ACT No

67/2010

of 2 February 2010

on conditions applicable to the placing on the market of chemical substances and chemical mixtures, amending certain acts (Chemicals Act)

The National Council of the Slovak Republic has adopted the following Act:

Title I

PART ONE

GENERAL PROVISIONS

Article 1

Scope

(1) This Act lays down classification, labeling, packaging of chemical substances (hereinafter only "substances") and chemical mixtures[1]) (hereinafter only "mixtures"), testing of substances[2]), requirements for safety data sheets[3]), principles of Good Laboratory Practice, conditions applicable to the placing on the market of substances and mixtures[4)], conditions applicable to the placing on the market of detergents[5]), conditions applicable to imports and exports of certain dangerous substances and certain dangerous mixtures[6]), rights and obligations of manufacturers[7]), importers[8]), downstream users[9]) and suppliers[10]) of substances and mixtures, competence of public administration bodies including inspection and supervision as regards observance

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[1]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31. 12. 2008), as amended.

[2]) Article 13 (3) of the Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30. 12. 2006), as amended.
Council Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 142, 31. 5. 2008), as amended.

[3]) Article 31 of the Regulation (EC) No 1907/2006, as amended.

[4]) Regulation (EC) No 1907/2006, as amended.
Regulation (EC) No 1272/2008, as amended.

[5]) Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (OJ special edition, chapter 13/vol. 34), as amended.

[6]) Regulation (EC) No 689/2008 of the European Parliament and of the Council concerning the export and import of dangerous chemicals (OJ L 204, 31. 7. 2008).

[7]) Article 2 (15) of the Regulation (EC) No 1272/2008, as amended.

[8]) Article 2 (17) of the Regulation (EC) No 1272/2008, as amended.

[9]) Article 2 (19) of the Regulation (EC) No 1272/2008, as amended.

[10]) Article 2 (26) of the Regulation (EC) No 1272/2008, as amended.

of provisions of this Act and of specific regulations[11]) and imposing and enforcing sanctions applicable for infringement of this Act and of specific regulations[11]).

(2) This Act shall not apply to substances and mixtures listed in specific regulations[12]).

Article 2
Definitions

For the purpose of this Act

a) existing substance means a substance listed in the European Inventory of Existing Commercial Chemical Substances[13]);

b) new substance means a substance which is not listed in the European Inventory of Existing Commercial Chemical Substances;

c) no-longer polymer means a substance listed in a specific regulation[14]);

d) article means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition;

e) test facility means an operational unit wherein non-clinical health and environmental safety studies (hereinafter only "non-clinical studies") are conducted; and in case of non-clinical studies which are conducted at more than one site, test facility means the site at which the non-clinical study director is located and all individual test sites which individually or collectively can be considered to be test facilities, and are owned by or are in legal possession of natural persons or legal persons;

f) non-clinical study means an experiment or set of experiments in which a test item is examined under defined laboratory conditions or in the environment to obtain data in its properties or its safety;

g) accrediting person[15]) means any person monitoring the Good Laboratory Practice compliance of test facilities and the fulfillment of other tasks concerning the principles of Good Laboratory Practice;

h) test facility inspection means an on-site examination of the test facility´s procedures and practices aiming at reaching a certain degree of compliance with Good Laboratory Practice principles, which is targeted at management structures and operational procedures of the test facility;

i) inspector means any person who performs the test facility inspections and non-clinical study audits on behalf of the accrediting person;

j) non-clinical study audit means a comparison of raw data and associated records during testing of substances or the comparison thereof with the final report in order to determine whether the raw data have been accurately recorded and to determine whether testing was carried out in accordance with the study plan and standard operating procedures.

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[11]) Regulation (EC) No 648/2004, as amended.
Regulation (EC) No 1907/2006, as amended.
Regulation (EC) No 689/2008.
Regulation (EC) No 1272/2008, as amended.

[12]) Article 2 of the Regulation (EC) No 1907/2006, as amended.
Article 2 (2) of the Regulation (EC) No 689/2008.
Article 1 (2), (3), (5) and (6) of the Regulation (EC) No 1272/2008, as amended.

[13]) Article 3 (20) (a) of the Regulation (EC) No 1907/2006, as amended.

[14]) Article 3 (20) (c) of the Regulation (EC) No 1907/2006, as amended.

[15]) Act No 505/2009 Coll. on accreditation of bodies responsible for conformity assessment and on amendment of certain Acts.

PART TWO

CLASSIFICATION, LABELLING AND PACKAGING OF SUBSTANCES AND MIXTURES, TESTING OF SUBSTANCES AND SAFETY DATA SHEET

Article 3

Classification, labeling and packaging of substances

(1) Manufacturers, importers and downstream users must classify their substance[16]) pursuant to a specific regulation[1]).

(2) Suppliers of substances must label and package their substances pursuant to a specific regulation[1]).

(3) Information on the label of the package must be stated in the official language.

Article 4

Classification, labeling and packaging of mixtures

(1) Manufacturers, importers and downstream users must classify their mixture[17]) pursuant to a specific regulation[1]).

(2) Suppliers of mixtures must label and package their mixtures pursuant to a specific regulation[1]).

(3) Information on the label of the package must be stated in the official language.

Article 5

Testing of substances

Testing of substances shall be carried out in compliance with requirements provided for in specific regulations[2]).

Article 6

Safety data sheet

(1) Whenever the supplier of a substance or mixture is under obligation to prepare a safety data sheet in accordance with a specific regulation[3]) he shall supply it in the official language to any recipient of the substance or mixture and to the National Toxicological Information Centre[18]).

(2) The supplier shall without delay update the safety data sheet[19]), forwarding its revised version within five working days from the date of its updating at the latest to any recipient whom he has been supplying with the substance or mixture for the last 12 months and to the National Toxicological Information Centre.

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[16]) Article 2 (7) of the Regulation (EC) No 1272/2008, as amended.
[17]) Article 2 (8) of the Regulation (EC) No 1272/2008, as amended.
[18]) Article 21 of the Act No 523/2004 Coll. on budgetary rules of public administration and on amendment of certain Acts, as subsequently amended.
[19]) Article 31 (9) of the Regulation (EC) No 1907/2006, as amended.

PART THREE

PLACING ON THE MARKET OF SUBSTANCES, MIXTURES, ARTICLES AND DETERGENTS

Article 7

Placing on the market of substances, mixtures and articles

(1) The placing on the market of substances, mixtures and articles[20]) shall be subject to specific regulations[4]).

(2) Where the mixture is a biocidal product or plant protection product, its placing on the market shall be subject to further specific regulations[21]).

(3) The list of no-longer polymers which have been assigned an European Community number shall be established by a generally binding regulation to be issued by the Ministry of Economy of the Slovak Republic (hereinafter only "Ministry of Economy").

(4) The European Inventory of Existing Commercial Chemical Substances shall be established by a generally binding regulation to be issued by the Ministry of Economy.

(5) Any particulars concerning general requirements on classification, labeling and packaging of dangerous substances and mixtures shall be established by a generally binding regulation to be issued by the Ministry of Economy.

Article 8

Placing on the market of detergents and surfactants intended for use in detergents

(1) The placing on the market of detergents and surfactants intended for use in detergents shall be subject to a specific regulation[5]).

(2) Manufacturers[22]) placing on the market detergents and surfactants shall be obliged

a) to classify, label and package detergents pursuant to this Act and pursuant to specific regulations[23]);

b) to provide to the National Toxicological Information Centre data sheet on detergent ingredients[24]).

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[20]) Article 2 (18) of the Regulation (EC) No 1272/2008, as amended.

[21]) Act No 217/2003 Coll. on conditions applicable to the placing of biocidal products on the market and on amendment of certain Acts, as subsequently amended.
Act No 193/2005 Coll. on plant health care, as subsequently amended.
Ordinance of the Government of the Slovak Republic No 152/2007 Coll. laying down details concerning the authorisation dossier for a biocidal product and details concerning the registration dossier for a low-risk biocidal product and detailed specification of data to be submitted before the placing on the market of a biocidal product and detailed specification of data to be submitted before the placing on the market of a low-risk biocidal product.
Ordinance of the Government of the Slovak Republic No 316/2007 Coll. laying down requirements for the dossier for active substances and plant protection products and uniform principles of expert assessment and registration of plant protection products.
Ordinance of the Government of the Slovak Republic No 373/2008 Coll. laying down requirements for placing on the market of plant protection products, as subsequently amended.

[22]) Article 2 (10) of the Regulation (EC) No 648/2004, as amended.

[23]) Regulation (EC) No 1272/2008, as amended.
Article 11 of the Regulation (EC) No 648/2004, as amended.

[24]) Article 9 (3) of the Regulation (EC) No 648/2004, as amended.

(3) Whenever the surfactants contained in detergents do not fulfill the requirement as regards biological degradability pursuant to a specific regulation[25]) they shall send to the Centre for Chemical Substances and Preparations (hereinafter only "the Centre") the application for the granting of derogation together with the dossier justifying the granting of such derogation for biological degradability pursuant to a specific regulation[26]).

[25]) Article 4 (2) of the Regulation (EC) No 648/2004, as amended.
[26]) Article 5 of the Regulation (EC) No 648/2004, as amended.

PART FOUR

GOOD LABORATORY PRACTICE

Article 9

Principles of Good Laboratory Practice

(1) Principles of Good Laboratory Practice constitute the quality system relating to organizational processes and conditions under which non-clinical studies are planned, performed, verified, recorded, archived and recorded.

(2) Non-clinical studies are performed on test facilities such as laboratories, greenhouses and fields.

(3) Principles of Good Laboratory Practice serve to obtain replicable and credible results of non-clinical studies by means of physico-chemical and biological testing systems as well as data concerning health and environmental safety thereof.

(4) Principles of Good Laboratory Practice apply to testing health and environmental safety of substances contained in human medicinal products, plant protection products, cosmetic products, veterinary medicinal products, food and animal feed additives and industrial substances and mixtures and in biocidal products.

