Regulation on the procedure and method of the assessment of risks to man and the environment of notified chemical substances

Adopted with Council of Ministers' Decree No. 324/03.12.2004

Promulgated, State Gazette No. 110/17.12.2004 (in force as of 1.01.2007)

Chapter One

GENERAL PROVISIONS

Article 1. (1) This Regulation shall determine the procedure and method of assessment of the risk to man and the environment of notified chemical substances.

(2) This regulation shall apply to any chemical substance notified pursuant to Chapter Three of the Protection Against the Harmful Impact of Chemical Substances and Preparations Act (PAHICSP).

Article 2. The assessment of the risk to man and the environment posed by a notified chemical substance shall be carried out on the basis of an expert assessment of the risk to man and an expert assessment of the risk to the environment.

Article 3. The expert assessments referred to in Article 2 shall be carried out by:

1. The Ministry of Health – for expert assessments of risk to man;

2. The Ministry of Environment and Water – for expert assessments of risk to the environment.

Chapter Two

EXPERT ASSESSMENTS OF RISK TO MAN AND THE ENVIRONMENT

Article 4. (1) The expert assessments of risk referred to in Article 3, Paragraphs 2 and 3 shall include:

1. hazard identification;

2. dose (concentration) - response (effect) assessment;

3. exposure assessment;

4. risk characterisation.

(2) In relation to particular effects for which an expert assessment of risk pursuant to Paragraph 1 is impracticable, the expert assessment shall be carried out on a case-by-case basis and shall include a full description of the methods used.

Article 5. (1) The expert assessment of risk to man shall be carried out in accordance with Art. 4, Para. 1 and Appendices No. 1 and No. 2.

(2) Hazard identification referred to in Article 4, Paragraph 1, item 1 shall be carried out on the basis of an assessment of the toxicological effects and the chemical and physical properties pursuant to Appendix No. 3 for the following populations:

1. workers and employees;

2. users;

3. humans exposed indirectly to the substance.

(3) Where the test appropriate to hazard identification in relation to a particular property or effect referred to in Article 4, Paragraph 2 has been conducted and the results have not led to classification of the substance as dangerous, when conducting the expert assessment of risk with respect to this property or effect, Article 4, Paragraph 1, items 2 -4 shall not be applied, unless newly obtained

information provides data that the substance may present danger.

(4) Where the test appropriate to hazard identification in relation to a particular property or effect referred to in Article 4, Paragraph 2 has not been conducted, an expert assessment of risk with respect to this property or effect shall not be conducted, unless newly obtained information provides data that the substance may present danger.

Article 6. (1) The expert assessment of risk to the environment shall be carried out in accordance with Art. 4, Para. 1 and Appendix No. 4.

(2) Where the substance has not been classified as dangerous to the environment, when conducting the expert assessment of risk with respect to this property or effect, Article 4, Paragraph 1, items 2 - 4 shall not be applied, unless newly obtained information provides data that the substance may present danger to the environment.

(3) Where the substance has been classified as dangerous to the environment, but the data available is insufficient to determine whether the classification is correct, hazard identification shall be carried out on the basis of additional information and data on the physical, chemical and toxicological properties.

(4) In the cases referred to in Paragraph 3, where through additional information and data it is found that the substance does not pose a danger to the environment, Article 4, Paragraph 1, items 2 -4 shall not be applied, unless newly obtained information provides data that the substance may be dangerous.

(5) In the cases referred to in Paragraph 3, where through additional information and data it is found that the substance is classified as dangerous to the environment, the expert assessment of risk to the environment shall be carried out pursuant to Paragraph 1.

Chapter Three

PROCEDURE AND METHOD OF RISK ASSESSMENT

Article 7. (1) Within 10 days of the issue of a certificate of registration of a notified chemical substance the Minister of Environment and Water shall send to the Minister of Health the technical dossier referred to in Article 10 of the PAHICSP for an expert assessment of risk to man.

(2) The Ministry of Health shall conduct an expert assessment of risk to man within 8 months of receipt of the technical dossier referred to in Paragraph 1.

(3) The Minister of Health shall send to the Minister of Environment and Water the expert assessment referred to in Paragraph 2 within 7 days after it is completed.

Article 8. The Ministry of Environment and Water shall conduct an expert assessment of risk to the environment within 8 months of the issue of a certificate of registration of a notified chemical substance.

Article 9. Where necessary, experts from the Civil Protection State Agency, the Ministry of Labour and Social Policy and other institutions shall be engaged additionally to conduct the expert assessments of risk to man and the environment.

Article 10. (1) On the basis of the expert assessments of risk the Minister of Environment and Water shall inform the person placing the notified chemical substance on the market of one of the following conclusions:

1. the substance does not pose a danger to man and the environment and until the next quantity determined with the provisions of Article 11 of the PAHICSP is reached the risk assessment need not be revised;

2. the substance poses a danger to man and the environment.

