163/2001 Coll.

ACT
of 5 April 2001

on chemical substances and chemical preparations

Amendment: 128/2002 Coll.
Amendment: 217/2003 Coll.
Amendment: 434/2004 Coll.
Amendment: 308/2005 Coll.
Amendment: 95/2007 Coll.
Amendment: 405/2008 Coll.

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

PART ONE

GENERAL PROVISIONS

Article 1

Scope

(1) This Act lays down

a) conditions applicable to the production 1), importation and exportation 2) of chemical substances 3) (hereinafter only “substance”), substances contained in chemical preparations 4) (hereinafter only “preparation”) and substances contained in products 5) (hereinafter only “product”) and placing thereof on the market 6);

b) rights and obligations of the entrepreneur 7), it means of the manufacturer, importer, downstream user, distributor, producer of an article, supplier of a substance or preparation, recipient of a substance or preparation, supplier of an article, recipient of an article, and the registrant 8);

c) requirements for classification, packaging, labelling and use in terms of protection of human life and health and the environment pursuant to a specific regulation 9);

d) conditions applicable to the placing on the market of detergents pursuant to a specific regulation 10);

e) conditions applicable to the importation and exportation of certain dangerous substances and certain dangerous preparations pursuant to a specific regulation 11);

f) competence of public administration bodies including inspection and supervision as regards observance of provisions of this Act;

g) imposing and enforcing fines applicable for infringement of provisions of this Act and of specific regulations 12);

(2) This Act shall not apply to substances and preparations listed in a specific regulation 13).

Article 2

Definitions

For the purpose of this Act:

a) Existing substance: means a substance listed in the European Inventory of Existing Commercial Substances (hereinafter only “EINECS”);

b) New substance: means a substance which is not listed in the European Inventory of Existing Commercial Substances (EINECS);

c) 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;

d) 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 on its properties or its safety;

e) Accrediting person: 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;

f) Test facility inspection: means an on-site examination of the test facility's procedures and practices to assess the degree of compliance with Good Laboratory Practice principles. During inspections, the management structures and operational procedures of the test facility are examined;

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

h) 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.

Article 3

Dangerous chemical substances and dangerous chemical preparations

(1) Chemical substances and chemical preparations dangerous to human life and health and the environment are

(a) explosive substances and preparations,
(b) oxidizing substances and preparations,
(c) extremely flammable substances and preparations,
(d) highly flammable substances and preparations,
(e) flammable substances and preparations,
(f) very toxic substances and preparations,
(g) toxic substances and preparations,
(h) harmful substances and preparations,
(i) corrosive substances and preparations,
(j) irritant substances and preparations,
(k) sensitizing substances and preparations,
(l) carcinogenic substances and preparations,
(m) mutagenic substances and preparations,
(n) substances and preparations which are toxic for reproduction,
(o) substances and preparations which are dangerous for the environment.

(2) Chemical substances and chemical preparations dangerous for humans are substances and preparations referred to in paragraph 1 f) to n) which may cause death or acute or chronic or repeated damage to health when inhaled, ingested or absorbed through the skin.

(3) Chemical substances and chemical preparations dangerous for the environment are substances and preparations referred to in paragraph 1 o) which, provided that they enter the environment, may present an immediate or delayed danger for one or more components of the environment.

(4) The List of Dangerous Chemical Substances with prescribed classification, labelling and determined concentration limits shall be laid down by a generally binding regulation to be issued by the Ministry of Economy of the Slovak Republic (hereinafter only “the Ministry of Economy”).

(5) Testing of substances must be carried out in accordance with requirements as provided for in a specific regulation 9).

(6) The list of substances which, before entering into force of a specific regulation 9), were considered to be notified 13a), or did not comply with the definition of polymers 13b) shall be laid down by a generally binding regulation to be issued by the Ministry of Economy.

(7) Graphic representation of warning symbols for dangerous substances and dangerous preparations, the list of specific risk labels to notify of dangerous properties of a substance and the list of labels for safe use of a substance and preparation shall be laid down by a generally binding regulation to be issued by the Ministry of Economy.

PART TWO

NOTIFICATION OF NEW CHEMICAL SUBSTANCES

Article 4

Repealed from 01.11.2008

Article 5

Repealed from 01.11.2008

Article 6

Repealed from 01.11.2008

Article 7

Repealed from 01.11.2008

Article 8

Repealed from 01.11.2008

Article 9

Repealed from 01.11.2008

Article 10

Repealed from 01.11.2008

Article 11

Repealed from 01.11.2008

Article 12

Repealed from 01.11.2008

Article 12a

Repealed from 01.11.2008

PART THREE

RISK ASSESSMENT OF CHEMICAL SUBSTANCES

Article 13

Repealed from 01.11.2008

Article 14

Repealed from 01.11.2008

Article 15

Repealed from 01.11.2008

Article 16

Repealed from 01.11.2008

Article 17

Repealed from 01.11.2008

Article 18

Repealed from 01.11.2008

Article 19

Repealed from 01.11.2008

Article 20

Repealed from 01.11.2008

Article 21

Repealed from 01.11.2008

Article 22

Repealed from 01.11.2008

PART FOUR

CLASSIFICATION, LABELLING, PACKAGING OF CHEMICAL SUBSTANCES AND CHEMICAL PREPARATIONS AND THE SAFETY DATA SHEET

Article 23

Classification of chemical substances

(1) The entrepreneur who places on the market a chemical substance which appears in the Inventory of Existing Commercial Chemical Substances and which has not yet been introduced into the List of Dangerous Chemical Substances with prescribed classification, labelling and determined concentration limits (hereinafter only “the list of dangerous substances”) shall be obliged to obtain all available data concerning the properties of that chemical substance.

(2) On the basis of available data, the entrepreneur who places on the market a dangerous chemical substance (Article 3) which has not yet been introduced into the List of Dangerous Chemical Substances shall be obliged such dangerous chemical substance

a) to provisionally classify,

b) to label with warning symbols,

c) to label with wording of the respective indications concerning specific risks,

d) to label with wording of the respective indications concerning safe use.

(3) The entrepreneur who places on the market a chemical substance listed in the List of Dangerous Chemical Substances shall be obliged to classify and label that substance in accordance with respective indications in this List.

(4) Particulars related to the general classification and labelling requirements for dangerous chemical substances shall be laid down by a generally binding regulation to be issued by the Ministry of Economy.

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

Article 24

Classification of chemical preparations

(1) Prior to his placing on the market of a chemical preparation the entrepreneur shall be obliged to establish whether the chemical substances contained in a chemical preparation present one or more dangerous properties and depending on the evaluation results classify it pursuant to Article 3. In classifying a chemical preparation it shall be proceeded

a) according to a conventional calculation method using specific concentration limits stated in the List of Dangerous Substances with prescribed classification; or

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

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

(2) In case it is proved that

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

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

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

(3) In case of dangerous chemical preparations of known composition which are being classified pursuant to paragraph 1 c) to re-evaluate 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 are to be carried out by the entrepreneur;

b) changes in the composition, through replacement or addition of one component or several components that may be but need not be dangerous, are to be carried out by the entrepreneur.

(4) To evaluate the hazard chemical preparations 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) the chemical substances contained in a chemical preparation are included in the List of Dangerous Chemical Substances and labeled with concentration limits necessary for the application of the said evaluating methods;

b) the chemical substances contained in a chemical preparation are not included in the List of Dangerous Chemical Substances or appear on the List without concentration limits that are necessary for application;

c) the chemical preparation contains at least one dangerous chemical substance that bears the labeling “Caution, the chemical substance has not been completely tested”; the labeling of the chemical preparation must comprise the warning “Caution, the chemical preparation contains a chemical substance which has not been completely tested”.

(5) If a dangerous chemical substance is present in the chemical preparation in the concentration equal to 1 % or more, the preparation must be treated in the same way as other dangerous chemical substances [Article 3 f) to o)] contained in the chemical preparation.

(6) Subject to classification shall be all chemical preparations that contain at least one dangerous chemical substance (Article 3). Components, additions, additives or impurities present in concentration by volume or by weight below that stated in the List of Dangerous Chemical Substances shall not be taken into account for the purpose of classification.

(7) The entrepreneur who supplies to the customer a dangerous chemical preparation, shall without delay furnish him/her with data serving for classification of the chemical preparation or those concerning an individual dangerous chemical 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) The particulars regarding classification, packaging and labeling of dangerous chemical substances shall be laid down by a generally binding regulation to be issued by the Ministry of Economy.

Article 25

Labelling

(1) The packaging of dangerous chemical substances or of dangerous chemical preparations shall bear the following data:

a) the name of the dangerous chemical substance, the name of the dangerous chemical substance or of dangerous chemical substances contained in the chemical preparation;

b) the trade name and seat, telephone number of the legal person or the name and surname, permanent residence, telephone number of the natural person that places a dangerous chemical substance or dangerous chemical preparation on the market;

c) the warning symbols and the wording of the indications of danger;

d) the wording of the indications of the specific risk;

e) the wording of the indications of the safe use;

f) EC number; EC number to be obtained

1) from the European Inventory of Existing Commercial Chemical Substances; or
2) from the List of New Chemical Substances; or
3) from the List of Dangerous Chemical Substances with Prescribed Classification, Labelling and Determination of Concentration Limits;

g) weight or volume.

(2) The entrepreneur shall package and provisionally label the chemical substances or chemical preparations set out in Article 3 f) and g) pursuant to paragraph 1, even if these are not subject to notification.

(3) The label on the package of a chemical substance or of a chemical preparation must have such dimensions in proportion to the size of the package and be 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 products must be indicated in the official language 16).

(4) Indications “non-toxic”, “non-poisonous”, “non-harmful to health”, “non-harmful to the environment” or any other indications to the effect that that a chemical substance or a chemical preparation is not dangerous may not appear on the package or on the label (sticker) of chemical substances or chemical preparations.

(5) The labels on packages of dangerous chemical substances and dangerous chemical preparations must comprise warning symbols such as “explosive”, “oxidizing”, “highly

flammable", "toxic", "very toxic", "corrosive", "harmful", "irritant" or "dangerous for the environment".

(6) Any advertisement 13c) for a dangerous chemical substance and any advertisement for a dangerous chemical preparation which mediates the purchase of a substance or a preparation without allowing the buyer to see the labeling of such a substance or of such a preparation before the conclusion of transaction, must state that the substance or the preparation is dangerous.

(7) The particulars concerning labelling requirements in respect of specific risk and safe use of chemical substances and chemical preparations, where the volume of package does not exceed 125 ml, shall be laid down by a generally binding regulation to be issued by the Ministry of Economy.