(5) Principles of Good Laboratory Practice apply to any non-clinical studies to be performed for the purpose of issuing permission allowing the placing on the market of human medicinal products, plant protection products, cosmetic products, veterinary medicinal products, food and animal feed additives and for the purpose of regulating industrial chemical substances and mixtures and biocidal products.

(6) As credible shall be considered only the results of non-clinical studies which are performed by the holder of the certificate of Good Laboratory Practice compliance (hereinafter only ”certificate”).

(7) When submitting results of non-clinical studies the certificate holder is obliged to confirm that the studies were carried out in compliance with principles of Good Laboratory Practice.

(8) As equivalent shall be considered any certificate issued by the accrediting persons of third countries.

(9) If the accrediting person is in doubt whether the laboratory of another EU Member State (hereinafter only “Member State”) claiming to comply with principles of Good Laboratory Practice has conducted non-clinical studies in compliance with principles of Good Laboratory Practice , he shall ask the respective Member State for further information or eventually for another inspection or audit to be made with respect to such non-clinical study; in addition he shall without delay communicate this fact to the Commission.

(10) The particulars concerning activity of test facilities, workload of their staff and particulars concerning activities and workload of inspectors performing inspections and verifying compliance with principles of Good Laboratory Practice shall be provided for by a generally binding regulation to be issued by the Ministry of Economy.

Article 10
Test facility

(1) The test facility wishing to apply for a certificate is required to have organizational structure ensuring compliance with principles of Good Laboratory Practice, including

a) a chart listing persons responsible for the management and operation of the test facility, including a chart listing non-clinical study directors and leading researchers and their workload description;

b) qualified personnel with training, practice and workload necessary for the conduct of the non-clinical study;

c) provision for premises, materials and apparatus necessary for the conduct of the non-clinical study;

d) adequate identification of tested substances and reference substances;

e) development of and compliance with standard operating procedures;

f) non-clinical study plan;

g) implementation of the quality assurance programme by designated personnel;

h) archiving of both valid and invalid versions of standard operating procedures, primary documents, non-clinical study plans, final non-clinical study reports.

(2) The test facility is required to have elaborated a quality assurance programme including the workload of personnel responsible for the implementation of the quality assurance programme. Such personnel report directly to the test facility management, are familiar with test procedures, are not involved in the conduct of the non-clinical study and

a) shall verify the non-clinical study plan which contains information on objectives, non-clinical tests and experiments necessary for the conduct of the non-clinical study;

b) shall verify any non-clinical study compliance with principles of Good Laboratory Practice; such verification consists of an internal inspection of:

1. non-clinical studies;
2. test facility; and
3. work processes;

c) shall keep records of internal inspections pursuant to b);

d) shall archive copies of non-clinical study plans and standard operating procedures applied on the test facility.

(3) The test facility must satisfy the terms subject which the certificate was issued throughout the period of its validity.

(4) The test facility shall forthwith inform the accredited person of any substantial changes relating to the certificate issued; such as changes concerning the subject and scope of activity, organizational changes, personnel changes directly linked with the certificate issued, changes in ownership or other legal possession of the test facility.

(5) The test facility shall enable persons authorized by the accrediting person access to premises and equipment, provide any data necessary for verification of Good Laboratory Practice compliance and give them assistance to the extent necessary for the fulfillment of their tasks.

(6) In addition to the activities stated in the preceding paragraphs, when applying the principles of Good Laboratory Practice, the test facility shall proceed in accordance with a generally binding regulation issued pursuant to Article 9 (10).

Article 11
Monitoring the principles of Good Laboratory Practice

(1) Before issuing a certificate, the accrediting person shall monitor test facility for its compliance with the National Programme pursuant to Article 12 (2) (c) by carrying out inspections and audit of non-clinical studies

(2) The monitoring of principles of Good Laboratory Practice shall be performed on behalf of the accrediting person by inspectors.

(3) While performing inspections, the inspector shall

a) keep confidentiality of business data either commercial, product related or technical, which are normally not available and either actually or potentially represent a material or immaterial value and are designated as confidential[27]);

b) prepare inspection reports while ensuring the data contained therein be made available only to inspection bodies referred to in Articles 26 to 32, and if possible, also to the test facility where the inspection is taking place or to the entity commissioning the non-clinical study;

c) verify compliance with principles of Good Laboratory Practice by any test facility claiming to apply principles of Good Laboratory Practice when testing substances pursuant to a specific regulation[28]);

d) archive records resulting from inspections of test facilities, records of non-clinical studies which were audited for national or international purposes

e) participate in training sessions; training sessions intended for inspectors must be provided for by the accrediting person;

f) participate in consultations concerning the monitoring of compliance with principles of Good Laboratory Practice including joint training activities, if necessary, together with inspectors of National Authorities monitoring compliance with principles of Good Laboratory Practice in Member States of the Organisation for Economic Cooperation and Development for the purpose of harmonizing the interpretation, application and monitoring of principles of Good Laboratory Practice;

g) avoid conflict of interests during inspections on test facilities under monitoring while auditing non-clinical studies in companies having commissioned such studies;

h) present his/her service card or letter of appointment issued by the accrediting person when entering premises where the inspection or audit of the non-clinical study is to be carried out;

i) abide by the present Act and the generally binding regulation issued pursuant to Article 9 (10) whenever performing inspection.

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[27]) Article 17 to 20 of the Commercial Code.
[28]) Regulation (ES) No 440/2008, as amended.

Article 12
National Programme

(1) The National Programme of compliance with principles of Good Laboratory Practice (hereinafter only "National Programme") shall be developed by the accrediting person.

(2) The National Programme contains

a) provisions concerning general inspections of test facilities and audit of one or several either ongoing or completed non-clinical studies;

b) provisions applicable to special inspections of test facilities or those concerning audits of non-clinical studies when requested by the inspection body referred to in Articles 25 to 31;

c) the definition of inspectors´ rights to enter test facilities and be given access to data in possession of test facilities including specimens, standard operating procedure dossiers and other documentation containing procedures with respect to verification of organizational processes and conditions applicable to planning, performing, monitoring and recording non-clinical studies, description of procedures, subsequent test facility inspections and non-clinical study audits.

Article 13
Certificate issue procedure

(1) The procedure for issuing the certificate starts on the day the accrediting person obtains written application for certificate from either a legal or natural person – entrepreneur (hereinafter only "applicant").

(2) Pursuant to paragraph (1) the application shall contain the following

a) trade name, identification number and applicant´s registered office if the applicant is a legal person; trade name, identification number, if he/she has been assigned one, and the place of business, it the applicant is a natural person – entrepreneur;

b) data concerning applicants legal form;

c) type of certificate required;

d) subject and scope of certificate required including relevant technical specifications;

e) name and surname of the person responsible for results of non-clinical studies and audits;

f) data on qualification and practical experience of applicant´s technical personnel;

g) data concerning provision for premises, apparatus and materials on the test facility;

h) applicant´s statement that

1. he/she shall make it possible for the accrediting person to verify in the form of inspection compliance with principles of Good Laboratory Practice;
2. his/her test facility satisfies conditions laid down in Article 10;
3. he/she has qualified personnel for the implementation of the quality assurance programme and an internal regulation elaborated with a view to secure adequate disposal of waste generated as a result of physico-chemical and biological testing systems
4. he/she has elaborated a list of procedures describing in what manner and by what means are to be carried tests or activities which are not specified in detail in study plans or test methods;

5. his/her computer system used for testing and auditing non-clinical studies is adequately protected against unauthorized changes or data loss;
6. he/she has developed procedures to secure archiving, keeping and storage of records and documents generated during the testing of chemical substances containing human medicinal products, plant protection products, cosmetic products, veterinary medicinal products, food and animal feed additives.

(3) To his/her application the applicant shall submit the dossier describing methods and procedures applied by the test facility.

(4) If the application for starting the procedure does not contain particulars pursuant to paragraphs (2) and (3), the accrediting person shall invite the applicant in writing to either add missing data to or remove any irregularities from the application within a fixed time limit while notifying him/her that failing this the procedure will be suspended. If the applicant fails to add the missing data or remove the irregularities within this time limit, the accrediting person shall suspend the procedure and return the application to the applicant.

(5) If the application is complete, the accrediting person shall deliver to the applicant on his request within 15 days the draft contract defining accreditation terms. With respect to the contents and form of the contract shall apply mutatis mutandis provisions of a specific regulation[29]).

(6) The accrediting person shall suspend the procedure and return the application to the applicant if the latter rejects the draft contract pursuant to paragraph (5) or the contract is not concluded for some other reason.

(7) The applicant may withdraw the application also for other reasons or without justification, however, he can do so only prior to the conclusion of the accreditation contract.

(8) In case the applicant has fulfilled all conditions under which the certificate is issued pursuant to the present Act and the generally binding regulations issued based on the present Act and specific regulations[30]), within 60 days of the completion of the inspection and audit of non-clinical studies shall issue for the sake of the applicant the certificate, delivering the copy thereof in electronic form to the Ministry of Economy and the Commission.

(9) If the applicant fails to fulfill the conditions applicable to the issue of the certificate as laid down in the present Act and the generally binding regulations issued based on the present Act and specific regulations[30]), he/she will be informed by the accrediting person that such a certificate will be not issued. The communication to this effect shall

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[29]) Articles 591 to 600 of the Commercial Code.

[30]) Act of the National Council of the Slovak Republic No 152/1995 Coll. on foodstuffs, as subsequently amended.
Act No 140/1998 Coll. on medicinal products and aids, on amendment of the Act No 455/1991n Coll. on business activities (Business Activities Act), as subsequently amended, and on amendment of the Act of the National Council of the Slovak Republic No 220/1996 Coll. on advertising, as subsequently amended.
Act No 337/1998 Coll. on veterinary care and on amendment of certain other Acts, as subsequently amended.
Act No 136/2000 Coll. on fertilizers, as subsequently amended.
Act No 217/2003 Coll., as subsequently amended.
Act No 193/2005 Coll., as subsequently amended.
Act No 271/2005 Coll. on the manufacture, placing on the market and use of feedstuffs (Feedstuffs Act).

be delivered in writing; it must contain reasons for which the issue of such certificate has been refused.

