217/2003 Coll.

ACT

of 21 May 2003

on conditions applicable to the placing of biocidal products on the market and on the amendment to certain Acts

(Consolidated text as to2nd March 2010)

As amended by the Act No 434/2004 Coll., the Act No 15/2006 Coll., the Act No 95/2007 Coll., the Act No 405/2008 Coll., the Act No 489/2008 Coll., and the Act No 67/2010 Coll.

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

Article I

PART ONE

FUNDAMENTAL PROVISIONS

Article 1

Scope of application

(1) This Act lays down rights and obligations of companies 1), other than those engaged in agricultural production, and registered according to a specific statutory regulation, that may wish to place on the market biocidal products, and the competence of state administrative authorities as regards the placing on the market of biocidal products, conditions concerning authorisation for the placing on the market of biocidal products, conditions concerning registration for the placing on the market of biocidal products, method to be used to evaluate efficacy of biocidal products, low- risk biocidal products, and protection from their adverse effects on humans and animals and the environment, verification and supervision of compliance with this Act.

(2) This Act shall not apply to medicinal products, veterinary preparations, narcotics, medical devices, foodstuffs, feedingstuffs, cosmetics, non-commercial goods in consumer packaging 2), plant protection products, radionuclide emitters and nuclear materials 3) and waste.

(3) This Act shall not affect specific rules concerning the transport of dangerous goods 4), technical requirements in respect of products 5), and chemical substances and preparations 6).

Article 2

Definitions

For the purposes of this Act:

a) a biocidal product means a product containing one or more active substances, put up in the form in which it is supplied to the user, intended to destroy, deter, render harmless, or otherwise exert a controlling effect on, any harmful organism by chemical or biological means; a list of biocidal product types with a indicative description of each type is given in the Annex 1,

b) an active substance means a chemical substance 7) or microorganism, including a virus or a fungus, intended for use in a biocidal product or in a low-risk biocidal product, having a general or specific action on or against harmful organisms,

c) a harmful organism means any organism which has an unwanted presence or a detrimental effect for humans, their activities or the products they use or produce, or for animals, or for the environment,

d) a low-risk biocidal product means a product which poses only a low risk to humans, animals and the environment and contains no substances of concern and as active substances no other than those included in the list of low-risk active substances, satisfying requirements for inclusion in the list of low-risk biocidal products,

e) a substance of concern means any substance, other than active substance, which, on account of its dangerous properties 8), has an inherent capacity to cause an adverse effect on humans, animals or the environment which is present or produced in a biocidal product, or in a low-risk biocidal product in such a concentration that these are to be classified 9) as dangerous,

f) a basic substance means a substance which has some minor use as a biocide either directly or in diluted form with a simple diluent which itself is not a substance of concern and is not sold directly for biocidal purposes and which is placed on the market without direct indication of its biocidal effect,

g) frame-formulation is a reference to specifications for a group of biocidal products or low-risk biocidal products having the same use and user type,

h) a residue means one or more of the substances present in a biocidal product or in a low-risk biocidal product which remains as a result of its use including the metabolites of such substances and products resulting from their degradation or reaction.

PART TWO

PLACING ON THE MARKET OF BIOCIDAL PRODUCTS AND LOW-RISK BIOCIDAL PRODUCTS

Article 3

Basic conditions for placing on the market of biocidal products and basic conditions for placing on the market of low-risk biocidal products

(1) The companies shall not place on the market 10) a biocidal product or a low-risk biocidal product, unless the Centre for Chemical Substances and Preparations (hereinafter "the Centre") has granted an authorisation 11) for the relevant biocidal product, or a registration of the relevant low-risk biocidal product, and they may do solely under conditions pursuant to Articles 7 and 8.

(2) A biocidal product or a low-risk biocidal product shall not contain substances other than those decided on by the Centre in accordance with Article 7 para 1.

(3) The companies wishing to import 12) a biocidal product, or a low-risk biocidal product in order to place the same on the market shall either submit to the customs authority a customs declaration together with the relevant decision of the Centre on its authorisation or the relevant decision of the Centre on its registration, by virtue of which they may import the biocidal product, or a low-risk biocidal product, or they shall submit a written statement to the effect that the biocidal product or the low-risk biocidal product is intended exclusively for the purposes of research, development and testing.

(4) Paras 1 and 2 shall not apply to a biocidal product and the active substance present therein, or to a low-risk biocidal product and the active substance present therein intended exclusively for the purposes of research, development and testing.

(5) The list of active substances, satisfying requirements for inclusion in the biocidal products, the list of low-risk active substances, satisfying requirements for inclusion in the low-risk biocidal products, and the list of basic substances (hereinafter "lists") shall be published by the Government of the Slovak Republic through Regulation.

Application for an authorisation for a biocidal product or application for a registration of a low-risk biocidal product

Article 4

(1) An application for an authorisation for a biocidal product or an application for a registration of a low-risk biocidal product shall be made to the Centre by the company manufacturing or importing the biocidal product in question or the low-risk biocidal product in question (hereinafter "the applicant"). Where the applicant is a natural person, he shall have his place of abode in the territory of the country which is contracting party to the European Economic Area Agreement, and where a legal person, he shall have his registered office or his organisational unit located in the territory of such a country. The application shall be

made in writing, in five copies, and in the official language 14) of the respective country or in the English language.

(2) An application for an authorisation for a biociadal product or an application for a registration of a low-risk biocidal product shall comprise the following:

a) name, surname, place of abode and place of business, where the applicant is a natural person; name and registered office, or organisational unit, where the applicant is a legal person,

b) identification data relating to the manufacturer of the biocidal product or low risk biocidal product,

c) identification data relating to the manufacturer of the active substance,

d) trade name of the biocidal product or low-risk biocidal product,

e) qualitative and quantitative composition of the biocidal product or low-risk biocidal product,

f) safety data sheet relating to the biocidal product or low-risk biocidal product elaborated in accordance with a specific statutory regulation 15).

(3) An application for an authorisation of a biocidal product or an application for a registration of a low-risk biocidal product includes also documentation files containing details of dossiers accompanying an application for an authorisation for a biocidal product and details of dossiers accompanying an application for a registration of a low-risk biocidal product, as well as detailed specification of data to be supplied before a biocidal product has been placed on the market and detailed specification of data to be supplied before a low-risk biocidal product has been placed on the market in accordance with a specific statutory regulation 15a) or a consent regarding provision of information to the second applicant and to subsequent applicants in accordance with Article 16. All submitted information must be consistent with current scientific and technical knowledge.

(4) In addition to information set out in paragraphs 2 and 3, an application for an authorisation of a biocidal product or an application for a registration of a low-risk biocidal product shall include basic information relating to each active substances present in the biocidal product or in the low-risk biocidal product in accordance with a specific statutory regulation 15a) or a consent regarding provision of information to the second applicant and to subsequent applicants in accordance with Article 16. All submitted information must be consistent with current scientific and technical knowledge.

(5) The applicant shall supplement information concerning the biocidal product or the low-risk biocidal product in accordance with paragraphs 2 to 4 with protocols providing a detailed and full description of tests carried out and bibliographical references to methods applied, together with a copy describing such methods. Tests on active substances present in a biocidal product or in a low-risk biocidal product shall be carried out by prescribed methods 16), in compliance with Good Laboratory Practice 17). Application of other than prescribed testing methods must be justified in the protocol. If requested to do so, the applicant must provide the

Centre, in addition to information set out in paragraphs 2 to 4, likewise with further information, if this is required to evaluate a biocidal product pursuant to Article 6.

Article 5

(1) If required by the Centre, the applicant shall provide the Centre with a free sample or model or a proposal of frame formulation of a biocidal product or a low-risk biocidal product, or directions in writing as to their use 18).

(2) The application for an authorisation for a biocidal product which requires carrying out experiments involving vertebrate animals shall be made by the applicant only after his enquiring of the Centre as to whether the product whose authorisation he seeks to obtain is or is not similar to or identical with, a biocidal product for which an authorisation has already been granted, and after receiving the name and adress of the holder or holders of the first authorisation for the relevant biocidal product. In addition, he shall submit a written statement to the effect that he intends to apply for an authorisation in his own interest and that he has available further information necessary for an authorisation. The Centre shall provide the applicant with information required, while communicating to the holder or holders of such authorisation the applicant´s name and address and encourage them to be cooperative so as to avoid a duplication of toxicological experiments on vertebrate animals .

(3) Where a biocidal product is either similar to or identical with, a biocidal product that has already been authorised under Article 7 and whose active substances, even as regards the degree of purity and type of impurities, are identical, the Centre may allow that the second and subsequent applicants, in replacement of information required under Article 4 paras 3, 4 or para 5, supply a certified written aggreement from the first holder of the authorisation for a biocidal product, and make use of information supplied by the latter to grant an authorisation for a biocidal product to the second and subsequent applicants.

(4) Where it is technically impossible to supply some information under Article 4, paras 3, 4 and 5, or where it is possible to replace required information by existing data from scientific publications or some other available resources, the applicant shall state these facts in his application with the inclusion therein of references to such resources.

(5) The Centre shall maintain applications for an authorisation for a biocidal product and applications for a registration of a low-risk biocidal product, together with information submitted and accompanying dossiers, for a period of 15 years. On request by the European Commission, the Centre shall make the documents accessible to competent authorities of countries which are contracting parties to the European Economic Area Agreement, which either authorise a biocidal product or register a low-risk biocidal product.

Article 6

Evaluation of a biocidal product
and evaluation of a low-risk biocidal product

(1) Evaluation of a biocidal product and evaluation of a low-risk biocidal product shall consist in considering the efficacy, the detrimental effect these may have on humans, their activities or the products they use or produce, or on animals or on the environment, or in considering the detrimental effect they may have on other living organisms and the environment.

(2) As regards the protection of human health, the Centre shall undertake the evaluation of a biocidal product and the evaluation of a low-risk biocidal product in conjunction with the Ministry of Health Service of the Slovak Republic (hereinafter "the Ministry of Health Service"), as regards the protection of the environment, it shall do the same in conjunction with the Ministry of the Environment of the Slovak Republic (hereinafter "the Ministry of the Environment"), as regards the protection of animals, in conjunction with the Ministry of Land Management of the Slovak Republic (hereinafter "the Ministry of Land Management"), and as regards the effects of biocidal products, in conjunction with independent natural persons 19) or legal persons authorised to engage in business activities 19).