(8) The packages of dangerous chemical substances and dangerous chemical preparations intended for use as laboratory chemicals must bear the name of the dangerous chemical substance or of the dangerous chemical preparation, warning symbol, indications of weight or volume, specific risk indication and safe use indication.

(9) The particulars concerning requirements with respect to the labelling of dangerous chemical substances and labelling of dangerous chemical preparations shall be laid down by a generally binding regulation to be issued by the Ministry of Economy.

Article 26

Packaging

(1) The entrepreneur may place dangerous chemical substances or dangerous chemical preparations on the market only if the packaging thereof is designed and adjusted in such a way that, throughout their use, the dangerous chemical substance or the dangerous chemical preparation cannot escape and put at risk or cause harm to human health or the environment.

(2) The dangerous chemical substances and dangerous chemical preparations shall be stored and placed on the market solely in packaging strong and solid enough in relation to weight and physico-chemical properties of their contents which prevents spontaneous escape or decomposition.

(3) The packaging containing dangerous chemical preparations sold or 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 packaging containing dangerous preparations must be clearly distinguishable from those normally used for foodstuffs 13d), feedstuffs 13e), drinking water 13d) and medicinal products 13f).

(5) The packaging containing dangerous chemical substances and dangerous chemical preparations intended for one-time use only must be sealed in such a way that when opened for the first time it becomes apparent that the fastening has been damaged.

(6) The seal on the package containing dangerous chemical substances and dangerous chemical preparations intended for repeated use must be designed in such a way that following its opening it can be resealed so that the contents cannot escape.

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

(8) The packaging containing dangerous chemical substances and dangerous chemical preparations [Article 3 f) to i)] to be placed on the market must be child-resistant and bear a tactile warning of danger 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 packaging containing dangerous substances and dangerous preparations that undergo transit transport must comply with specific regulations 13g) applicable to international transport.

(10) The entrepreneur shall be obliged to ask the Ministry of Economy for consent

a) to label the packaging containing chemical substances and chemical preparations in some other way, using labels (stickers) where the package is too small or otherwise unfit for labeling and cannot be labeled in accordance with Article 25 paragraph 3;

b) to label the packaging containing chemical substances and chemical preparations other than explosive, very toxic or toxic, using labels (stickers) in such a way that they will not bear respective warning symbols in so far as they contain a dangerous chemical substance in such small quantities that there is no reason to fear any danger to life and health of persons handling them, nor any danger to some other persons or the environment, but only the name of the dangerous chemical substance or of the dangerous chemical preparation;

c) to label the packaging containing chemical substances and chemical preparations which are explosive, very toxic or toxic, using labels (stickers) in such a way that they will bear only the respective warning symbols in so far as they contain the chemical substance in such small quantities that there is no reason to fear any danger to health of persons handling them, nor any danger to some other persons.

(11) The Ministry of Economy shall grant the consent pursuant to Article 10 after obtaining the opinion from the Ministry of Health Service of the Slovak Republic (hereinafter only “the Ministry of Health service”).

(12) The particulars concerning requirements with respect to the packaging of dangerous chemical substances and dangerous chemical preparations as well as those concerning technical specifications for labeling and packaging of dangerous chemical substances and dangerous chemical preparations shall be laid down by a generally binding regulation to be issued by the Ministry of Economy.

(13) The particulars concerning aerosol sprays shall be laid down by a generally binding regulation to be issued by the Ministry of Economy.

Article 27

Safety data sheet

The supplier of a substance or preparation shall be obliged to prepare a safety data sheet in accordance with a specific regulation 13h) and to supply it in the official language 16) to any recipient of the substance or preparation and to the National Toxicological Information Centre established pursuant to a specific regulation 13i).

PART FIVE

PLACING ON THE MARKET OF SUBSTANCES, PREPARATIONS AND DETERGENTS

Article 28

Placing on the market of dangerous substances and dangerous preparations

(1) The manufacturing, import, export and placing on the market or use of substances, preparations or articles cannot be prohibited, restricted or impeded if they satisfy the requirements under this Act, generally binding regulations issued for the purpose of implementation thereof and a specific regulation 9), with the exception of dangerous chemical substances the manufacture, placing on the market and use of which is restricted or prohibited pursuant to a specific regulation 23a).

(2) Substances, other than those contained in preparations pursuant to specific regulations 23b), cannot be placed on the market either on their own or in preparations if they do not satisfy the requirements for classification, labeling and packaging pursuant to Articles 23 to 26, the requirements laid down in generally binding regulations issued pursuant to Article 24 paragraph 8, Article 25 paragraph 9 and Article 26 paragraph 12, and in case of registered substances in accordance with information obtained pursuant to a specific regulation 23c).

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

(1) Manufacturers 23c) placing on the market detergents and surfactants intended for use in detergents shall be obliged

a) to classify, package and label detergents, including detergents containing a dangerous substance pursuant to Articles 23 to 26 and pursuant to a specific regulation 23d);

b) to provide to the Toxicological Information Centre detergent ingredients data sheet 23e).

(2) If manufacturers ask the Centre for Chemical Substances and Preparations (hereinafter only “the Centre”) to be granted an exemption from provisions applicable to the placing on the market of detergents and surfactants, they shall be required to submit to the Centre and to the European Commission the dossier justifying the granting of exemption according to a specific regulation 23f).

(3) The fulfilment of duties imposed pursuant to paragraphs 1 and 2 and pursuant to a specific regulation 23fa) shall be supervised by the Slovak Trade Inspection.

Article 29a

Reporting on the use of perfluorooctane sulfonates placed on the market

Entrepreneurs, the Fire and Rescue Service, In-house Fire Brigades and the Mining Rescue Service 23faa) shall, by 1 December 2008, report to the Centre in electronical form

a) processes which benefit from the exemption applicable to mist suppressants for non-decorative hard chromium (VI) plating and wetting agents for use in controlled electroplating systems where the amount of perfluorooctane sulfonates released into the environment is minimised by fully applying relevant best available techniques developed pursuant to a specific regulation 23fab) and the amounts of perfluorooctane sulfonates used in and released from them;

b) existing stocks of fire-fighting foams containing perfluorooctane sulfonates.

Article 30

Principles of Good Laboratory Practice

(1) The principles of Good Laboratory Practice constitute the quality system relating to organisational processes and conditions under which non-clinical studies are planned, performed, verified, recorded, archived and reported. Non-clinical studies are performed on test facilities such as laboratories, green houses and fields.

(2) 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.

(3) Principles of Good Laboratory Practice apply to testing chemical substances contained in human medicinal products, plant protection products, cosmetic products, veterinary medicinal products, food and animal feed additives and in industrial chemical substances and preparations and in biocidal products. Principles of good laboratory practice apply to any non-clinical studies to be performed for the purpose of issuing permission allowing placing on the market 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 preparations and biocidal products.

(4) 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 “the certificate holder”) pursuant to Article 30d paragraph 9. 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. If the accrediting person is in doubt whether the laboratory of another Member State claiming to comply with principles of Good Laboratory Practice, has conducted non-clinical studies in compliance with principles of Good Laboratory Practice, it shall ask the respective Member State for further information or, if necessary, for another inspection or audit to be made with respect to such non-clinical study. In addition, it shall without delay communicate this fact to the European Commission.

(5) As equivalent shall be considered any certificates issued by the accrediting person of a third country.

(6) 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 regulation to be issued by the Government of the Slovak Republic.

Article 30a

Test facility

(1) The test facility pursuant to Article 2 c) wishing to apply for a certificate of Good Laboratory Practice compliance (hereinafter only “certificate”) is required to have a well-established organisational 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 an elaborated quality assurance programme including the workloads 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 non-clinical studies and

a) shall verify the non-clinical study plan which contains information on objectives, non-clinical tests and experiments necessary for the conduct of a 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 any approved non-clinical study plans and standard operating procedures applied on the test facility.

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

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

(5) The test facility shall enable persons authorised by the accrediting person access to premises and equipment, provide any data necessary for verification of Good Laboratory Practice compliance and to provide them assistance to the extent necessary for the fulfilment 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 30 paragraph 6.

Article 30b

Monitoring the principles of Good Laboratory Practice

(1) Before issuing a certificate, the accrediting person shall monitor test facilities for their compliance with the principles of Good laboratory Practice and fulfilment of other tasks with respect to principles of Good laboratory Practice 23fac). It conducts the monitoring activity in accordance with the National Programme of Good Laboratory Practice Principles (hereinafter only “National Programme”) using the specific monitoring scheme for verifying compliance with principles of Good Laboratory Practice by test facilities in the form of non-clinical study inspections and audits.

(2) The monitoring of principles of Good Laboratory Practice shall be performed by the accrediting person using for that purpose an adequate number of inspectors. The inspectors must have required qualification and practical experience depending on test facilities included

in the National Programme. Moreover, the National Programme defines intervals at which Good Laboratory Practice compliance on test facilities is to be assessed, contains number and comprehensiveness of non-clinical studies performed on test facilities as well as number and type of inspections or audits required by inspection bodies referred to in Article 37c to 37i and safeguards

a) confidentiality of business information, of commercial, production or technical data which are normally not available and either actually or potentially represent a material or immaterial value and are designated as confidential 23fad) by inspectors and any other persons who may gain access to confidential information as a result of Good Laboratory Practice compliance monitoring activities;

b) that confidential data contained in inspection reports be made available only to inspection bodies referred to in Article 37c to 37i and, if possible, also to the test facility where inspection is taking place or to the entity commissioning the non-clinical study;

c) verification of Good Laboratory Practice principles compliance by any test facility claiming to apply principles of Good Laboratory Practice in testing substances pursuant to Article 3 paragraph 5;

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

(3) Inspectors with qualification and practical experience shall fulfil requirements pursuant to paragraph 2 and will be required to

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

b) participate in consultations 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 harmonising the interpretation, application and monitoring of principles of Good Laboratory Practice;

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

d) present either their service card or letter of appointment issued by the accrediting person inspection, when entering premises where the inspection or audit of non-clinical study is to be performed;

e) when performing inspections, to abide by the present Act and by a generally binding regulation issued pursuant to Article 30 paragraph 6.

Article 30c

National Programme

The National Programme contains

a) provisions on general inspections of test facilities as well as those concerning audits of one or several either on-going 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 Article 37c to 37i;

c) the definition of inspectors´ right 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 organisational 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 30d

Certificate issue procedure

(1) The procedure for issuing the certificate starts on the day the accrediting person obtains applicants written application for certificate (hereinafter only “applicant”) 23fb).

(2) The applicant can be either a legal person or a natural person – entrepreneur.