(10) The certificate shall contain

a) name of the accrediting person having issued the certificate and its seat;

b) trade name, identification number and applicant´s registered office if the applicant is a legal person; trade name, identification number, if he/she has been assigned one, and the place of business, it the applicant is a natural person – entrepreneur;

c) subject and scope indicating the respective non-clinical studies performed by the applicant;

d) name and surname of the person or persons acting in capacity of the applicant´s statutory body or as a member of the statutory body, specifying in what manner they act on behalf of the applicant;

e) certificate number and the date of its entry into force;

f) conditions of issue and validity of the certificate;

g) any further data, if needed.

(11) The certificate shall enter into force on the day which is specified therein as the date of its entry into force.

(12) The accrediting person shall keep a list of certificate holders and make it public on its website as well as in the Official Journal of the Office of Standards, Metrology and Testing of the Slovak Republic, annually as to 30 June and 31 December.

Article 14
Repealing the certificate

(1) Where during a repeated inspection targeted at compliance with principles of Good Laboratory Practice the accrediting person finds any nonconformities with respect to the certificate issued which cannot be removed on the spot, it shall invite the certificate holder within an adequate time limit which in case of laboratories will not be longer than three months and in case of greenhouses and fields not longer than the next growth period, while ordering the certificate holder to report the removal of such nonconformity. The accrediting person shall verify the removal of nonconformity by undertaking a subsequent inspection on the test facility or by performing a subsequent non-clinical study audit. At he same time it shall communicate its action to the Ministry of Economy and the Commission.

(2) If the certificate holder fails to remove nonconformities pursuant to paragraph (1), the accrediting person shall notify the certificate holder in writing of the initiation of the certificate repealing procedure.

(3) The certificate repealing procedure starts on the day of receipt by the certificate holder of the procedure initiation notification.

(4) The accrediting person shall repeal the certificate if the certificate holder

a) has failed to remove nonconformities within the fixed time limit pursuant to paragraph (1) and ceases to satisfy conditions under which the certificate has been issued;

b) has failed to inform the accrediting person on any facts stated in Article 10 (4) or if

c) has gone into liquidation.

(5) In its decision repealing the certificate the accrediting person shall state any particulars concerning differences between data contained in the certificate issued and the inspection results susceptible to influence the validity of non-clinical studies performed on the test facility.

(6) The accrediting person shall deliver the decision repealing the certificate to the certificate holder, while making it public in the Official Journal of the Office of Standards, Metrology and Testing of the Slovak Republic and forwarding a copy thereof in the electronic form to the Ministry of Economy and the Commission.

Article 15
Objections procedure

(1) The test facility or the certificate holder may object in writing to action or specific steps taken by the accrediting person in the course of the certificate issue procedure or during the certificate repealing procedure within ten days, unless a longer period has been agreed, of the notice by the inspector of irregularities as regards respective actions and procedures. The objections shall be submitted to the accrediting person without having suspensory effect.

(2) The accrediting person shall be obliged to deal with objections without delay and review the procedure or objection attacked and within 60 days take decision on any objection submitted.

(3) If the accrediting person concludes the objections are well founded, it shall arrange the removal of such irregularity at the costs of whoever may have caused it. It shall inform in writing the applicant or certificate holder of the removal of such irregularity within three days.

(4) If the accrediting person concludes objections are not well founded, it shall inform the test facility of this fact in writing within three days of the completion of the objection review.

PART FIVE

EXPORT AND IMPORT OF CERTAIN DANGEROUS SUBSTANCES AND EXPORT AND IMPORT OF CERTAIN DANGEROUS MIXTURES

Article 16

Export and import of certain dangerous substances and export and import of certain dangerous mixtures

(1) Export and import of certain dangerous substances and export and import of certain dangerous mixtures are subject to a specific regulation[6])

(2) The exporter or importer who either exports or imports certain dangerous substances or certain dangerous mixtures the use of which is restricted because of their effects on human life and health and the environment or which are subject to the interim Prior Informed Concern procedure (hereinafter only "PIC procedure")[6])

a) shall apply with the Ministry of Economy to be granted consent as to the export or import thereof;

b) shall provide the Ministry of Economy with information pursuant to a specific regulation[31]).

(3) The PIC procedure means the activity carried out by Competent Authorities of the importing country or by those of the exporting country when considering the possibilities of exporting, importing and placing on the market of certain dangerous substances or certain dangerous mixtures[32]).

(4) The import licence for certain dangerous substances or certain dangerous mixtures[6]) shall be issued by the Ministry of Economy following the positions taken by the Ministry of Environment of the Slovak Republic (hereinafter only "Ministry of Environment") and by the Ministry of Health Service of the Slovak Republic (hereinafter only "Ministry of Health Service"); the same procedure applies to certain dangerous substances or certain dangerous mixtures intended for plant protection, following the position taken by the Ministry of Land Management of the Slovak Republic (hereinafter only "Ministry of Land Management").

(5) Where certain dangerous substance or certain dangerous mixtures are exported or imported under conditions of emergency or accidents when any delay in export or import can put at risk human life and health or the environment in the country of destination and the Competent Authority of the country of destination requires so, the Ministry of Economy shall issue the licence within seven days of the receipt of the application.

(6) The export or import of a certain dangerous substance or the export or import of a certain dangerous mixture shall take place upon presentation to customs authorities of the document confirming assignment of a reference number and of accompanying documents.

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[31]) Article 9 of the Regulation (EC) No 689/2008.
[32]) Article 6 of the Regulation (EC) No 689/2008.

PART SIX
COMPETENCES OF STATE ADMINISTRATION BODIES

Article 17
State administration bodies

Pursuant to this Act and pursuant to specific regulations[11]), state administration in the sphere of classification, labeling, packaging and placing on the market of substances, substances contained in mixtures and substances in articles and concerning conditions of their use shall be carried out by

a) the Ministry of Economy,
b) the Ministry of Health Service
c) the Ministry of Environment
d) the Ministry of Land Management,
e) The Centre.

Article 18
Ministry of Economy

(1) The Ministry of Economy shall
   a) constitute the Competent Authority pursuant to a specific regulation[33]) responsible for fulfilling tasks and cooperation[11]) with the Commission and the European Chemicals Agency (hereinafter only "Agency")[34]);
   b) regulate state administration within the scope of the present Act and specific regulations[11]);
   c) in conjunction with the Ministry of Health Service, Ministry of Environment, Ministry of Land Management and the Centre secure and coordinate the fulfillment of international cooperation tasks within the scope of the present Act and specific regulations[11]);
   d) issue, following the positions taken by the Ministry of Environment, Ministry of Land Management and the Public Health Authority of the Slovak Republic (hereinafter only "Public Health Authority"), prior consent to imports of certain dangerous substances and certain dangerous mixtures and substances which are subject to PIC procedure;
   e) pursuant to a specific regulation[6]) take decisions concerning export of certain dangerous substances and certain dangerous mixtures the use of which is restricted because of their effects on human life and health and of substances subject to PIC procedure;
   f) keep records of legal or natural persons – entrepreneurs importing or importing certain dangerous substances and certain dangerous mixtures which are subject to PIC procedure;

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[33]) Article 8 (1) of the Regulation (EC) No 648/2004, as amended.
Article 121 of the Regulation (EC) No 1907/2006, as amended.
Article 21 (1) and (3) and Article 7 of the Regulation (EC) No 1102/2008 of the European Parliament and of the Council of 22 October 2008 on the banning of exports of metallic mercury and certain mercury compounds and mixtures and the safe storage of metallic mercury (OJ L 304, 14. 11. 2008).
Article 43 of the Regulation (EC) No 1272/2008, as amended.

[34]) Article 3 (18) of the Regulation (EC) No 1907/2006, as amended.

g) ensure, by means of the accrediting person, fulfillment of tasks referred to in a specific regulation issued pursuant to Article 9 (10)[30]);

h) eventually grant, if the Ministry of Defence of the Slovak Republic (hereinafter only "Ministry of Defence") requires so, derogations from provisions of specific regulations[35]) for substances contained in mixtures or substances in mixtures or substances in articles if armed forces need them to secure the defence of the country;

i) constitute an appellate body in matters where the Centre has taken decision in the first instance;

j) fulfill tasks pursuant to a specific regulation[36]).

(2) In addition to tasks stated in paragraph (1) the Ministry of Economy shall fulfill tasks pursuant to a specific regulation[37]).

Article 19
Ministry of Health Service

The Ministry of Health Service shall

a) cooperate with the Ministry of Economy in the fulfillment of tasks assigned to the Competent Authority pursuant to specific regulations[38]);

b) receive, through the National Toxicological Information Centre in the position of the Competent Authority pursuant to a specific regulation[39]), information from manufacturers or importers or downstream users placing mixtures on the market as well as information concerning proposed curative or preventive measures; in particular as a response to health risk or

c) take suitable curative measures in case of potential damage to health due to effects of substances.

Article 20
Ministry of Environment

(1) The Ministry of Environment shall

a) cooperate with the Ministry of Economy in the fulfillment of tasks assigned to the Competent Authority pursuant to a specific regulation[38])

b) take position concerning the import of certain dangerous substances and certain dangerous mixtures subject to PIC procedure based on the opinion prepared by a specific professional organisation[40]);

c) take position concerning the import of certain dangerous substances and certain dangerous mixtures based on the opinion prepared by a specific professional organization.

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[35]) Article 2 (3) of the Regulation (EC) No 1907/2006, as amended.
Article 1 (4) of the Regulation (EC) No 1272/2008, as amended.

[36]) Article 117 of the Regulation (EC) No 1907/2006, as amended.
Article 46 (2) and Article 47 of the Regulation (EC) No 1272/2008, as amended.

[37]) Articles 122 to 124 of the Regulation (EC) No 1907/2006, as amended.

[38]) Article 117 (1) and Article 121 of the Regulation (EC) No 1907/2006, as amended.
Article 43 of the Regulation (EC) No 1272/2008, as amended.

[39]) Article 45 of the Regulation (EC) No 1272/2008, as amended.

