to eliminate accidents if spillage of the substance has occurred;

2.10. emergency medical assistance in the case of injury or poisoning of a person; and

2.11. packaging of the substance.

3. Physical and chemical properties of the new chemical substance:

3.1. state of aggregation if the temperature is 20°C and the pressure — 101,3 kPa;

3.2. melting point;

3.3. boiling point;

3.4. relative density;

3.5. vapour pressure;

3.6. surface tension;

3.7. water solubility;

3.8. partition coefficient — n-octanol solubility of the substance in relation to water solubility;

3.9. flash point;

3.10. flammability;

3.11. explosiveness;

3.12. self-ignition temperature;

3.13. oxidising properties; and

3.14. granulometry (for substances which are marketed in a form which may present danger to the respiratory tract an analysis shall be required to determine the distribution of particles by sizes).

4. Toxicological studies in respect of acute toxicity which may be caused by the new chemical substance if it is administered orally or inhaled, as well as if it comes into contact with skin — skin irritation, eye irritation and skin sensitisation shall be determined:

4.1. acute toxicity for substances other than gases shall be assessed by at least two methods (one of which — oral administration). The second an assessment method shall be chosen depending on the properties of the substance and the possible effect on humans;

4.2. acute toxicity for substances which are gases or volatile liquids shall be assessed by inhalation; and

4.3. the repeated dose shall be determined (in the most appropriate manner, taking into account the possible effect on humans, the acute toxicity and properties of the substance. In the absence of contra-indications the oral administration shall be given the preference) and the repeated dose toxicity (28 days).

5. Other toxicological studies:

5.1. mutagenicity of the new chemical substance shall be determined:

5.1.1. by using the bacteriological (reverse mutation) method with and without metabolic activation;

5.1.2. by testing chromosome aberrations or damage. If there are no contra-indications the test shall be conducted under laboratory circumstances (in vitro) with and without metabolic activation; or

5.1.3. by conducting additional tests (in accordance with laboratory methods approved by the Minister for Environmental Protection and Regional Development) if a positive result has been obtained in any of the tests referred to in Sub-paragraphs 5.1.1 or 5.1.2 of this Annex;

5.2. toxic effect of the new chemical substance for reproduction shall be tested (minutes); and

5.3. toxicokinetic an assessment of the new chemical substance.

6. Ecotoxicological studies:

6.1. effect of the new chemical substance on organisms:

6.1.1. acute toxicity for fish;

6.1.2. acute toxicity for daphnia (*Daphnia magna*);

6.1.3. growth-inhibitor test on algae; and

6.1.4. bacterial inhibition (if biodegradation may be affected by the inhibitory effect of a substance on the bacteria, prior to testing of biodegradation bacterial inhibition of the new chemical substance shall be tested);

6.2. degradation of the new chemical substance:

6.2.1. biodegradation; or

6.2.2. other type of degradation. If the new chemical substance is not biologically degradable its hydrolysis rate shall be determined depending on the pH level; and
6.3. absorption and desorption test of the new chemical substance.

7. Possibilities of preventing the harmful effect of the new chemical substance:
7.1. in industry, entrepreneurial activities or crafts:
7.1.1. recycling of the substance;
7.1.2. possibilities of preventing or reducing the adverse effects or undesirable consequences of the substance; or
7.1.3. possibilities of purification or utilisation of the substance by purifying or disposing — incineration of waste, water or wastewater treatment, pollution control at the point of emission or otherwise;
7.2. in general use by inhabitants:
7.2.1. recycling of the substance;
7.2.2. prevention or reduction of the adverse effects or undesirable consequences of the substance; or
7.2.3. possibilities of purification or utilisation of the substance by purifying or disposing — incineration of waste, water or wastewater treatment, pollution control at the point of emission or otherwise.

Acting for the Minister for
Environmental Protection and Regional Development —
Minister for Transport A. Gorbunovs

Annex 4
Cabinet Regulation No. 340
6 August 2002

Content of the Technical Dossier if the New Chemical Substance is an Intermediate Product and One Tonne and More of the New Chemical Substance is Manufactured or Imported per Year

1. Information specified in Annex 2 of these Regulations and the following studies and tests:
    1.1. vapour pressure;
    1.2. explosiveness;
    1.3. self-ignition temperature;
    1.4. oxidising properties;
    1.5. granulometric composition; and
    1.6. acute toxicity for daphnia.