(3) Having examined information obtained from the evaluation of a biocidal product and from the evaluation of a low-risk biocidal product, the ministries referred to in paragraph 2 shall make a position in writing of such information to the Centre. In considering effects of a biocidal product or of a low-risk biocidal product, the ministries referred to in paragraph 2 shall evaluate their effects

a) on human health,

b) on animals

c) on the environment,

d) on target organisms.

(4) With reference to written positions to be obtained from the ministries referred to in paragraph 2, the Centre shall prepare a final evaluation of a biocidal product or that of a low-risk biocidal product, stating therein their action under normal conditions of their use and under the worst case conditions of their use, including their storage, disposal and disposal of material treated with them.

(5) The ministries referred to in paragraph 2 shall notify the Centre of their respective positions in writing, no later than within 90 days, in case of evaluation of a biocidal product, and no later than within 30 days, in case of a low-risk biocidal product, of the date on which they have received the Centre´s request to assess effects of biocidal products on target organisms and the impact they may have on human and animal health and the environment.

(6) Procedure and principles relating to the assessment of biocidal products and low-risk biocidal products and specific activities of individual central authorities of the state administration within the framework of assessment of biocidal products and low-risk biocidal products and assessment of active substances intended for biocidal products shall be specified in detail by generally binding regulations to be issued by the Ministry of Economy.

Authorisation of a biocidal product
or registration of a low-risk biocidal product

Article 7

(1) Having ascertained that the applicant has submitted a full and true dossier and having completed the evaluation of a biocidal product or of a low-risk biocidal product, the Centre shall neither authorise nor register such product, unless

a) active substances contained therein are included in lists, with the exception of the list of basic substances,

b) in the light of current scientific and technical knowledge and from the evaluation of the dossier pursuant to Article 4 paras 3, 4 and 5 it is shown, that under given conditions of use, a biocidal product or a low-risk biocidal product and the material treated with them

1. is sufficiently effective,

2. when used as proposed, presents no unacceptable effects on target organisms or non-target organisms, such as resistence or cross-resistence, or an unnecessary suffering or pain for vertebrate animals,

3. when used as proposed, either itself, or as a result of its residues, causes no harmful effects to human and animal health,

4. with regard to its fate and distribution in the environment, either itself, or as a result of its residues, causes no harmful effects to the environment, in particular as regards contamination of surface water, ground water and drinking water,

c) it is possible to identify and determine by analytical methods the active substances present in a biocidal product, or in a low-risk biocidal product, and if necessary, all toxicologically and ecotoxicologically significant impurities, substances of concern, co-formulants, residues of significance, by their effect on human and animal health and the environment, resulting from their authorised use,

d) testing results of an active substance present in a biocidal product, or in an low-risk biocidal product, and its physical and chemical properties are deemed acceptable for the purposes of authorised use, storage and transport of these products.

(2) In its decision on authorisation for a biocidal product or in its decision on registration of a low-risk biocidal product under paragraph 1, the Centre shall stipulate conditions under which these may be placed on the market.

(3) An authorised biocidal product, classified according to a specific statutory regulation 9) as toxic, very toxic, or as a category 1 or 2 carcinogen, or as a category 1 or 2 mutagen, or classified as toxic for reproduction category 1 or 2, may not be placed on the market for the needs of retail consumers 20).

(4) Where provisions of legally binding Acts of the European Communities and the European Union impose conditions for the issue of an authorisation for a biocidal product and for the use of a biocidal product, in particular where these are intended to protect the health of distributors, users, workers and consumers or animal health or the environment, the Centre shall authorise the relevant biocidal product, if and when conditions set out within the framework of measures taken by competent authorities of the European Union are complied with.

(5) The Centre shall not authorise a biocidal product, or register a low-risk biocidal product unless it has received in accordance with Article 6 a consenting position in writing from the Ministry of Health Service, Ministry of the Environment and from the Ministry of Land Management.

(6) The Centre shall decide on the authorisation for a biocidal product no later than within 360 days of the receipt of the application. In case of a low-risk biocidal product, the Centre shall decide on registration no later than within 60 days of the receipt of the application.

(7) An authorisation for a biocidal product or a registration of a low-risk biocidal product shall not be transferred to another company and shall not be subject to bankruptcy or execution proceedings.

(8) The Centre shall authorise a biocidal product or register a low-risk bocidal product for a period not exceeding the period over which the relevant active substance remains included in the lists, with the exception of the list of active substances. The period may not exceed 10 years from the date of first or renewed inclusion of an active substance in the lists referred to for each product type in the first sentence.

(9) Where the applicant requires of the Centre to determine the frame formulation for a biocidal product or a low-risk biocidal product, in its decision on authorisation for a biocidal product, or in its decision on registration of a low-risk biocidal product, the Centre shall determine the relevant frame formulation. A biocidal product or a low-risk biocidal product with the same frame formulation must contain the same active substances, having the same properties, and may vary in composition from an authorised biocidal product, or from a registered low-risk biocidal product within this group only where and to the extent, it does not lead to a decrease in its efficacy, or to an increase in risks associated with presence of respective components; a variation from composition of an authorised biocidal product, or from that of a registered low-risk biocidal product, may include only a reduction in the percentage composition of an active substance, or an alternation in the percentage composition of one or more active substances, and/or the replacement of one or more pigments, dyes and perfumes by others presenting the same or lower risk and which do not decrease its efficacy.

10) The Centre shall maintain, both in writing and in electronic form, and publish a register of authorisations issued for biocidal products and a register of registrations issued for low-risk biocidal products.

(11) The holder of an authorisation or a registration under paragraph 6, shall communicate to the Centre, without delay and as soon as it becomes known to him, any new information concerning a biocidal product or a low-risk biocidal product, susceptible to be of consequence with respect to decisions on authorisations issued for biocidal products or to decisions on registrations issued for low-risk biocidal products; this concerns in particular

a) changes in the composition of the product,

b) new knowledge with regard to effects of an active substance present in the product on human and animal health or the environment.

c) changes in the content and kinds of impurities or co-formulants,

d) changes in the concentration of residues,

e) development of resistence in target organisms

f) other significant changes, such as method of packaging, or

g) changes concerning the manufacturer of an active substance.

(12) The Centre shall communicate information under paragraph 11 to competent authorities of other Member States which either authorise a biocidal product or register a low-risk biocidal product, and to the European Commission (Article 17 para 1).

Article 8

(1) The companies wishing to place on the market a biocidal product containing an active substance which is not included in the list of active substances included in a specific statutory regulation 20a) shall be under obligation to communicate to the Centre, prior to his placing on the market of such product, information referred to in Article 4 paras 2, 3 and 5, and make a statement to the effect that the relevant active substance is intended for use as an active substance in a biocidal product or in a low-risk biocidal product and prove that the relevant active substance will be classified, packaged and labelled in accordance with a specific statutory regulation 21).

(2) Before granting permission for placing a biocidal product on the market, the Centre shall ask for positions pursuant to Article 7 para 5 and at the same time, having first submitted a summary of dossiers from companies, it shall ask for positions from competent authorities of respective countries which are contracting parties to the European Economic Area Agreement and from the European Commission.

(3) The Centre shall not permit placing a biocidal product pursuant to paragraph 1 on the market, unless the ministries forward a consenting position in accordance with Article 6 and provided no competent authority of a country which is contracting party to the European Economic Area Agreement raises objections to the summary of dossiers submitted by the Centre. Where a competent authority of a country which is contracting party to the European Economic Area Agreement raises objections to the summary of dossiers submitted on account that it is impossible to come to a conclusion that the active substance satisfies requirements under Article 13 and that the biocidal product complies with conditions under Article 7 para 1 c) and d), and where the European Commission, acting on the proposal from the Centre, concludes that the active substance, intended for use in a biocidal product, does not satisfy requirements referred to in Article 13, the Centre shall not permit placing the relevant biocidal product on the market.

(4) Where the European Commission concludes that the active substance in a biocidal product pursuant to Article 1 satisfies requirements under Article 13 and the biocidal product complies with conditions under Article 7 para 1 c) and d), the Centre shall permit placing the relevant biocidal product on the market.

(5) The Centre shall apply to the European Commission to enter in the lists the active substance which is present in the biocidal product in accordance with paragraphs 3 and 4.

(6) Information pursuant to paragraph 1 may be submitted likewise by companies having their place of abode, registered office, place of business or agent in the territory of a third state, in so far as these satisfy conditions set out in a specific statutory regulation 21) and in this Act.

(7) The period for which a permission for placing a biocidal product pursuant to paragraph 1 on the market is granted, may not exceed three years; this periodor may be extended for a period of one year where over the period of three preceding years the evaluation of active substances, satisfying requirements for inclusion in the lists has not been completed, provided the active substance complies with conditions under Article 13.

Article 9

(1) The Centre shall authorise a biocidal product, or register a low-risk biocidal product for a period of 120 days, provided it is necessary to eliminate the danger of epidemics or excessive multiplication of harmful organisms and viruses which cannot be contained by some other means, and the active substances contained therein have not as yet been included in the lists pursuant to Article 3 para 5, while complying with procedure pursuant to Articles 12 and 13. The Centre shall grant to the applicant an authorisation for a biocidal product, or a registration for a low-risk biocidal product without delay, upon receipt of the application for an authorisation of a biocidal product, or upon receipt of a registration for an low-risk biocidal product; time limits laid down in Article 7 para 6 shall not apply to these proceedings.

(2) The Centre shall without delay inform competent authorities of countries which are contracting parties to the European Economic Area Agreement and the European Commission of proceedings pursuant to paragraph 1 as well as of reasons for which a biocidal product has been authorised or a low-risk biocidal product registered. Should the European Commission require so, the Center shall either modify or cancel an authorisation for a biocidal product, or a registration of a low- risk biocidal product.

Article 10

Authorisation for a biocidal product
or registration of a low-risk biocidal product
based on mutual recognition

(1) The Centre shall grant an authorisation for a biocidal product, which has already been authorised in another Member State, following an application made by the applicant having his place of abode, registered office, place of business or agent in a Member State, within 120 days of the application being received. The Centre shall register a low- risk biocidal product within 60 days of the application being received. Time limits laid down in the first and second sentences shall be binding on the Centre provided the relevant active substances are included in the lists, with the exception of the list of basic substances, while conforming to conditions set out therein.