[40]) Article 2 (1) (f) of the Act No 525/2003 Coll. on public administration of environmental care and on amendment of certain Acts, as amended by the Act No 587/2004 Coll.

(2) Through the Slovak Environmental Agency seated in Bratislava the Ministry of Environment shall

a) provide the Centre upon its request with available expert opinions, information and expertises;

b) cooperate with the Centre in the sphere of environmental risk assessment;

c) fulfill tasks pursuant to specific regulations[41]) in case a substance on its own, a substance contained in a mixture or a substance in an article poses an immediate risk, which is not adequately controlled, to the environment and take suitable interim measures; it shall notify the Centre thereof;

d) cooperate with the Centre in drafting the proposal for harmonised classification and labeling of substances[42]) in relation to their effects on the environment and for their listing as persistent, bioaccumulative and toxic or very persistent and very bioaccumulative substances;

e) provide necessary support on request to the rapporteur or corapporteur if a representative of the Slovak Republic has been appointed to this position by the Commission or the Agency, supplying him/her with expertises and documents he/she needs in order to fulfill this task.

Article 21
Ministry of Land Management

(1) The Ministry of Land Management takes position concerning the import of

a) certain dangerous substances and certain dangerous mixtures intended for plant protection and determines conditions of their use;

b) certain dangerous substances and certain dangerous mixtures subject to PIC procedure.

(2) Shall cooperate with the Ministry of Economy in the fulfillment of tasks assigned to the Competent Authority pursuant to specific regulations[38]).

Article 22
The Centre

(1) The Centre is a state administration body having the status of a national authority of the Slovak Republic in the sphere of the placing on the market of substances, mixtures, detergents and biocidal products, evaluation of substances, classification, labelling, packaging of substances and mixtures within the scope of the present Act and specific regulations[43]).

(2) The Centre shall

a) constitute a Competent Authority pursuant to specific regulations[43]) responsible for the fulfillment of tasks and cooperation with the Commission and the Agency[44]);

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[41]) Article 129 of the Regulation (EC) No 1907/2006, as amended.
Article 52 of the Regulation (EC) No 1272/2008, as amended.

[42]) Article 43 (1) of the Regulation (EC) No 1272/2008, as amended.

[43]) Regulation (EC) No 678/2004, as amended.
Regulation (EC) No 1907/2006, as amended.
Regulation (EC) No 1272/2008, as amended.

[44]) Article 121 of the Regulation (EC) No 1907/2006, as amended.

b) fulfill tasks pursuant to specific regulations[45]);

c) constitute the Competent Authority responsible for proposals of harmonized classification and labelling pursuant to a specific regulation[46]);

d) provide advice to manufacturers, importers, distributors, downstream users and other parties concerned with respect to their responsibilities and obligations pursuant to the present Act and specific regulations[47]);

e) secure international exchange of information with national authorities of the member States, Commission, Agency and bodies of the Organisation for Economic Cooperation and Development and cooperates with them in risk assessment of substances as well as in obtaining and supplying relevant data and participate in session of respective Commission committees, in working sessions organized by the bodies of Member States, Commission, Agency and bodies of the Organisation for Economic Cooperation and Development;

f) cooperate with the Ministry of Economy in preparing for the Commission reports on implementation into the legal system of the Slovak Republic of legally binding acts of the European Communities and the European Union in the sphere of substances, mixtures and detergents and in preparing national legislation in the sphere of placing on the market of substances, mixtures and biocidal products;

g) obtain expert opinions from the Public Health Authority, Regional Public Health Authority seated in Banská Bystrica and from the Slovak Environmental Agency seated in Bratislava; it may obtain expert opinions from independent domestic and foreign experts, professional and scientific institutions in the matters linked with the fulfillment of its tasks;

h) cooperate with state administration bodies, inspection bodies, acting in conjunction with them within the scope of its powers pursuant to the present Act and specific regulations[43]);

i) submit to the Ministry of Economy proposal for the appointment of a member on the risk assessment Committee, socio-economic analysis Committee and Member States Committee[48]);

j) receive applications for granting derogations from the requirement on biological degradability of surfactants intended for use in detergents pursuant to Article 8 (3), examines and evaluates them and keeps the Commission informed pursuant to a specific regulation[49]).

(3) The Centre is a budget organization financially linked to the budget of the Ministry of Economy. The Centre is a service office employing civil servants who perform civil service and the employer of employees who perform activities in the public interest.

(4) The Centre is headed by the Director to be appointed or recalled by the Minister of Economy upon agreement with the Minister of Health Service and the Minister of Environment.

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[45]) Article 9 (3) and (8), Article 16, Article 20 (4), Article 22 (1) and (2), Article 36, Articles 41 to 45, Article 46 (1), (3) and (4), Articles 48 to 50, Article 51 (1) and (2), Article 59 (1) to (3) and (5), Article 64 (5), Article 66 (2), Article 69 (4) and (5), Article 72 (3), Article 73 (2), Article 87 (1), Article 103 (3), Article 111, Article 117 (1), Articles 121 to 124 of the Regulation (EC) No 1907/2006, as amended.

[46]) Article 37 and Article 43 of the Regulation (EC) No 1272/2008, as amended.

[47]) Article 124 of the Regulation (EC) No 1907/2006, as amended.
Article 44 of the Regulation (EC) No 1272/2008, as amended.

[48]) Article 85 (1) to (3) of the Regulation (EC) No 1907/2006, as amended.

[49]) Article 5 (3) of the Regulation (EC) No 648/2004, as amended.

(5) The Director of the Centre shall be only a citizen of the Slovak Republic with permanent residence in the Slovak Republic, with full legal capacity, of good character and repute, with a university degree in the required field; being of good character and repute shall be deemed whoever has not been lawfully convicted of an economic crime or of a criminal offence against property or of any other intentional criminal offence concerning professional conduct. Absence of criminal records shall be proven by an excerpt from the Criminal Register not older than three months.

Article 23
Inspection bodies

Inspection bodies are:

a) the Slovak Trade Inspection and inspectorates of the Slovak Trade Inspection,
b) the Public Health Authority, Regional Public Health Authorities and the Regional Public Health Authority seated in Banská Bystrica,
c) the Slovak Environmental Inspection and Inspectorates,
d) the National Labour Inspectorate and Labour Inspectorates,
e) the Central Mining Authority and District Mining Authorities,
f) Customs Authorities,
g) the Ministry of Defence.

Article 24
Performing inspections

(1) For the purpose of performing inspections the inspection bodies referred to in Article 23 designate their employees (hereinafter only "designated persons"). To perform inspections the inspection bodies may invite natural persons with required qualification (hereinafter only "invited persons").

(2) The legal or natural person – entrepreneur on whose premises inspection is to be carried out shall be obliged
   a) to submit to the designated persons any documents and written materials relating to the subject of inspection;
   b) to enable to the designated persons the inspection of premises where substances and mixtures are manufactured, developed, stored, sold or used in another way;
   c) to enable to the designated persons taking samples of substances, mixtures or articles to the extent and in quantity required and participate in the analysis of these samples on the spot.

(3) The legal or natural person – entrepreneur shall be entitled
   a) to take the same control samples of substances, mixtures or articles as those being taken by inspection bodies pursuant to paragraph (2) (c);
   b) to obtain a copy of the inspection protocol and make comments as to its contents.

(4) If the legal or natural person – entrepreneur disagrees with measures imposed pursuant to Article 32, he/she may submit objections which are to be incorporated in the respective inspection records or he/she may submit them in writing within three days of the imposition of these remedial measures. The objections shall be dealt with by the inspection body superior to the inspection body which has imposed

the respective measure. The decision concerning objections will be final and the superior inspection body shall deliver it to the legal or natural person – entrepreneur.

(5) The inspection bodies referred to in Article 23 shall cooperate in performing the inspections and while doing this abide by specific regulations[50]).

(6) The procedure in the matter of remedial action, administrative offences pursuant to Articles 32 to 35 shall be initiated by the inspection body which will be the first to expose the breach of obligations. The inspection bodies referred to in paragraph (5) shall inform each other whenever such a procedure has been initiated. Where the inspection bodies initiate the procedure in the matter of remedial action or administrative offences for one and the same breech of the present Act and specific regulations[11]) on the same day, the procedure will be finished and the penalty imposed

a) by the Slovak Trade Inspection in case of an offence exposed on the market;

b) by the Slovak Environmental Inspection in case of an offence exposed on the manufacturer´s premises.

(7) The inspection bodies referred to in Article 23, with the exception of Ministry of Defence, shall forward summary reports containing results of inspections performed, remedial measures and penalties imposed to the Ministry of Economy no later than 20 October 2011 while any subsequent summary reports shall be submitted every five years of the submission of the first report.

Article 25

The Slovak Trade Inspection and Inspectorates of the Slovak Trade Inspection

(1) The Slovak Trade Inspection shall

a) cooperate with the Centre, Public Health Authority, Slovak Environmental Inspection, National Labour Inspectorate, Central Mining Authority and Customs Authorities;

b) be responsible for the enforcement of obligations laid down in specific regulations[11]);

c) cooperate with inspection bodies of Member States and participate in the sessions of the Forum[51]);

d) submit to the Ministry of Economy the proposal for the appointment of Forum members[52]);

e) inform the Public Health Authority, Slovak Environmental Inspection, National Labour Inspectorate, Central Mining Authority of the results of negotiations and tasks defined at working sessions held by inspection bodies of the Member States and the Forum;

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[50]) For example the Act of the National Council of the Slovak Republic No 51/1988 Coll. on mining activity, explosives and state mining administration, as subsequently amended, the Act of the National Council of the Slovak Republic No 10/1996 Coll. on supervision of public administration, as subsequently amended, the Act No 128/2002 Coll. on state inspection of the internal market in the matters of consumer protection and on amendment of certain Acts, as subsequently amended, the Act No 525/2003 Coll., as subsequently amended, the Act No 355/2007 Coll. on protection, support and development of public health and on amendment of certain Acts, as subsequently amended.

[51]) Article 86 of the Regulation (EC) No 1907/2006, as amended.