2. An overview of the studied toxic and ecotoxic properties of the substances with a structure similar to the notified new chemical substance. If the relevant data are available (particularly in respect to chronic toxicity and reproductive toxicity), a summary of the relevant data shall be provided.

3. Detailed characterisation and evaluation of the manufacturing and utilisation processes of the new chemical substance at all sites of manufacturing or use in accordance with Sub-paragraphs 14.16.5 and 14.16.6 of these Regulations, specifying:
    3.1. the quantity and composition of the potential emissions of the substance or waste (polluting substances — mg/l, mg/kg or kg/t);
    3.2. detailed information regarding chemical reactions in the technological process;
    3.3. information regarding activities with residues or waste of the technological process (for example, production and processing waste is discharged to wastewater or liquid and solid waste is incinerated);
    3.4. information regarding how cleaning and maintenance of all equipment is performed;
    3.5. detailed an assessment of the harmful effects of the possible emission or accidental spillage of the substance on human organism and the environment during the whole circulation cycle of the substance; and
    3.6. detailed description regarding emission or accidental spillage reduction, restriction or elimination measures if emission or spillage may cause harmful effects.

4. A description of the provision of fulfilment of the requirements specified in Sub-paragraphs 14.6, 14.7, 14.8 and 14.9 of these Regulations.

5. A description of the technical measures taken in accordance with Sub-paragraph 14.16.1 of these Regulations in order to prevent, during the whole circulation cycle of the new chemical substance, the possibility of the substance to escape from the packaging, means of transport, research or technological equipment or other closed system, in respect of:
    5.1. the possible emission, accidental spillage or waste;

5.2. taking of samples;
5.3. moving and transportation, including unloading and loading; and
5.4. repair, technical maintenance and cleaning.

6. Characterisation of the effectiveness of technical measures. The effectiveness of technical measures shall be determined by the construction of a closed functional element and its technical specifications, for example, leak-tightness and ventilation. Not all functional elements of the closed system are to be characterised and detailed information regarding every seal or efficiency of integrated exhaust ventilation need not be provided but there shall be the information which could help to verify whether the assertions regarding the efficiency of the system and ensuring of control are true. The effectiveness of technical measures shall be characterised by the following basic criteria for the an assessment of closed systems intended for the use of chemical substances:

6.1. criterion for the an assessment of operation of closed system which characterises the probability of undesirable consequences or adverse effects when handling the substance in the chemical, technological and associated processes (depending on the construction of the functional element);

6.2. criterion for the an assessment of monitoring and technical maintenance of closed systems which is determined depending on the following additional measures which are taken on a permanent basis to ensure leak-tightness (a system, a functional element or a part of the equipment is nominally leak-proof if during the leak-tightness tests, monitoring or checking thereof (for example, using foaming agents or leak-detection devices) it is not possible to detect leaks or the leakage rate is less than 0,00001 mbar 1 x s–1):

6.2.1. checking of the equipment and leakage control (including leak control, visual and other examination of the equipment, using appropriate devices for detection of the location of the biggest leakage points), inspection of separable connections, air pollution or leakage control, automatic leakage control of those connections; and

6.2.2. planned and monitored technical maintenance or repair measures in respect of damages, as well as precautionary measures and environmental and human health protection measures — depending on the properties, quantity of the intermediate product, construction of the equipment and the results of the checking of the repaired functional elements.

7. An assessment of the effectiveness of technical measures taken in respect of the functional elements of the equipment in order to determine the effectiveness index of the technical measures on the basis of examination of the equipment. The technical measures effectiveness index shall be determined by using numerical criteria (from 0.5 to 4) by means of which the operation and monitoring of the systems shall be assessed (0.5 — highly effective measures, 1 — effective measures, 2 — partly effective measures, 4 — ineffective measures). The following an assessment criteria for operation or monitoring and technical maintenance of closed systems shall be used:

7.1. criterion 0.5 — for closed systems if:

7.1.1. the effectiveness index of all functional elements is 0.5;

7.1.2. direct skin contact of the intermediate product is not possible;

7.1.3. only functional elements of closed type have been used in the systems the leak-tightness of which is guaranteed, including static seals with welded or soldered connections, hermetically sealed seals of non-static connections; and