(2) Pursuant to paragraph 1, applications must include certified copies of authorisations or registrations issued by the competent state authority, which has taken a decision in respect of

the first authorisation of a biocidal product, or in respect of the first registration of a low-risk biocidal product.

(3) Should the Centre establish that conditions for the placing on the market of a biocidal product or of a low-risk biocidal product in the Slovak Republic, as a result of climate or breeding period of target organisms, substantially differ from those in the state where such biocidal product has been authorised for the first time or where a low-risk biocidal product has been registered for the first time, or if it is demonstrated that the target organism has developed an unacceptable tolerance and a resistance to it, the Centre shall adjust conditions relating to labelling set out in Article 20 para 1 e), f), g), k) and l) 2. which are stated in an authorisation for a biocidal product or in a registration of a low-risk biocidal product.

(4) Where the Centre after considering an application pursuant to paragraph 1 decides that a biocidal product or a low-risk biocidal product does not satisfy conditions pursuant to Article 7 para 1 and that an authorisation for a biocidal prduct or a registration of a low-risk biocidal product must be either refused or restricted, the Centre shall not authorise such biocidal product, or shall not register such low-risk biocidal product, informing thereof without delay competent authorities of countries which are contracting parties to the European Economic Area Agreement and the European Commission.

(5) Where the Centre after considering an application pursuant to paragraph 1 concludes that a low- risk biocidal product is not in compliance with Article 2 d), it shall not register such low-risk biocidal product, consulting the matter with the competent authority of the country which is contracting party to the European Economic Area Agreement, which has registered the low-risk biocidal product for the first time. Unless an agreement is reached within 90 days, the Centre shall refer the matter at issue to the European Commission. If the competent authority of the European Union concludes that the relevant biocidal product is in compliance with Article 2 d), the Centre shall register the low-risk biocidal product in question.

(6) The Centre need not accept applications pursuant to paragraph 1 in case of biocidal product types 15, 17 and 23 set out in the Annex 1, where their use may pose a threat to animal health. It shall forward its position together with justification to the competent authorities of countries which are contracting parties to the European Economic Area Agreement and the European Commission.

(7) Before authorising a biocidal product or registering a low-risk biocidal product pursuant to paragraph 1, or when proceeding in accordance with paragraphs 3 to 6, the Center shall ask for positions pursuant to Article 7 para 5. The Ministry of Health Service, Ministry of the Environment and the Ministry of Land Management shall forward their positions in writing to the Centre withing 60 days and in case of a low-risk biocidal product within 30 days of the request being received. The Centre shall not authorise a biocidal product, or register or a low-risk biocidal product, unless it receives consenting positions from the said ministries with regard to such authorisation or registration. Where the Ministry of Health Service, the Ministry of the Environment and the Ministry of Land Management fail to forward their positions in writing within 10 days following the end of the time limit fixed for communication of their positions the Centre shall deem them consenting.

(8) The Centre may ask the Ministries referred to in paragraph 7 to agree to the evaluation of a biocidal product or low-risk biocidal product to be performed either by the Competent

Authority of another European Union Member State or by that of a country which is party to the European Economic Area Agreement. If the said Ministries fail to respond to such request within 10 days of its receipt, the Centre shall ask either the Competent Authority of another European Union Member State or that of the country which is party to the European Economic Area Agreement to perform the evaluation of a biocidal product or a low-risk biocidal product; in this case provisions of paragraph 7 shall not apply.

Article 11

Modification and cancellation of an authorisation for a biocidal product or modification and cancellation of a registration of a low-risk biocidal product

(1) The Centre may modify an authorisation for a biocidal product, or a registration of a low-risk biocidal product

a) on the basis of information notified pursuant to Article 7 para 11,

b) in the light of new developments in scientific and technical knowledge or as a result of new requirements relating to the protection of the environment, or

c) if this is reasonably required by a company, which was granted an authorisation for a biocidal product, or a registration of a low-risk biocidal product and provided authorisations and registrations modified in this way comply with conditions laid down in Article 7 para 1.

(2) Where a modification of an authorisation for a biocidal product or a modification of a registration of a low-risk biocidal product concerns the extension of their uses, the modification shall be implemented in compliance with specific conditions applicable to the active substance included in the list of active substances, satisfying requirements for inclusion in the list of biocidal products, or in lists, with the exception of the list of basic substances.

(3) Where a modification of an authorisation for a biocidal product or a modification of a registration of a low-risk biocidal product includes a change to specific conditions, laid down for the active substance pursuant to paragraph 2, the Centre shall implement such modification only after the reappraisal of the active substance pursuant to Article 12.

(4) The Centre shall cancel an authorisation for a biocidal product or a registration for a low-risk biocidal product, provided

a) the active substance is no longer included in the lists pursuant to Article 3 para 5,

b) one of the conditions laid down in Article 7 para 1 c) to e) has not been fulfilled,

c) an analysis of a biocidal product or of a low-risk biocidal product reveals that their properties do not conform to those stated in the dossier pursuant to Article 4,

d) it is discovered that false or misleading particulars were supplied concerning the facts on the basis of which an athorisation for a biocidal product or a registration of a low-risk biocidal product were granted, or

e) the company that was granted either an authorisation for a biocidal product or a registration of a low-risk biocidal product, requests so.

(5) When cancelling an authorisation for a biocidal product or a registration of a low-risk biocidal product, the Centre shall set a deadline for the disposal, storage, marketing or use of existing stocks of such product and for the handing back of the cancelled authorisation for a biocidal product or of the cancelled registration of a low-risk biocidal product. The same procedure shall apply to termination of an authorisation for a biocidal product or to that of a registration of a low-risk biocidal product, if a company requests so.

(6) In accordance with procedures laid down in paragraphs 1 or 4, the Centre shall require from the company, which was granted an authorisation for a biocidal product or a registration of a low-risk biocidal product, as well as from the competent ministries pursuant to Article 7 para 5, to forward their respective positions. The company that was granted an authorisation for a biocidal product, or a registration of a low-risk biocidal product, and the competent ministries shall forward their positions to the Centre in writing within 30 days of the request being received. The Centre shall not modify a decision on authorisation for a biocidal product or a decision on registration of a low-risk biocidal product pursuant to paragraph 1 unless it has received consenting positions from the ministries with regard to modification of an authorisation for a biocidal product or to a registration of a low-risk biocidal product, while taking into account the holders position.

(7) The Centre shall communicate its cancellation or modification of a decision on authorisation for a biocidal product or of its cancellation or modification of a decision on registration of a low-risk biocidal product, as well as the reasons for this

a) to the company that was granted such authorisation or registration,

b) to the Slovak Trade Inspection,

c) to customs authorities,

d) to competent authorities of countries which are contracting parties to the European Economic Area Agreement and the European Commission.

(8) An appeal by a company against a decision taken by the Centre in respect of cancellation or modification of an authorisation for a biocidal product or in respect of cancellation and modification of a registration of a low-risk biocidal product shall not result in any dilatory effect.

Article 12

Procedure for inclusion of active substances in the lists

(1) The manufacturer or the importer of an active substance who applied to the Centre for the inclusion of an active substance in the lists pursuant to Article 3 para 5 (hereinafter “the applicant”) shall be under obligation to supply under conditions pursuant to Article 4

a) basic and additional information on an active substance,

b) basic information on at least one biocidal product or one low-risk biocidal product cotaining the active substance, whose inclusion in the list is required.

(2) The Centre may require from the applicant that in cases referred to in paragraph 1 b), in addition to basic information, he should supply additional physical and chemical, toxicological and ecotoxicological data, if it be necessary to evaluate a biocidal product as regards the nature of active substances, biocidal product type or low-risk biocidal product type, method of use and expected exposure of humans, animals and the environment to the active substance contained therein.

(3) The Centre shall consider whether or not the applicant has supplied a full dossier. Provided the dossier is complete and true, the Centre shall forward a summary of the dossier to the other Member States and to the European Commission. Provided the dossier is complete and duly executed, the Centre shall communicate the applicant that it accepts for the dossier to be forwarded to the other Member States and the European Commission. In doing this, it may ask the European Commission that the dossier be evaluated by the competent authority of another Member State within the time period of 10 months of the request being received from the European Commission.

(4) Provided the Centre does not ask the European Commission that the evaluation be carried out by another competent authoritiy of a country which is contracting party to the European Economic Area Agreement, it shall evaluate the dossier itself pursuant to Article 6 no later than within 12 months of its receipt. A copy of the evaluation, together with the proposal as to whether the relevant active substance should or should not be included in the lists shall be sent by the Centre to the applicant, competent authorities of the countries which are contracting parties to the European Economic Area Agreement and to the European Commission.

(5) The Centre shall suspend evaluation of the dossier submitted and require from the applicant to supply additional information in case it becomes apparent such information is necessary to complete the evaluation of the relevant active substance. The period between the suspension of evaluation of the dossier submitted and the receipt of information required shall not be included in the time limit pursuant to paragraph 4. The Centre shall inform the competent authorities of countries which are contracting parties to the European Economic Area Agreement and the European Commission on which grounds the evaluation of the dossier submitted has been suspended.

(6) Paragraph repealed as from 1. February 2006.

(7) Paragraph repealed as from 1. February 2006.

Article 13

Recommendation for the inclusion of an active substances in the lists

(1) The Centre shall recommend the European Commission, based on current scientific and technical knowledge, to include an active substance in the lists for a period not exceeding 10 years, provided it can be supposed that biocidal products or low-risk biocidal products in which the active substance is present, fulfil the requirements under Article 7 para 1 c) to e).

(2) The recommendation for inclusion of an active substance in the lists can be made conditional on

a) requirements on the minimum degree of purity of the active substance,

b) determination of the maximum content of certain impurities,

c) determination of the type of biocidal product wherein the active substance may be used,

d) determination of the manner and area of use,

e) designation of the category of users,

f) determination of the acceptable operator exposure level,

g) determination of the acceptable daily intake and of maximum residue limit,

h) determination of the fate and behavior of the active substance in the environment and of its impact on animals,

i) determination of other particular conditions resulting from the evaluation of the dossier submitted.