[52]) Article 86 (1) of the Regulation (EC) No 1907/2006, as amended.

f) constitute an appellate body in the matters decided upon in the first instance by the Inspectorates.

(2) The Inspectorates of the Slovak Trade Inspection shall

a) perform inspection, pursuant to a specific regulation[53]), targeted at compliance with provisions of specific regulations[11]), the present Act and generally binding legal regulations issued on the basis of the present Act;

b) determine conditions of and fixed time limits for remedial action to remove irregularities with respect to the classification, labeling, packaging and placing on the market of substances on their own, substances contained in mixtures or substances contained in articles and with respect to their use pursuant to specific regulations[11]), to the present Act and generally binding legal regulations issued on the basis of the present Act[11]);

c) impose remedial action to remove illegal conditions pursuant to Article 32 in the field of classification, labeling, packaging and placing on the market of substances on their own, substances contained in mixtures or substances contained in articles or as regards their use; if there is a potential risk of damage to health and the environment, or if such damage has already occurred, shall eventually impose the disposal of the respective dangerous substance or dangerous mixture or dangerous article at the costs of their owner or holder, if the identity of the owner is not known, and impose fines pursuant to Articles 33 to 35.

d) cooperate with the Centre, Regional Public Health Authorities, Slovak Environmental Inspection, Labour Inspectorates, District Mining Authorities and with Customs Authorities.

Article 26

The Public Health Authority, Regional Public Health Authorities and the Regional Public Health Authority seated in Banská Bystrica

(1) The Public Health Authority shall

a) supply the Centre with information where in performance of national health supervision and inspection by Regional Public Health Authorities pursuant to specific regulations[54]) it finds the registered substances pose potential threat to human health[55]);

b) constituter an appellate body in the matters decided upon in the first instance by the Regional Public Health Authority;

c) take position with respect to the import of certain dangerous substances and certain dangerous mixtures subject to PIC procedure;

d) inform the Ministry of Health Service of any interim measures taken by Regional Public Health Authorities;

e) fulfill, based on interim measures taken by Regional Public Health Authorities pursuant to paragraph (2) (c), tasks pursuant to specific regulations[41]) whenever a substance on its own, a substance contained in a mixture or a substance contained in an article poses an immediate risk, which is not adequately controlled, to human life and health and take suitable interim measures; it shall notify the Centre thereof;

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[53]) Act No 128/2002 Coll., as subsequently amended.
[54]) Articles 5, 6, 12, 30 and 54 of the Act No 355/2007 Coll., as subsequently amended.
[55]) Article 124 (1) of the Regulation (EC) No 1907/2006, as amended.

(2) Regional Public Health Authorities shall

a) supervise, within the scope of specific regulations[54]), compliance with provisions of the present Act;

b) perform national health supervision over human health protection including health and safety at work and in particular over chemical substances classified as carcinogenic, mutagenic and toxic to reproduction and impose action pursuant to Article 32 of the present Act; if there is a potential risk of damage to human health or life or if it has already occurred, they shall eventually impose the disposal of the respective dangerous substance or dangerous mixture or dangerous article at the costs of their owner or holder, if the identity of the owner is not known, and impose fines pursuant to Articles 33 to 35.

c) take suitable interim measures concerning the restriction of a substance of its own, a substance in a mixture or a substance in an article whenever it is found that for the sake of health protection an intervention is necessary; they shall forthwith inform the Public Health Authority of the restrictive measures taken, justifying their decision and presenting scientific and technical information on which the restriction is based ;

d) cooperate with the Centre as regards effects of substances on human health;

e) provide the Public Health Authority with information whenever they find the placing on the market and use of a substance on its own, a substance contained in a mixture or a substance contained in an article poses a potential risk to human health which is not adequately controlled.

(3) the Regional Public Health Authority seated in Banská Bystrica shall

a) fulfill tasks pursuant to paragraph (2);

b) provide the Centre upon request with available expert opinions, information and expertises;

c) cooperate with the Centre in the sphere of assessment of health risks posed by substances on their own, substances in a mixture or substances in an article;

d) cooperate with the Centre to prepare the proposal for harmonised classification and labeling of substances[42]) as regards their effects on human life and health and to list substances as karcinogenic, mutagenic and toxic to reproduction or respirosensitising or as substances with similar effects;

e) eventually take suitable interim measures, stating reasons which led to this decision, where a substance or a mixture poses a serious risk to human health because of its classification, labeling or packaging[56]);

f) provide the representative of the Slovak Republic appointed by the Commission or the Agency as a rapporteur or corapporteur upon his/her request necessary support, expertises and documents he/she may need to fulfill his/her task.

Article 27

The Slovak Environmental Inspection

(1) The Head Office shall

a) cooperate with the Centre, Slovak Trade Inspection, Public Health Authority, National Labour Inspectorate, Central Mining Authority and Customs Authorities;

[56]) Article 52 of the Regulation (EC) No 1272/2008, as amended.

b) inform the Centre whenever in performing inspections pursuant to specific regulations[4]) it concludes registered substances constitute potential risk to the environment[57]);

c) constitute an appellate body in matters decided upon in the first instance by Environmental Inspectorates[57]);

(2) The Environmental Inspectorates shall

a) supervise within the scope of a specific regulation[57]) compliance with provisions of the present Act and specific regulations[4]);

b) determine conditions and fix time limits for remedial action whenever in performance of inspection[58]) it exposes irregularities with respect to manufacture and use of substances on their own, substances in mixtures and substances in articles pursuant to the present Act, legal regulations issued for the purpose of its implementation and to specific regulations[4])

c) impose remedial action to remove illegal conditions pursuant to Article 32 in the field of classification, labeling, packaging and manufacture of substances on their own, substances contained in mixtures or substances contained in articles or as regards their use; if there is a potential risk of damage to the environment, or if such damage has already occurred, shall eventually impose the disposal of the respective dangerous substance or dangerous mixture or dangerous article at the costs of their owner or holder, if the identity of the owner is not known, and impose fines pursuant to Articles 33 to 35.

Article 28

The National Labour Inspectorate and Labour Inspectorates

(1) The National Labour Inspectorate shall

a) cooperate with the Centre, Slovak Trade Inspection, Public Health Authority, Slovak Environmental Inspection, Central Mining Authority and Customs Authorities;

b) inform the Centre whenever in performing inspections pursuant to a specific regulation[59]) it concludes registered substances constitute potential risk to human health;

(2) The Labour Inspectorates shall

a) supervise within the scope of a specific regulation[59]) compliance with provisions of the present Act and specific regulations[4]);

b) cooperate with the Centre, Regional Public Health Authorities, Slovak Environmental Inspection, District Mining Authorities and Customs Authorities;

Article 29

The Central Mining Authority and District Mining Authorities

(1) The Central Mining Authority shall

a) be responsible for enforcement of duties as provided for in specific regulations[4]);

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[57]) Act No 525/2003 Coll., as subsequently amended.

[58]) Article 9 of the Act No 525/2003 Coll., as subsequently amended.

[59]) Act No 125/2006 Coll. on labour inspection and on amendment of the Act No 82/2005 Coll. on illegal work and illegal employment and on amendment of certain Acts, as subsequently amended.

b) cooperate with the Centre, Slovak Trade Inspection, Public Health Authority, Slovak Environmental Inspection, National Labour Inspectorate and Customs Authorities;

c) constitute an appellate body in the matters decided upon in the first instance by District Mining Authorities.

(2) The District Mining Authorities shall

a) supervise, pursuant to a specific regulation[60]) compliance with provisions of a specific regulation[4]) of the present Act and generally binding legal regulations issued on the basis of the present Act;

b) determine conditions and fix time limits for remedial action whenever in performing in performing inspection[61]) they expose irregularities in the placing on the market or use of substances on their own, substances in mixtures or substances in articles pursuant to the present Act and specific regulations[4]);

c) impose remedial action to remove illegal conditions pursuant to Article 32 in the field of use of substances on their own, substances contained in mixtures or substances contained in articles; if there is a potential risk of damage to human health and the environment, or if such damage has already occurred, shall eventually impose the disposal of the respective dangerous substance or dangerous mixture or dangerous article at the costs of their owner or holder, if the identity of the owner is not known, and impose fines pursuant to Articles 33 to 35.

d) Forward to the Centre available information on any potential risk posed by registered substances to human health and the environment, exposed during enforcement and monitoring.

Article 30
Customs Authorities

The Customs Authorities[62]) shall

a) supervise import and export of substances pursuant to specific regulations[6]) as well as the fulfillment of specific tasks pursuant to the present Act;

b) check the labeling and packaging of substances and mixtures being imported and exported for compliance with specific regulations[11]);

c) not release into circulation any dangerous substances on their own, dangerous substances in mixtures or dangerous substances in articles the import of which does not satisfy requirements set out in Article 16 or those stated in specific regulations[11]) save for substances imported for scientific and research purposes, for the purpose of national defence or to meet the needs of supervisory bodies;

d) submit to the Slovak Trade Inspection proposal for starting procedure whenever a breach of obligations pursuant to b) is revealed.

[60]) Act of the National Council of the Slovak Republic No 51/1988 Coll., as subsequently amended.

[61]) Articles 40 and 41 of the Act of the National Council of the Slovak Republic No 51/1988 Coll., as subsequently amended.

[62]) Article 9 of the Act No 652/2004 Coll. on state administration bodies in the field of customs and on amendment of certain Acts, as subsequently amended.

Article 31
Ministry of Defence

The Ministry of Defence shall

a) supervise compliance with the provisions of the present Act within armed forces and by legal persons falling within its constituent competences having been granted derogation from the present Act;

b) provide the Centre with information whenever it finds the use of substances, mixtures or articles within armed forces and by legal persons falling within its constituent competences pose direct risk to human health which is not adequately controlled;

c) submit to the Ministry of Economy a summary report concerning results of inspections conducted within armed forces and legal persons falling within its constituent competences as well as concerning remedial action and fines imposed over the respective calendar year as top the 31 March of the next year.