7.1.4. elements equipped with integrated exhaust ventilation system have been used in the systems (closed exhaust ventilation system the power, construction and dimensions of which prevent escape of the intermediate product from the system and ensure that all gases, vapour and dust that have got therein are captured and carried away, as well as prevent flowing thereof into the work environment);

7.2. criterion 0.5 — partially closed functional elements with highly effective exhaust ventilation (open or semi-closed exhaust ventilation system the construction and dimensions of which ensure that the intermediate product does not spread beyond the catchment area and it may be considered that the intermediate product does not get into the work environment);

7.3. criterion 1 — for systems with the following functional elements (functional elements not always ensure that the concentration of the intermediate product in the air of the work environment does not exceed the permitted limit values):

7.3.1. closed functional elements leak-tightness of which is not ensured (for example, for filling and emptying of road tankers, drums or containers with special closed or fixed equipment, without taking other additional measures); and

7.3.2. partially closed functional elements with effective exhaust ventilation (open or semi-closed exhaust ventilation system the construction and dimensions of which ensure that the intermediate product does not spread beyond the catchment area, and largely prevent the release of a chemical substance in the air of the work environment) if the relevant measurements attest that the concentration of the intermediate product in the air of the work environment does not exceed the permitted limit value (for example, vacuum packing equipment for big packages with effective exhaust ventilation);

7.4. criterion 2 — for systems with the following functional elements (functional elements do not ensure that the concentration of the intermediate product in the air of the work environment does not exceed the permitted limit values):

7.4.1. partially closed functional elements with simple exhaust ventilation; and

7.4.2. open functional elements with simple exhaust ventilation, for example, pneumatic conveyance or spiral conveyors with exhaust ventilation;

7.5. criterion 4 — for systems with the following functional elements (functional elements do not ensure that the concentration of the intermediate product in the air of the work environment does not exceed the permitted limit values):

7.5.1. open or partially closed functional elements, for example, for open filling or emptying or manual filling of containers or big packages without taking additional measures; and

7.5.2. systems with natural ventilation.

8. A description and justification if there are deviations from the criteria specified in Paragraph 7 of this Annex in respect of:

8.1. possible emission, accidental spillage and waste;

8.2. sample taking;

8.3. moving and conveyance, including unloading and loading; or

8.4. repair, technical maintenance and cleaning.

9. An assessment of the adverse effects of the new chemical substance on the environment and human health or undesirable consequences which is justified by monitoring data or results of the technical simulation an assessment (in accordance with Sub-paragraph 14.16.4 of these Regulations) if the an assessment criteria specified in Paragraph 7 of these Regulations are not met.

10. Characterisation of the equipment or parts of the equipment which in accordance with the effectiveness an assessment of the performed technical measures have the highest effectiveness indexes of the technical measures (the measures taken are the least effective).

11. Changes planned which may cause adverse effects of the new chemical substance on human organism or the environment (including changes in the functional elements of the equipment), another user or another site of utilisation.

Acting for the Minister for Environmental
Protection and Regional Development —
Minister for Transport A. Gorbunovs

Annex 5
Cabinet Regulation No. 340
6 August 2002

Content of the Technical Dossier if the New Chemical Substance is a Polymer

1. General Provisions

1. In order to reduce the necessary quantity of studies, groups of polymers may be specified in the technical dossier. In the relevant technical dossier the studies conducted on the basis of the following properties of the most representative members of the group shall be specified:

1.1. variable number-average molecular weight (hereinafter — Mn) for homopolymers (a polymer consisting of only one kind of monomer units);

1.2. variable composition with Mn approximately constant for copolymers (a polymer consisting of two or more kinds of monomer units);

1.3. Mn variable with composition approximately constant for copolymers, if Mn > 1000;

1.4. differences in the effects of the representative members of the group — additional tests of other members of the group if differences in the effects of the representative members of the group have been observed depending on the Mn or composition-range; and

1.5. monomer properties — the available information on the properties of the monomers may be taken into account for the an assessment of the properties of polymers.