(2) In the cases referred to in Paragraph 1, item 2, the Minister of Environment and Water shall:

1. require from the person placing the notified chemical substance on the market to submit additional information for review of the risk assessment when the next quantity determined with the provisions of Article 11 of the PAHICSP is reached; or

2. require from the person placing the notified chemical substance on the market to submit further information immediately, or

3. require from the person placing the notified chemical substance on the market to take measures for reducing the risk.

(3) The person placing the notified chemical substance on the market may file an objection within 14 days of the date of receipt of the conclusion referred to in Paragraph 1.

(4) The Minister of Environment and Water shall review the objection filed and within 10 days of receiving it shall notify in writing the person placing the notified chemical substance of its final conclusion.

Article 11. The Minister of Environment and Water shall issue a certificate of assessment of risk to man and the environment posed by notified chemical substances in accordance with Appendix No. 5 within 12 moths of the issue of the certificate of registration of the notified chemical substance pursuant to Article 8, Paragraph 7 of the PAHICSP.

Article 12. (1) Where additional information in accordance with the provisions of Article 11 of the PAHICSP is received for the substance for which risk assessment pursuant to Article 11 has been conducted, the Minister of Environment and Water shall review and, where necessary, revise the risk assessment and notify thereof the person placing the notified chemical substance on the market in writing.

(2) The revision of the risk assessment referred to in Paragraph 1 shall be carried out pursuant to the provisions of Articles 7 through 11.

ADDITIONAL PROVISIONS

§ 1. For the purpose of this Regulation:

1. "Lowest-observed-adverse-effect dose (concentration)" is the minimum dose (concentration) which causes an observed adverse effect on test animals or humans.

2. "Hazard identification" is the identification of the adverse effects which a substance may cause;

3. "Measures for risk reduction" is the activities related to the lessening of the risks for man and/or the environmental compartments in connection with the placing of the substance on the market. They may include:

a) modifications to the classification, packaging or labelling of the notified substance;

b) modifications to the safety data sheet of the notified substance;

c) modifications to the recommended methods and precautions or emergency measures proposed by the notifier in the technical dossier of the notification.

4. "No-observed-adverse-effect dose (concentration)" is the maximum dose (concentration) which does not cause an observed adverse effect on test animals or humans.

5. "Exposure assessment" is the determination of the emissions, pathways and rates of movement of a substance and its transformation or degradation in order to estimate the concentrations/doses to which human populations or environmental compartments are or may be exposed.

6. "Predicted environmental concentration" is the concentration which will eventually be found in the environment after use of the substance.

7. "Dose (concentration) — response (effect) assessment" is the estimate of the relationship

between the dose, or level of exposure, of the substance and the incidence and severity of the effect.

8. “Predicted no-effect concentration” the maximum concentration which would not cause adverse effects in the environmental compartments.

9. “Median lethal concentration” is the concentration which causes lethality in 50 per cent of the studied test animals in case of inhalation.

10. “Median lethal dose” is the dose which causes lethality in 50 per cent of the studied test animals in case of oral or dermal administration.

11. "Risk characterization” is the estimation of the incidence and severity of the adverse effects likely to occur in a human population or environmental compartment due to actual or predicted exposure to a substance. It may include 'risk estimation', i.e., the quantification of that likelihood.

FINAL PROVISIONS

§ 2. This Regulation is adopted pursuant to Article 13 of the Protection Against the Harmful Impact of Chemical Substances and Preparations Act.

§ 3. This Regulation shall become effective as of 1 January 2005.

Appendix I
to Article 5, Paragraph 1

Principles for expert assessment of risks to man owing to the toxicological effects of the substance

1. Hazard identification	1.1. Where the test appropriate to identification of a particular effect has been conducted and the results have shown that the substance is not dangerous, when conducting the expert assessment of risk to man in relation to that property or effect, compliance with Article 4, Paragraph 1, items 2, 3 and 4 of the Regulation shall not be required, unless there are other grounds for concern, e.g. positive in vitro test results for mutagenicity.
	1.2. Where the test appropriate to identification of a particular effect has not been conducted, an assessment of risk to man in relation to that property or effect shall not be conducted, unless there are other reasonable grounds for concern, e.g. exposure considerations or indications of potential toxicity from structure activity relationships.
2. Dose (concentration) — response (effect) assessment of the substance, where appropriate	2.1. The dose – response relationship shall be assessed for repeated dose toxicity and for toxicity for reproduction and where appropriate the no-observed-adverse-effect dose/concentration shall be determined. Where the no-observed-adverse-effect dose/concentration cannot be determined, the lowest-observed-adverse-effect dose/concentration shall be determined.
	2.2. Where it is not possible to derive the no-observed-adverse-effect or the lowest-observed-adverse-effect dose/concentration for acute toxicity, the median lethal dose or the medial lethal concentration or, where the fixed dose procedure has been used, the discriminating dose shall be derived; for corrosivity and irritation, it shall be determined whether the substance has an inherent capacity to cause such effects