PART SEVEN
REMEDIAL ACTION AND ADMINISTRATIVE OFFENCES

Article 32
Remedial action

(1) Any legal or natural person – entrepreneur who fails to fulfill his/her obligations relating to classification, packaging or labeling as provided for by the present Act shall be obliged to bring any formalities of classification, labeling and packaging into compliance with the present Act within the time limit as set forth by the competent inspection body.

(2) Any legal or natural person – entrepreneur who fails to supply the safety data sheet pursuant to Article 6 shall be required to do so within the time limit as set forth by the competent inspection body.

(3) Any legal or natural person – entrepreneur who violates the ban or restriction with respect to placing on the market or use of a dangerous substance or dangerous mixture shall be obliged to withdraw such a dangerous substance or dangerous mixture, to which the ban or restriction apply, from the market within the time limit as set forth by the competent inspection body.

(4) Any legal or natural person – entrepreneur who violates the ban or restriction with respect to placing on the market or use of certain dangerous substances or certain dangerous mixtures shall be obliged to withdraw such dangerous substances or dangerous mixtures, to which the ban or restriction apply, from the market within the time limit as set forth by the competent inspection body.

(5) If they fail to do so within the fixed time limit pursuant to paragraphs (1) to (4) the competent inspection body shall initiate the procedure to withdraw the substance or mixture or article from the market. The appeal against the decision imposing the withdrawal of the substance or mixture or article from the market shall not have suspensory effect.

Article 33
Administrative offences

(1) Any legal or natural person – entrepreneur who place on the market substances or mixtures shall commit an administrative offence if

a) they fail to ensure for substances or mixtures to be packaged and sealed pursuant to a specific regulation[63]);

b) they fail to ensure for substances or mixtures to be labeled pursuant to Article 4;

c) they fail to prepare the safety data sheet in the official language pursuant to Article 6;

d) they fail to forward the safety data sheet prepared in the official language pursuant to a specific regulation[3]) to the National Toxicological Information Centre;

e) they fail to forward the updated safety data sheet to the National Toxicological Information Centre pursuant to Article 6;

f) they place on the market a dangerous substance or dangerous mixture without complying with requirements pursuant to Article 7.

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[63]) Article 35 of the Regulation (EC) No 1272/2008, as amended.

(2) Any legal or natural person – entrepreneur shall commit an administrative offence if prior to their placing on the market they fail to classify substances or mixtures or if they fail to conform to procedures and requirements pursuant to Article 3.

(3) Any legal or natural person – entrepreneur carrying out activities defined by a specific regulation[64]) shall commit an administrative offence if they fail to supply the Commission, Ministry of Economy and Ministry of Environment within the fixed time limit[65]) with information required as set out in a specific regulation[64]).

Article 34

(1) The manufacturer or importer shall commit an administrative offence, acting in breach of specific regulations[4]), whenever

a) they manufacture or place on the market a substance on its own, a substance in a mixture or a substance in an article without having them registered;

b) they fail to apply for registration of a substance on its own or a substance contained in a mixture;

c) they fail to apply for registration of a substance contained in articles;

d) they fail to notify the Agency of a substance contained in articles

e) the fail to provide the Agency with information on a substance manufactured or imported for the purpose of product and process orientated research and development;

f) the fail to notify the Agency of the higher threshold value which has been reached in the manufacture or import of the registered substance;

g) if they fail to assess the chemical safety of the substance and to prepare the chemical safety report;

h) if they fail to apply for registration of an isolated intermediate;

i) if they fail to apply for registration of a transported isolated intermediate;

j) they start manufacture or import of a substance or an article within the time limit of less than three weeks of application for registration;

k) they fail to update registration and classification data;

l) they fail to enquire with the Agency in case of registration of a phase-in substance or a non-phase-in substance which has not been pre-registered whether any application for registration has already been submitted with respect to the same substance;

m) they fail to minimize exposure to the substance, for which they have already been granted authorization;

n) they fail to examine within the required time limit the existing authorization for placing on the market or use of the substance;

o) they fail to indicate on the label (label, sticker) the authorization number prior to placing on the market of a substance or mixture containing such a substance for which they have been granted authorization or if they fail to put thereon respective hazard pictograms, signal words, hazard statements and precautionary statements;

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[64]) Article 6 (1) and (2) of the Regulation (EC) No 1102/2008.
[65]) Article 6 (3) of the Regulation (EC) No 1102/2008.

p) they fail to provide the Agency with information or update the same;

q) they fail to fulfill they duties within fixed time limits;

r) they manufacture, place on the market or use a substance, mixture or article without complying with defined conditions;

s) they fail to notify the Agency of substances which are subject to registration and substances which they place on the market on their own or contained in a mixture in concentration exceeding concentration limits stated in specific regulations[1]) for the purpose of inclusion of such substance in the classification and labeling inventory.

(2) The supplier shall commit an administrative offence, acting in breach of specific regulations[4]), whenever

a) he fails to supply the recipient of a substance or mixture with the safety data sheet prepared pursuant to Article 6;

b) he fails to supply the recipient on his request with the safety data sheet concerning the mixture which does not satisfy criteria for classification as dangerous;

c) he fails to update the safety data sheet;

d) he fails to supply the recipient of a substance contained in a mixture, and for which the safety data sheet need not be supplied, with information or neglects to update the same;

e) he fails to supply the recipient with information concerning an article which contains a substance satisfying criteria for safe use of the article;

f) he fails to supply the consumer of an article on his request with information enabling its safe use; or

g) he fails to collect and keep information on testing, registration, as well as other findings concerning substances, mixtures and on-site isolated intermediates.

(3) The downstream user shall commit an administrative offence, acting in breach of specific regulations[4]), whenever

a) he fails to fulfill his obligations within fixed time limits;

b) he fails to prepare the chemical safety report;

c) he fails to report to the Agency information he is supposed to as a downstream user;

d) he fails to satisfy requirements within fixed time limits;

e) he fails to supply the Agency with information within the fixed time limit;

f) he fails to minimise exposure to the substance;

g) he fails to provide for an existing authorization for use of a substance to be examined within the fixed time limit;

h) he fails to indicate on the label the authorisation number prior to placing on the market of a substance or mixture containing the substance for which he has been granted authorisation;

i) he fails to inform the Agency on the use of the substance;

j) he places on the market or uses a substance, mixture or article without fulfilling stipulated conditions;

k) he fails to notify the Agency of any substance he places on the market either on its own or contained in a mixture in concentration exceeding the concentration limits referred to in specific regulations[1]) for the purpose of inclusion of such substance in the classification and labelling inventory.

(4) The registrant shall commit an administrative offence, acting in breach of specific regulations[4]), whenever

a) he fails to specify and implement suitable measures aimed at adequately controlling risks exposed in chemical safety assessment;

b) he fails to keep or update the chemical safety report;

c) he fails to supply the Agency with information within the fixed time limit;

d) he fails to supply the Agency with information whenever manufacture or import of a substance or article is stopped or whenever the downstream user ceases to use them.

(5) The actor in the supply chain shall commit an administrative offence, acting in breach of specific regulations[4]), whenever he fails to supply the next actor in the supply chain or distributor up the supply chain with information on a substance, mixture or article he may have obtained,

(6) The distributor shall commit an administrative offence, acting in breach of specific regulations[1]), whenever he places on the market a substance on its own, a substance in a mixture or a substance contained in an article without observing imposed restrictions.

(7) The member of the Substance Information Exchange Forum shall commit an administrative offence, acting in breach of specific regulations[4]), whenever he refuses to supply the document containing data on study-related costs or whenever he refuses to supply the study itself.

(8) The employer operating on the territory of the Slovak Republic shall commit an administrative offence, acting in breach of specific regulations[4]), whenever he fails to enable his employees and the representatives thereof access to information on substances on their own, substances contained in mixtures or substances contained in articles which the employees make use of or to the effects of which they are exposed while performing their work.

Article 35

The manufacturer, importer, downstream user and supplier shall commit an administrative offence, acting in breach of specific regulations[11]), whenever they

a) they fail to report to the Ministry of Economy the export of a substance set out in a specific regulation[6]);

b) they fail to report to the Ministry of Economy the first export of a substance set out in a specific regulation[6]);

c) they fail to inform the Ministry of Economy of the quantity of a substance exported during the respective calendar year[6]);

d) they fail to supply the Ministry of Economy on its request with information on a substance pursuant to a specific regulation[6]);

e) the fail to supply either the Commission or the Agency on their request with information pursuant to a specific regulation[6]);

f) they violate stipulated conditions when exporting a substance[6]);

g) they export a substance later than six months before the end of its useful life[66]);

h) they fail to secure that the plant protection product being exported bear the label or sticker indicating specific information pursuant to a specific regulation[4]);

i) they fail to ensure that the plat protection product being exported satisfy purity requirement pursuant to specific regulations[4]);

j) they export a substance or article contrary to specific regulations[4]);

k) they fail to package and seal the substance being exported[4]), label it pursuant to Article 4 or supply the safety data sheet pursuant to Article 6;

l) they place on the market a detergent or surfactant intended for use in detergents in contrary to conditions, characteristics and threshold values defined in a specific regulation[5]);

m) they fail to keep information pursuant to a specific information[5]);

n) they fail to ensure adequate testing pursuant to Article 5 when placing the substance or mixture on the market;

o) they lack documentation pursuant to a specific regulation[5]);

p) they fail to make available to the National Toxicological Information Centre the ingredients data sheet for detergents being placed on the market[5]) in case they are manufacturers or importers of the detergent, if they change its properties or create or modify the label;

q) they fail to label the detergent[5]);

r) they manufacture, place on the market or use a substance contrary to a specific regulation[67]).