(3) The Centre shall not recommend the European Commission to include in the lists any active substance which is classified as carcinogenic, mutagenic, toxic for reproduction or sensitising or as bioaccumulative and not readily degradable. A carcinogenic substance, a mutagenic substance, a substance toxic for reproduction, or a sensitising substance, or a substance which is bioccumulative or does not readily degrade may be included in the list referred to in the first sentence only with reference to the concentration ranges 8) within which the substance can be used.

(4) Recommendations for the inclusion of an active substance in the lists pursuant to paragraph 1 shall be limited to the types of biocidal products stated in Annex 1 for which a dossier has been submitted in accordance with Article 12 para 1 b).

(5) The inclusion of an active substance in the lists pursuant to paragraph 1 may be renewed on one or more occasions for periods not exceeding 10 years. The initial inclusion, as well as any renewed inclusion, may be reviewed at any time, provided either the Centre or the European Commission acquires information indicating that any of the conditions laid down in paragraphs 1 to 3 are no longer satisfied.

(6) The Centre shal either not apply for an active substance to be included in the lists pursuant to paragraph 1 or shall cancel its decision on inclusion in the lists referred to in paragraph 1 if

a) the evaluation carried out in accordance with Article 12 para 4 shows that under normal conditions under which it may be used, a biocidal product containing the active substance may pose a risk to human and animal health and to the environment, or

b) there is another active substance in the lists, with the exception of the list of basic substances, which presents a significantly lower risk than the original substance to human and animal health or the environment.

(7) The Centre shall not recommend the inclusion of an active substance in the lists pursuant to paragraph 1, if an alternative substance or substances pursuant to paragraph 6 have already been included in the lists and these present similar or lesser effect on the target organism without significant economic and practical disadvantages for the user and without an increased risk to human and animal health and the environment. This decision shall be sent by the Centre to competent authorities of countries which are contracting parties to the European Economic Area Agreement and to the European Commission.

(8) To apply procedure under paragraphs 6 and 7, the following conditions must be observed:

a) the chemical diversity of active substances should be adequate to minimise occurance of resistence in the target organism,

b) these procedures shall apply only to the active substances present in a biocidal product or in a low- risk biocidal product of the same type,

c) the level of risk to human and animal health or to the environment under the normal conditions of use of an active substance, which is either refused for entry or removed from a list, shall be significantly higher,

d) it will be possible to acquire experience form use in practice, if it is not already available.

Article 14

Research and development

(1) A biocidal product or a low-risk biocidal product, unauthorised or unregistered by the Centre, and an active substance, not complying with requirements laid down in Article 8 paras 1 and 2, may be introduced on the market for the purposes of research and development and the conduct of tests and experiments 22), which are necessary with respect to making an application pursuant to Article 12.

(2) The companies conducting research and development for the purposes of making an application pursuant to Articles 4 and 12, or a notification pursuant to Article 8 shall be under obligation to maintain for the whole period during which tests and experiments are conducted, as well as for the period of 15 years following their completion, records of a biocidal product or of a low-risk biocidal product, or of the active substance present therein, including

a) their identity and identity of the active substance,

b) information concerning labelling and quantities supplied, names and adresses of companies that received a biocidal product or a low risk biocidal product or the active substance,

c) all available data on possible effects of a biocidal product or of a low-risk biocidal product or of the active substance on human and animal health or impact on the environment.

(3) If requested so by the Centre, the companies conducting research and development shall supply to the Centre without delay records pursuant to paragraph 2.

(4) The companies carrying out research and development shall be under obligation to notify to the Centre the data referred to in paragraph 2, together with information on the completion of research and development in respect of a biocidal product or a low-risk biocidal product or an active substance and on any transfer of property rights thereto.

(5) Where the tests and experiments may result in a release into the environment of a biocidal product or of a low-risk biocidal product or of an active substance, the company carrying out research and development, or intending to undertake tests and experiments, must apply the Centre for an authorisation to carry out these tests and experiments and submit data necessary for the evaluation of the application, and imposition of conditions in order to reduce to an acceptable level adverse influence such tests and experiments that may have on the environment.

(6) The Centre may either prohibit to carry out tests and experiments or impose certain restrictions on them, if it discovers they present a risk to human and animal health and the environment; appeals against such prohibition of tests and experiments shall result in no dilatory effects.

(7) Before deciding on the possibility of undertaking tests and experiments pursuant to paragraph 5 and prior to taking a decision pursuant to paragraph 6, the Centre shall ask for positions in writing from the Ministry of Health Service, Ministry of the Environment and the Ministry of Land Management. The said ministries shall forward to the Centre in writing their positions concerning the possible conduct of tests and experiments pursuant to paragraph 5 and procedure pursuant to paragraph 6 within 30 days of the request being received. The Centre shall not authorise the tests or experiments under paragraph 5 unless the positions sent by the ministries are consenting.

Article 15

Confidentiality

(1) The applicant pursuant to Articles 4 and 12 and the companies making a notification pursuant to Article 8 may indicate to the Centre which information contained in the dossier should not be disclosed to third persons, and apply to the Centre in writing to treat such information as confidential 23).

(2) The Centre shall take a decision in respect of confidentiality of information on the basis of applications made in accordance with paragraph 1. Confidentiality shall not apply to:

a) information referred to in Article 4 para 2 a) and b),

b) names and concentrations of active substances present in a biocidal product or in alow-risk biocidal product, and to names of biocidal products and low-risk biocidal products,

c) names of substances present in a biocidal product or in a low-risk biocidal product which are regarded as dangerous and contribute to the classification of the product,

d) physical and chemical data concerning a biocidal product or a low-risk biocidal product or an active substance, to the exclusion of identification numbers, chemical formulae and chemical terms of other substances contained threin, such as those set out under b) and c),

e) methods of rendering a biocidal product or a low-risk biocidal product or an active substance and their packaging harmless,

f) a summary of the results of tests to establish an active substance´s or a biocidal product´s or a low-risk biocidal product´s efficacy and effects on humans, animals and the environment,

g) precautions to reduce dangers from handling, storage, transport and use of a biocidal product, or a low-risk biocidal product or an active substance,

h) safety data sheets,

i) methods of analysis,

j) procedures to be followed and measures to be taken in case of spillage or leakage of a biocidal product or a low-risk biocidal product or an active substance,

k) first aid and medical advice to be given in case of injury to persons using a biocidal product or a low-risk biocidal propduct or an active substance.

(3) Confidential information may be disclosed only to:

a) persons evaluating a biocidal product or a low-risk biocidal product or an active substance (Article 6 para 2),

b) the Toxicological and Information Centre of the Clinic of Occupational Medicine and Toxicology,

c) customs authorities and the Slovak Trade Inspection,

d) the competent authorities of countries which are contracting parties to the European Economic Area Agreement and the European Commission.

(4) Persons referred to in paragraph 3 may not disclose or make accessible to other persons information, indicated by the applicant or the companies as confidential pursuant to paragraph 1.

(5) Where the applicant or the companies themselves make public previously condifential information they must inform the Centre thereof.

Article 16

Provision of information to the second applicant and to subsequent applicants

(1) The Centre shall not use information supplied by an applicant (Articles 4 and 12) or by a company (Article 8) for the benefit of another applicant unless these persons have

submitted the first applicant´s or company´s agreement in writing allowing to use such information.

(2) Without an agreement in writing from the first applicant or company, the Centre shall not use for the benefit of another applicant or company any information

a) concerning an active substance which was not present on the market before the 14 May 2000 and is included in the list of active substances, satisfying requirements for inclusion in the list of biocidal products, or in the lists, with the exception of the list of basic substances for a period of less than 15 years since its first entry on the lists,

b) concerning an active substance which was not present on the market before 14 May 2000

1. for a period, as laid down by a specific statutory regulation 24) applicable to confidentiality of information on active substances, and by 14 May 2010 at the latest,

2. for a period of 10 years since the first entry of an active substance in the lists, with the exception of the list of basic substances,

c) concerning a biocidal product which was not present on the market before 14 May 2000 and was authorised or registered less than 10 years ago,

d) concerning a biocidal product which was not present on the market before 14 May 2000 and contains one or more identified active substances

1. for a period, as laid down by a specific statutory regulation 24), and by 14 May 2000 at the latest,

2. for a period of 10 years since the first entry of an active substabce present in a biocidal product in the lists, with the exception of the list of basic substances,

e) concerning existing active substances notified as basic substances, for the purposes of modification of an authorisation or registration under Article 11, or renewal of the entry or modification of requirements for entry of an active substance in the list pursuant to Article 13, if renewed less than 5 years ago; this is without prejudice to the obligation of complying with time limits laid down under a) to d).

Article 17

Information exchange

(1) Within 30 days from the end of each quarter the Centre shall inform other Member States and the European Commission of all biocidal products or low-risk biocidal products, which have been either authorised or registered or which had their authorisation or registration refused, cancelled, modified or renewed, indicating:

a) name and address of the company that was granted an authorisation for a biocidal product, or a registration of a low-risk biocidal product,

b) name of the biocidal product or the low-risk biocidal product,

c) name and amount of active substances and dangerous substances present in a biocidal product or in a low-risk biocidal product, and classification thereof,

d) type of biocidal product or low-risk biocidal product, and use or uses for which they are authorised or registered,

e) type of formulation for a biocidal product or a low-risk biocidal product (powders, liquid concentrates, granules, etc.),

f) determined limits on residues,

g) conditions of an authorisation for a biocidal product or of a registration of a low-risk biocidal product, and where relevant, reasons for their restricted use, modification or cancellation,

h) indication as to whether the product is a special type of biocidal product or low-risk biocidal product or whithin frame formulation.

(2) On an annual basis, the Centre shall draw up a list of published decisions on authorisation for biocidal products and a list of published decisions on registration of low-risk biocidal products in the territory of the Slovak Republic and shall communicate those lists to the competent authorities of countries which are contracting parties to the European Economic Area Agreement and the European Commission.

(3) Provided the Centre receives a summary of the dosiers in accordance with Article 8 para 3 or Article 12 para 3 and comes to the conclusion that the dossiers are incomplete or untrue, it shall notify this fact without delay to the competent authority of the country which is contracting party to the European Economic Area Agreement, responsible for the evaluation of the dossiers and to the competent authorities of other Member States and the European Commission.