(3) Pursuant to paragraph 1, the application shall contain the following:

a) the trade name, identification number and applicant´s registered office if the applicant is a legal person; the trade name, identification number and place of business if the applicant is a natural person – entrepreneur;

b) data concerning applicant´s 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 shall make it possible for the accrediting person to verify Good Laboratory Practice compliance in the form of inspections;
2. his test facility satisfies conditions laid down in Article 30a;
3. he 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 tests;

4. he has elaborated a list of procedures describing in what manner and by what means are to be carried out tests or activities which are not specified in detail in study plans or test methods;
5. his computer system used for testing and auditing non-clinical studies is adequately protected against unauthorised changes or data loss;
6. he has developed procedures to secure archiving, keeping and storage of records and materials used during testing chemical substances contained in human medicinal products, plant protection products, cosmetic products, veterinary medicinal products, food and animal feed additives.

(4) To his application the applicant shall submit the extract form judicial records for the statutory representative of the test facility issued not later than three months ago and documentation describing methods and procedures used by the test facility.

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

(6) In response to the application the accrediting person shall deliver to the applicant within 15 days of the completion of the application the draft contract defining accreditation conditions. With respect to the contents and form of the contract shall apply mutatis mutandis provisions of the specific regulation 23fb).

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

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

(9) 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 23fc), within 60 days of the completion of the inspection and audit of non-clinical studies the accrediting person shall issue for the sake of the applicant the certificate, delivering the copy thereof in electronic form to the Ministry of Economy and the European Commission. If the applicant fails to fulfil conditions stated in Article 30a he will be informed by the accrediting person that such a certificate will not be issued. The communication to this effect shall be delivered to the applicant in writing; it must contain reasons for which the issue of such certificate has been refused.

(10) The certificate shall contain the following

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

b) applicant´s trade name and registered office or place of business together with his identification number if he has been assigned one;

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 information, if needed.

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

(12) The accrediting person shall keep a list of certificate holders and makes it public on its web site 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 30e

Repealing the certificate

(1) Where during a subsequent inspection on Good Laboratory Practice compliance the accrediting person finds any non-conformities with the certificate issued which cannot be removed on the site, it shall invite the certificate holder to do so within an adequate time limit which in case of laboratories will not be longer than three months and in case of green houses and fields longer than the next growth period, ordering the certificate holder to inform it of the removal of such non-conformity. The accrediting person shall verify the removal of non-conformity by undertaking a subsequent inspection on the test facility or by performing a non-clinical study audit. At the same time it shall inform on its procedure the bodies referred to in Article 30d paragraph 9.

(2) If the certificate holder fails to remove non-conformities 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 delivery to 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 non-conformities within the fixed time limit pursuant to paragraph 1 and does not fulfil conditions under which the certificate has been issued;

b) has failed to inform the accrediting person of any facts stated in Article 30a paragraph 4, or if

c) has gone into liquidation.

(5) 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 delivering a copy thereof in the electronic form to the bodies referred to in Article 30d paragraph 9.

(6) 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.

Article 30f

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 10 days unless a longer period has been agreed, of the notice by the inspector of irregularities in the fulfilment of specific steps. 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 action attacked; it shall take a decision on the objection submitted within 60 days at the latest.

(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 3 days.

(4) If the accrediting person concludes objections are not well founded, it shall inform the test facility in writing of this fact within 3 days of the completion of the objection review.

Article 30g

There are no generally binding administrative procedure regulations 23fca) that would apply either to certificate issue procedure or certificate repealing procedure or objections procedure pursuant to Article 30f.

PART SIX

IMPORT AND EXPORT

Article 31

Import and export of certain dangerous substances and certain dangerous preparations and the interim Prior Informed Consent procedure

(1) A specific regulation 11) applies to export and import of certain dangerous substances and certain dangerous preparations.

(2) The entrepreneur who either imports or exports certain dangerous substances or certain dangerous preparations 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 Consent procedure (hereinafter only “PIC procedure”) and which are stated in a specific regulation 11)

a) shall apply with the Ministry of Economy to be granted consent with respect to the placing thereof on the market;

b) shall provide information pursuant to a specific regulation 23fcb).

(3) The PIC procedure means an activity carried out by competent authorities of the importing country or exporting country when considering the possibilities of importing, exporting and placing on the market of certain dangerous substances or certain dangerous preparations 23fcc).

(4) The import licences for certain dangerous substances or certain dangerous preparations 23fcc) shall be issued by the Ministry of Economy following the position taken by the Ministry of Environment of the Slovak Republic (hereinafter only “Ministry of Environment”), Ministry of Health Service; the same procedure applies to certain dangerous substances or certain dangerous preparations used in plant protection products following the position taken by the Ministry of Land Management of the Slovak republic (hereinafter only “Ministry of Land Management”).

(5) Where certain dangerous substances or certain dangerous preparations are imported or exported under conditions of emergency or accidents when any delay in import or export 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) Import or export of certain dangerous substances or certain dangerous preparations shall take place upon presentation to customs authorities of the document confirming assignment of a reference number and accompanying documents.

Article 32

Repealed from 01.11.2008

PART SEVEN

COMPETENCES OF STATE ADMINISTRATION BODIES

Article 32a

State administration bodies

Pursuant to this Act, state administration in the sphere of placing on the market of substances on their own, substances contained in preparations and substances contained in articles and the use thereof is carried out by

a) Ministry of Economy,

b) Ministry of Health Service,

c) Ministry of Environment,

d) Ministry of Land Management,

e) the Centre.

Article 33

The Ministry of Economy

(1) The Ministry of Economy

a) is the competent authority pursuant to a specific regulation 23h) responsible for fulfilling tasks and cooperation with the European Commission and the European Chemical Agency 23ha) (hereinafter only “Agency”);

b) regulates state administration in the sphere of manufacturing, import, export and placing on the market of substances on their own, substances contained in preparations, substances contained in articles, detergents and biocidal products;

c) in conjunction with the Ministry of Health Service, Ministry of Environment, Ministry of Land Management and the Centre it secures and coordinates the fulfilment of international cooperation tasks in the sphere of manufacturing, use, control and free movement of substances on their own, substances contained in preparations and substances contained in articles;

d) ensures coordination of inspection activities pursuant to this Act and specific regulations 12);

e) following the position taken by the Ministry of Health Service, Ministry of Environment and Ministry of Land Management it issues prior consent to the import of certain dangerous substances and certain dangerous preparations and substances subject to PIC procedure;

f) pursuant to a specific regulation 11) it takes decisions concerning export of certain dangerous substances and certain dangerous preparations the use of which is restricted because of their effects on human life and health and substances subject to PIC procedure;

g) keeps records of entrepreneurs importing or exporting certain dangerous substances or certain dangerous preparations which are subject to PIC procedure as well as the list of certain dangerous substances or certain dangerous preparations;

h) by means of the accrediting person ensures fulfilment of tasks referred to in a specific regulation 10);

i) gives consent to exceptions with respect to packaging and labelling of substances and preparations pursuant to Article 26 paragraphs 10 and 11;

j) upon request of the Ministry of Defence of the Slovak Republic (hereinafter only "Ministry of Defence") may grant exceptions for substances on their own, substances contained in preparations or substances contained in articles if the armed forces require so to ensure the defence of the state and the use of which is either banned or restricted by a specific regulation 23a);

k) constitutes an appellate body in matters where the Centre has taken decisions.

(2) In addition to tasks stated in paragraph 1 the Ministry of Economy fulfils also the tasks set out in a specific regulation 23hb).

Article 34

The Ministry of Health Service

(1) The Ministry of Health Service cooperates with the Ministry of Economy in the fulfilment of tasks assigned to the competent authority pursuant to a specific regulation 23i).

Article 35

The Ministry of Environment

(1) The Ministry of Environment

a) cooperates with the Ministry of Economy in the fulfilment of tasks assigned to the competent authority pursuant to a specific regulation 23i);

b) takes position concerning the import of certain dangerous substances and certain dangerous preparations subject to the PIC procedure based on the opinion prepared by a specific professional organisation 23j);

c) takes position concerning the import of certain dangerous substances and certain dangerous preparations based on the opinion prepared by a specific professional organisation;

(2) The Ministry of Environment, by means of the Slovak Environmental Agency seated in Bratislava, provides the centre on its request available expert opinions, information and expertises 23k), cooperates with the Centre in the sphere of environmental risk assessment, fulfils tasks to a specific regulation 23k) and if it concludes that the placing on the market or use of a substance on its own, a substance contained in a preparation or a substance contained in an article pose a direct threat to the environment which are not adequately controlled and need to be dealt with, it fulfils tasks pursuant to a specific regulation 23k), informing thereof the Centre, it takes position concerning the substance evaluation and the proposal for harmonised classification and labelling and listing substances as persistent, bioaccumulative and toxic or very persistent and very bioaccumulative substances; if the representative of the Slovak Republic has been appointed by the European Commission or the Agency as a rapporteur or corapporteur, it will provide him on his request the necessary support, expertises and documents he needs in order to fulfil his tasks as a rapporteur or corapporteur.

Article 36

The Ministry of Land Management of the Slovak Republic

The Ministry of Land Management of the Slovak Republic takes position concerning the import of

a) certain dangerous chemical substances and certain dangerous chemical preparations intended for plant protection use and determines conditions of their use.

b) certain dangerous chemical substances and certain dangerous chemical preparations subject to PIC procedure.

Article 37

The Centre for Chemical Substances and Preparations

(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, preparations, detergents and biocidal products, classification, labelling and listing of substances as well as evaluation of substances upon their placing on the market.

(2) The Centre

a) is a competent authority pursuant to a specific regulation 23h) responsible for the fulfilment of tasks and cooperation with the European Commission and the Agency 23ha);

b) fulfils tasks pursuant to a specific regulation 23l);

c) ensures international exchange of information with national authorities of the EU Member States, the European Commission, the Agency and of the bodies of the Organisation for Economic Cooperation and Development and cooperates with them in risk assessment of substances and obtaining and supplying relevant data and participates in sessions of respective European Commission committees, working sessions organised by the bodies of the EU Member States, the European Commission, the Agency and OECD bodies;

d) cooperates with the Ministry of Economy in preparing for the European 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, preparations and detergents and in preparing nation legislation in the sphere of placing on the market of substances, preparations, biocidal products and detergents;

e) obtains expert opinions from the Public Health Authority of the Slovak Republic (hereinafter only “Public Health Authority”), regional Public Health Authority seated in Banská Bystrica and the Slovak Environmental Agency seated in Bratislava 23j); it may obtain expert opinions also from independent domestic and foreign experts, professional and scientific institutions in the matters linked with the fulfilment of its tasks;

f) in the fulfilment of the tasks resulting from specific regulations 12) it cooperates with state administration authorities, inspection bodies, providing them assistance within its competences;

g) submits to the Ministry of Economy proposals for the appointment of a member on the Risk Assessment Committee, Socio-economic analysis Committee and Member States Committee 23la);

h) by 27 December 2007 it shall communicate to the European Commission the list of

1. processes to which applies exemption pursuant to Article 29a a) and quantities of perfluorooctane sulfonates used in and released from them;
2. existing stocks of fire-fighting foams containing perfluorooctane sulfonates pursuant to Article 29a b).