Article 36

Pursuant to Article 24 (6) the respective inspection body shall impose a fine

a) from EUR 10,000 to EUR 16,500 in case of an administrative offence pursuant to Article 33 (3), Article 34 (3) (h) and (j) and (4) (b), Article 35 (c), (g) to (i);

b) from EUR 16,501 to EUR 30,000 in case of an administrative offence pursuant to Article 33 (1) (c) to (e), Article 34 (1) (g), Article 34 (2) (b) to (d) and (g), Article 34 (3) (a), (c) to (g) and (k), Article 34 (4) (a), (c) and (d), Article 34 (5), Article 35 (a), (b), (d) to (f), (k), (m) to (p);

c) from EUR 30,001 to EUR 50,000 in case of an administrative offence pursuant to Article 33 (1) (a) and (b), Article 33 (2), Article 34 (1) (d) to (f), (k), (l), (n) and (o), Article 34 (2) (a), (e) and (f), Article 34 (3) (b) and (i), Article 34 (7) and (8), Article 35 (j), (l) and (q);

d) from EUR 50,001 to EUR 99,500 in case of an administrative offence pursuant to Article 33 (1) (f), Article 34 (1) (a) to (c), (h) to (j), (m) and (p) to (s), Article 34 (6), Article 35 (r).

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[66]) Article 13 (10) of the Regulation (EC) No 689/2008.

[67]) Article 67 of the Regulation (EC) No 1907/2006, as amended.
Annex XVII to the Regulation (EC) No 1907/2006, as amended.
Regulation (EC) No 1272/2008, as amended.

Article 37

(1) When fixing the amount of the fine account will be taken of the seriousness of the administrative offence, in particular as regards its modus operandi, its harmful effects on the human health or the environment and circumstances under which it has been committed.

(2) The responsibility for an administrative offence ceases to exist if the inspection body fails to take action on its account within two years of the day such offence was brought to its knowledge but no later than within five years of its commitment.

(3) Fines imposed by inspection bodies pursuant to the present Act shall accrue to the state budget; proceeds from any fine imposed by the Slovak Environmental Inspection shall accrue to the Environmental Fund[68]).

Article 38
Administrative fines

(1) Manufacturers, importers or distributors obstructing or hampering the performance of inspection activities by an inspection body may be imposed by the latter an administrative fine of up to EUR 3,300.

(2) If the legal or natural person – entrepreneur does not make it possible to perform the inspection of compliance with Good Laboratory Practice or prevents inspection bodies from entering the land, premises and workplaces used for testing purposes, the competent inspection body may impose an administrative fine of up to EUR 3,300.

(3) The administrative fine may be imposed repeatedly if the behaviour resulting in obstruction or hampering of inspection or supervisory activities persists despite invitation by the competent inspection body for such behaviour to be ceased or if the irregularities exposed have not been removed within the time limit fixed by the inspection body. The sum of administrative fines imposed repeatedly must not exceed EUR 16,500.

(4) The administrative fine may be imposed within two months of the day on which the behaviour pursuant to paragraphs (1) and (2) was brought to the knowledge of the respective inspection body, but no later than within one year of the day such behaviour occurred.

(5) The administrative fine imposed pursuant to the present Act shall accrue to the state budget.

[68]) Article 3 (a) of the Act No 587/2004 Coll. on the Environmental Fund and on amendment of certain Acts.

PART EIGHT
GENERAL, TRANSITIONAL AND REPEALING PROVISIONS

Article 39
General provisions

(1) Authorised persons who participate directly in inspections pursuant to the present Act shall be obliged to maintain confidentiality, may be neither employees nor members of the executive or supervisory bodies with the legal or natural person – entrepreneur who manufactures, imports, exports or places on the market substances and mixtures, not even for the period of one year following the termination of employment in a public agency.

(2) Procedure pursuant to the present Act shall be subject to general regulations on administrative procedure, save for Articles 13, 14 and 15.

Article 40
Transitional provisions

(1) The person occupying the position of the Director of the Centre pursuant to existing regulations shall be deemed as the Director of the Centre pursuant to the present Act as of the day the present Act enters into force.

(2) Rights and obligations resulting from employment and property rights as well as from other relations concerning the Centre for Chemical Substances and Preparations established pursuant to the existing Act shall pass on to the Centre pursuant to the present Act.

Transitional provisions for classification, labelling and packaging of substances effective up to 30 November 2010

Article 41
Classification of substances

(1) Any legal or natural person – entrepreneur placing on the market a substance which does not appear in a specific regulation[69]) shall be obliged to obtain all available data concerning the properties of such substance.

(2) Any legal or natural person – entrepreneur placing on the market a substance which does not appear in a specific regulation[69]) shall be obliged to provisionally classify and label the dangerous substance on the basis of available data.

(3) Any legal or natural person – entrepreneur placing on the market a substance which appears in a specific regulation[69]) shall be obliged to classify and label the substance as stated in such specific regulation.

(4) Where the substance was classified in compliance with paragraphs (1) to (3) before 1 December 2010, the manufacturers, importers and downstream users may change the classification of a substance or a mixture using the translation table contained in a specific regulation[70]).

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[69]) Annex VI Part 3 of the Regulation (EC) No 1272/2008, as amended.
[70]) Annex VII of the Regulation (EC) No 1272/2008, as amended.

Article 42
Labelling of substances

(1) The packaging of dangerous substances shall bear the following data:
   a) name of the dangerous substance;
   b) trade name, seat and telephone number of the legal person or the name and surname, permanent residence and telephone number of the natural person who places the dangerous substance on the market;
   c) warning symbols and wording of the indications of hazard;
   d) wording of the indications of specific risks;
   e) wording of the indications of safe use;
   f) EC number from the European Inventory of Existing Commercial Chemical Substances, List of New chemical Substances or List of No-longer Polymers;
   g) Weight or volume.

(2) The label on the package of a substance shall be of such dimensions in proportion to the size of the package and affixed, executed and designed in such a way as to be clearly visible for as long as the package is in use. The label on the package as well as instruction manuals, folders and other documents concerning the substance shall be indicated in the official language.

(3) Indications "non-toxic", "non-poisonous", "non-harmful to health", "non-harmful to the environment" or any other indications to the effect that the substance constitutes no hazard may not appear either on the package or on the label (label, sticker).

(4) The labels on the packages of dangerous substances shall bear warning symbols such as "explosive", "oxidizing", "highly flammable", "extremely flammable", "toxic", "very toxic", "corrosive", "harmful", "irritant" or "hazardous to the environment".

(5) Any advertisement[71]) of a dangerous substance which promotes the selling of the substance without allowing the buyer to see its labeling before the transaction has been concluded, the legal or natural person – entrepreneur shall state that the substance is dangerous.

(6) The packages of dangerous substances intended for use as laboratory chemicals shall bear the name of the dangerous substance, warning symbols, indications of weight or volume, specific risk indications and safe use indications.

Article 43
Packaging of substances

(1) Any legal or natural person – entrepreneur may place on the market dangerous substances only if the packaging thereof is adjusted in such a way that while in use they cannot escape and put at risk or cause harm to the human health or the environment.

(2) Dangerous substances shall be stored, transported and placed on the market solely in packagings strong and solid enough in relation to weight and physico-chemical properties of their contents to prevent spontaneous escape or decomposition.

[71]) Act No 147/2001 Coll. on advertising and on amendment of certain Acts, as subsequently amended.

(3) The packagings containing dangerous substances sold and made available to the consumer may not exhibit an attractive shape or decoration susceptible to mislead the consumer or arouse curiosity in children.

(4) The packagings of dangerous substances shall be clearly distinguishable from those normally used for foodstuffs[72]), feedstuffs[73]), drinking water[72]) and medicinal products[74]).

(5) The packagings of dangerous substances intended for one-time use only shall be sealed in such a way that when opened for the first time it becomes apparent the fastening has been damaged.

(6) The seal on the package containing dangerous substances intended for repeated use shall be designed in such a way that when opened it can be resealed so that the contents cannot escape.

(7) The packagings containing in any quantity extremely flammable substances, highly flammable substances, very toxic substances, toxic substances, corrosive substances and harmful substances to be retailed or made otherwise accessible to consumers shall be fitted with a seal designed in such a way that when first opened a part of the seal will be irreparably damaged. The fastenings of very toxic substances, toxic substances and corrosive substances shall be child-resistant and the packaging must bear a tactile warning of hazard for the sake of persons with impaired vision and the blind. The packagings containing extremely flammable substances, highly flammable substances and harmful substances must bear a tactile warning of hazard for the sake of persons with impaired vision and the blind.

(8) The packagings containing dangerous substances to be placed on the market shall be child-resistant and bear a tactile warning of hazard for the sake of persons with impaired vision and the blind. This measure shall not apply to aerosols classified and labelled as extremely flammable or highly flammable alone.

(9) The packagings containing dangerous substances that undergo transit transport shall comply with specific regulations[75]) applicable to international transport.

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[72]) Act of the National Council of the Slovak Republic No 152/1995 Coll., as subsequently amended.
[73]) Act No 271/2005 Coll.
[74]) Act No 140/1998 Coll., as subsequently amended.
[75]) Act No 513/2009 Coll. on railways and on amendment of certain Acts.
Act of the National Council of the Slovak Republic No 168/1996 Coll. on road transport, as subsequently amended.
Act No 8/2009 Coll. on road traffic and on amendment of certain Acts, as subsequently amended.
Act No 143/1998 Coll. on civil aviation (Aviation Act) and on amendment of certain Acts, as subsequently amended.
Act No 338/2000 Coll. on inland navigation and on amendment of certain Acts, as subsequently amended.
Act No 435/2000 Coll. on maritime navigation, as subsequently amended.
Decree of the Minister of Foreign Affairs No 64/1987 Coll. on the European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR).
Decree of the Minister of Foreign Affairs No 8/1985 Coll. on the Convention Concerning the International Carriage by Rail (COTIF).

Transitional provisions for classification, labelling and packaging of substances applicable to amendments effective from 1 December 2010 to 31 May 2015

Article 44

(1) During the period from 1 December 2010 to 31 May 2015 substances shall be classified pursuant to Article 41 and pursuant to a specific regulation[1]).

(2) During the period from 1 December 2010 to 31 May 2015 substances shall be labeled and packaged pursuant to a specific regulation[1]).

(3) Substances placed on the market before 1 December 2010 which were classified, labeled and packaged pursuant to regulations effective up to 31 March 2010 or pursuant to Article 41 up to 1 December 2012 need not be labeled and packaged pursuant to a specific regulation[1]).