PART THREE

CLASSIFICATION, PACKAGING, LABELLING AND NOTIFICATION OF POISONING AND INSPECTION RESULTS

Article 18

Classification

Biocidal products and low-risk biocidal products which do not contain microorgamisms as an active substance, shall be classified in accordance with a specific statutory regulation 9).

Article 19

Packaging

Biocidal products and low-risk biocidal products shall be packaged in accordance with a specific statutory regulation 25).

Article 20

Labelling

(1) Packaging of biocidal products and low-risk biocidal products shall be labelled in accordance with a specific statutory regulation 25); the label must show clearly, legibly, indelibly and in the official language 14) the following:

a) the identity of every active substance and its concentration in metric units 26),

b) the authorisation number, registration number or notification number under which a biocidal product has been authorised, a low-risk biocidal product registered or a biocidal product notified,

c) the type of biocidal product or low-risk biocidal product (water dispersible powder, emulsifiable concentrate, granulate, etc.),

d) the uses for which a biocidal product has been authorised or a low-risk biocidal product registered (wood preservative, disinfectant, etc.),

e) directions for use and the dose rate, expressed in metric units, for each use,

f) side effects (direct or indirect),

g) first aid instructions,

h) if the biocidal product or the low-risk biocidal product is accompanied by a leaflet, the sentence “Read attached instructions before use”,

i) directions for safe disposal of a biocidal product or a low-risk biocidal product, and of their packagings, where relevant, any prohibition on reuse of packaging,

j) biocidal product or low-risk biocidal product batch number or designation, and the expiry date relevant to normal conditions of storage,

k) period of time needed for the biocidal effect and

l) other information, if needed due to the product´s properties and uses, in particular

1. categories of users, for professional use and consumer use,

2. information on any specific danger to the environment in case of animals, and measures to be taken to avoid contamination of water,

3. information necessary with respect to protection of workers from risks related to exposure to microorganisms at work, in case of biocidal products containing microorganisms.

(2) Information referred to in para 1 c), e), f), i), j), k) and l) 2. may be indicated not only on the packaging but likewise on leaflets to be transmitted to every buyer.

(3) The packaging of biocidal products and accompanying leaflets shall not carry indications "low-risk product", "non-toxic", "harmless", "harmless to the environment", or any similar indications to the effect that a biocidal product is not dangerous.

(4) Where biocidal products such as rodenticides, avicides, molluscicides, insecticides, acaricides and other preparations intended for control of other arthropods are at the same time subject to classification, packaging and labelling in accordnace with a specific statutory regulation 27), they may be packaged and labelled in accordance with such specific regulation in so far as this does not conflict with conditions applying to authorisation of biocidal products or registration of low-risk biocidal products according to this Act.

(5) The obligation to label the packaging in the official language 13) shall not exclude the possibility of simultaneous labelling in other languages.

Article 21

Promotion and Advertising

(1) When advertising 28) a biocidal product or a low-risk biocidal product, the companies must indicate the sentence "Use biocides safely. Always read the label and product information before use". In relation to the whole advertisement, the sentences shall be clearly distinguishable by size and character shape. The word "biocides" may be replaced with a more specific description, such as "wood preservatives", "disinfectants", "anti-fouling products", etc.

(2) The advertising materials shall not mention information: "low-risk biocidal product", "non-toxic", "harmless", "harmless to the environment" and shall not mislead 29) the potential user.

Article 22

Notification of poisoning and notification of inspections

(1) Notification of poisoning caused by biocidal products or low-risk biocidal products or active substances shall be carried out in accordance with a specific statutory regulation 30).

(2) Every year by 31 August, the Ministry of Interior of the Slovak Republic, Ministry of Defence of the Slovak Republic and Ministry of Transport, Posts and Telecommunications of the Slovak Republic shall forward to the Ministry of Health Serivce of the Slovak Republic reports of cases of poisoning caused by biocidal products or low-risk biocidal products.

(3) Every year by 30 September, the Ministry of Health Service shall forward to the Centre a summary report on the cases of poisoning caused by biocidal products and low-risk biocidal products. The reports received shall be incorporated into the summary report pursuant to paragraph 2.

(4) Every year by 30 September, the Slovak Trade Inspection shall forward to the Centre a report on breaches of obligations in connection with the placing on the market of biocidal products or low-risk biocidal products it may discover.

(5) From the date the Treaty on accession of the Slovak Republic to the European Union comes into force, every three years by 30 November, the Centre shall forward to the European Commission a summary report on compliance with this Act and on cases of poisoning caused by biocidal products and low-risk biocidal prducts.

PART FOUR

STATE ADMINISTRATION AND IMPOSITION OF SANCTIONS

Article 23

State Administration

State administration in the field of the placement on the market of biocidal products and low-risk biocidal products shall be executed by:

a) Ministry of Health Service,

b) Ministry of the Environment,

c) Ministry of Land Management,

d) Ministry of Economy,

e) Slovak Trade Inspection,

f) customs authorities,

g) the Centre.

Article 24

Ministry of Health Service

The Ministry of Health Service

a) shall communicate to the Centre its position in respect of authorisations for biocidal products and registrations of low-risk biocidal products as regards protection of human and animal health,

b) shall communicate to the Centre its position in respect of the evaluation of efficacy of human hygiene biocidal products and disinfectants,

c) shall maintain records of cases of poisoning caused by biocidal products and low-risk biocidal products and

d) shall communicate to the Centre its positions in accordance with Article 6 para 5 and Article 10 para 7.

Article 25

Ministry of the Environment

The Ministry of the Environment shall communicate to the Centre its position in respect of

a) authorisations for biocidal products or registrations of low-risk biocidal products,

b) proceedings undertaken by the Centre pursuant to Article 6 para 5 and Article 10 para 7,

as regards protection of the environment.

Article 26

Ministry of Land Management

The Ministry of Land Management shall communicate to the Centre its position in respect of

a) authorisations for biocidal products or registrations of low-risk biocidal products,

b) proceedings undertaken by the Centre pursuant to Article 6 para 5 and Article 10 para 7,

as regards protection of animals.

Article 27

Ministry of Economy

The Ministry of Economy

a) shall manage state administration in the field of the placement on the market of biocidal products or low-risk biocidal products,

b) shall be an appeals authority in the matters decided on by the Centre.

Article 28

Slovak Trade Inspection

The Slovak Trade Inspection shall be an inspection authority in accordnace with a specific statutory regulation 31). In making inspections the Slovak Trade Inspection

a) shall supervise compliance with provisions of this Act by companies,

b) shall impose penalties in connection with administrative offences under this Act,

c) may impose, in conjunction with the Centre [Article 30 h)], on companies that have placed on the market a biocidal product or a low-risk biocidal prodduct contrary to this Act either to withdraw at their own costs the biocidal product or low-risk biocidal product or active substance from the market or render them harmless or proceed in accordance with Article 11 para 5,

d) may itself proceed pursuant to c), and at the costs to be covered by whoever may have committed irregularities, where there is an immediate risk posed to human and animal health and the environment,

e) shall inform its superior bodies, the Centre and companies of the experience it may acquire from inspections,

f) every year by 30 September it shall forward to the Centre a report on breaches of obligations connected with the placing on the market of biocidal products and low-risk biocidal prducts, it may discover.

Article 29

Customs Authorities

The customs authorities shall not release an imported biocidal product into proposed circulation 10) without the relevant decision on authorisation for a biocidal product or without the relevant decision on registration of a low-risk biocidal product or a importer´s declaration in writing to the effect that the relevant biocidal product or low-risk biocidal product is intended exclusively for the purposes of research and development or for testing purposes. The companies shall be under obligation to state in their customs declaration authorisation number or registration number, under which the Centre has such products registered. In case of any doubts customs authorities may ask the Centre to provide professional assistance.

Article 30

The Centre

The Centre

a) shall issue decisions on authorisations for biocidal products and registrations of low-risk biocidal products, as well as decisions on modifications or cancellations of decisions regarding authorisations for biocidal products and registrations of low-risk biocidal products, maintaining all the relevant dossiers for a period of 15 years,

b) shall receive applications for inclusion of active substances in the lists, with the exception of lists of basic substances,

c) shall evaluate the dossiers submitted pursuant to a) as regards protection of human and animal health and the environment,

d) shall forward to customs authorities copies of decisions on authorisations for biocidal products or those on registrations of low-risk biocidal products, as well as possible modifications or cancellations thereof,

e) shall maintain records of authorised biocidal products and registered low-risk biocidal products, publishing the list thereof,

f) shall designate frame formulations of biocidal products in accordance with Article 7 para 9,

g) shall receive notifications under Article 14 para 4 and issue decisions pursuant to Article 14 paras 5 and 6,

h) shall act in conjunction with the Slovak Trade Inspection pursuant to Article 28 c),

i) shall ensure international information exchange under this Act with competent authorities of countries which are contracting parties to the European Economic Area Agreement and the European Commission,

j) participates in the assessment of active substances in accordance with specific statutory regulations 31a),

k) provides for the assessment of active substances for which it is rapporteur and cooperates with the applicant in their assessment in accordance with specific statutory regulations 31a),

l) submits applications to the European Commission, regarding extension of the period for placing on the market of those biocidal active substances which must be inevitably used in accordance with a specific statutory regulation 31b).

Article 30a

Assessment and Evaluation Charges

(1) Assessment of submitted dossiers for completeness pursuant to Article 12, paragraph 3 for

a) the first combination of an active substance and the type of product for active substances fulfilling criteria for inclusion among biocidal products or for low-risk substances fulfilling criteria for inclusion among low-risk biocidal products … 33 200.00 Euro,

b) any additional combination of an active substance and the type of product for active substances fulfilling criteria for inclusion among biocidal products or for low-risk substances fulfilling criteria for inclusion among low-risk biocidal products … 8 300.00 Euro.

(2) Active substance evaluation pursuant to Article 12, paragraph 4 for

a) the first combination of an active substance and the type of product for the purposes of its inclusion among active substances fulfilling criteria for inclusion among biocidal products or for its inclusion among low-risk substances fulfilling criteria for inclusion among low-risk biocidal products … 166 000.00 Euro,

b) any additional combination of an active substance and the type of product for the purposes of its inclusion among active substances fulfilling criteria for inclusion among biocidal products or for its inclusion among low-risk substances fulfilling criteria for inclusion among low-risk biocidal products … 41 500.00 Euro.