(3) The Centre is a budget organisation financially linked to the budget of the Ministry of Economy. The Centre is a service office employing civil servants who perform civil service 23m) and the employer of employees who perform activities in the public interest 23n).

(4) The Centre is headed by the director to be appointed or recalled by the Minister of Economy of the Slovak Republic upon agreement of the Minister of Health service of the Slovak Republic and the Minister of Environment of the Slovak Republic.

(5) The director of the Centre may be only a citizen of the Slovak Republic with permanent residence in the Slovak Republic, legal capacity, good character and repute and university degree in the required field.

INSPECTION BODIES

Article 37a

Pursuant to this Act Inspection bodies are

a) the Slovak Trade Inspection and local inspectorates,

b) the Public Health Authority and Regional Public Health Authorities

c) the Slovak Environmental Inspection;

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 37b

Performing inspections

(1) The inspection bodies referred to in Article 37c to 37i designate for the purpose of performing inspections 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 entrepreneur on whose premises inspection is taking place shall be obliged

a) to submit to the designated persons any documents relating to the subject of inspection;

b) to enable to the designated persons the inspection of premises where substances and preparations are manufactured, developed, stored, sold or otherwise used;

c) to enable to the designated persons to take samples of substances, preparations or articles to the extent and quantity required and participate in the analysis of these samples on the spot.

(3) The entrepreneur shall be entitled

a) to take the same samples of substances, preparations or articles as those being taken by inspection bodies pursuant to paragraph 2 c);

b) to obtain a copy of the inspection protocol and to make comments to its contents.

(4) If the entrepreneur disagrees with the measures imposed pursuant to Article 40a he may submit objections which are to be recorded or he may submit them in writing within three days of imposition of these measures. The objections shall be dealt with by the inspection body superior to the inspection body which has imposed the measure. The decision concerning objections will be final and the superior inspection body shall deliver it to the entrepreneur.

(5) The inspection bodies referred to in Article 37c to 37h shall cooperate in performing the inspections and while doing this abide by specific regulations 23m).

(6) The procedure in the matter of remedial action, administrative offences pursuant to Articles 40a to 40d 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 offence concerning the placing on the market of a substance on its own, of a substance contained in a preparation or of a substance contained in an article on the same day, the procedure shall be completed and the fine 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.

Article 37c

The Slovak Trade Inspection and local inspectorates

(1) The Slovak Trade Inspection

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

b) shall cooperate with inspection bodies of the EU Member Sates and participate in the sessions of the Forum 23n);

c) shall submit to the Ministry of Economy every five years the summary report containing inspection results, remedial action and fines imposed. The first report shall be submitted by 31 March 2010;

d) shall submit to the Ministry of Economy the proposal for the appointment of Forum members 23n);

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

f) constitutes an appellate body in the matters decided upon in the first instance by local inspectorates.

(2) The local inspectorates

a) shall monitor within the scope of specific regulations 23o) compliance with provisions laid down in this Act, in generally binding legal regulations issued on the basis of this Act and specific regulations 23p);

b) shall determine conditions and fix time limits for remedial action whenever they find irregularities with respect to the placing on the market or the use of substances on their own, substances contained in preparations and substances contained in articles pursuant to this Act, its implementation legal regulations and specific regulations 23p);

c) shall impose remedial actions to remove illegal conditions pursuant to Article 40a in the sphere of the placing on the market or the use of substances on their own, substances contained in preparations and substances contained in articles if there is a potential risk to health and the environment or if such risk has already occurred, it may impose the disposal of the dangerous substance or dangerous preparation 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 Article 40e to 40 g;

d) shall maintain the system of inspections and other activities as the circumstances may require it, pursuant to a specific regulation 23r);

e) shall cooperate with the Centre, the Regional Public Health Authorities, the Slovak Environmental Inspection, the Labour Inspectorates, the District Mining Authorities and customs authorities.

Article 37d

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

(1) The Public Health Authority

a) shall supply the Centre with information where in performance of state health supervision and inspection by regional Public Health Authorities pursuant to a specific regulation 23s) it finds the registered substances pose potential threat to human health;

b) shall submit to the Ministry of Economy every five years the summary report containing inspection results, remedial action and fines imposed. The first report shall be submitted by 31 March 2010;

c) constitutes an appellate body in the matters decided upon in the first instance by regional Public health Authority;

d) shall take position with respect to the import of certain dangerous substances and certain dangerous preparations subject to PIC procedure 11);

e) shall inform the Commission, the Agency and other Member States of the fact that it has taken interim measures concerning the restriction of a substance on its own, a substance contained in a preparation or a substance contained in an article even if such a substance satisfies requirements pursuant to a specific regulation 9) or that it has been informed that the regional Public health Authority has done so, justifying its decision and presenting scientific and technical information on which such an interim measure is based 23k).

(2) The regional Public Health Authorities

a) shall monitor within the scope of a specific regulation 23s) compliance with provisions of this Act, generally binding legal regulations issued on the basis of this Act and specific regulations 12);

b) shall perform state supervision over human health protection including health and safety at work and in particular over chemical substances classified as carcinogenous, mutagenous and chemical substances harmful to reproduction and impose action pursuant to Article 40 of this Act;

c) shall impose remedial action to remove illegal conditions pursuant to Article 40 if there is a risk to human life or health or if such risk has already occurred, it may impose the disposal of the dangerous substance or dangerous preparation 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 Article 40e to 40 g;

d) shall take suitable interim measures concerning the restriction of a substance on its own, a substance contained in a preparation or a substance contained in an article even if such a substance satisfies requirements pursuant to a specific regulation 9), if it concludes that such an intervention is necessary for the protection of human health and shall forthwith inform the Centre and the Public Health Authority of measures taken, justifying its decision and presenting scientific or technical information on which the restrictive measure is based pursuant to a specific regulation 23t);

e) shall cooperate with the centre in the sphere of harmful effects on human health;

f) shall supply the Public Health Authority with information if they find that the placing on the market or use of the substance on its own, substance contained in a preparation or substance contained in an article constitutes a direct risk to human health which is not adequately controlled.

(3) The Regional Public Health Authority of the Slovak Republic seated in Banská Bystrica

a) shall provide upon request by the Centre available expert opinions, information and expertises 23t), cooperate with the Centre in the sphere of health risk assessment and substance evaluation and if it concludes that the placing on the market or the use of a substance on its own, a substance contained in a preparation or a substance contained in an article constitutes a direct risk to human health which is not adequately controlled and which needs to be dealt with, it shall inform the Centre thereof, it shall take position concerning substance evaluation and proposal for harmonising classification and labelling and listing the substance as carcinogenous, mutagenous, harmful to reproduction and reprotoxic or respirosensitizing or having other similar effects;

b) shall upon request provide necessary support, expertises and documents he needs for the fulfilment of his tasks to the representative of the Slovak Republic appointed by the European Commission or the Agency as rapporteur or corapporteur.

Article 37e

The Slovak Environmental Inspection

The Slovak Environmental Inspection

a) shall monitor within the scope of a specific regulation 23u) compliance with provisions of this Act, generally binding legal regulations issued on the basis of this Act and specific regulations 23p);

b) shall determine conditions and fix time limits for remedial action whenever in performance of inspection 23v) it finds irregularities with respect to the manufacture or use of substances on their own, substances contained in preparations and substances contained in articles pursuant to this Act, its implementation legal regulations and specific regulations 23p);

c) shall impose remedial actions to remove illegal conditions pursuant to Article 40a in the sphere of the manufacture or use of substances on their own, substances contained in preparations and substances contained in articles; if there is a potential risk to the environment or if such risk has already occurred, it may impose the disposal of the dangerous substance or dangerous preparation 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 Article 40e to 40 g;

d) shall maintain the system of inspections and other activities as the circumstances may require it, pursuant to a specific regulation 23r);

e) shall cooperate with the Centre, the Regional Public Health Authorities, the Slovak Environmental Inspection, the Labour Inspectorates, the District Mining Authorities and customs authorities;

f) shall submit to the Ministry of Environment every five years a summary report containing inspection results, imposed remedial action and fines, supplying the Ministry of Economy with a copy thereof. The first report shall be submitted by 31. March 2010;

g) shall forward to the centre information whenever in performance of inspection pursuant to a specific regulation 9) it concludes registered substances constitute a potential risk to the environment 23u).

Article 37f

The National Labour Inspectorate and Labour Inspectorates

(1) The National Labour Inspectorate

a) shall cooperate with the centre, the Slovak Trade Inspection, the Public Health Authority, the Slovak Environmental Inspection, the Central Mining Authority and customs authorities;

b) shall submit to the Ministry of Environment every five years a summary report containing inspection results, imposed remedial action and fines. The first report shall be submitted by 31. March 2010;

c) shall forward to the Centre information if in performance of inspection pursuant to a specific regulation 23w) it finds registered substances constitute potential risk to human health.

(2) The Labour Inspectorates

a) shall monitor within the scope of a specific regulation 23w) provisions of this Act, generally binding legal provisions issued on the basis of this Act and specific regulations 23p);

b) shall cooperate with the Centre, Regional Public Health Authorities, the Slovak Environmental Inspection, the District Mining Authorities and customs authorities.