(4) Where a substance was classified before 1 December 2010 pursuant to regulations effective up to 31 March 2010 or pursuant to Article 41, manufacturers, importers and downstream users can change the classification using the table contained in a specific regulation[1]).

Transitional provisions for classification, labelling and packaging of mixtures effective up to 31 May 2015

Article 45
Classification of mixtures

(1) Prior to placing on the market a mixture, any legal or natural person – entrepreneur shall be obliged to establish whether the substances contained in a mixture present one or more dangerous properties and depending on the evaluation results classify such mixture accordingly. When classifying a mixture it shall be proceeded

a) according to a conventional calculation method using concentration limits stated therein; or

b) by labeling and defining concentration limits using those stated in a specific regulation[69]); or

c) by testing in so far as the respective testing method allow to acquire knowledge on its physico-chemical properties.

(2) In case it is proven that

a) toxic effects on human life and health differ from toxicological data originating from scientifically verified sources or from those computed using the conventional calculation method, the mixture shall be classified depending on the effects on human life and health and the environment;

b) the actual effect the mixture has on human life and health and the environment is more severe and conventional calculation methods would underestimate the toxic hazard or ecotoxic hazard involved, for the purpose of classification the said more severe effect shall be taken into account;

c) the actual effect the mixture has on human life and health and the environment is milder and conventional calculation methods would overestimate the toxic hazard or ecotoxic hazard involved, for the purpose of classification the said milder effect shall be taken into account;

(3) In case of dangerous mixtures of known composition which are being classified pursuant to paragraph(1) (c), to reevaluate the hazard to human life and health and the environment the method referred to in paragraph (1) (a) shall be applied where

a) changes in the composition of the original concentration (percentage by weight) of one dangerous component or of several dangerous components shall be carried out by the legal or natural person – entrepreneur;

b) changes in the composition through replacement or addition of one or several components that may but need not be dangerous shall be carried out by the legal or natural person – entrepreneur.

(4) To assess the hazard mixtures may present to human life and health and the environment it shall be proceeded in conformity with paragraph (1) (a) with reference to the conventional calculation method and using concentration limits where

a) substances contained in mixtures are included in a specific regulation[69]) with indication of concentration limits necessary for the application of the said assessment methods;

b) substances contained in a mixture are not included in a specific regulation[69]) or appear therein without indication of concentration limits necessary for the application;

c) the mixture contains at least one substance labelled with the statement "Caution, the chemical substance has not been completely tested"; the label of such mixture must bear the warning "Caution, the mixture contains a substance which has not been completely tested".

(5) If a dangerous substance is present in a mixture in the concentration equal to 1 % or more the mixture shall be treated in the same way as very toxic substances and mixtures, toxic substances and mixtures, harmful substances and mixtures, corrosive substances and mixtures, irritant substances and mixtures, sensitizing substances and mixtures, carcinogenic substances and mixtures, reprotoxic substances and mixtures and substances and mixtures harmful to the environment, contained in the mixture.

(6) Subject to classification shall be any mixtures which contain at least one dangerous substance. Components, addition, additives or impurities present in concentration by volume or weight inferior to that stated in a specific regulation[69]).

(7) Any legal or natural person – entrepreneur who supplies to the customer a dangerous mixture shall without delay furnish him data serving for classification of the mixture or those concerning an individual dangerous substance contained therein. The customer shall at the same time undertake not to disclose such data to another customer without prior consent of the first supplier.

(8) Starting from 1 April 2010 mixtures may be classified pursuant to paragraphs (1) to (7).

(9) Where the mixture was classified pursuant to paragraphs (1) to (7) before 1 June 2015, manufacturers, importers and downstream users may change the classification of a substance or a mixture using the translation table contained in a specific regulation[70]).

Article 46
Labelling of mixtures

(1) The packaging of dangerous mixtures shall bear the following data:
   a) trade name or other name of the mixture;
   b) trade name, seat and telephone number of the legal person or the name and surname, permanent residence and telephone number of the natural person – entrepreneur who places the dangerous mixture on the market;
   c) names of substances the presence of which in a mixture led to its classification as carcinogenic, mutagenic and reprotoxic to human health;
   d) warning symbols and wording of the indications of hazard;
   e) wording of the indications of specific risks;
   f) wording of the indication of safe use;
   g) weight or volume.

(2) The label on the package of a mixture shall be of such dimensions in proportion to the size of the package and affixed, executed and designed in such a way as to be clearly visible for as long as the package is in use. The label on the package as well as instruction manuals, folders and other documents concerning the mixture shall be indicated in the official language.

(3) Indications "non-toxic", "non-poisonous", "non-harmful to health", "non-harmful to the environment" or any other indications to the effect that the mixture constitutes no hazard may not appear either on the package or on the label (label, sticker).

(4) The labels on the packages of dangerous mixtures shall bear warning symbols such as "explosive", "oxidizing", "highly flammable", "extremely flammable", "toxic", "very toxic", "corrosive", "harmful", "irritant" or "hazardous to the environment".

(5) Any advertisement[71]) of a dangerous mixture which promotes the selling of the mixture without allowing the buyer to see its labeling before the transaction has been concluded, the legal or natural person – entrepreneur shall state that the mixture is dangerous.

(6) The packages of dangerous mixtures intended for use as laboratory chemicals shall bear the name of the dangerous mixture, warning symbols, indications of weight or volume, specific risk indications and safe use indications.

(7) Starting from 1 December 2010 mixtures may be labeled pursuant to paragraphs (1) to (6).

Article 47
Packaging of mixtures

(1) Any legal or natural person – entrepreneur may place on the market dangerous mixtures only if the packaging thereof is adjusted in such a way that while in use they cannot escape and put at risk or cause harm to the human health or the environment.

(2) Dangerous mixtures shall be stored, transported and placed on the market solely in packagings strong and solid enough in relation to weight and physico-chemical properties of their contents to prevent spontaneous escape or decomposition.

(3) The packagings containing dangerous mixtures sold and made available to the consumer may not exhibit an attractive shape or decoration susceptible to mislead the consumer or arouse curiosity in children.

(4) The packagings of dangerous mixtures shall be clearly distinguishable from those normally used for foodstuffs[72]), feedstuffs[73]), drinking water[72]) and medicinal products[74]).

(5) The packagings of dangerous mixtures intended for one-time use only shall be sealed in such a way that when opened for the first time it becomes apparent the fastening has been damaged.

(6) The seal on the package containing dangerous mixtures intended for repeated use shall be designed in such a way that when opened it can be resealed so that the contents cannot escape.

(7) The packagings containing in any quantity extremely flammable mixtures, highly flammable mixtures, very toxic mixtures, toxic mixtures, corrosive mixtures and harmful mixtures to be retailed or made otherwise accessible to consumers shall be fitted with a seal designed in such a way that when first opened a part of the seal will be irreparably damaged. The fastenings of very toxic mixtures, toxic mixtures and corrosive mixtures shall be child-resistant and the packaging must bear a tactile warning of hazard for the sake of persons with impaired vision and the blind. The packagings containing extremely flammable mixtures, highly flammable mixtures and harmful mixtures must bear a tactile warning of hazard for the sake of persons with impaired vision and the blind.

(8) The packagings containing dangerous mixtures to be placed on the market shall be child-resistant and bear a tactile warning of hazard for the sake of persons with impaired vision and the blind. This measure shall not apply to aerosols classified and labelled as extremely flammable or highly flammable alone.

(9) The packagings containing dangerous mixtures that undergo transit transport shall comply with specific regulations[75]) applicable to international transport.

(10) Starting from 1 December 2010 mixtures may be packaged pursuant to paragraphs (1) to (9).

Transitional provisions for classification, labelling and packaging of mixtures applicable to amendments effective from 1 June 2015

Article 48

(1) Mixtures placed on the market before 1 June 2015 and classified, labeled and packaged pursuant to regulations effective up to 31 March 2010 and pursuant to Article 46 need not be labeled and packaged pursuant to a specific regulation[76]) starting from 1 June 2017.

(2) Where a mixture was classified before 1 June 2015 pursuant to regulations effective up to 31 March 2010 or pursuant to Article 46, manufacturers, importers and downstream users may change the classification of the mixture using the table contained in a specific regulation[77]).

[76]) Article 61 (4) of the Regulation (EC) No 1272/2008, as amended.
[77]) Article 61 (5) of the Regulation (EC) No 1272/2008, as amended.

Article 49
Repealing provisions

The following shall be repealed:

1. Act No 163/2001 Coll. on chemical substances and chemical preparations, as subsequently amended;
2. Ordinance of the Government of the Slovak Republic No 298/2007 Coll. laying down particulars concerning activity of test facilities, workload of their staff and particulars concerning activities and workload of inspectors performing inspections and verifying compliance with principles of Good Laboratory Practice;
3. Decree of the Ministry of Economy of the Slovak Republic No 515/2001 Coll. on details concerning the contents of safety data sheets;
4. Order of the Ministry of Economy of the Slovak Republic No 8/2001 List of chemical substances not subject to notification;
5. Order of the Ministry of Economy of the Slovak Republic No 2/2002 for the implementation of the Act No 163/2001 Coll. on chemical substances and chemical preparations, as amended by the Order No 214/2005, Order No 1/2006, Order No 3/2007, Order No 3/2008, Order No 1/2009 and order No 4/2009;
6. Order of the Ministry of Economy of the Slovak Republic No 8/2003 on the European Inventory on Existing Commercial Chemical Substances (EINECS) as to 1 June 2015.

Title VII
Entry into force

(1) This Act takes effect on 1 April 2010, save for titles II and IV which take effect on the day of its promulgation and for paragraph (3) of Title I which takes effect on 1 December 2010 and for paragraph (4) of Title I which takes effect on 1 June 2015.

(2) Articles 41 to 43 in Title I cease to be effective on 30. November 2010, paragraphs (44) to (47) of Title I cease to be effective on 31 May 2015 and paragraph (48) of Title I ceases to be effective on 31 May 2017.

Ivan Gašparovič in his own hand

Pavol Paška in his own hand

Robert Fico in his own hand