(3) Issue of the decision on authorization of a biocidal product pursuant to Article 7 … 6 600.00 Euro.

(4) Issue of the decision on registration of a biocidal product pursuant to Article 7 … 3 300.00 Euro.

(5) The charges paid for assessment and evaluation made pursuant to paragraphs 1 to 4 can be used to cover the costs for preparation of an expert opinion by an expert institution or an expert; the Centre will accept also an expert opinion prepared by an expert or by the competent authority for placing the biocidal product on the market in a European Union Member State or in a country which is party to the European Economic Area Agreement.

(6) If the Centre asks the competent authority of another European Union Member State or that of the country which is party to the European Economic Area Agreement to carry out tasks set out in paragraphs 1 to 4, the centre may use charges paid for the tasks set out in paragraphs 1 to 4 to cover payments due to the authority of another European Union Member State or that which is party to the European Economic Area Agreement; the Centre may use no more than 10 per cent of the charges paid for the tasks set out in paragraphs 1 to 4 to cover costs related with translation of the dossier into English.

(7) In respect of any other tasks which are carried out by the Centre pursuant to the present Act, the charges shall be levied under a specific regulation 32).

(8) The Centre shall refund the payee the full amount of charges collected pursuant to paragraphs 1 to 4 if the task could not have been preformed or the procedure undertaken for causes which are not imputable to the latter or if the payee has paid a charge without being obliged to do so.

(9) The Centre shall refund any sum the payee has paid in excess of the amount due (hereinafter “surplus payment”).

(10) The charge paid pursuant to paragraph 8 and the surplus payment pursuant to paragraph 9 shall be refunded by the Centre within no more than 30 days of the date when it finds out the charge or surplus payment is to be refunded.

(11) If the proceeding did not take place for causes imputable to the payee, the Centre may on payees request decide to refund the charge, but to the amount of no more than 65 % of the charge paid. The charge to be refunded shall be rounded up to Eurocents.

(12) It will be not possible to make appeal against the decision concerning charge (surplus payment) refund. The decision takes effect on the date of its receipt.

(13) The charge or surplus payment will not be refunded provided the sum to be refunded does not exceed 1.65 Euro. This will not apply to the charge to be refunded pursuant to paragraph 8.

(14) The entitlement to charge or surplus payment refund becomes extinct upon expiry of three years from the end of calendar year in which the charge was paid.

(15) Any charges paid for the tasks set out in paragraphs 1 to 4 but not used by the Centre shall accrue to the national budget 32).

Article 31

Administrative Offences

(1) An administrative offence in the field of the placing on the market of biocidal products or low-risk biocidal products and active substances shall be committed by any company which

a) has placed on the market an unauthorised biocidal product or an unregistered low-risk biocidal product or has done so in breach of Article 8 para 1,

b) has failed to withdraw from the market a biocidal product or a low-risk biocidal product or an active substance by the fixed deadline, or which has failed to render the same harmless by the fixed deadline pursuant to Article 28 c), or which has failed to comply with the time limits, as laid down in relevant decisions, for rendering harmless, storage, marketing or use of existing stocks of a biocidal product or a low-risk biocidal product pursuant to Article 11 para 5,

c) has failed to comply with requirements relating to packaging or labelling of a biocidal product or a low-risk biocidal product, as set out in Articles 19 and 20, or which has neglected its obligations in connection with the advertising pursuant to Article 21,

d) has carried out experiments and tests contrary to Article 14 para 5 or para 6, or which has failed to make a notification pursuant to Article 33 para 1 or para 2,

e) has failed to make a notification pursuant to Article 14 para 4 or which has neglected to maintain records pursuant to Article 14 para 2 or which has failed to proceed in accordance with Article 3 para 3,

(2) In connection with administrative offences, The Slovak Trade Inspection may impose penalties on companies

a) pursuant to paragraph 1 a), up to the amount of 2 500 000 Sk,
b) pursuant to paragraph 1 b), up to the amount of 1 200 000 Sk
c) pursuant to paragraph 1 c), up to the amount of 1 000 000 Sk,
d) pursuant to paragraph 1 d), up to the amount of 600 000 Sk,
e) pursuant to paragraph 1 e), up to the amount of 100 000 Sk.

(3) When considering imposition of a penalty and the amount thereof, the Slovak Trade Inspection shall take into account seriousness, nature length of time and consequences resulting from such offences.

(4) The Slovak Trade Inspection may waive imposition of a penalty, if

a) a remedy occurs immediately after failure to fulfil an obligation has been discovered,

b) an effective cooperation has been provided,

c) there has arisen no risk to human and animal health or to the environment.

(5) Penalties may be imposed within one year of the date when the Slovak Trade Inspection discovers any breach or neglect of obligations, and no later than within three years of the date when such breach or neglect of obligations occurred.

(6) In case of a repeated breach or neglect of obligations, as referred to in paragraph 1, which occurs within three years of the date the relevant decision on imposition of penalty came into force, the Slovak Trade Inspection may impose a penalty three times the amount of the previous one.

(7) Under this Act the proceeds from penalties imposed shall constitute an income for the state budget.

PART FIVE

COMMON, TRANSITIONAL AND FINAL PROVISIONS

Article 32

Common Provisions

Unless otherwise provided for in this Act, proceedings under this Act shall be subject to general rules applicable to administrative procedure 11).

Article 33

Transitional Provisions

(1) The companies that have placed on the market a biocidal product and wish to place it on the market also after this Act comes into force, shall communicate by 31 December 2003 to the Centre the following:

a) name, surname, place of abode, and place of business, where the applicant is a natural person, authorised to engage in business activities; name and registered office or organisational unit, where the applicant is a legal person,

b) name of the biocidal product,

c) chemical name and international identification numbers of active substances, if such numbers are available, and their concetrations,

d) chemical names of other substances present in the biocidal product, international identification numbers and their concentrations included,

e) biocidal product type according to Annex 1,

f) category of users only for professional use or only for the consumer,

g) protocol on determination of product efficacy under the conditions of good laboratory practice (GLP),

h) label with text on the packaging,

i) instructions for use, unless indicated on the packaging,

j) approximative amount of the biocidal product placed on the market over a calendar year,

k) safety data sheet,

l) date of the placing on the market of the biocidal product.

(2) Companies wishing to place on the market, after this Act becomes effective, a biocidal product containing only such active substances which are stated in a specific statutory regulation 20a), shall communicate to the Centre information set out in paragraph 1 a) to i) and k) before such biocidal product is placed on the market.

(3) The Centre may specify conditions of use or prohibit the placing on the market, in respect of a biocidal product or a low-risk biocidal product placed on the market in accordance with paragraps 1, 2 or 3, provided such biocidal product or such low-risk biocidal product does not comply with requirements pursuant to Article 7 para 2 b) to d).

(4) In case the placing on the market of a biocidal product or of a low-risk biocidal product is prohibited pursuant to paragraph 4, the Centre shall set the time limit whithin which the stocks of a biocidal product or of a low-risk biocidal product are to be rendered harmless, stored, marketed or used; an appeal against the Centre´s decision shall have no dilatory effect.

(5) As of the date the Treaty on accession of Slovakia to the European Union comes into force, the obligation imposed on the companies pursuant to Article 3 para 3 shall not apply to biocidal products or low-risk biocidal products imported from the Member States of the European Union; customs authorities shall not apply procedure referred to in Article 29 with respect to biocidal products or low-risk biocidal products imported from the Member States of the European Union.

Article 33a

Transitional Provisions

(1) The company that places on the market a biocidal product containing solely active substances listed in a specific regulation 33) before this Act takes effect, shall submit to the Centre an application for extending the period of temporary placing the biocidal product on the market which shall contain the following:

a) name, surname, place of abode or place of temporary residence and place of business, where the applicant is a natural person, authorised to engage in business activities; name and registered office or organisational unit, where the applicant is a legal person,

b) name of the biocidal product,

c) notification number pursuant to Article 20, paragraph 1(b).

(2) The company that wishes to place on the market a biocidal product containing solely active substances listed in a specific regulation 33) following the entry into force of the present Act shall submit to the Centre an application for temporary placing of the biocidal product on the market which shall contain information pursuant to Article 33a, paragraph 1 a) and b) as well as the following:

a) chemical name and international identification numbers of active substances, if available, and their concentrations,

b) chemical names of other substances contained in the biocidal product, including international identification numbers, if available, and their concentrations,

c) type of biocidal product pursuant to Annex 1,

d) category of users only for professional use or only for the consumer,

e) protocol on determination of biocidal product efficacy,

f) label with text on the packaging,

g) instructions for use, unless indicated on the packaging,

h) safety data sheet.

(3) Following the assessment of the application for completeness and adequacy pursuant to paragraph 1 or of the application pursuant to paragraph 2 the Centre shall issue a decision on the temporary placing of the biocidal product on the market which shall not expire later than:

a) on 14 May 2014 where a Commission decision has not been taken pursuant to a specific regulation 34) with respect to any active substance contained in the biocidal product and where inclusion in the list stated in a specific regulation 35) of all active substances contained therein has not become effective,

b) within 12 months from the entry into force of the Commission decision taken pursuant to a specific regulation 34) where a Commission decision has been taken pursuant to a specific regulation 34) with respect to at least one active substance contained therein; the deadline according to the first sentence may not expire later than on 14 may 2014; it is impossible to make appeals against the decision of the Centre,

c) the deadline pursuant to a specific regulation 35) following which biocidal products must be placed on the market in compliance with Articles 7 and 10 of the Act, save products containing more than one active substance, for which the deadline for bringing into compliance shall be determined depending on the deadline for the inclusion of the last active substance in the list pursuant to a specific regulation 35); where the deadline according to the first sentence expires later than on 14 May 2014, the validity of the decision may expire later than on 14 May 2014.