2. Content of the Technical Dossier Regarding Polymers for Testing of which General Test Programme is Utilised

2.1. Polymers the Annual Trade Volume of which is One Tonne and More or the Total Trade Volume is Five Tonnes and More

2. The information specified in Annex 3 of these Regulations.

3. Identity of the polymer:

3.1. number-average molecular weight;

3.2. molecular weight distribution;

3.3. identity and concentration of monomers and starting substances which are bound in the polymer; and

3.4. properties of end groups and identity and frequency of reactive functional groups of the polymer characterised by the identity and percentage of non-reacted monomers.

4. Information characterising biodegradation of the polymer (if the polymer is biologically degradable).

5. Physical-chemical properties of the polymer:

5.1. water extractivity;

5.2. light-stability if the polymer is not specifically stabilised against the effect of light; and

5.3. long-term extractivity (leachate test). Depending on the results of the test, in separate cases other appropriate tests on the obtained leachate shall be conducted.

2.2. Polymers the Annual Trade Volume of which is 100 kg and More but Less than One Tonne or the Total Trade Volume is 500 kg and More

6. The information specified in Annex 2 of these Regulations.

7. Identity of the polymer:

7.1. number-average molecular weight;

7.2. molecular weight distribution;

7.3. identity and concentration of monomers and starting substances which are bound in the polymer; and

7.4. properties of end groups and identity and frequency of reactive functional groups of the polymer characterised by the identity and percentage of non-reacted monomers.

8. Information characterising biodegradation of the polymer (if the polymer is biologically degradable).

9. Water extractivity of the polymer.

2.3. Polymers the Annual Trade Volume of which is Less than 100 kg or the Total Trade Volume is Less than 500 kg

10. The information specified in Annex 1 of these Regulations.

11. Identity of the polymer:

11.1. number-average molecular weight;

11.2. molecular weight distribution;

11.3. identity and concentration of monomers and starting substances which are bound in the polymer; and

11.4. properties of end groups and identity and frequency of reactive functional groups of the polymer characterised by the identity and percentage of non-reacted monomers.

12. Information characterising biodegradation of the polymer (if the polymer is biologically degradable).

3. Content of the Technical Dossier Regarding Biologically Inert Polymers or Polymers with Similar Properties

3.1. Criteria for Determining Biologically Inert Polymers or Polymers with Similar Properties

13. Polymers may be regarded as biologically inert (with high average molar weight, a low content of low molecular weight compounds and a low water solubility or extractivity) polymers or polymers with similar properties if they meet the following criteria:

13.1. high average molecular weight;

13.2. extractivity in water is less than 10 mg/l (in the test impurities and additives shall not be taken into account); and

13.3. the molecule (component) of the polymer contains less than 1% of the substance with molecular weight less than 1000 (refers only to molecules (components) which are direct derivatives, including monomers, but does not refer to other components, for example, additives and impurities).

14. In order to evaluate whether the polymer may be regarded as biologically inert, non-readily degradable polymer:

14.1. it shall be determined whether the polymer meets all criteria referred to in Paragraph 13 of this Annex — if the annual trade volume of the polymer is one tonne and more or the total trade volume is five tonnes and more; or

14.2. it shall be determined whether the polymer meets all criteria referred to in Sub-paragraphs 13.1 and 13.2 of this Annex — if the annual trade volume of the polymer is less than one tonne or the total trade volume is less than five tonnes.

3.2. Polymers the Annual Trade Volume of which is One Tonne and More or the Total Trade Volume is Five Tonnes and More

15. Information regarding manufacturing or import of the polymer:

15.1. the name, the legal address and the location of the manufacturer;

15.2. the name and the legal address of the importer; and

15.3. the location of the production site.

16. Identity of the polymer:

16.1. the name in the IUPAC nomenclature;

16.2. usual the name, trade the name, abbreviations and other the names;

16.3. CAS number and CAS the name (if available);

16.4. molecular formula and structural formula:

16.4.1. average molecular weight;

16.4.2. molecular weight distribution;

16.4.3. identity and concentration of monomers and starting substances which are bound in the polymer; and

16.4.4. properties of end groups and identity and frequency of reactive functional groups of the polymer;

16.5. composition of the polymer:

16.5.1. degree of purity (%);

16.5.2. impurities (including by-products) and non-reacted monomers;

16.5.3. percentage of main impurities and non-reacted monomers;

16.5.4. nature and percentage of stabilising agents, inhibitors and other impurities contained by the polymer (ppm and %);

16.5.5. spectral analyses data (ultraviolet (UV), infrared (IR), nuclear magnetic resonance (NMR) spectrometry or mass spectrometry); and

16.5.6. gel permeation chromotography;

16.6. determination methods:

□□□□□□□□ a full description of the methods utilised or a list of the relevant bibliography; and

16.6.2. information on the analytical methods known to the notifier which allow detection of a polymer and its transformation products after discharge into the environment, as well as determination of the direct effect on humans.