Article 37g

The Central Mining Authority and District Mining Authorities

(1) The Central Mining Authority

a) shall cooperate with the centre, the Slovak Trade Inspection, the Public Health Authority, the Slovak Environmental Inspection, the Central Mining Authority and customs authorities;

b) shall every five years submit to the Ministry of Economy a summary report on inspection results, imposed remedial action and fines based on the data from District Mining Authorities. The first report shall be submitted by 31. March 2010;

c) shall forward to the Centre available information indicating whether enforcement and monitoring activities revealed any potential risk registered substances may constitute to human health and the environment, based on the data obtained from District Mining Authorities;

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

(2) The District Mining Authorities

a) shall monitor within the scope of a specific regulation 23x) compliance with provisions of this Act, generally binding legal provisions issued on the basis of this Act and a specific regulation 9);

b) shall determine conditions and fix time limits for remedial action whenever in performance of inspection 23y) they find irregularities with respect to the placing on the market or use of substances on their own, substances contained in preparations and substances contained in articles pursuant to this Act, its implementation legal regulations and a specific regulation 9);

c) shall impose remedial actions to remove illegal conditions pursuant to Article 40a in the sphere of the use of substances on their own, substances contained in preparations and substances contained in articles; if there is a potential risk to health and the environment or if such risk has already occurred, they may impose the disposal of the dangerous substance or dangerous preparation 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 Article 40e to 40 g;

d) shall maintain the system of inspections and other activities as the circumstances may require it, pursuant to a specific regulation 23r);

Article 37h

Customs Authorities

The Customs Authorities

a) shall monitor import and export of substances pursuant to specific regulations 23z as well as the fulfilment of specific tasks pursuant to this Act;

b) shall verify whether the packaging and labelling of imported and exported substances and preparations satisfy requirements pursuant to Articles 25 and 26 and those provided for by specific regulations 12);

c) shall not release into circulation dangerous substances on their own, dangerous substances contained in preparations and dangerous substances contained in articles the import of which does not satisfy requirements set out in Article 28 paragraph 2 and those stated in specific regulations 23p) save for substances imported for scientific and research purposes, for the purpose of the national defence or to meet the needs of supervisory bodies;

d) shall submit to the Slovak Trade Inspection proposal for starting procedure whenever a non-fulfilment of obligations pursuant to b) is revealed;

e) shall submit to the Ministry of Economy proposals concerning state administration management with respect to import of certain dangerous substances and certain dangerous preparations;

f) shall every five years submit to the Ministry of Economy a summary report concerning inspection results, imposed remedial action and fines. The first report shall be submitted by 31. March 2010.

Article 37i

The Ministry of Defence

The Ministry of Defence

a) shall monitor compliance with the provisions of this Act within armed forces and by legal persons falling within its constituent competences, having been granted an exception from this Act;

b) shall inform the Centre whenever it finds that the use of a substance, preparation or article within armed forces or by legal persons falling within its constituent competences represents a direct threat to human health which is not adequately controlled;

c) shall submit to the Ministry of Economy a summary report on inspection results in armed forces and legal entities falling within its constituent competences, on imposed remedial action and fines for every calendar year, as a rule to 31 March of the next year.

PART EIGHT

REMEDIAL ACTION AND ADMINISTRATIVE OFFENCES

Article 38

Repealed from 01.11.2008

Article 39

Repealed from 01.11.2008

Article 40

Repealed from 01.11.2008

Article 40a

Remedial action

(1) The entrepreneur who fails to fulfil his obligations relating to classification, packaging or labelling as provided for by this Act, shall be obliged to accomplish any formalities of classification, packaging and labelling in accordance with this Act within the time limit as defined by the competent inspection body.

(2) The entrepreneur who fails to furnish the safety data sheet pursuant to Article 27 shall be required to do so within the time limit as defined by the competent inspection body.

(3) The entrepreneur who violates the ban or restriction with respect to placing on the market or use of a dangerous substance or a dangerous preparation shall be obliged to withdraw such dangerous substance or dangerous preparation to which the ban or restriction apply from the market within the time limit as defined by the inspection body.

(4) The entrepreneur who violates the ban or restriction with respect to placing on the market or use of a certain dangerous substance or a certain dangerous preparation shall be obliged to withdraw such dangerous substance or dangerous preparation to which the ban or restriction apply from the market within the time limit as defined by the inspection body.

(5) If he fails to do so within the time limit provided for in paragraphs 1 to 4 the competent inspection body shall initiate the procedure to withdraw the substance or preparation or article from the market. The appeal against the decision imposing the withdrawal of the substance or preparation or article shall not have suspensory effect.

(6) The inspection bodies referred to in Article 37c to 37i within the framework of their inspection activities shall until 1 December 2008 monitor the fulfilment of tasks stated in Article 37b paragraph 2 a); shall inform the Centre of their findings by 1 January 2008. If the entrepreneurs or competent institutions 23faa) have failed to fulfil the notification obligation, they shall be ordered by the inspection bodies to take action aimed at fulfilling the notification obligation.

(7) If the entrepreneurs fail to take action imposed by the inspection bodies pursuant to paragraph 6, the inspection bodies shall proceed pursuant to Article 40h.

Administrative offences

Article 40b

(1) The entrepreneur placing on the market substances or preparations shall commit an administrative offence if

a) he fails to ensure for the substances or preparations to be packaged and sealed pursuant to Article 26;

b) he fails to ensure for substances or preparations to be labelled pursuant to Article 25;

c) he fails to prepare the safety data sheet pursuant to a specific regulation 9) in the official language pursuant to Article 27;

d) he fails to forward to the National Toxicological Information Centre the safety data sheet pursuant to a specific regulation 9) in the official language pursuant to Article 27;

e) repealed from 01.06.2009.

(2) The entrepreneur shall commit an administrative offence if he fails to classify substances or preparations or comply with procedures and conditions pursuant to Articles 23 and 24 prior to their placing on the market.

Article 40c

(1) The manufacturer or importer shall commit an administrative offence whenever he acts in breach of a specific regulation 9) by

a) manufacturing or placing on the market a substance on its own, a substance contained in a preparation or a substance contained in an article without having it registered;

b) failing to apply for registration of the substance on its own or the substance contained in a preparation;

c) failing to apply with the Agency for registration of a substance contained in articles;

d) failing to notify the Agency of a substance contained in articles;

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

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

g) failing to assess the chemical safety of the substance and to prepare the chemical safety report;

h) failing to apply for registration of an isolated intermediate;

i) failing to apply for registration of a transported isolated intermediate;

j) starting manufacture or import of a substance or article within the time limit of less than three weeks from the date applying for registration;

k) failing to update registration data;

l) failing to inquire with the Agency in case of registration of a phase-in substance 24) 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) failing to minimise exposure to the substance for which he has already been granted an authorisation;

n) failing to examine within the required time limit the existing authorisation for placing on the market or use of a substance;

o) failing to indicate on the label the authorisation number prior to placing on the market of a substance, preparation containing the substance for which he has been granted authorisation;

p) failing to provide the Agency with any information or by failing to update it;

q) failing to fulfil his duties in fixed time limits;

r) manufacturing, placing on the market or using a substance, preparation or article without satisfying the relevant conditions.

(2) The supplier shall commit an administrative offence whenever he acts in breach of a specific regulation 9) by

a) failing to provide the recipient of a substance or preparation on his request with the safety data sheet prepared in accordance with Article 27;

b) failing to provide the recipient on his request with the safety data sheet concerning the preparation which does not satisfy the criteria for classification as a dangerous preparation;

c) failing to update the safety data sheet;

d) failing to provide the recipient of a substance contained in a preparation and for which the safety data sheet need not be supplied with information or by failing to update it;

e) failing to provide the recipient with information concerning an article containing a substance satisfying safe use criteria for;

f) failing to provide the consumer of an article on his request with information enabling its safe use; or

g) failing to collect and keep information on testing, registration and other findings relating to substances and preparations and isolated intermediates on the site.

(3) The downstream user shall commit an administrative offence whenever he acts in breach of a specific regulation 9) by

a) failing to fulfil his obligations within fixed time limits;

b) failing to prepare a chemical safety report;

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

d) failing to satisfy requirements within fixed time limits;

e) failing to provide the Agency with information within the fixed time limit;

f) failing to minimise exposure to the substance;

g) failing to examine within the fixed time limit the existing authorisation for use of a substance;

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

i) failing to inform the Agency on the use of the substance;

j) placing on the market or using the substance, preparation or article without fulfilment of the relevant conditions.

(4) The registrant shall commit an administrative offence whenever he acts in breach of a specific regulation 9) by

a) Failing to determine and implement suitable measures aimed at adequately controlling risks revealed in chemical safety assessment;

b) failing to keep or update the chemical safety report;

c) failing to provide the Agency with information within the fixed time limit;

d) failing to provide 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 whenever he acts in breach of a specific regulation 9) by failing to provide the next actor in the supply chain or the upstream distributor with information on a substance or preparation or article he may have obtained.

(6) The distributor shall commit an administrative offence whenever he acts in breach of a specific regulation 9) by placing on the market a substance on its own, a substance contained in a preparation or a substance contained in an article without observing relevant restrictions.

(7) The participant in a Substance Information Exchange Forum (SIEF) shall commit an administrative offence whenever he acts in breach of a specific regulation 9) by refusing to supply a document containing data on study-related costs or by refusing to provide the study itself.

(8) The employer seated on territory of the Slovak Republic shall commit an administrative offence whenever he acts in breach of a specific regulation 9) by failing to enable his employees and their representatives access to information on substances on their own, substances contained in preparations or substances contained in articles which their employees use or to the effects of which they are exposed while performing their work.

Article 40d

The entrepreneur shall commit an administrative offence whenever he acts in breach of specific regulations by

a) failing to report in due course of time to the Ministry of Economy the export of a substance referred to in a specific regulation 11);

b) failing to report in due course of time to the Ministry of Economy the first export of a substance pursuant to a specific regulation 11);

c) failing to report in due course of time to the Ministry of Economy the quantity of a substance exported during the calendar year;

d) failing to provide the Ministry of Economy on its request with information on the substance pursuant to a specific regulation 11);

e) failing to provide the European Commission on its request with information pursuant to a specific regulation 23p);

f) violating relevant conditions when exporting a substance 12);

g) exporting a substance later than 6 months before the end of its useful life 12);

h) failing to secure that the plant protection product being exported bear the label indicating specific information pursuant to a specific regulation 9);

i) failing to ensure that the plant protection product being exported satisfy purity requirements pursuant to a specific regulation 9);

j) exporting a substance or article contrary to a specific regulation 9);

k) failing to package and seal the substance being exported pursuant to Article 26, to label it pursuant to Article 25 or by failing to provide the safety data sheet in breach of a specific regulation 9);

l) placing on the market a detergent or surfactant intended for use in detergents contrary to conditions, characteristics and threshold values defined in a specific regulation 9);

m) failing to keep information pursuant to a specific regulation 10);

n) failing to ensure adequate testing 9) when placing the substance or preparation on he market 10);

o) lacking documentation pursuant to a specific regulation 10);

p) failing to make available to the National Toxicological Information centre 10) the ingredients data sheet for detergents being placed on the market 10);

q) fails to label the detergent 10);

r) manufacturing, placing on the market or using a substance listed contrary to a specific regulation 25).