(4) The company that placed a biocidal product on the market pursuant to paragraphs 1 and 2 and wishes to do so also after the inclusion of the active substance in the lists 35) takes effect, shall submit to the Centre the application for authorisation of the biocidal product or for registration of the low-risk biocidal product pursuant to Article 7 or shall submit a certified copy confirming the receipt of the application for authorisation of the biocidal product or registration of the low-risk biocidal product by another Member State Competent Authority together with the statement to the effect that following the decision taken by another Member State Competent Authority which has already decided concerning the first authorisation of the biocidal product or the registration of the low-risk biocidal product an application will be made pursuant to Article 10.

(5) Following the assessment of the application for completeness and adequacy pursuant to paragraph 4 the Centre shall issue a decision on the extension of the period of temporary placing of the biocidal product on the market, whose validity may not expire later than within 18 months from the date the inclusion of the active substance in the lists 35) takes effect.

(6) The Centre can modify, repeal or restrict the validity of the decisions taken pursuant to paragraphs 3 or 5 where:

a) the biocidal product does not meet the requirements pursuant to Article 7, paragraph 1 b) to d),

b) the Commission decision has been taken pursuant to a specific regulation with respect at least one active substance contained therein 34),

c) all active substances contained therein have been included in the lists 35),

d) the biocidal product does not meet conditions for authorisation set out in the lists 35).

(7) If the Centre imposes a ban on the placing of the biocidal product on the market pursuant to paragraph 6 it shall set a deadline for the disposal, storage, marketing or use of existing stocks of the biocidal product. Appeals against the Centre´s decisions have no suspensive effect.”.

Article 34

Final provision

This Act transposes the legal act of European Communities and of the European Union as set out in Annex 2.

Article II

The Act no. 163/2001 Coll. on chemical substances and chemical preparations, as amended by the Act no. 128/2002 Coll. shall be amended as follows:

1. The words “and biocidal products 4a)” shall be inserted in Article 1 para 2 c) after the word “fertilizers 4)”.

2. In Article 5 para 1, point a) shall read:

“a) polymer containing in combined form less than two percents of a new chemical substance,”

3. In Article 5, the following point e) shall be added to paragraph 1:

“e) the substance included in the list of chemical substances which are not subject to notification.”.

4. In Article 10, paragraph 5 shall read:

“(5) Article 4 para 1 h) shall not apply to repeated notification of a new chemical substance.”.

5. In Article 26 para 7, in the second sentence the words “of very toxic substances and products, toxic substances and products and caustic substances and products” shall be inserted after the word “Conclusions”, the word “packagings” after the words “opening by children”, and the following sentence shall be added at the end: “Packagings of extremely flammable substances and products, highly flammable substances and products and harmful substances and products shall bear a tactile warning against danger for the sake of persons with impaired vision and blind persons.”.

6. In Article 37, paragraph 1 shall read:

“(1) The Centre for Chemical Substances and Preparations shall be a state administration authority with the status of a Competent Authority of the Slovak Republic in the field of notification of new chemical substances, placing on the market of biocidal products, clasification and registration of chemical substances, as well as evaluation of risks in connection with their placing on the market.”.

7. In Article 40, the following point d) shall be added to paragraph 3:

“d) failed to comply with conditions laid down in Article 4 paras 1 to 6, Article 7 paras 1 to 3, Article 8 paras 1 to 7 and para 9, Article 12, Article 14 paras 1 and 2, Article 15 para 1, Article 17 para 1, Article 18, Article 20 paras 1 and 2, Article 42 paras 1 to 3, in particular by neglecting to provide information on a chemical substance; penalisation applies to any chemical substance, even if making part of a chemical preparation.”.

Article III

The Act of the National Council of the Slovak Republic no. 145/1995 Coll. on administrative charges, as amended by the Act of the National Council of the Slovak Republic no. 123/1996 Coll., by the Act of the Slovak National Council no. 224/1996 Coll., by the Act no. 70/1997 Coll., by the Act no. 1/1998 Coll., by the Act no. 232/1999 Coll., by the Act no. 3/2000 Coll., by the Act no. 142/2000 Coll., by the Act no. 211/2000 Coll., by the Act no. 468/2000, Coll., by the Act no. 553/2001 Coll., by the Act no. 96/2002 Coll., by the Act no. 118/2002 Coll., by the Act no. 215/2002 Coll., by the Act no. 237/2002 Coll., by the Act no. 418/2002 Coll., by the Act no. 457/2002 Coll., by the Act no. 465/2002 Coll., by the Act no. 477/2002 Coll., by the Act no. 480/2002 Coll., by the Act no. 553/2002 Coll., shall be amended as follows:

In the Tariffs of administrative charges, Part VIII shall be amended as follows:

1. In item 153 the word “registration” shall be replaced by the word “notification”.

2. In item 153 points b) and c) shall be deleted.

3. In item 153, the words “pursuant to a) to c)” in Note shall be deleted.

4. After item 153 the following new item 153a shall be inserted:

“Item 153a

1. Issuance of a decision regarding authorisation for a biocidal product …….. 200 000 Sk

2. Issuance of a decision regarding registration of a low-risk biocidal product ……100 000 Sk

3. Modification of a decision regarding authorisation for a biocidal product or modification of a decision regarding registration of a low-risk biocidal product ……... 75 000 Sk

4. Issuance of a decision regarding authorisation for a biocidal product or issuance of a decision regarding registration of a low-risk biocidal product based on mutual recognition …. ……. 50 000 Sk

Note

1. The Centre for Chemical Substances and Preparations shall levy charges according to point one for applications made under Article 4 para 2 of the Act no. 217/2003 Coll. on conditions relating to the placing on the market of biocidal products and on the amendment to certain other Acts.

2. The Centre for Chemical Substances and Preparations shall levy charges according to point two for applications made under Article 4 para 4 of the Act no. 217/2003 Coll.

3. The Centre for Chemical Substances and Preparations shall levy charges according to point three for applications made under Article 11 para 1 c), Article 7 para 9 of the Act no. 217/2003 Coll.

4. The Centre for Chemical Substances and Preparations shall levy charges according to point four for applications made under Article 10 of the Act no. 217/2003 Coll.”.

Article IV

Entry into Force

This Act shall enter into force on the 1 July 2003, to the exclusion of Article 5 para 5 of the second sentence, Article 7 paras 4 and 12, Article 8 paras 2 to 5, Article 9 para 2, Article 10 paras 1, 4 and 5, Article 11 para 7 d), Article 12 paras 3 to 7, Article 13, Article 15 para 3 d) and Article 17, which shall enter into force on the day of entry into force of the Treaty on accession of the Slovak Republic to the European Eunion.

The Act no. 434/2004 Coll. entered into force on 1 August 2004.

The Act no. 15/2006 Coll. entered into force on 1. February 2006.

The Act no. 95/2007 Coll. entered into force on 1 April 2007.

Rudolf Schuster by his own hand

Pavol Hrušovský by his own hand

Mikuláš Dzurinda by his own hand

This is an unofficial translation
Centre for Chemical Substances and Preparations
Slovak Republic

ANNEX 1

Number	Product type	Usage areas
Disinfectants (These product types exclude cleaning products that are not intended for use as biocidal products with guaranteed effect, including washing liquids, powders and similar products)		
1	Human hygiene biocidal products	Products used for human hygiene with the purpose of general disinfection, other than products with healing effects and products with primary cosmetical and only supplemetary biocidal effects such as anti-microbial soaps, shampoos to control dandruff and oral-care products.
2	Private and public health area disinfectants and other biocidal products	Products used for the disinfection of air, surfaces, materials, equipment and furniture which are not used for direct food or feed contact in private, public or industrial areas, as well as products used as algaecides. Products used against fungi and algae in constructions such as glasshouses, not to be applied on plants but on windows, equipment, desks, knives, etc. Products used for the disinfection of empty warehouses, containers, bags and barrels. Products used for the treatment of river-beds. Algaecidal products used for areas comprising substrates other than soil on playgrounds, parking places, pavements, paths, monuments, etc. Usage areas include also swimming pools, aquariums, bathing and other waters, air-conditioning units, walls and floors in health and other institutions, disinfection of medical equipment, chemical toilets, waste water, hospital waste. Exclude herbicides for agricultural and non-agricultural uses, algaecides applied on soils, areas comprising other soil substrates or into the water for plant protection purposes (e.g. race-courses, golf-courses, aquariums, etc.) and products used for the disinfection of surfaces in glasshouses against microorganisms which may infest plants and subsequently grow on them.
3	Veterinary hygiene biocidal products	Products used for veterinary hygiene purposes including products used in areas in which animals

		are housed, kept or transported. Include products intended for overall disinfection of animals, but exclude products with healing effects.
4	Food and feed area disinfectants	Products used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage, or consumption of food, feed or drink (including drink water) for humans and animals.
5	Drinking water disinfectants	Products used for the disinfection of drinking water (for both humans and animals).
Preservatives		
6	In-can preservatives	Products used for the preservation of manufactured products, other than foodstuffs or feeding stuffs, by the control of microbial deterioration to ensure their shelf life, including photographic films preservatives.
7	Film preservatives	Products used for the preservation of films or coatings by the control of microbial deterioration in order to protect the initial properties of the surface of materials or (such as paints, plastics, sealants, wall adhesives, binders, papers, art works, etc.).
8	Wood preservatives	Proucts used for the preservation of wood from and including saw-mill stage, and wood products by the control of wood-destroying or wood-disfiguring organisms.
9	Fibre, leather, rubber and polymerised materials preservatives	Products used for the preservation of fibrous or polymerised materials (such as leather, rubber, paper, plastics or textile products) by the control of microbiological deterioration.
10	Masonry preservatives	Products used for the preservation and remedial treatment of masonry or other construction materials other than wood by the control of microbiological algal attack.
11	Preservatives for liquid-cooling and processing systems	Products used for the preservation of water and other liquids used in cooling and processing systems by the control of harmful organisms such as microbes, algae and mussels. Exclude drinking water preservation products.
12	Slimicides	Products used for the prevention or control of slime growth on materials, equipment and structures, used in industrial processes (e.g. on wood and paper pulp, and porous sand strata in oil extraction).
13	Metalworking-fluids preservatives	Products used for the preservation of metalworking fluids by the control of microbial deterioration.
Pest control products		
14	Rodenticides	Products used for the control of mice, rats or other