17. Information regarding the polymer:

17.1. information regarding the manufacturing process and effects of the polymer related to the manufacturing process on humans and the environment (without specifying precise details of the manufacturing process, particularly those which are a commercial secret);

17.2. technological process utilised in manufacturing;

17.3. an estimate of the effect related to manufacturing on the work environment and the environment;

17.4. intended use of the polymer and the effect related thereto on humans and the environment:

17.4.1. the intended types of use of the polymer;

17.4.2. technological process during which the polymer is manufactured, used or treated (if known);

17.4.3. an assessment of the effects on the work environment and the environment;

17.4.4. information whether the polymer is intended to be offered or sold as a chemical substance or in the composition of a chemical product;

17.4.5. concentration of the polymer in the relevant chemical product (if known);

17.4.6. the fields or sectors where the polymer is intended to be used (for example, industry, agriculture, crafts);

17.4.7. recipient of the polymer (if known and if it can be identified); and

17.4.8. quantity and composition of waste resulting from the intended type of use of the polymer (if known);

17.5. manufacturing and import an estimate in each type of use of the polymer:

17.5.1. the total quantity of production or imports in the first calendar year (tonnes per year);

17.5.2. the total quantity of production or imports in the following calendar years (tonnes);

17.5.3. the total quantity of production or imports of the polymer broken down according to the types of use thereof expressed as percentage (in the first and following calendar years); and

17.5.4. the total quantity of production or imports of the polymer broken down according to the fields or sectors of use thereof expressed as percentage (in the first and following calendar years);

17.6. recommended methods and safety measures in respect of:

17.6.1. activities with the polymer;

17.6.2. storage of the polymer;

17.6.3. transportation of the polymer;

17.6.4. fire safety of the polymer;

17.6.5. other possible danger of the polymer, particularly chemical reaction with water; and

17.6.6. susceptibility of the polymer to explode if it is in the form of a dust (specify if necessary);

17.7. measures to eliminate accidents if spillage of the polymer has occurred;

17.8. emergency assistance in the case of injury or poisoning of a person; and

17.9. packaging of the polymer.

18. Physical-chemical properties of the polymer:

18.1. state of aggregation if the temperature is 20°C and the pressure — 101,3 kPa;

18.2. melting range (thermal stability tests);

18.3. relative density;

18.4. water extractivity;

18.5. flash point;

□□□□□□explosion limits;

18.7. self-ignition temperature;

18.8. particle size (for polymers the type of trade packaging of which may cause danger to the respiratory tract shall require a test to determine the particle distribution according to sizes in the trade packaging of the polymer);

18.9. thermal stability; and

18.10. extractivity with:

18.10.1. water (at 37°C temperature) if pH 2 and pH 9; and

18.10.2. cyclohexane.

19. Toxicological studies if they are necessary in accordance with Sub-paragraphs 33.9, 49.2, 49.3, 50.1.2 or 50.1.3 of these Regulations. Under specific circumstances, on the basis of the presence of reactive groups, structural or physical characteristics, knowledge regarding the characteristic properties of low molecular weight components of the relevant polymer or potential effect, appropriate studies shall be conducted, particularly in respect of toxicity by inhalation, taking into account the possible effect on the respiratory tract.

20. Ecotoxicological studies if they are necessary in accordance with Sub-paragraphs 33.9, 49.2, 49.3, 50.1.2 or 50.1.3 of these Regulations. Under specific circumstances, on the basis of the presence of reactive groups, structural or physical characteristics, knowledge regarding the characteristic properties of low molecular weight components of the relevant polymer or potential effect, appropriate studies or additional studies shall be conducted, particularly in respect of:

20.1. light-stability, if the polymer is not specifically stabilised against the effect of light; and

20.2. long-term extractivity (leachate test). Depending on the results of the test, in separate cases other appropriate tests on the leachate shall be conducted.

21. Possibilities of preventing or reducing the adverse effects of the polymer:

21.1. in industry, entrepreneurial activities and crafts:

21.1.1. recycling or re-utilisation;

21.1.2. preventing or reducing the adverse effects or undesirable consequences; and

21.1.3. utilisation by purifying or disposing — incineration of waste, water or wastewater treatment, polluted emission control;

21.2. in general use by inhabitants:

21.2.1. recycling or re-utilisation;

21.2.2. preventing or reducing the adverse effects or undesirable consequences; and

21.2.3. utilisation by purifying or disposing — incineration of waste, water or wastewater treatment, pollution control at the point of emission or otherwise.

3.3. Polymers the Annual Trade Volume of which is Less than One Tonne or the Total Trade Volume is Less than Five Tonnes

22. Information regarding manufacturing or import of the polymer:

22.1. the name, the legal address and the location of the manufacturer;

22.2. the name and the legal address of the importer; and

22.3. the location of the production site.

23. Identity of the polymer:

23.1. the name:

23.1.1. the name in the IUPAC nomenclature;

23.1.2. usual the name, trade the name, abbreviations and other the names; and

23.1.3. CAS number and CAS the name (if available);

23.2. molecular formula and structural formula:

23.2.1. number-average molecular weight;

23.2.2. molecular weight distribution;

23.2.3. identity and concentration of monomers and other starting substances which are bound in the polymer; and

23.2.4. properties of end groups and the identity and frequency of reactive functional groups of the polymer;

23.3. composition of the polymer:

23.3.1. degree of purity (%);

23.3.2. impurities (including by-products and non-reacted monomers);

23.3.3. percentage of main impurities and non-reacted monomers;

23.3.4. nature and percentage of stabilising agents, inhibitors and other impurities contained by the polymer (ppm and %);

23.3.5. spectral analyses data (ultraviolet (UV), infrared (IR), nuclear magnetic resonance (NMR) spectrometry or mass spectrometry); and

23.3.6. gel permeation chromotography;

23.4. determination methods:

23.4.1. a full description of the methods used or a list of the relevant bibliography;

23.4.2. information on the analytical methods known to the notifier which allow detection of a polymer and its transformation products after discharge into the environment, as well as determination of the direct effect on humans.

24. Information regarding the polymer:

24.1. information regarding the manufacturing process and effects of the polymer related to the manufacturing process on humans and the environment (without specifying precise details of the manufacturing process, particularly those which are a commercial secret);

24.2. technological process of manufacturing;

24.3. an estimate of the effect related to manufacturing on the work environment and the environment;

24.4. intended use of the polymer and the effect associated thereto on humans and the environment:

24.4.1. the intended types of use of the polymer;

24.4.2. technological process during which the polymer is manufactured, used or treated (if known);

24.4.3. an assessment of the effects related to the use on the work environment and the environment;

24.4.4. information regarding whether the polymer is intended to be offered or sold as a chemical substance or in the composition of a chemical product;

24.4.5. concentration of the polymer in the relevant chemical product (if known);

24.4.6. the fields or sectors where the polymer is intended to be used (for example, industry, agriculture, crafts);

24.4.7. recipient of the polymer (if known and if it can be identified); and

24.4.8. quantity and composition of waste resulting from the intended type of use of the polymer (if known);

24.5. manufacturing and import an estimate in each type of use of the polymer:

24.5.1. the total quantity of production or imports in the first calendar year (tonnes);

24.5.2. the total quantity of production or imports in the following calendar years (tonnes per year);

24.5.3. the total quantity of production or imports of the polymer broken down according to the types of use thereof expressed as percentage (in the first and following calendar years); and

24.5.4. the total quantity of production or imports of the polymer broken down according to the fields and sectors of use thereof expressed as percentage (in the first and following calendar years);

24.6. recommended methods and safety measures in respect of:

24.6.1. activities with the polymer;

24.6.2. storage of the polymer;

24.6.3. transportation of the polymer;

24.6.4. fire safety of the polymer;

24.6.5. other danger of the polymer, particularly chemical reaction with water; and

24.6.6. susceptibility of the polymer to explode if it is in the form of a dust (specify if necessary);

24.7. measures to eliminate accidents if spillage of the polymer has occurred;

24.8. emergency assistance in the case of injury or poisoning of a person; and

24.9. packaging of the polymer.

25. Physical-chemical properties of the polymer:

25.1. state of aggregation if the temperature is 20°C and the pressure — 101,3 kPa;

25.2. melting range (thermal stability tests);

25.3. relative density;

25.4. water extractivity; and

25.5. flash point.

26. Toxicological or ecotoxicological studies if they are necessary in accordance with Sub-paragraphs 33.9, 49.2, 49.3, 50.1.2 or 50.1.3 of these Regulations.

Acting for the Minister for Environmental
Protection and Regional Development —
Minister for Transport A. Gorbunovs

Annex 6
Cabinet Regulation No. 340
6 August 2002

Additional Studies if the Trade Volume of the New Chemical Substance has Increased

1. Additional studies of the physical-chemical properties of the new chemical substance shall depend on the results of the studies obtained in accordance with Annex 3 of these Regulations. Analytical methods may be developed additionally in order to be able to observe and detect the new chemical substance and its transformation products, as well as studies regarding thermal decomposition products.

2. Level 1 toxicological studies:

2.1. studies regarding the effect of the new chemical substance on animal reproduction:

2.1.1. studies regarding males and females of one generation of one species utilising the most appropriate method of studies and manner of performance;

2.1.2. studies regarding the effect of the new chemical substance on reproduction in the second generation if the results in respect of the first generation are equivocal; and

2.1.3. examination of positive indications utilising official teratology studies if signs of toxic effects for reproduction have been obtained therein which depend on the dose;

2.2. teratology studies (for one species, most appropriate manner of performance) if the toxic effects of the new chemical substance have not been evaluated in studies regarding effects of the new chemical substance on reproduction;

2.3. studies regarding sub-chronic or chronic toxicity of the new chemical substance, including special studies (one species, male and female, most appropriate manner of performance) if the results of the repeated-dose study in accordance with Annex 3 of these Regulations or other relevant information demonstrate the need for appropriate studies. The main signs which indicate the need for such studies are the following:

2.3.1. serious or irreversible lesions;

2.3.2. undesirable consequences or adverse effects are not caused only by very small dose or concentration of the new chemical substance; or

2.3.3. similarity of the chemical structure of the new chemical substance being studied to other chemical substances which have been recognised as hazardous;

2.4. additional studies regarding mutagenicity or screening studies for carcinogenesis. If results of both types of studies are:

2.4.1. negative — further studies shall be conducted in conformity with the specific properties and the intended use of the substance;

2.4.2. positive — additional studies shall be conducted by other *in vivo* methods, determining the same or different study end points; and

2.5. basic toxicokinetic information.

3. Level 1 ecotoxicological studies:

3.1. prolonged toxicity studies with daphnia (*Daphnia magna*) (21 days);

3.2. studies or tests on higher plants;

3.3. studies or tests on earthworms;

3.4. further toxicity studies with fish;

3.5. tests for species accumulation (preferably with fish);

3.6. additional studies regarding degradation of the new chemical substance, if degradation has not been sufficiently tested in the studies in accordance with Annex 3 of these Regulations; and

3.7. further studies regarding absorption or desorption of the new chemical substance depending on the results of the studies specified in Annex 3 of these Regulations.

4. Level 2 toxicological studies. The studies programme shall cover the following aspects (unless it has been proven that they need not be complied with):

4.1. chronic toxicity studies;

4.2. carcinogenicity studies;

4.3. studies regarding the effect of the new chemical substance on reproduction (for example, three-generation studies) — only if an effect on reproduction has been established in studies prescribed in Paragraphs 1, 2 and 3 of this Annex;

4.4. studies regarding toxicity effects on peri-natal and postnatal development;

4.5. teratology studies (species not employed in the studies prescribed in Paragraphs 1, 2 and 3 of this Annex);

4.6. additional toxicokinetic studies of biotransformation and pharmacokinetics; and

4.7. additional tests to investigate organ or system toxicity.

5. Level 2 ecotoxicological studies:

5.1. additional tests for accumulation, degradation, mobility and absorption or desorption of the new chemical substance;

5.2. further toxicity studies with fish;

5.3. toxicity studies with birds; and

5.4. additional toxicity studies with other organisms.

Acting for the Minister for Environmental
Protection and Regional Development —
Minister for Transport A. Gorbunovs