Article 40e

The respective inspection body pursuant to Article 37b paragraph 6

a) from 300,000 Sk to 500,000 Sk in case of an administrative offence pursuant to Article 40c paragraph 4 b) and Article 40d paragraph 1 c), g) to i);

b) from 500,001 Sk to 900,000 Sk in case of an administrative offence pursuant to Article 40b paragraph 1 c), and d), Article 40c paragraph 1 g), Article 40c paragraph 2 b) to d) and g), Article 40c paragraph 3 a), c) to e), f), h), and j), Article 40c paragraph 4 a), c) and d), Article 40c paragraph 5, Article 40d a), b), d) to f), k) m) to p);

c) from 900,001 Sk to 1 300,000 Sk in case of an administrative offence pursuant to Article 40b paragraph 1 a) and b), Article 40b paragraph 2, Article 40c paragraph 1 d) to f), l), l), n) and o), Article 40c paragraph 2 a), e) and f), Article 40c paragraph 3 b), Article 40c paragraphs 7 and 8, Article 40d j), l) and q);

d) from 1 300,001 Sk to 3 000,000 Sk in case of an administrative offence pursuant to Article 40b paragraph 1 e), Article 40c paragraph 1 a) to c), h) to j), m) and p) to r), Article 40c paragraph 6, Article 40d r).

Article 40f

(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 human health or the environment and circumstances under which it has been committed.

(2) The person ceases to be responsible for an administrative offence if the inspection body fails to take action on its account within two years of being notified thereof but no later than within 5 years of its commitment.

(3) Fines imposed by inspection bodies pursuant to this Act shall accrue to the state budget; proceeds from any fine imposed by the Slovak Environmental Inspection accrue to the Environmental Fund 26).

Article 40g

Administrative fines

(1) Any manufacturer, importer or distributor obstructing or hampering the performance of inspection activity by an inspection body may be imposed by the latter by an administrative fine of up to 100,000 Sk.

(2) If the entrepreneur does not make it possible to perform the inspection of Good Laboratory Practice compliance 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 100,000 Sk.

(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 to cease such activity or if the irregularities revealed have not been removed within the time limit fixed by the inspection body. The sum of the repeatedly imposed administrative fines must not exceed 500,000 Sk.

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

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

PART NINE

GENERAL AND TRANSITIONAL PROVISIONS

Article 41

General provisions

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

(2) Procedure pursuant to this Act shall be subject to general regulations on administrative procedure 23fca save if this Act provides for otherwise.

Article 41a

(1) Throughout the text of this Act the words “chemical substance” and “chemical preparation” shall be replaced with the words “substance” and “preparation” in the respective grammatical form save Article 24 paragraph 4 c) and Article 29 paragraph 2.

(2) Throughout the text of this Act the words “very poisonous” and “poisonous” shall be replaced with the words “very toxic” and “toxic” in all grammatical forms.

(3) Wherever in generally binding regulations reference is made to

a) “very poisonous”, it means “very toxic",

b) “poisonous” it means “toxic”.

Article 42

Transitional provisions

(1) By 28 February 2002, the entrepreneur shall be obliged to make notification to the Centre of the list of chemical substances he has placed on the market for the period of three years before this Act takes effect, in individual quantities exceeding 100 kg annually or exceeding 1 000 kg in total. For each chemical substance he/she shall indicate

a) the name of the chemical substance (IUPAC);

b) CAS number or any other number of the chemical substance, it assigned (EINECS number or EC number);

c) annual quantity of the chemical substance manufactured or imported;

d) information concerning the use or expected use of the chemical substance.

(2) The entrepreneur who has manufactured or imported or placed on the market an existing chemical substance as such or an existing chemical substance contained in a preparation in quantities exceeding 1 000 tons annually, shall by 28 February 2002 submit to the Centre a data summary on manufacture, importation and the placing on the market.

(3) The entrepreneur who has manufactured or imported or placed on the market an existing chemical substance as such or an existing chemical substance contained in a preparation in quantities exceeding 10 tons, but not exceeding 1 000 tons annually, shall by 28 February 2003 submit to the Centre a data summary on manufacture, importation and the placing on the market of that chemical substance.

(4) When placing on the market a new chemical substance or an existing chemical substance or an existing chemical preparation, the entrepreneur may, where it is justifiable and for the period starting on the day this Act takes effect up to 31 December 2003, proceed pursuant to regulations that have been hitherto in effect 26) if he/she obtains the consent to do so from the Ministry of Economy.

(5) Measures imposed by inspection bodies with a view to remedy irregularities in the sector of detergents and cleaning agents (Article 29) shall, as of 31 December 2003, not apply to

a) low-foaming alkene oxide additives on such substances as alcohols, alkylphenols, glycols, polyols, fatty acids, amides or amines used in dish-washing products;

b) alkali-resistant terminally blocked alkyl and alkyl-aryl polyglycol ethers and substances of the type referred to in a), used in cleaning agents for the food and metal-working industries.

(6) Paragraph 5 shall apply to non-ionic surfactants that will be placed on the market after this Act takes effect only if they have a higher level of biodegradability than already existing products for the same application.

Article 42a

By means of this Act are being transposed the legal Acts of the European Communities and the European Union stated in the Annex.

Article 42b

The person who fulfils the function of the director of the centre pursuant to regulations that have been hitherto in effect shall be considered as the director of the Centre pursuant to this Act as of the day it takes effect.

Article 42c

Transitional provision applying to amendments effective as of 1 November 2008

The assessment of risks new substances may represent for human life and health and the environment which is performed by the Centre pursuant to Articles 4 to 22 shall cease to be performed on 30 November 2008.

Article 43

Repealing provisions

The following shall be repealed:

Articles 10, 11 and Article 14 paragraphs 1 and 2 of the Regulation of the Government of the Slovak Republic No. 206/1988 Coll. on poisons and certain other substances harmful to health.

Article 43a

The Order of the Ministry of Economy of the Slovak Republic No. 423/2001 Coll. on particulars concerning the methods for monitoring biological degradability of surfactants contained in detergents and cleaning agents and on requirements applicable to the placing thereof on the market shall be repealed.

Article 43b

The following shall be repealed:

1. The Order of the Ministry of Economy of the Slovak Republic No. 401/2001 Coll. on particulars concerning procedures for import or export of certain dangerous chemical substances and certain dangerous chemical preparations the placing on the market of which is restricted due to their effects on human life and health and the environment, and on particulars concerning procedures for import or export of certain dangerous chemical substances and certain dangerous chemical preparations which are subject to the interim Prior Informed Consent procedure.

2. The Decree of the Ministry of Economy of the Slovak Republic No. 7/2001 The list of certain dangerous chemical substances and certain dangerous chemical preparations the placing on the market of which is restricted due to their effects on human life and health and to the environment and the list of certain dangerous chemical substances and certain dangerous chemical preparations which are subject to the interim Prior Informed Consent procedure (Announcement No. 402/2001 Coll.).

Article 43c

Repealing provisions

The following shall be repealed:

1. the Order of the Ministry of Economy of the Slovak Republic No. 331/2001 Coll. laying down particulars concerning classification and labelling of di(2-ethylhexyl)-phthalate;

2. the Order of the Ministry of Economy of the Slovak Republic No. 511/2001 Coll. on particulars concerning assessment of risks arising from existing chemical substances and new chemical substances to human life and health and to the environment;

3. the Order of the Ministry of Economy of the Slovak Republic No. 67/2002 Coll. issuing the list of certain chemical substances and certain chemical preparations the placing on the market and use of which is restricted or prohibited, as amended;

4. the Order of the Ministry of Economy of the Slovak Republic No. 13/2002 Coll. of 11 December 2002 issuing the list of existing chemical substances placed on the market and exempted from the obligation to report data on high volumes of existing chemical substances and from the obligation to report data on lower volumes of existing chemical substances (Announcement No. 12/2003 Coll.).

Article 44

This Act takes effect on 1 June 2001.

The Act No. 128/2002 Coll. took effect on 1 April 2002.

The Act No. 217/2003 Coll. took effect on 1 July 2003.

The Act No. 434/2004 Coll. took effect on 1 August 2004.

The Act No. 308/2005 Coll. took effect on 1 August 2005 save point nineteen, point twenty, Article 33 j) to l) in point twenty three, point twenty nine, point thirty one, point thirty eight, point thirty nine in Article I and save Article III which took effect on 8 October 2005 and save Article 33 m) in point twenty three, point twenty four, point thirty four, point thirty five and point forty in Article I which took effect on 1 January 2006.

The Act No. 95/2007 Coll. took effect on 1 April 2007.

The Act No. 405/2008 Coll. took effect on 1 November 2008, save Article 40c paragraph 3 g) and Article 40d f) which took effect on 1 June 2009. The provision of Article 40b paragraph 1 e) expired on 1 June 2009.