		rodents. Exclude products used exclusively for the protection of plants grown on fields and plant products temporarily stored on fields.
15	Avicides	Products used for the control of birds, other than products used for the protection of plants or plant products.
16	Molluscicides	Products used Exclude products used for the protection of plants and plant products by the control of molluscs.
17	Piscicides	Products used for the control of fish. Exclude products for the treatment of fish diseases.
18	Insecticides, acaricides and other products to control other arthropods	Products used for the control of arthropods (e.g. insects, mites, arachnids, crustaceans, etc.), including products used for the control of external parasites in areas in which animals are housed, kept or transported, with the exception of situations when the animals are present in the treated areas at the time when the product is still active. Products used for the disinfection of empty warehouses or containers, bags, barrels, shower-baths etc., other than those intended exclusively for the storage of plants and plant products. Products used for the control of mites and other arthropods in textile. Exclude products intended for direct contact with the human body and for the treatment of animals, including baths containing insecticides and products containing insecticides or other active substances intended for the control of harmful organisms (collars, ear tags, etc.) or used for the inhibition of their growth or reproduction (growth regulators). Also exclude products for the protection of plants and plant products.
19	Repellents or attractants	Products used for repelling (repellents) or attracting individuals of opposite gender (attractants) of harmful organisms (invertebrates such as fleas and mosquitoes, vertebrates such as birds), which at the same time would have a lethal effect on these organisms or would reduce their reproductive ability, including products that are used for human or veterinary hygiene either directly or indirectly and products containing repellents (collars, ear tags, etc.) and products repelling dogs and cats. Exclude products for the protection of plants and

		plat products, food and feedstuffs.
Other biocidal products		
20	Preservatives for food and feedstocks	Products used for the preservation of food or feedstuffs by the control of harmful organisms, which are not intended for direct contact with food or feedstuffs (e.g. fumigants used in warehouse rooms intended for storage of food such as cheese or meat).
21	Antifouling products	Products used to control growth and settlement of fouling organisms (microorganisms and higher forms of plant and animal species) on vessels, aquaculture equipment or other structures used in water.
22	Embalming or taxidermist fluids	Products used for the disinfection and preservation of human or animal corpses, or parts thereof.
23	Control of other vertebrates	Products used for the control of vermin, other than products intended for the protection of plants and plant products.

ANNEX 2

LIST OF LEGAL ACTS OF THE EUROPEAN COMMUNITIES AND OF THE EUROPEAN UNION TRANSPOSED BY THE SLOVAK REPUBLIC

Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24. 4. 1998).

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1) Article 2 para 2 a) to d) of the Commercial Code.
Article 12a to 12 e of the Act no. 105/1990 Coll. on private enterprising by citizens, as subsequently amended.

2) Article 54 of the Act no. 42/1980 Coll. on economic relations with other countries, as subsequently amended.
Regulation of the Ministry of Economy of the Slovak Republic no. 222/1997 Coll., prohibiting non-commercial exports and imports of things, as subsequently amended.

3) Act no. 130/1998 Coll. on peaceful use of nuclear energy and on the amendment to the Act no. 174/1968 Coll. on state expert supervision over health and safety at work, as amended by the Act of the Slovak national Council no. 256/1994 Coll., as amended by the Act no. 470/200 Coll.

4) Such as the Act of the National Council of the Slovak Republic no. 168/1996 Coll. on the carriage by road, as subsequently amended, Decree of the Minister of Foreign Affairs no. 64/1987 Coll. on the European Agreement on the international carriage of dangerous goods by road (ADR), Act of the Slovak National Council no. 315/1996 Coll. on the traffic on terrestrial communications, as subsequently amended, Act of the Slovak National Council of the Slovak Republic no. 164/1996 Coll. on railroads and on the amendment to the Act no.

455/1991 Coll. on business activities (Business Activities Act), as subsequently amended, as amended by the Act no. 58/1997 Coll., Decree of the Minister of Foreign Affairs no. 8/1985 Coll. on the Convention concerning international carriage by rail (COTIF), Act no. 143/1998 on civil aviation (Aviation Act) and on the amendment to certain Acts, as amended by the Act no. 37/2002 Coll., Act no. 338/2000 Coll. on inland navigation and on the amendment to certain Acts.

4a) The Act no. 217/2003 Coll. on conditions relating to the placing on the market of biocidal products and on the amendment to certain other Acts.

5) Act no. 264/1999 Coll. on technical requirements in respect of products and on the assessment of conformity and on the amendment to certain Acts, as amended by the Act no. 436/2001 Coll.

6) Act no. 163/2001 Coll. on chemical substances and chemical preparations, as amended by the Act no. 128/2002 Coll.

7) Article 2 of the Act no. 163/2001 Coll., as amended by the Act no. 128/2002 Coll.

8) Article 3 paras 1 and 4 of the Act no. 163/2001 Coll.

9) Article 23 of the Act no. 163/2001 Coll., as amended by the Act no. 128/2002 Coll.
Article 24 of the Act no. 163/2001 Coll.

10) Articles 160 to 165 of the Customs Code.
Article 2 para 1 e) of the Act no. 264/1999 Coll., as amended by the Act no. 436/2001 Coll.

11) Act no. 71/1967 Coll. on administrative procedure (Administrative Code), as amended by the Act no. 215/2002 Coll.

12) Article 2 n) of the Customs Code.

14) Act of the National Council of the Slovak Republic no. 270/1995 Coll. on the official language of the Slovak Republic, as subsequently amended.

15) Article 27 of the Act no. 163/2001 Coll., as amended by the Act no. 128/2002 Coll.
Decree of the Ministry of Economy of the Slovak Republic no. 515/2001 Coll. on details and contents of safety data sheets.

15a) Decree of the Ministry of Economy of the Slovak Republic no. 375/2003 Coll. establishing details of dossiers accompanying the application for the authorisation of a biocidal product and details of dossiers accompanying the application for the registration of a low-risk biocidal product and detailed specification of data to be supplied before a biocidal product has been placed on the market and detailed specification of data to be supplied before a low-risk biocidal product has been placed on the market.

16) Article 6 of the Act no. 163/2001 Coll.

17) Article 30 of the Act no. 163/2001 Coll.

18) Articles 9 to 11 of the Act no. 634/1992 Coll. on consumer protection, as subsequently amended.

19) Act no. 36/1967 Coll. on experts and interpreters.

20) Article 6a of the Act no. 634/1992 Coll., as subsequently amended.

20a) Commission Regulation (EC) no. 2032/2003 of 4 November 2003 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 8/EC of the European Parliament and of the Council concerning the placing of biocidal on the market, and amending Regulation (EC) No 1896/2000 (Official Journal of the European Communities L 307, 24. 11. 2003).

21) Articles 23 to 26 of the Act no. 163/2001 Coll., as amended by the Act no. 128/2002 Coll.

22) Article 21 of the Act no. 488/2002 Coll. on veterinary care and on the amendment to certain other Acts.
Articles 6 and 30 of the Act no. 163/2001 Coll.
Decree of the Ministry of the Economy of the Slovak Republic no. 65/2002 Coll. detailing procedure concerning verification of and compliance with, the principles of good laboratory practice, and detailing certification of good laboratory practice and procedure for checks on compliance with the principles of good laboratory practice (principles of good laboratory practice), as amended by the Decree of the Ministry of Economy of the Slovak Republic no. 406/2002 Coll. and Corrigendum published in the Section 184/2002 Coll.

23) Articles 17 to 20 of the Commercial Code, as subsequently amended.
Articles 8 to 12 of the Act no. 211/2000 Coll. on free access to information and on the amendment to certain other Acts (Act on freedom of information).

24) Act no. 527/1990 Coll. on on inventions, industrial models and improvement proposals, as subsequently amended.
Act no. 478 Coll. on commercial models, as subsequently amended.
Act no. 55/1997 Coll. on registerede marks, as amended by the Act no. 577/2001 Coll.
Act no. 146/2000 Coll. on protection of semiconductor products topography.
Act no. 435/2001 Coll. on patents, additional protective certifications and on the amendment to certain other Acts (Patent Act), as amended by the Act no. 402/2002 Coll.

25) Articles 25 to 26 of the Act no. 163/2001 Coll., as amended by the Act no. 128/2002 Coll.

26) Act no. 142/2000 Coll. on metrology and on the amendment to certain other Acts.

27) Act of the Slovak National Council of the Slovak Republic no. 285/1995 Coll. on plant health care, as amended by the Act no. 471/2001 Coll.

28) Act no.147/2001 Coll. on advertising, and on the amendment to certain other Acts, as amended by the Act no. 23/2002 Coll.

29) Article 45 of the Commercial Code, as subsequently amended.

30) Act of the National Council of the Slovak Republic no. 277/1944 Coll. on health care, as subsequently amended.

31) Articles 4 to 9 of the Act no.128/2002 Coll. on state inspection of the internal market in the matters concerning consumer protection, and on the amendment to certain other Acts.

31a) Commission Regulation (EC) no. 1896/2000 of 7 September 2000 on he first phase of the programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council on biocidal products (OJ L 228, 8. 9. 2000, as amended by the Commission Regulation (EC) no. 2032/2003 of 4 November 2003 (OJ L 307, 24. 11. 2003).
Commission Regulation (EC) no. 2032/2003 of 4 November 2003 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 8/EC of the European Parliament and of the Council concerning the placing of biocidal on the market, and amending Regulation (EC) No 1896/2000 (OJ L 307, 24. 11. 2003).

31b) Commission Regulation (EC) No 1048/2005 of 13 June 2005 amending Regulation (EC) no. 2032/2003 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 178, 9. 7. 2005).

32) Annex Tariff of Administrative Charges, part 8, item 153a of the Act No. 145/1995 Coll. as subsequently amended

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33) Annex II to the Commission Regulation (EC) No. 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 325, 11.12.2007).

34) Article 4, paragraph 2 of the Regulation (EC) No. 1451/2007.

35) Regulation of the Government of the Slovak Republic No. 329/2007 Coll. issuing the list of active substances fulfilling criteria for inclusion among biocidal products, as amended by the Regulation of the Government of the Slovak Republic No. 189/2008 Coll. and by the Regulation of the Government of the Slovak Republic No. 24/2009 Coll.

Regulation of the Government of the Slovak Republic No. 188/2008 Coll. issuing the list of low-risk active substances fulfilling criteria for inclusion among low-risk biocidal products.”.