	2.3. For mutagenicity and carcinogenicity, it shall be determined whether the substance is a mutagen or a carcinogen. Where a substance is a non-genotoxic carcinogen, the no-observed-adverse-effect or the lowest-observed-adverse-effect dose/concentration shall be identified.
	2.4. With respect to skin and respiratory sensitization it shall be determined whether the substance is a chemical allergen, as it is impractical to identify the no-observed-adverse-effect or the lowest-observed-adverse-effect dose/concentration for a subject having specific antibodies to a given substance.
3. Exposure assessment	3.1. The exposure assessment shall be made through a quantitative or qualitative estimate of the dose/concentration of the substance to which a population is or may be exposed. Such estimation shall take account of spatial and temporal variations in the exposure pattern.
	3.2. The exposure assessment shall be based on the information in the technical dossier and on any other reliable information. Particular account shall be taken of: • reliable data from exposure measurement; • the quantity of the substance on the market; • the form in which the substance is marketed and/or used – chemical substance or preparation; • use category – professional or non-professional and degree of containment; • data related to the production technology, where necessary; • physical and chemical properties of the substance including, where relevant, those conferred by the process; • likely routes of exposure and potential for absorption; • the frequency and duration of exposure; • type and size of specific exposed populations where such information is available.
	3.3. Where predictive methods are used for estimation of exposure levels, preference shall be given to relevant monitoring data from substances with analogous use and exposure patterns.
	3.4. If a substance is contained in a preparation, consideration of exposure to the substance shall be necessary only if the preparation is classified dangerous on the basis of the toxicological properties of the substance, unless there are other reasonable grounds for concern.
4. Risk characterisation	4.1. Where, for any of the effects set out in Appendix No. 3, a no-observed-adverse-effect or lowest observed adverse effect dose/concentration has been identified, the risk characterization shall entail comparison of this dose/concentration with the estimate of the dose-concentration to which one or more populations will be exposed. Where a no-observed-adverse-effect or lowest observed adverse effect dose/concentration has been determined for the effects set out in Appendix No. 3 and a quantitative estimate of exposure is available, the ratio between the exposure level and the no-observed-adverse-effect/lowest observed adverse effect dose/concentration shall be derived.
	4.2. Where, for any of the effects set out in Appendix No. 3, it is impossible to determine a no-observed-adverse-effect or lowest observed adverse effect dose/concentration, the risk characterization in relation to those effects shall entail an evaluation of the likelihood that the effects will occur, on the basis of the quantitative and/or qualitative information on exposure relevant to the human populations. Where, despite a no-observed-adverse-effect or lowest observed adverse effect dose/concentration not having been determined, the test results nevertheless demonstrate a relationship between dose/concentration and the severity of an adverse effect or where, in connection with a test method which entails the use of only one dose or concentration, it is possible to evaluate the relative severity of the effect, such information shall also be taken into account in evaluating the likelihood of the effect occurring.

	4.3 In making conclusions, the following shall be taken into account: • the uncertainty arising from the variability in the experimental data and intra- and interspecies variation; • the nature and severity of the effect; • the characteristics of the population to which the quantitative and/or qualitative information on exposure applies.
	4.4. Where a risk characterization is carried out in relation to more than one toxicological effect or human population, the competent authority shall issue individual conclusions for each effect or population. An integrated assessment of the toxicological effect of the substance shall be made on the basis of the individual conclusions
	4.5. When issuing the certificate, with relation to Article 10, Paragraph 3, item 3, the competent authority shall take into account that decreased exposure of a population or an environmental compartment may be related to increased exposure of another population or environmental compartment.

Appendix II
to Article 5, Paragraph 1

Principles for expert assessment of risks to man owing to the physical and chemical properties of the substance

1. Hazard identification	1.1. Where the test appropriate to hazard identification in relation to a particular property has been conducted and the results have shown that the substance is not classified dangerous, when conducting an assessment of risks to man in relation to that property, Article 4, Paragraph 1, items 2, 3 and 4 shall not apply, unless there are other reasonable grounds to do so.
	1.2. Where the test appropriate to hazard identification in relation to a particular property has not been conducted, an expert assessment of risk to man in relation to that property shall not be conducted, unless there are other grounds to do so.
2. Exposure assessment	Where risk characterization is conducted in relation to a specific property or effect pursuant to Article 5, Paragraphs 3 and 4, during exposure assessment it shall be necessary only to determine the reasonably foreseeable conditions of use on the basis of the information on the substance included in the technical dossier.
3. Risk characterisation	The risk characterization shall entail an evaluation of the likelihood that adverse effects will be caused to the populations by the properties of the substance under the reasonably foreseeable conditions of its use.
4. Integration	Where different recommendations for risk reduction measures have been made in relation to different effects of the substance or different human populations, they shall be integrated by the competent authority.