Rudolf Schuster in his own hand

Jozef Migaš in his own hand

Mikuláš Dzurinda in his own hand

ANNEX

LIST OF TRANSPOSED LEGAL ACTS OF THE EUROPEAN COMMUNITIES AND THE EUROPEAN UNION

1. Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous

substances (OJ special edition, chapter 13/vol. 1; OJ 196, 16.8.1967), as amended by Council Directive 69/81/EEC of 13.3.1969 (OJ L 68, 19.3.1969), Council Directive 70/189/EEC of 6.3.1970 (OJ L 59, 14.3.1970), Council Directive71/144/EEC of 22.3.1971 (OJ special edition, chapter 13/vol. 1; OJ L 74, 29.3.1971), Council Directive 73/146/EEC of 31.5.1973 (OJ special edition, chapter 13/vol. 2; OJ L 197, 25.6.1973), Council Directive 75/409/EEC of 24.6.1975 (OJ special edition, chapter 13/vol. 3; OJ L 183, 14.7.1975), Commission Directive 76/907/EEC of 14.7.1976 (OJ special edition, chapter 13/vol. 3; OJ L 360, 30.12.1976), Commission Directive 79/370/EEC of 30.1.1979 (OJ special edition, chapter 13/vol. 3; OJ L 88, 7.4.1979), Council Directive 79/831/EEC of 18.9.1979 (OJ special edition, chapter 13/vol. 5; OJ L 259, 15.10.1979), Council Directive 80/1189/EEC of 4.12.1980 (OJ special edition, chapter 13/vol. 6; OJ L 366, 31.12.1980), Commission Directive 81/957/EEC of 23.10.1981 (OJ special edition, chapter 13/vol. 6; OJ L 351, 7.12.1981), Commission Directive 82/232/EEC of 25.3.1982 (OJ special edition, chapter 13/vol. 6; OJ L 106, 21.4.1982), Commission Directive 83/467/EEC of 29.7.1983 (OJ special edition, chapter 13/vol. 6; OJ L 257, 16.9.1983), Commission Directive 84/449/EEC of 25.4.1984 (OJ special edition, chapter 13/vol. 7; OJ L 251, 19.9.1984), Commission Directive 86/431/EEC of 24.6.1986 (OJ special edition, chapter 13/vol. 8; OJ L 247, 1.9.1986), Council Directive 87/432/EEC of 3.8.1987 (OJ special edition, chapter 13/vol. 8; OJ L 239, 21.8.1987), Commission Directive 88/302/EEC of 18.11.1987 (OJ special edition, chapter 13/vol. 9; OJ L 133, 30.5.1988), Commission Directive 88/490/EEC of 22.7.1988 (OJ special edition, chapter 13/vol. 9; OJ L 259, 19.9.1988), Council Directive 90/517/EEC of 9.10.1990 (OJ special edition, chapter 13/vol. 10; OJ L 287, 19.10.1990), omission Directive 91/325/EEC of 1.3.1991 OJ L 180, 8.7.1991), Commission Directive 91/326/EEC of 3.3.1991 (OJ L 180, 8.7.1991), Commission Directive 91/410/EEC of 22.7.1991 (OJ special edition, chapter 13/vol. 9; OJ L 228, 17.8.1991), Commission Directive 91/632/EEC of 28.10.1991 (OJ special edition, chapter 13/vol. 13; OJ L 338, 10.12.1991), Council Directive 92/32/EEC of 30.4.1992 (OJ special edition, chapter 13/vol. 11; OJ L 154, 5.6.1992), Commission Directive 92/37/EEC of 30.4.1992 (OJ special edition, chapter 13/vol. 11; OJ L 154, 5.6.1992), Commission Directive 93/21/EEC of 27.4.1993 (OJ special edition, chapter 13/vol. 12; OJ L 110, 4.5.1993), Commission Directive 93/72/EEC of 1.9.1993 (OJ special edition, chapter 13/vol. 12; OJ L 258, 16.10.1993), Commission Directive 93/105/EC of 25.11.1993 (OJ special edition, chapter 13/vol. 12; OJ L 294, 30.11.1993), Commission Directive 93/101/EC of 11.11.1993 (OJ special edition, chapter 13/vol. 13; OJ L 13, 15.1.1994), Commission Directive 94/69/EC of 19.12.1994 (OJ special edition, chapter 13/vol. 14; OJ L 381, 31.12.1994), Commission Directive 96/54/EC of 30.7.1996 (OJ special edition, chapter 13/vol. 17; OJ L 248, 30.9.1996), Directive of the European Parliament and of the Council 96/56/EC of 3.9.1996 (OJ special edition, chapter 13/vol. 17; OJ L 236, 18.9.1996), Commission Directive 97/69/EC of 5.12.1997 (OJ special edition, chapter 13/vol. 19; OJ L 343, 13.12.1997), Commission Directive 98/73/EC of 18.9.1998 (OJ special edition, chapter 13/vol. 21; OJ L 305, 16.11.1998), Commission Directive 98/98/EC of 15.12.1998 (OJ special edition, chapter 13/vol. 22; OJ L 355, 30.12.1998), Directive of the European Parliament and of the Council 1999/33/EC of 10.5.1999 (OJ special edition, chapter 13/vol. 24; OJ L 199, 30.7.1999), Commission Directive 2000/32/EC of 19.5.2000 (OJ special edition, chapter 13/vol. 25; OJ L 136, 8.6.2000), Commission Directive 2000/33/EC of 25.4.2000 (OJ special edition, chapter 13/vol. 25; OJ L 136, 8.6.2000), Commission Directive 2001/59/EC of 6.8.2001 (OJ special edition, chapter 13/vol. 26; OJ L 225, 21.8.2001).

2. Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (OJ special edition,

chapter 13/vol. 3; OJ L 262, 27.9.1976), as amended by Council Directive 79/663/EEC of 24 July 1979 (OJ special edition, chapter 13/vol. 5; OJ L 197, 3.8.1979), Council Directive 82/806/EEC of 22 November 1982 (OJ special edition, chapter 13/vol. 6; OJ L 339, 1.12.1982), Council Directive 82/828/EEC of 3 December 1982 (OJ special edition, chapter 13/vol. 6; OJ L 350, 10.12.1982), Council Directive 83/264/EEC of 16 May 1983 (OJ special edition, chapter 13/vol. 7; OJ L 147, 6.6.1983), Council Directive 83/478/EEC of 19 September 1983 (OJ special edition, chapter 13/vol. 7; OJ L 263, 24.9.1983), Council Directive 85/467/EEC of 1 October 1985 (OJ special edition, chapter 13/vol. 8; OJ L 269, 11.10.1985), Council Directive 85/610/EEC of 20 December 1985 (OJ special edition, chapter 13/vol. 8; OJ L 375, 31.12.1985), Council Directive 89/677/EEC of 21 December 1989 (OJ special edition, chapter 13/vol. 10; OJ L 398, 30.12.1989), Council Directive 89/678/EEC of 21 December 1989 (OJ special edition, chapter 13/vol. 10; OJ L 398, 30.12.1989), Council Directive 91/157/EEC of 18 March 1991 (OJ special edition, chapter 13/vol. 10; OJ L 78, 26.3.1991), Commission Directive 98/101/EC of 22 December 1998 (OJ special edition, chapter 13/vol. 23; OJ L 1, 5.1.1999), Council Directive 91/173/EEC of 21 March 1991 (OJ special edition, chapter 13/vol. 10; OJ L 85, 5.4.1991), Council Directive 91/338/EEC of 18 June 1991 (OJ special edition, chapter 13/vol. 10; OJ L 186, 12.7.1991), Council Directive 91/339/EEC of 18 June 1991 (OJ special edition, chapter 13/vol. 10; OJ L 186, 12.7.1991), Commission Directive 91/659/EEC of 3 December 1991 (OJ special edition, chapter 13/vol. 11; OJ L 363, 31.12.1991), Directive of the European Parliament and of the Council 94/27/EC of 30 June 1994 (OJ special edition, chapter 13/vol. 13; OJ L 188, 22.7.1994), Directive of the European parliament and of the Council 94/48/EC of 7 December 1994 (OJ special edition, chapter 13/vol. 13; OJ L 331, 21.12.1994), Commission Directive 96/55/EC of 4 September 1996 (OJ special edition, chapter 13/vol. 17; OJ L 231, 12.9.1996), Commission Directive 97/10/EC of 26 February 1997 (OJ special edition, chapter 13/vol. 18; OJ L 68, 8.3.1997), Directive of the European Parliament and of the Council 97/16/EC of 10 April 1997 (OJ special edition, chapter 13/vol. 18; OJ L 116, 6.5.1997), Commission Directive 97/64/EC of 10 November 1997 (OJ special edition, chapter 13/vol. 19; OJ L 315, 19.11.1997), Directive of the European Parliament and of the Council 97/56/EC of 20 October 1997 (OJ special edition, chapter 13/vol. 19; OJ L 333, 4.12.1997), Directive of the European Parliament and of the Council 1999/43/EC of 25 May 1999 (OJ special edition, chapter 13/vol. 24; OJ L 142, 5.6.1999), Commission Directive 1999/77/EC of 26 July 1999 (OJ special edition, chapter 13/vol. 24; OJ L 207, 6.8.1999), Directive of the European Parliament and of the Council 2001/41/EC of 19 June 2001 (OJ special edition, chapter 13/vol. 26; OJ L 194, 18.7.2001), Commission Directive 2001/90/EC of 26 October 2001 (OJ special edition, chapter 13/vol. 26; OJ L 283, 27.10.2001), Commission Directive 2001/91/EC of 29 October 2001 (OJ special edition, chapter 13/vol. 26; OJ L 286, 30.10.2001), Directive of the European Parliament and of the Council 2002/45/EC of 25 June 2002 (OJ special edition, chapter 13/vol. 29; OJ L 177, 6.7.2002), Directive of the European Parliament and of the Council 2002/61/EC of 19 July 2002 (OJ special edition, chapter 13/vol. 29; OJ L 243, 11.9.2002), Commission Directive 2002/62/EC of 9 July 2002 (OJ special edition, chapter 13/vol. 29; OJ L 183, 12.7.2002), Commission Directive 2003/2/EC of 6 January 2003 (OJ special edition, chapter 13/vol. 31; OJ L 4, 9.1.2003), Commission Directive 2003/3/EC of 6 January 2003 (OJ special edition, chapter 13/vol. 31; OJ L 4, 9.1.2003), Directive of the European Parliament and of the Council 2003/11/EC of 6 February 2003 (OJ special edition, chapter 13/vol. 31; OJ L 42, 15.2.2003), Directive of the European Parliament and of the Council 2003/34/EC of 26 May 2003 (OJ special edition, chapter 13/vol. 31; OJ L 156, 25.6.2003), Directive of the European Parliament and of the Council 2003/36/EC of 26 May 2003 (OJ special edition, chapter 13/vol. 31; OJ L 156, 25.6.2003), Directive of the European Parliament and of the Council 2003/53/EC of 18 June 2003 (OJ special edition, chapter

13/vol. 31; OJ L 178, 17.7.2003), Commission Directive 2004/21/EC of 24 February 2004 (OJ special edition, chapter 13/vol. 34; OJ L 57, 25.2.2004), Commission Directive 2004/96/EC of 27 February 2004 (OJ L 301, 28.9.2004), Commission Directive 2004/98/EC of 30 September 2004 (OJ L 305, 1.10.2004), Directive of the European Parliament and of the Council 2005/59/EC of 26 October 2005 (OJ L 309, 25.11.2005), Directive of the European Parliament and of the Council 2005/69/EC of 16 November 2005 (OJ L 323, 9.12.2005), Directive of the European parliament and of the Council 2005/84/EC of 14 December 2005 (OJ L 344, 27.12.2005), Directive of the European Parliament and of the Council 2005/90/EC of 18 January 2006 (OJ L 33, 4.2.2006), Directive of the European Parliament and of the Council 2006/122/EC of 12 December 2006 (OJ L 372, 27.12.2006), Commission Directive 2006/139/EC of 20 December 2006 (OJ L 384, 29.12.2006), Directive of the European Parliament and of the Council 2007/51/EC of 25 September 2007 (OJ L 257, 3.10.2007).

3. Directive 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice (OJ special edition, chapter 15/vol. 8; OJ L 50, 20.2.2004).

4. Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (OJ special edition, chapter 15/vol. 8; OJ L 50, 20.2.2004).

5. Directive 2006/121/EC of the European Parliament and of the Council of 18 December 2006 amending Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances in order to adapt it to Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency (OJ L 396, 30.12.2006).

6. Directive 2006/122/EC of the European Parliament and of the Council of 12 December 2006 amending for the 30th time Council Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (perfluorooctane sulfonates) (OJ L 372, 27.12.2006).

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1) Article 3 paragraph 8 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).

2) Article 3 paragraph 10 of the Regulation (EC) No. 1907/2006.

3) Article 3 paragraph 1 of the Regulation (EC) No. 689/2008 of the European Parliament and of the Council of 17 June 2008 on export and import of dangerous chemicals (OJ l 204, 31.7.2008).

4) Article 3 paragraph 2 of the Regulation (EC) No. 1907/2006.
Article 2 paragraph 4 of the Regulation (EC) No. 648/2004.
Article 3 paragraph 2 of the Regulation (EC) No. 689/2008.

4a) The Act No. 217/2003 Coll. on conditions applicable to the placing of biocidal products on the market and on amendment of certain acts.

5) Article 3 paragraph 3 of the Regulation (EC) No. 1907/2006.

6) Article 3 paragraph 12 of the Regulation (EC) No. 1907/2006.

7) Article 2 paragraph 2 a) to c) of the Commercial Code.

8) Article 3 paragraphs 4, 7, 9, 11, 13, 14, 32 and 32 to 35 of the Regulation (EC) No. 1907/2006.
Article 2 paragraph 10 of the Regulation (EC) No. 648/2004.

9) Regulation (EC) No. 1907/2006.

10) Regulation (EC) No. 648/2004.

11) Regulation (EC) No. 689/2008.

12) Regulation (EC) No. 1907/2006.
Regulation (EC) No. 648/2004.
Regulation (EC) No. 689/2008.

13) Article 2 of the Regulation (EC) No. 1907/2006.
Article 3 of the Regulation (EC) No. 689/2008.

13a) Article 3 paragraph 21 of the Regulation (EC) No. 1907/2006.

13b) Article 3 paragraph 5 of the Regulation (EC) No. 1907/2006.

13c) The Act No. 147/2001 Coll. on advertising and on amendment of certain acts, as amended.

13d) The Act of the National Council of the Slovak Republic No. 152/1995 Coll. on foodstuffs, as amended.

13e) The Act No. 271/2005 Coll. on the manufacture, placing on the market and use of feedstuffs (Feedstuffs Act).

13f) The Act No. 140/1998 Coll. on medicinal products and aids, on amendment of the Act No. 455/1991 Coll. on business activities (Business Activities Act), as amended, and on amendment of the Act of the National Council of the Slovak Republic No. 220/1996 Coll. on advertising.

13g) The Act of the National Council of the Slovak Republic No. 164/1996 Coll. on railroads and on amendment of the Act No. 455/1991 Coll. on business activities (Business Activities Act), as amended.
The Act of the National Council of the Slovak Republic No. 168/1996 Coll. on road transport, as amended.
The Act No. 315/1996 Coll. on the road traffic, as amended.
The Act No. 143/1998 Coll. on civil aviation (Aviation Act) and on amendment of certain acts, as amended.
The Act No. 338/2000 Coll. on inland navigation and on amendment of certain acts, as amended.
The Act No. 435/2000 Coll. on maritime navigation, as amended.
The Order of the Minister of Foreign Affairs No. 8/1985 Coll. on the Convention Concerning International Carriage by Rail (COTIF).
The Order of the Minister of Foreign Affairs No. 64/1987 Coll. on the European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR).

13h) Article 31 of the Regulation (EC) No. 1907/2006.

13i) Article 21 of the Act No. 523/2004 Coll. on budgetary rules of public administration and on amendment of certain acts, as amended by the Act No. 548/2005 Coll.

14a) The Act No. 193/2005 Coll. on plant health care.

16) The Act of the National Council of the Slovak Republic No. 270/1995 Coll. on the official language of the Slovak Republic, as amended.

23) The Act No. 147/2001 Coll. on advertising and on amendment of certain acts.

23a) Article 67 of the Regulation (EC) No. 1907/2006.
Annexes I and II to the Regulation of the European Parliament and of the Council (EC) No. 850/2004 of 29 April 2004 on persistent organic pollutants and amending Directive 79/11/EEC (OJ special edition, chapter 15/vol. 8; OJ L 33, 8.2.1979), as amended.

23b) The Act of the National Council of the Slovak Republic No. 152/1995 Coll.; the Decree of the Ministry of Land Management of the Slovak Republic and of the Ministry of Health Service of the Slovak Republic delivering part one and chapters one, two and three of part two of the Codex Alimentarius of the Slovak Republic (Announcement No. 195/1996 Coll.); the Act No. 76/1998 Coll. on the protection of Earth´s ozone layer and on amendment of the Act No. 455/1991 Coll. on business activities (Business Activities Act), as amended; the Act No. 129/1998 Coll. on the ban of chemical weapons and on amendment of certain acts; the Act No. 139/1998 Coll. on narcotic drugs, psychotropic substances and preparations, as amended; the Act No. 140/1998 Coll.; the Act No. 337/1998 Coll. on veterinary care and on amendment of certain other acts, as amended; the Act No. 136/2000 Coll. on fertilizers, as amended; the Act No. 217/2003 Coll. on conditions applicable to the placing of biocidal products on the market and on amendment of certain acts; the Act No. 271/2005 Coll.; the Act No. 331/2005 Coll. on State administration authorities in the matters of drug precursors and on amendment of certain acts; the Act No. 355/2007 Coll. on protection, support and development of public health and on amendment of certain acts.

23c) Articles 12 and 13 of the Regulation (EC) No. 1907/2006.

23d) Article 11 of the Regulation (EC) No. 648/2004.

23e) Article 9 paragraph 3 of the Regulation (EC) No. 648/2004.

23f) Article 4 paragraph 2 and Article 5 of the regulation (EC) No. 648/2004.

23fa) Regulation (EC) No. 648/2004.

23faa) For example the Act No. 315/2001 Coll. on Fire and rescue Service, as amended; Act No. 129/2002 Coll. on Integrated Rescue System, as amended; Article 7 of the Act of the National Council of the Slovak Republic No. 51/1988 Coll. on mining activity, explosives and on the State Mining Administration, as amended.

23fab) Article 5 paragraphs 1, 2 and 5 and Annex No. 1 to the Act No. 245/2003 Coll. on integrated environmental pollution prevention and control and on amendment of certain acts, as amended.

23fac) 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.

23fad) Articles 17 to 20 of the Commercial Code.

23fb) Articles 591 to 600 of the Commercial Code.

23fc) The Act No. 271/2005 Coll. on the manufacture, placing on the market and use of feedstuffs (Feedstuffs Act).
The Act of the National Council of the Slovak Republic No. 152/1995 Coll. on foodstuffs, as amended.
The Act No. 140/1998 Coll. on medicinal products and aids, on amendment of the Act No. 455/1991 Coll. on business activities (Business Activities Act), as amended, and on amendment of the Act of the National Council of the Slovak Republic No. 220/1996 Coll. on advertising, as amended.
The Act No. 337/1998 Coll. on veterinary care and on amendment of certain other acts, as amended.
The Act No. 136/2000 Coll. on fertilizers, as amended by the Act No. 555/2004 Coll.
The Act No. 217/2003 Coll. on conditions applicable to the placing of biocidal products on the market and on amendment of certain acts, as amended.
The Act No. 193/2005 Coll. on plant health care.

23fca) The Act No. 71/1967 Coll. on administrative procedure (Code of Administrative Procedure), as amended.

23fcb) Article 9 of the Regulation (EC) No. 689/2008.

23fcc) Annex I Part 2 and 3 of the Regulation (EC) No. 689/2008.

23g) Regulation of the European Parliament and of the Council (EC) No. 304/2003 of 28 January 2003 on exports and imports of dangerous chemicals. Council Decision 2003/106/EC of 19 December 2002 concerning the approval, on behalf of the European Community, of the Rotterdam Convention on the Prior Informed Consent Procedure for certain hazardous chemicals and pesticides in international trade (OJ L 063, 6.3.2003).

23h) Article 121 of the Regulation (EC) No. 1907/2006.
Article 8 paragraph 1 of the Regulation (EC) No. 648/2004.

23ha) Article 3 paragraph 18 and Article 75 of the Regulation (EC) No. 1907/2006.

23hb) Articles 122 to 124 of the Regulation (EC) No. 1907/2006.

23i) Article 117 and Article 121 of the Regulation (EC) No. 1907/2006.

23j) Article 2 paragraph 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.

23k) Article 129 of the Regulation (EC) No. 1907/2006.

23l) Article 9 paragraphs 3 and 8; Article 16; Article 20 paragraph 4; article 22 paragraphs 1 and 2; Article 36; Articles 41 to 45; Article 46 paragraphs 1, 3 and 4; Articles 48 to 50; Article 51 paragraphs 1 and 2; Article 59 paragraphs 1 to 3 and 5; Article 64 paragraph 5; Article 66 paragraph 2; Article 69 paragraphs 4 and 5; Article 72 paragraph 3; Article 73 paragraph 2; Article 87 paragraph 1; Article 103 paragraph 3; Article 111; Article 115; Article 117 paragraph 1; Articles 121 to 124 of the Regulation (EC) No. 1907/2006.

23la) Article 85 paragraphs 1 to 3 of the Regulation (EC) No. 1907/2006.

23m) For example the Act No. 355/2007 Coll.; 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 amended; the Act No. 525/2003 Coll.; the Act of the National Council of the Slovak Republic No. 51/1988 Coll., as amended; the Act of the National Council of the Slovak Republic No. 10/1996 Coll. on supervision of public administration, as amended.

23n) Article 86 paragraph 1 of the Regulation (EC) No. 1907/2006.

23o) The Act No. 128/2002 Coll.

23p) Regulation (EC) No. 1907/2006.
Regulation (EC) No. 648/2004.
Regulation (EC) No. 689/2008.
Annex No. I to the Regulation (EC) No. 850/2004.

23r) Article 125 of the Regulation (EC) No. 1907/2006.

23s) Articles 5, 6, 12, 30 and 54 of the Act No. 355/2007 Coll.

23t) Annex XV to the Regulation (EC) No. 1907/2006.

23u) The Act No. 525/2003 Coll., as amended.

23v) Article 9 of the Act No. 525/2003 Coll., as amended.

23w) The Act No. 125/1988 Coll. on labour inspection, and on the amendment of the Act No. 82/2005 on illegal work and illegal employment and on amendment of certain acts, as amended.

23x) The Act of the National Council of the Slovak Republic No. 51/1988 Coll., as amended.

23y) Articles 40 and 41 of the Act of the National Council of the Slovak Republic No. 51/1988 Coll., as amended.

23z) Regulation (EC) No. 1907/2006.
Regulation (EC) No. 689/2008.

24) Article 3 paragraph 20 of the Regulation (EC) No. 1907/2006.

25) Article 67 of the Regulation (EC) No. 1907/2006.
Annex XVII to the Regulation (EC) No. 1907/2006.
Article 3 of the Regulation (EC) No. 850/2004.

26) Article 3 a) of the Act No. 587/2004 Coll. on the environmental fund and on amendment of certain acts.