Appendix III
to Article 5, item 2

Toxicological effects	1. Acute toxicity; 2. Irritation; 3. Corrosivity; 4. Sensitization; 5. Repeated dose toxicity; 6. Mutagenicity; 7. Carcinogenicity; 8. Toxicity for reproduction;
Physical and chemical properties	1. Explosivity; 2. Flammability; 3. Oxidizing potential.

Appendix IV
to Article 6, item 1

Principles for expert assessment of risks to the environment

1. Hazard identification	1.1 When conducting an expert assessment of risk posed by substances not classified dangerous for the environment, the following shall be taken into account for the hazard identification: • indications of bioaccumulation potential; • the shape of the toxicity/time curve in ecotoxicity testing; • indications of other adverse effects on the basis of toxicity studies; data on structurally analogous substances.
	1.2. Where the substance is not classified dangerous for the environment and for which there are insufficient data on effects on organisms , it shall be necessary to: • submit additional information when the quantity of notified substance placed on the market reaches the next tonnage, or • submit immediately additional information not contained in the technical dossier;
2. Dose (concentration) - response (effect) assessment, where appropriate	2.1. The dose (concentration) — response (effect) assessment shall determine the predicted no-effect concentration. The predicted no-effect concentration shall be determined on the basis of the information in the technical dossier and the ecotoxicity studies pursuant to Chapter II of the PAHICSP.
	2.2. The predicted no-effect concentration shall be calculated by applying the safety assessment factor to the values resulting from tests on organisms (median lethal dose or concentration, no-observed-effect dose or concentration, lowest-observed-effect dose or concentration, etc.)
	2.3. The safety assessment factor is an expression of the degree of uncertainty in extrapolation from test data on a limited number of species to the real environment.
3. Exposure assessment	3.1. The objective of the exposure assessment shall be to determine the predicted environmental concentration (PEC). Where this is impracticable, a qualitative estimation shall be made.

	3.2. A qualitative estimation of exposure through a PEC shall be made where emissions, discharges, disposal or distributions of the substance into the environmental compartments are foreseeable.
	3.3. The predicted environmental concentration shall be estimated on the basis of the following information from the technical dossier: 1. reliable data on exposure; 2. the quantity of the substance on the market; 3. the form in which the substance is marketed and/or used – chemical substance or preparation; 4. use category – professional or non-professional; 5. relative share of the substance in the products; 6. data related to the production technology, where processing occurs; 7. physico-chemical properties of the substance, including those conferred by the process – boiling point, vapour pressure, surface tension, water solubility, partition coefficient n-octanol/water; 8. pathways to environmental compartments and degree of adsorption/desorption and degradation; 9. frequency and duration of exposure;
	3.4. For substances placed on the market in quantities at or below 10 tonnes per annum or 50 tonnes cumulative, the PEC shall be determined only for the environmental compartments of the area in which the substance will be released.
4. Risk characterisation	4.1. Risk characterization shall be based on the ratio between the predicted environmental concentration and the predicted no-effect concentration. If the ratio is equal to or less than one, the competent authority shall issue the conclusion that the substance does not pose a risk to the environment. If the ratio is greater than one, the competent authority shall issue a conclusion pursuant to Article 10, Paragraph 2, item 2 of the Regulation.
	4.2. If it is not possible to derive the ratio between the predicted environmental concentration and the predicted no-effect concentration, the risk characterization shall entail a qualitative evaluation of the likelihood that an effect will occur under the expected conditions of exposure.
5. Integration	Where risk characterization is carried out in relation to more than one environmental compartment, the competent authority shall issue individual conclusions for each compartment. An integrated assessment of the substance shall be made on the basis of the individual conclusions. When issuing the certificate, with relation to Article 10, Paragraph 3, item 3, the competent authority shall take into account that decreased exposure of a population or an environmental compartment may be related to increased exposure of another population or environmental compartment.

Appendix V
to Article 11

MINISTRY OF ENVIRONMENT AND WATER

Certificate
of assessment of the risks to man and the environment of notified chemical substances

№……. dated ..... 200…

Notifier:

Address: …….....

BULSTAT: ……..

Tax No.: ……

Certificate of registration
of the notified chemical substance No. ……/……...

Quantity of the notified chemical substance placed on the market ……
…….....

The substance ……..….....….a danger to man and the environment
(does not pose/poses)

Signature:

Seal of the MoEW: