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ACT

of 12 September 2013

on competencies of national administrative authorities for the making available on the market and use of biocidal products and amending certain Acts (the Biocides Act)

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

Article 1

Subject matter

This Act regulates the competencies of national administrative authorities for the making available on the market and the use of biocidal products and treated articles and for the evaluation of active substances contained in biocidal products (hereinafter only "active substance") pursuant to a specific regulation.[1])

Article 2

National Administrative Authorities

(1) The making available on the market and use of biocidal products under the present Act and in accordance with a specific regulation[1]) shall be administered within their respective competencies by:

a) the Ministry of Economy of the Slovak Republic (hereinafter only "Ministry of Economy"),
b) the Centre for Chemical Substances and Preparations (hereinafter only "Centre"),[2])
c) the Ministry of the Environment of the Slovak Republic (hereinafter only "Ministry of the Environment"),
d) the Ministry of Land Management and Rural Development of the Slovak Republic (hereinafter only "Ministry of Land Management and Rural Development"),
e) the Ministry of Health Service of the Slovak Republic (hereinafter only "Ministry of Health Service"),
f) the Slovak Trade Inspection,[3])
g) the Slovak Environmental Inspection,[4])
h) the National Labour Inspectorate,[5])
i) the State Veterinary and Food Administration of the Slovak Republic and Regional Veterinary and Food Administration (hereinafter only "Veterinary and Food Administration"),[6])
j) customs authorities,[7])
k) the Ministry of Defence of the Slovak Republic (hereinafter only "Ministry of Defence").

(2) Every year by 31 January, the Ministry of Interior of the Slovak Republic on behalf of the Police Force of the Slovak Republic and Firefighting and Rescue Corps of the Slovak Republic, Ministry of Defence, Ministry of Justice of the Slovak Republic and Ministry of Transport, Construction and Regional Development of the Slovak Republic shall forward to

the Ministry of Health Service a report on cases of poisoning caused by biocidal products or a group of biocidal products (hereinafter only "biocidal product") and on incidence of occupational diseases caused by biocidal products. The report shall also contain information on measures adopted to mitigate risks of poisonings caused by biocidal products and incidence of occupational diseases caused by biocidal products.

Article 3

Ministry of Economy

The Ministry of Economy

a) shall be the competent authority fulfilling tasks in accordance with a specific regulation[8]) and cooperating with the European Commission and the European Chemicals Agency (hereinafter only "Agency"),[9])
b) shall manage administration as regards the making available on the market and use of biocidal products,
c) shall be the appellate body in the matters concerning the making available on the market and use of biocidal products, decided by the Centre in the first instance,
d) shall grant exemptions for biocidal products and treated articles, where required in the interest of the defence of the Slovak Republic,[10])
e) shall fulfill notification obligations in accordance with a specific regulation,[11])
f) shall issue its opinion, intended for the Centre, as to the granting of authorisation for a biocidal product in accordance with a specific regulation.[12])

Article 4

The Centre

(1) The Centre shall

a) constitute the competent authority[8]) cooperating with the European Commission and the Agency to the extent as defined in a specific regulation,[1])
b) ensure the evaluation of biocidal products and evaluation of active substances and the international exchange of information between competent authorities of the EU Member States, competent authorities of other countries which are parties to the Agreement on the European Economic Area and Switzerland, the European Commission, the Agency and the bodies of the Organisation for Economic Cooperation and Development, with which it cooperates in the evaluation of biocidal products and active substances, in obtaining and making available data critical to the evaluation thereof, shall attend the meetings of the Committees of the European Commission, of the Agency and working sessions of the competent authorities of the European Union Member States and of other countries which are parties to the Agreement on the European Economic Area and Switzerland held by the European Commission and the Agency,[13])
c) decide on
    1. the authorisation of a biocidal product under a simplified procedure,[14])
    2. the national authorisation of a biocidal product and its renewal,[15])
    3. the authorisation of a biocidal product by means of mutual recognition,[16])
    4. the cancellation, review and amendment of the authorisation of a biocidal product,[17])
d) authorise parallel trade for a biocidal product,[18])

e) grant exemptions for the making available on the market and use of a biocidal product which does not fulfill the conditions for authorisation in accordance with a specific regulation,[19])
f) receive notifications concerning experiments and tests of an unauthorised biocidal product or non-approved active substance intended for use in a biocidal product, shall approve experiments and tests of an unauthorised biocidal product or non-approved active substance intended for use in a biocidal product,[20])
g) open and maintain an account for the third-party funds where it shall deposit amounts paid by legal persons or natural persons – entrepreneurs[21]) for the provision of professional services under the present Act and in accordance with a specific regulation,[1])
h) submit to the Ministry of Economy by 1 June 2015 and subsequently every five years by 31 March of the respective year a report on the implementation of the present Act, containing, inter alia, information on the use of nanomaterials in biocidal products and potential risks they can pose, and in conjunction with the Ministry of Economy shall prepare a report for the European Commission,
i) set up and keep on its website the Register for Biocidal Products made available on the market of the Slovak Republic,
j) forward to the European Commission the request to decide whether the substance is a nanomaterial or whether a product is a biocidal product or a treated article,[22])
k) informs the public on the benefits and risks associated with biocidal products and ways minimising their use,[23])
l) permit the use of data submitted to the Centre for the purposes set out in a specific regulation,[24])
m) record in the Register for Biocidal Products[25]) information pursuant to paragraph 1 letter c) and d),
n) provide advice to legal persons or natural persons – entrepreneurs engaged the in making available on the market and use of biocidal products as to their obligations under this Act and in accordance with a specific regulation.[1])

(2) The Centre may conduct activities pursuant to paragraph 1 letter b) in conjunction with

a) any legal person established by the Ministry of Land Management and Rural Development in accordance with a specific regulation[26]) or
b) the competent authority of another European Union Member State or of another country which is a party to the Agreement on the European Economic Area and Switzerland, exclusively empowered to decide on whether to make available on the market within its territory, or
c) an expert.[27])

(3) Persons referred to in paragraph 2 shall be considered as persons cooperating in the evaluation of a biocidal product, an active substance or a part thereof (hereinafter only "evaluation").

(4) The Centre shall conclude a contract with a person cooperating in the evaluation.[28])

(5) If the Centre concludes a contract with a person other than legal person referred to in paragraph 2 letter a), it shall inform thereof the Ministry of Land Management and Rural Development.

(6) The contract pursuant to paragraph 4 concluded with an expert shall in addition to general particulars contain the written statement by the expert confirming that over the last five years

a) he had no employment relationship nor any similar one with a legal person or natural person – entrepreneur who requests a professional service to be performed pursuant to this Act or a specific regulation,[1])
b) has not been nor is a member on a decision-making or administrative body of a legal person or natural person – entrepreneur who requests a professional service to be performed pursuant to this Act or a specific regulation,[1])
c) he has not been nor is a member of a scientific or research team of a legal person or natural person – entrepreneur who requests a professional service to be performed pursuant to this Act or a specific regulation,[1])
d) he does not receive any benefits on account of his scientific or research activities from a legal person or natural person – entrepreneur who requests a professional service to be performed pursuant to this Act or a specific regulation,[1])
e) he has not received nor does he receive any benefits from a legal person or natural person – entrepreneur who requests a professional service to be performed pursuant to this Act or a specific regulation,[1])
f) he has not been nor is personally interested in favouring any a legal person or natural person – entrepreneur who requests a professional service to be performed pursuant to this Act or a specific regulation,[1])

(7) The person cooperating in the evaluation shall carry out the same to the extent stipulated in the contract while taking into account principles and procedures in accordance with a specific regulation.[29]) He shall submit results thereof in a written report stating therein whether he recommends the authorisation of the evaluated biocidal product or of the evaluated active substance to be approved. Where the person cooperating in the evaluation concludes that there exists a risk to the human health, animal health or to the environment as a result of cumulative effects arising from the use of biocidal products containing the same active substance or some other active substances, he shall submit to the Centre information concerning such risks to the extent as provided for in a specific regulation.[30])

(8) The details on specific activities undertaken by persons cooperating in the evaluation shall appear in the contract conclude pursuant to paragraph 4, depending on the type of the biocidal product or of the active substance being evaluated.

(9) Based on written reports presented pursuant to paragraph 7, the Centre shall prepare a draft report summarising assessment conclusions for the biocidal product or a draft report summarising assessment conclusions for the active substance.

(10) The Centre shall defend the draft report summarizing assessment conclusions pursuant to paragraph 9 before the competent authority of the European Commission in close conjunction with the persons cooperating in the valuation pursuant to paragraph 2.

Article 5

Ministry of the Environment

(1) The Ministry of the Environment

a) shall issue a binding opinion on whether to grant authorisation to make available a biocidal product or allow the use thereof pursuant to Article 4 paragraph 1 letter e), stating therein that such making available or use of a biocidal product is necessary because of the threat to the environment, where such threat cannot be contained by other means, and shall provide the Centre with any assistance required,
b) shall submit to the Ministry of Economy annually by 31 March a report containing information on adverse effects on the environment arising from the use of biocidal products.[31])

(2) The Ministry of the Environment may establish a legal person designated to fulfill the tasks pursuant to paragraph 1.[26])

Article 6

Ministry of Land Management and Rural Development

(1) The Ministry of Land Management and Rural Development

a) shall forward to the Centre the evaluation results pursuant to article 4 paragraph 7,
b) shall issue a binding opinion on whether to grant authorisation to make available a biocidal product or allow the use thereof pursuant to Article 4 paragraph 1 letter e), stating therein that such making available or use of a biocidal product is necessary because of the threat to animal health, where such threat cannot be contained by other means, and shall provide the Centre with any assistance required,
c) shall take provisional measures in accordance with a specific regulation,[32]) provided the authorised biocidal product constitutes a serious immediate or long-term risk to animal health, stating on which grounds the decision has been taken and supplementing data which led to the adoption of such provisional measure and shall, without delay, inform thereof the Ministry of Economy and the Centre.
d) shall submit to the Ministry of Economy annually by 31 March a report containing information on detected adverse effects of biocidal products on animals and on significant incidence of residua of active substances in food and feed.

(2) The Ministry of Land Management and Rural Development may establish a legal person designated to fulfill the tasks pursuant to paragraph 1[26]) enjoying the status of a person cooperating in the evaluation pursuant to Article 4 paragraph 2 letter a).

Article 7

Ministry of Health Service

The Ministry of Health Service shall

a) receive safety data sheets for the biocidal products being made available, supplied by the National Toxicological Information Centre as the competent authority in accordance with a special regulation,[33])
b) forward to the Ministry of Economy and to the Centre annually by 31 March a summary report on cases of poisoning caused by biocidal products and incidence of occupational diseases caused by biocidal products, especially as regards vulnerable groups,[34]) and any special measures aimed at mitigating the risk of poisonings caused by biocidal products and risks of occupational diseases caused by biocidal products. It shall also incorporate in the summary report any reports received pursuant to Article 2 paragraph 2,
c) forward to the Centre information whenever in performing health supervision in accordance with a specific regulation[35]) it becomes aware of a potential risk posed to human health by biocidal products and active substances or by treated articles.

Article 8

Slovak Trade Inspection

The Slovak Trade Inspection shall

a) supervise compliance with conditions applicable to the making available on the market of biocidal products and treated articles in accordance with a specific regulation[37]) when performing inspections with respect to the selling and provision of services to consumers in accordance with a specific regulation[36])
b) cooperate for the purposes of this Act with the Ministry of Economy, the Centre, the Slovak Environmental Inspection, the National Labour Inspectorate, the Veterinary and Food Administration body and the customs authorities,
c) cooperate with the inspection authorities of the European Union Member States and inspection authorities of other countries which are parties to the Agreement on the European Economic Area and Switzerland,
d) decide on measures removing irregularities as regards the making available on the internal market of biocidal products, in matters concerning consumer protection,
e) order the withdrawal of a biocidal product from the market and the disposal of a dangerous biocidal product which does not meet the requirements set out in a special regulation[1]) at the expense of its owner or its holder, provided the identity of the owner is not known and shall impose penalties pursuant to Articles 17 and 18.

Article 9

Slovak Environmental Inspection

The Slovak Environmental Inspection shall

a) cooperate, for the purposes of this Act, with the Ministry of Economy, the Centre, the National Labour Inspectorate, the Veterinary and Food Administration body and the customs authorities,
b) forward to the Centre information whenever in performing inspections in accordance with a specific regulation[38]) it becomes aware of a potential risk posed by a biocidal product to the environment,[39])
c) ensure supervision over the use of a biocidal product which was authorised by the Centre in accordance with a specific regulation[19]) based on the binding opinion issued by the Ministry of the Environment pursuant to Article 5 paragraph 1 letter a),
d) determine conditions and set time-limits to make remedies, whenever in performing inspections it reveals irregularities in the production of a biocidal product or active substances or treated articles under this Act and in accordance with a specific regulation,[1])
e) impose remedial measures pursuant to Article 15 paragraph 6 in case of non-compliance with specific regulations,[40]) provided there exists a danger of damage to the environment or provided it has already been done, it may order the disposal of the biocidal product and active substances or of the treated article at the expense of the owner or of their holder, provided the identity of the owner is not known and shall impose penalties pursuant to Articles 17 and 18,
f) adopt provisional measures in the sphere of environmental protection in accordance with a specific regulation,[32]) provided the authorised biocidal product constitutes a serious immediate or long-term risk to the environment, stating on which grounds the decision has been taken and supplementing data which led to the adoption of such provisional measure and shall, without delay, inform thereof the Ministry of Economy and the Centre.

Article 10

National Labour Inspectorate

The National Labour Inspectorate shall

a) cooperate, for the purposes of this Act, with the Ministry of Economy, the Centre, the Slovak Trade Inspection, the Slovak Environmental Inspection, the Veterinary and Food Administration body and the customs authorities,
b) forward to the Centre information, whenever in performing inspections in accordance with a specific regulation[41]) it becomes aware of a potential risk posed by biocidal products and active substances or treated articles as regards health and safety at work.

Article 11

Veterinary and Food Administration body

The Veterinary and Food Administration body shall

a) cooperate, for the purposes of this Act, with the Ministry of Economy, the Centre, the Slovak Trade Inspection, the Slovak Environmental Inspection and the customs authorities,
b) request in writing the Ministry of Land Management and Rural Development to take any appropriate provisional measure pursuant to Article 6 paragraph 1 letter c), whenever it becomes aware the biocidal product which has been authorised in accordance with a specific regulation[1]) constitutes a serious immediate or long-term risk to animal health, informing thereof in writing the Ministry of Economy and the Centre,
c) forward to the Centre information, whenever in performing inspections in accordance with a specific regulation[42]) it becomes aware of a potential risk posed by a biocidal product and active substances to animals,
d) ensure supervision over the use of a biocidal product which has been authorised by the Centre in accordance with a specific regulation[19]) based on the binding opinion issued by the Ministry of Land Management and Rural Development pursuant to Article 6 paragraph 1 letter b).

Article 12

Customs authorities

(1) Customs authorities shall perform inspection within customs supervision exercised in accordance with a specific regulation.[43]) In doing this, the customs authorities shall cooperate with the Ministry of Economy, the Centre, the Slovak Trade Inspection, the Slovak Environmental Inspection and the Veterinary and Food Administration body.

(2) In case of any doubts as to whether the goods are a biocidal product or a treated article bound to meet the requirements in accordance with a specific regulation,[44]) prior to release thereof in the customs territory of the Slovak Republic, the customs authorities shall ask the Centre to give its position.

Article 13

Ministry of Defence

The Ministry of Defence shall

a) supervise compliance with provisions of this Act and of a specific regulation[1]) in armed forces and by legal persons it may have established,
b) forward to the Ministry of Economy the request for granting exemptions in accordance with a specific regulation,[10])
c) supply to national administrative authorities pursuant to Article 2 paragraph 1 letters f), g) and i) and to the Centre relevant information, where in performing inspection it reveals that

1. the use of a biocidal product in accordance with the authorisation constitutes a serious immediate or long-term risk to human health, animal health or to the environment,
2. a biocidal product is being made available contrary to a specific regulation, [45]) or
3. a biocidal product does not satisfy any condition in pursuant to Article 20 paragraph 1,

d) forward to the Ministry of Economy annually by 31 March a summary report on results of inspections performed in armed forces and legal persons it may have established and on remedial measures and penalties imposed.

Article 14

Payments, annual fees and charges

(1) The Centre shall collect

a) payments for provision of professional services supplied at the request of a legal person or of a natural person – entrepreneur in accordance with a specific regulation,[46])
b) annual fees for biocidal products made available on the market of the Slovak Republic,
c) administrative charges in accordance with a specific regulation.[47])

(2) Payments received by the Centre pursuant to paragraph 1 letter a) shall be used to remunerate persons cooperating in the evaluation on the basis of a contract concluded pursuant to Article 4 paragraph 4 and to cover provision of any related professional services supplied to the Centre. Payments made pursuant to the first sentence shall be kept on the account opened pursuant to article 4 paragraph 1 letter g). The funds representing the amount of expenses incurred to the Centre in relation to provision of professional services pursuant to the first sentence shall constitute the Centre´s income. In case a legal person or natural person – entrepreneur fails to pay within the time-limit set by the Centre in its invitation, after the fruitless expiration of the said time-limit, the Centre shall suspend proceedings.

(3) Where the professional service has not been supplied because of faults on the part of the legal person or natural person – entrepreneur applying for it, the centre shall reject the request and return the payment pursuant to paragraph 1 letter a),[48]) however not in excess of 60 % of the amount paid. The remainder shall be transferred on the Centre´s revenue account.

(4) Where the professional service has not been supplied without a fault on the on the part of the legal person or natural person – entrepreneur applying for it, the Centre shall return the payment pursuant to paragraph 1 letter a) in full.

(5) The Centre shall also return the part of payment pursuant to paragraph 1 letter a) which has not been used for the purpose pursuant to paragraph 2.

(6) No appeal shall be admissible against the Centre´s decision as regards the return of payments pursuant to paragraph 4 or paragraph 5. The decision becomes final on the day of its receipt.

(7) The part of payment pursuant to paragraph 5 shall not be returned where it does not exceed the sum of EUR 10.

(8) The entitlement to receive back the payment pursuant to paragraph 4 or paragraph 5 shall be forfeited following the expiry of three years of the end of the calendar year in which the payment was made.

(9) Annual fees received by the Centre pursuant to paragraph 1 letter b) shall be transferred on the Centre´s revenue account. Annual fees are due every calendar year by 30 June after the respective decision on the making available on the market of a biocidal product has been issued. In case annual fees have not been paid, the Centre shall issue a decision terminating the availability of a biocidal product on the market of the Slovak Republic. No appeal shall be admissible against the Centre´s decision taken pursuant to the preceding sentence.

(10) The object, required particulars and tariffs applicable to payments for professional services supplied by the Centre and to annual fees for biocidal products made available on the market of the Slovak Republic shall be laid down by the Ordinance of the Government of the Slovak Republic.

Article 15

Inspections

(1) The national administrative authority pursuant to Article 2 paragraph 1 letters f), g), i) or letter k) shall supervise, within the scope of its competencies, compliance with the provisions of this Act, of a specific regulation, [1]) of legally binding acts of the European Union adopted for the purpose of its implementation and compliance with decisions adopted on the basis thereof.

(2) The national administrative authority pursuant to Article 2 paragraph 1 letters f), g), i) or letter k) may designate natural persons with required qualification (hereinafter only “designated person) to perform inspections.

(3) Any legal person of natural person – entrepreneur on whose premises inspection is to be carried out shall have the following obligations towards the national administrative authority pursuant to Article 2 paragraph 1 letters f), g), i) or letter k) or towards the designated person

a) to submit, in accordance with a specific regulation,[49]) technical or any other documentation relating to the subject of inspection, including quality and safety of a biocidal product, active substances and treated articles,
b) to enable the access to and inspection of premises where a biocidal product is being manufactured, developed, sold or used,
c) to enable taking samples of a biocidal product to the extent and in quantity required for the purpose of assessing safety, quality and conformity thereof and to be present on the spot,
d) to submit, within the time-limit set by the national administrative authority pursuant to Article 2 paragraph 1 letters f), g), i) or letter k), a report on remedies of revealed irregularities or causes thereof, unless remedial measures imposed have not been implemented in the course of inspection.

(4) Any legal person or natural person – entrepreneur shall be entitled

a) to take control samples in addition to those having been taken pursuant to paragraph 3 letter c),
b) to obtain an identical copy of the protocol on the testing of a biocidal product for its safety and quality,
c) to submit objections as to the way inspection was carried out, as regards irregularities revealed and remedial measures imposed, as stated in the written record of the inspection.

(5) The objection pursuant to paragraph 4 letter c) can be submitted within five days on the receipt of the written report detailing the course of inspection carried out by the national administrative authority pursuant to Article 2 paragraph 1 letters f), g), i) or letter k). The objection to the remedial measures imposed shall have no suspensive effect. The objections shall be decided by the national administrative authority pursuant to Article 2 paragraph 1 letters f), g), i) or letter k) which has revealed the irregularities, within 15 days of receipt thereof. No appeal shall be admissible against the decision taken in the matter of objections.

(6) Any legal person or natural person – entrepreneur shall be under obligation to eliminate irregularities revealed in the course of the inspection in accordance with the present Act, a specific regulation,[1]), legally binding acts of the European Union adopted for the purpose of its implementation, decisions adopted on the basis thereof, and to implement, within the fixed time-limit, the remedial measure imposed by the national administrative authority pursuant to Article 2 paragraph 1 letters f), g), i) or letter k).

(7) When the national administrative authority pursuant to Article 2 paragraph 1 letter f) or letter k) in performing inspections reveals that the use of an authorised biocidal product constitutes a serious immediate or long-time risk to human health, animal health or to the environment, it shall initiate proceedings regarding suspension of the making available on the market of a biocidal product or proceedings regarding temporary ban on its use. It shall without delay inform thereof the Ministry of Economy and the Centre, stating the grounds for its decision.

(8) When a biocidal product is not being made available on the market in compliance with a specific regulation[45]) or when it fails to meet any condition pursuant to Article 20 paragraph 1, the competent national administrative authority pursuant to Article 2 paragraph 1 letters f), g) or letter i) shall start proceedings regarding withdrawal of the biocidal product from the market.

(9) The national administrative authority pursuant to Article 2 paragraph 1 letters f), g), i) or letter i) shall communicate the final decision on the withdrawal of the biocidal product from the market to the Centre and shall ask for the removal from the Registry for Biocidal Products made available on the market of the Slovak Republic. The appeal against the decision on the withdrawal of a biocidal product from the market and the removal thereof from the Register for Biocidal Products made available on the market of the Slovak Republic shall have no suspensive effect.

(10) The national administrative authorities pursuant to Article 2 paragraph 1 letters f), g), i) or letter k) shall forward annually by 31 March summary reports on the results of inspections performed, remedial measures and penalties imposed, to the Ministry of Economy.

Administrative offences

Article 16

(1) Any legal person or natural person – entrepreneur which makes a biocidal product available on the market shall commit an administrative offence if

a) it fails to ensure for the biocidal product to be classified, packaged and labeled in accordance with requirements of a specific regulation,[50])
b) it fails to ensure for a safety data sheet to be prepared or updated or provided in accordance with a specific regulation,[33])
c) it makes available on the market a biocidal product which does not meet requirements under this Act and in accordance with a specific regulation[1]) and for which an exemption has not been granted in accordance with a specific regulation,[40])
d) it places on the market a biocidal product before its inclusion in the Register of Biocidal Products made available on the market of the Slovak Republic,
e) it promotes the making available of the biocidal product by means of advertisement which is contrary to a specific regulation,[52])
f) it fails to inform the Centre that it is terminating the making available on the market the biocidal product pursuant to Article 20 paragraph 6.

(2) Any legal person or natural person – entrepreneur shall commit an administrative offence if it fails to comply with procedures and conditions laid down by a specific regulation[1]) before the biocidal product has been placed on the market.

(3) Any legal person or natural person – entrepreneur shall commit an administrative offence if

a) it fails to keep information or to ensure confidentiality of obtained information on a biocidal product and active substances in accordance with a specific regulation,[53])
b) it fails to inform the Centre and the Agency on adverse effects a biocidal product or the active substances may have on human life and health, the environment or animals or it fails to do so with respect to any other information susceptible to have an impact on the authorisation of the biocidal product,[54])
c) it fails to withdraw from the market a biocidal product after the authorisation thereof has been cancelled or amended,
d) it obstructs or hampers performance of inspection,
e) it fails to enable access to land, premises and workplaces where a biocidal product or an active substance is being manufactured, processed or handled in another way.

(4) Any legal person or natural person – entrepreneur which is responsible for making available on the market of a treated article shall commit an administrative offence if

a) the article was treated with a biocidal product which contains an active substance not complying with requirements set out in a specific regulation,[55])
b) it fails to label the treated article or to provide information thereon in the official language in accordance with a specific regulation.[56])

(5) Where proceedings regarding administrative offences are initiated by national administrative authorities pursuant to Article 2 paragraph 1 letters f), g), i) or letter k) for the

same breach of this Act and of a specific regulation[1]) and on the same day, the proceedings shall be completed and penalties imposed

a) in case of inspection on the internal market in matters concerning consumer protection by the Slovak Trade Inspection,
b) in case of veterinary inspection by the Veterinary and Food Administration body,
c) in case of manufacture and use of a biocidal product within the framework of environmental care by the Slovak Environmental Inspection.

Article 17

The competent national administrative authority pursuant to Article 2 paragraph 1 letters f), g), i) or k), shall impose a penalty

a) from EUR 1,000 to EUR 5,000 in case of an administrative offence pursuant to Article 16 paragraph 3 letter a),
b) from EUR 1,000 to EUR 9,999 in case of an administrative offence pursuant to Article 16 paragraph 1 letter f),
c) from EUR 1,000 to EUR 16,500 in case of an administrative offence pursuant to Article 16 paragraph 1 letter a) and Article 16 paragraph 4 letter b),
d) from EUR 1,000 to EUR 30,000 in case of an administrative offence pursuant to Article 16 paragraph 1 letter b),
e) from EUR 1,000 to EUR 50,000 in case of an administrative offence pursuant to Article 16 paragraph 2,
f) from EUR 1,000 to EUR 70,000 in case of an administrative offence pursuant to Article 16 paragraph 1 letters c), d), e) and Article 16 paragraph 4 letter a),
g) from EUR 3,000 to EUR 99,999 in case of an administrative offence pursuant to Article 16 paragraph 3 letters b) and c),
h) EUR 3,300 in case of an administrative offence pursuant to Article 16 paragraph 3 letters d) and e).

Article 18

(1) When determining the amount of penalty it shall be taken into account in particular the seriousness of the administrative offence, the method, duration, consequences thereof and the value of economic benefit that was or should have been the result of the administrative offence. The penalty for an administrative offence shall be imposed at such an amount that exceeds the undue economic advantage obtained as a result of the administrative offence. The national administrative authority pursuant to Article 2 paragraph 1 letters f), g), i) or letter k) shall also take into account whether the person upon which the penalty is imposed repeatedly committed an administrative offence within three years from the date the final decision imposing a penalty.

(2) If the value of the economic benefit which was or should have been the result of the administrative offence exceeds the upper limit of the penalty imposable for the administrative offence, the administrative authority may impose a penalty exceeding the said upper limit.

(3) The proceedings regarding the imposition of penalty can be started within two years from the day when the national administrative authority pursuant to Article 2 paragraph 1 letters f),

g), i) or letter k) becomes aware of the breach of obligation. The penalty may not be imposed if three years have elapsed from the breach of obligation.

(4) Proceeds from the penalty imposed by the national administrative authority pursuant to Article 2 paragraph 1 letters f), g), i) or letter k) shall accrue to the national budget; proceeds from the penalty imposed by the national administrative authority pursuant to Article 2 paragraph 1 letter g) shall accrue to the Environmental fund.[57])

Article 19

Proceedings

Proceedings under this Act shall be subject to general rules on administrative proceedings,[58]) insofar as Article 15 paragraph 5, article 20 paragraph 3 or a specific regulation[59]) do not provide otherwise.

Article 20

Transitory provisions

(1) Biocidal products for which the Centre has issued a decision authorising their placing on the market in accordance with existing regulations and with respect to which as to 1 November 2013 still apply respective decisions, shall be considered as biocidal products made available on the market[60]) under this Act and in accordance with a specific regulation;[61]) these biocidal products may be made available on the market

a) provided all active substances contained in the biocidal product are existing active substances[62]) and were or are evaluated in accordance with a specific regulation[63]) and have not yet been approved for the given product type,
b) by submitting an application for authorisation of a biocidal product in accordance with a specific regulation[64]) or an application for a parallel mutual recognition of the biocidal product in accordance with a specific regulation[65]) provided the biocidal product does not contain other active substances save the existing ones, no later than by the date of approval of the active substance contained in the biocidal product for the given product type; provided the biocidal product contains more than one active substance, then no later than by the date of approval of the last active substance contained in the biocidal product for the given product type; after satisfying these conditions, legal persons or natural persons – entrepreneurs may continue making biocidal products available on the market, however, for the period of two years at maximum from the date of approval of the last active substance contained in this biocidal product,
c) in case that at least one active substance contained in the biocidal product pursuant to letter a) has not been approved in accordance with a specific regulation,[66]) legal persons or natural persons – entrepreneurs shall terminate the making available on the market of the biocidal product within 365 days from the date of such decision,
d) provided the Centre does not receive an application pursuant to letter b), legal persons or natural persons – entrepreneurs shall terminate the making available on the market of the biocidal product within 180 days from the date of approval of the active substance; legal persons or natural persons – entrepreneurs shall ensure the disposal of existing stocks of the biocidal product at their own expense within 365 days from the date of approval of the active substance and all those having acquired the biocidal product for their own needs

may continue using existing stocks for a period not exceeding 365 days from the date of approval of the active substance, or

e) provided the obligation to comply with time-limits stated under letter d) and to terminate the making available on the market of the biocidal product applies to legal persons or natural persons – entrepreneurs even if the Centre or the competent authority of another European Union Member State or the competent authority of a country which is party to the Agreement on the European Economic Area and Switzerland, rejects the application for authorisation of the biocidal product submitted pursuant to letter d) or if these competent authorities do not decide on granting authorisation for the biocidal product.

(2) Any legal person or natural person – entrepreneur wishing to place by 1 November 2013 on the market[67]) a biocidal product which satisfies conditions pursuant to paragraph 1 letter a) shall ask the Centre to include the biocidal product in the Register for Biocidal Products made available on the market of the Slovak Republic, communicating to the Centre the following data:

a) the 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 organizational unit, where the applicant is a legal person,
b) the trade name of the biocidal product,
c) the chemical name and EU identification number and CAS number of active substances, provided such numbers are available, and their concentrations in metric units; provided the biocidal product is intended for more than one type of biocidal product, it shall communicate this information for each combination of active substances and each type of biocidal product separately,
d) chemical names and EU identification numbers and CAS number of other substances contained in the biocidal product, provided such numbers are available, and their concentrations in metric units,
e) the type number of the biocidal product in accordance with a specific regulation,[68])
f) the category of users for professional use only or for the consumer only,
g) the protocol on determination of the biocidal product efficacy,
h) the text on the packaging label,
i) instructions for use, unless indicated on the packaging,
j) safety data sheet.

(3) Having evaluated applications pursuant to paragraph 2, the Centre shall within 60 days issue a decision on inclusion of a biocidal product in the Register for Biocidal Products made available on the market of the Slovak Republic and following the assignment of a registration number shall enter the biocidal product on the Register for Biocidal Products made available on the market of the Slovak Republic. The making available on the market of biocidal products pursuant to the preceding sentence is subject to conditions and time-limits pursuant to paragraph 1 letter b) to letter e). The following data shall be recorded in the Register for Biocidal Products made available on the market of the Slovak Republic, which the Centre publishes on its website:

a) the trade name of the biocidal product,
b) the name of the decision holder,
c) the registration number of the biocidal product
d) the type or types of the biocidal product,
e) CAS numbers of the active substances contained in the biocidal product,

f) the date of inclusion of a biocidal product in the Register for Biocidal Products made available on the market of the Slovak Republic,

(4) The Centre shall include in the Register of Biocidal Products made available on the market of the Slovak Republic biocidal products pursuant to paragraph 1; the date of inclusion of the biocidal product in the Register for Biocidal Products made available on the market of the Slovak Republic shall be the date of entry into force of this Act. Registration number of biocidal products made available on the market pursuant to paragraph 1 shall remain unchanged.

(5) Biocidal products which may be made available on the market of the Slovak Republic pursuant to paragraph 2 can be placed on the market no sooner than on the day following the inclusion in the Register for Biocidal Products made available on the market of the Slovak Republic and following the publication of registration on the Centre´s website pursuant to paragraph 3; this measure shall not apply to biocidal products made available on the market pursuant to paragraph 1.

(6) The decision holder pursuant to paragraph 1 or paragraph 3 who terminates the making available on the market of a biocidal product on grounds referred to in paragraph 1 letters b) to e) or at his own request, shall notify thereof the Centre in writing, justification included, no later than within five days from the date obligation to terminate the making available on the market pursuant to paragraph 1 letters b) to e) arose or within five days from the date on which he terminated the making the biocidal product available on the market of the Slovak Republic at his own request. Based on such notification, the Centre shall remove the biocidal product from the Registry for Biocidal Products made available on the market of the Slovak Republic.

(7) The national administration authorities pursuant to Article 2 paragraph 1 letters f), g), i) or letter k) which within their activities reveal that a legal person or natural person – entrepreneur failed to satisfy any condition referred to in paragraph 1, shall notify thereof the Centre. Based on such notification, the Centre shall remove the biocidal product from the Registry for Biocidal Products made available on the market of the Slovak Republic.

(8) Proceedings initiated, yet not resulting in a final decision before 1 November 2013 shall be completed under existing regulations save if such proceedings are subject to a specific regulation.[69])

(9) The competencies of the Centre under legislation in force by 31 December 2013 shall be transferred to the Ministry of Economy.

(10) Where legislation in force by 31 December 2013 refers to the “Centre” in all grammatical forms, this shall be understood to mean the “Ministry of Economy” in the appropriate grammatical form.

(11) Rights and obligations resulting from labour relationships, property rights and other legal relationships shall be transferred from the Centre to the Ministry of Economy as of 1 January 2014.

Article 21

Repealing provisions

The following shall be repealed:

1. The Act No 217/2003 Coll. on conditions applicable to the placing of biocidal products on the market and amending certain acts, as amended by the Act No 434/2004 Coll., Act No 15/2006 Coll., Act No 95/2007 Coll., Act No 405/2008 Coll., Act No 489/2008 Coll., Act No 67/2010 Coll. and by the Act No 339/2012 Coll.,

2. The Ordinance of the Government of the Slovak Republic No 152/2007 Coll. laying down details concerning the authorisation dossier for a biocidal product and details concerning the registration dossier for a low-risk biocidal product and detailed specification of data to be submitted before the placing on the market of a biocidal product and detailed specification of data to be submitted before the placing on the market of a low-risk biocidal product.

3. The Decree of the Ministry of Economy of the Slovak Republic No 383/2003 Coll. laying down details concerning procedure and specification as regards principles applicable to the evaluation of biocidal products and evaluation of low risk biocidal products.

Article II

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 National Council of the Slovak Republic No 224/1996, Act No 70/1997 Coll., Act No 1/1998 Coll., Act No 232/1999 Coll., Act No 3/2000 Coll., Act No 142/2000 Coll., Act No 211/2000 Coll., Act No 468/2000 Coll., Act No 553/2001 Coll., Act No 96/2002 Coll., Act No 118/2002 Coll., Act No 215/2002 Coll., Act No 237/2002 Coll., Act No 418/2002 Coll., Act No 457/2002 Coll., Act No 465/2002 Coll., Act No 477/2002 Coll., Act No 480/2002 Coll., Act No 190/2003 Coll., Act No 217/2003 Coll., Act No 245/2003 Coll., Act No 450/2003 Coll., Act No 469/2003 Coll., Act No 583/2003 Coll., Act No 5/2004 Coll., Act No 199/2004 Coll., Act No 204/2004 Coll., Act No 347/2004 Coll., Act No 382/2004 Coll., Act No 434/2004 Coll., Act No 533/2004 Coll., Act No 541/2004 Coll., Act No 572/2004 Coll., Act No 578/2004 Coll., Act No 581/2004 Coll., Act No 633/2004 Coll., Act No 653/2004 Coll., Act No 656/2004 Coll., Act No 725/2004 Coll., Act No 5/2005 Coll., Act No 8/2005 Coll., Act No 15/2005 Coll., Act No 93/2005 Coll., Act No 171/2005 Coll., Act No 308/2005 Coll., Act No 331/2005 Coll., Act No 341/2005 Coll., Act No 342/2005 Coll., Act No 473/2005 Coll., Act No 491/2005 Coll., Act No 538/2005 Coll., Act No 558/2005 Coll., Act No 572/2005 Coll., Act No 573/2005 Coll., Act No 610/2005 Coll., Act No 14/2006 Coll., Act No 15/2006 Coll., Act No 24/2006 Coll., Act No 117/2006 Coll., Act No 124/2006 Coll., Act No 126/2006 Coll., Act No 224/2006 Coll., Act No 342/2006 Coll., Act No 672/2006 Coll., Act No 693/2006 Coll., Act No 21/2007 Coll., Act No 43/2007 Coll., Act No 95/2007 Coll., Act No 193/2007 Coll., Act No 220/2007 Coll., Act No 279/2007 Coll., Act No 295/2007 Coll., Act No 309/2007 Coll., Act No 342/2007 Coll., Act No 343/2007 Coll., Act No 344/2007 Coll., Act No 355/2007 Coll., Act No 358/2007 Coll., Act No 359/2007 Coll., Act No 460/2007 Coll., Act No 517/2007 Coll., Act No 537/2007 Coll., Act No 548/2007 Coll., Act No 571/2007 Coll., Act No 577/2007 Coll., Act No 647/2007 Coll., Act No 661/2007 Coll., Act No 92/2008 Coll., Act No 112/2008 Coll., Act No 167/2008 Coll., Act No 214/2008 Coll., Act No 264/2008 Coll., Act No 405/2008 Coll.,

Act No 408/2008 Coll., Act No 451/2008 Coll., Act No 465/2008 Coll., Act No 495/2008 Coll., Act No 514/2008 Coll., Act No 8/2009 Coll., Act No 45/2009 Coll., Act No 188/2009 Coll., Act No 191/2009 Coll., Act No 274/2009 Coll., Act No 292/2009 Coll., Act No 304/2009 Coll., Act No 305/2009 Coll., Act No 307/2009 Coll., Act No 465/2009 Coll., Act No 478/2009 Coll., Act No 513/2009 Coll., Act No 568/2009 Coll., Act No 570/2009 Coll., Act No 594/2009 Coll., Act No 67/2010 Coll., Act No 92/2010 Coll., Act No 136/2010 Coll., Act No 144/2010 Coll., Act No 514/2010 Coll., Act No 556/2010 Coll., Act No 39/2011 Coll., Act No 119/2011 Coll., Act No 200/2011 Coll., Act No 223/2011 Coll., Act No 254/2011 Coll., Act No 256/2011 Coll., Act No 258/2011 Coll., Act No 324/2011 Coll., Act No 342/2011 Coll., Act No 363/2011 Coll., Act No 381/2011 Coll., Act No 392/2011 Coll., Act No 404/2011 Coll., Act No 405/2011 Coll., Act No 409/2011 Coll., Act No 519/2011 Coll., Act No 547/2011 Coll., Act No 49/2012 Coll., Act No 96/2012 Coll., Act No 251/2012 Coll., Act No 286/2012 Coll., Act No 336/2012 Coll., Act No 339/2012 Coll., Act No 351/2012 Coll., Act No 439/2012 Coll., Act No 447/2012 Coll., Act No 459/2012 Coll., Act No 8/2013 Coll., Act No 39/2013 Coll., Act No 40/2013 Coll., Act No 72/2013 Coll., Act No 75/2013 Coll., Act No 94/2013 Coll., Act No 96/2013 Coll., Act No 122/2013 Coll., Act No 154/2013 Coll. and Act No 213/2013 Coll. shall be amended as follows:

1. In the Tariffs of administrative charges, Part VIII Financial administration and trade activity, in item 153, the letter a) shall be deleted.

The existing letters b) and c) shall be renamed as letters a) and b).

2. In the Tariffs of administrative charges, Part VIII Financial administration and trade activity, the item 153a shall read as follows:

“Item 153a

1. Approval of an active substance	EUR 2,000
2. Renewal of the approval of an active substance	EUR 1,000
3. National authorisation of a biocidal product	EUR 750
4. Union authorisation	EUR 1,000
5. National authorisation of a group of biocidal products	EUR 1,250
6. Union authorisation of a group of biocidal products	EUR 1,500
7. Mutual recognition in sequence of a biocidal product or mutual recognition in parallel of a biocidal product	EUR 500
8. Mutual recognition in sequence of a group of biocidal products or mutual recognition in parallel of a group of biocidal products	EUR 750
9. Renewal of a national authorisation of a group of biocidal products pursuant to a special regulation or renewal of a Union authorisation of a group of biocidal products	EUR 500
10. Amendment of authorisation at the request of the authorisation holder	EUR 1,000
11. Inclusion of a biocidal product in the Register for Biocidal Products made available on the market of the Slovak Republic	EUR 300
12. Modification of a decision of the Centre for Chemical Substances and Preparations regarding inclusion of a biocidal product in the Register for Biocidal Products made available on the market of the Slovak Republic	EUR 150
13. Deletion of a biocidal product from the Registry for Biocidal Products made available on the market of the Slovak Republic at a legal person´s or a natural person´s – entrepreneur´s own request	EUR 100”.

Article III

The Act No 525/2003 Coll. on state administration of environmental care and amending certain acts, as amended by the Act No 205/2004 Coll., Act No 587/2004 Coll., Act No 15/2005 Coll., Act No 345/2012 Coll. and by the Act No 180/2013 Coll. shall be amended as follows:

In Article 9 paragraph 1, after letter d) a new letter e) shall be inserted which reads as follows:
"e) performs activities of an inspection authority in accordance with specific regulations,[10a])"

The existing letter e) shall be renamed as letter f).

The footnote under reference 10a shall read as follows:
"[10a]) Act No 67/2010 Coll. on conditions applicable to the placing on the market of chemical substances and chemical mixtures, amending certain acts (Chemicals Act), as amended by the Act No 339/2012 Coll.
Act No 319/2013 Coll. on competencies of national administrative authorities for the making available on the market and use of biocidal products and amending certain Acts (the Biocides Act).".

Article IV

The Act No 67/2010 Coll. on conditions applicable to the placing on the market of chemical substances and chemical mixtures, amending certain acts (Chemicals Act), as amended by the Act No 339/2012 Coll., shall be amended as follows:

1. In Article 24, paragraph 7 shall read as follows:
"(7) The inspection bodies referred to in Article 23 letters a) to f) shall forward summary reports on results of inspections performed, remedial measures and penalties imposed in accordance with a specific regulation[50a]) to the Ministry of Economy no later than 1 April 2017 while any subsequent summary reports shall be submitted every five years of the submission of the first report.".

The footnote under reference 50a shall read as follows:
"[50a]) Article 46 paragraph 1 of the Regulation (EC) No 1272/2008, as amended.".

2. In Article 24, paragraph 8 shall be added which shall read as follows:
"(8) The inspection bodies referred to in Article 23 letters a) to f) shall forward summary reports on results of inspections performed, remedial measures and penalties imposed in accordance with a specific regulation[50b]) to the Ministry of Economy no later than 1 March 2015 while any subsequent summary reports shall be submitted every five years of the submission of the first report.".

The footnote under reference 50b shall read as follows:
"[50b]) Articles 117 and 127 of the Regulation (EC) No 1907/2006, as amended.".

3. In Article 26 paragraph 2, letter d) shall be deleted.

The existing letter e) shall be renamed as letter d).

4. In Article 26 paragraph 3, letters c), d) and f) shall be deleted.

The existing letter e) shall be renamed as letter d).

5. In Article 31, letter c) shall be deleted.

6. In Article 33 paragraph 1, letter b) shall read as follows:
“b) they fail to ensure for substances or mixtures to be labeled pursuant to Articles 3 and 4.”.

7. In Article 46 paragraph 1, letter c) shall read as follows:
“c) names of substances whose concentration in the mixture led to the classification of the mixture into hazard categories very toxic, toxic, corrosive, harmful, in hazard classes
1. category 1, 2 or 3 carcinogen,
2. category 1, 2 or 3 mutagen,
3. toxic for reproduction category 1, 2 or 3,
4. very toxic, toxic or harmful by its non-lethal effect after single exposure,
5. toxic or harmful after repeated or prolonged exposure to the substance,
6. sensitising,”.

8. In Article 47, paragraph 5 shall be deleted.

The existing paragraphs 6 to 10 shall be renamed as paragraphs 5 to 9.

9. In Article 47 paragraph 7, the first sentence shall be deleted.

10. In Article 48 paragraph 2, the words “Article 46” shall be replaced by the words “Article 45”.

11. In Article 49 point five, the words “and Order No 4/2009” shall be replaced by the words “and Order No 5/2009”.

Article V

Entry into force

This Regulation shall enter into force on the 1 November 2013 except for Article I, Article 20, paragraphs 9 to 11 which shall enter into force on the 1 January 2014.

Ivan Gašparovič by his own hand

Pavol Paška by his own hand

Robert Fico by his own hand

Footnotes:

[1]) Regulation of the European Parliament and of the Council (EU) No 528/2012 of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27. 6. 2012).
[2]) Article 22 of the Act No 67/2010 Coll. on conditions applicable to the placing on the market of chemical substances and chemical mixtures, amending certain acts (Chemicals Act), as amended by the Act No 339/2012 Coll.
[3]) Article 3 of the Act No 128/2002 Coll. on state control of internal market in the matters of consumer protection, amending certain acts, as subsequently amended.
[4]) Article 1 paragraph 1 letter d) of the Act No 525/2003 Coll. on national administration of environmental care, amending certain acts.
[5]) Articles 5 to 6 of the Act No 125/2006 Coll. on labour inspection, amending Act No 82/2005 Coll. on illegal work and illegal employment, amending certain acts, as subsequently amended.
[6]) Articles 6 and 8 of the Act No 39/2007 Coll. on veterinary care, as subsequently amended.
[7]) Article 9 of the Act No 652/2004 Coll. on customs national administrative authorities, amending certain acts, as subsequently amended.
[8]) Article 81 paragraph 1 of the Regulation (EU) No 528/2012.
[9]) Article 3 paragraph 1(x) of the Regulation (EU) No 528/2012.
[10]) Article 2 paragraph 8 of the Regulation (EU) No 528/2012.
[11]) Article 65 paragraph 3, Article 81 paragraph 3 and Article 88 of the Regulation (EU) No 528/2012.
[12]) Article 19 paragraph 5 of the Regulation (EU) No 528/2012.
[13]) Articles 4 to 53, Article 54 paragraphs 3, 4 and 6, Articles 55 and 56 , Article 75 paragraph 2 and Article 82 of the Regulation (EU) No 528/2012.
[14]) Articles 25 to 27 of the Regulation (EU) No 528/2012.
[15]) Articles 29 to 31 and Article 55 paragraph 2 of the Regulation (EU) No 528/2012.
[16]) Articles 32 to 40 of the Regulation (EU) No 528/2012.
[17]) Articles 48 to 52 of the Regulation (EU) No 528/2012.
[18]) Article 53 of the Regulation (EU) No 528/2012.
[19]) Article 55 of the Regulation (EU) No 528/2012.
[20]) Article 56 paragraphs 2 and 3 of the Regulation (EU) No 528/2012.
[21]) Articles 18 and 19 of the Civil Code.
Article 2 paragraph 2 of the Commercial Code.
[22]) Article 3 paragraph 3 of the Regulation (EU) No 528/2012.
[23]) Article 17 paragraph 5 third sentence of the Regulation (EU) No 528/2012.
[24]) Article 64 of the Regulation (EU) No 528/2012.
[25]) Article 71 of the Regulation (EU) No 528/2012.
[26]) Articles 21 and 22 of the Act no 523/2004 Coll. on public administration budgetary rules, amending certain Acts, as subsequently amended.
[27]) Articles 16 to 18 of the Act No 382/2004 Coll. on experts, interpreters and translators, amending certain acts, as subsequently amended.
[28]) For example, Articles 591 to 600 of the Commercial Code, Article 51, Articles 733 to 736 of the Civil Code, as amended by the Act No 509/1991 Coll.
[29]) Articles 8, 10 and 11, Article 14, Articles 18 to 24, Articles 29 to 34, Articles 40, 44 and 46 of the Regulation (EU) No 528/2012.
[30]) Annex XV, section II, point 3 of the Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals

Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30. 12. 2006), as amended.
[31]) Article 65 paragraph 3(c) of the Regulation (EU) No 528/2012.
[32]) Article 88 of the Regulation (EU) No 528/2012.
[33]) Article 70 of the Regulation (EU) No 528/2012.
Article 31 of the Regulation (EC) No 1907/2006.
Article 6 and Article 19 letter b) of the Act No 67/2010 Coll.
[34]) Article 3 paragraph 1(ad) of the Regulation (EU) No 528/2012.
[35]) Article 54 of the Act No 355/2007 Coll. on Public health protection, support and development, amending certain acts, as subsequently amended.
[36]) Act No 128/2002 Coll., as subsequently amended.
[37]) Article 17 paragraph 1, Articles 52, 58, 69 and 72 of the Regulation (EU) No 528/2012.
[38]) Article 9 paragraph 1 letter a) of the Act No 525/2003 Coll.
[39]) Article 15 paragraph 1, Article 19 paragraph 1(b)(iv), Article 19 paragraph 4(c) of the Regulation (EU) No 528/2012.
Article 129 of the Regulation (EC) No 1907/2006, as amended.
Article 52 of the Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31. 12. 2008), as amended.
[40]) Articles 55 and 56 of the Regulation (EU) No 528/2012.
[41]) Act No 125/2006 Coll., as subsequently amended.
[42]) Article 6 of the Act No 39/2007 Coll., as subsequently amended.
[43]) Article 3 of the Act No 199/2004 Coll. “the Customs Act”, amending certain acts, as amended by the Act No 331/2011 Coll.
[44]) Article 17 paragraph 1 and Article 58 of the Regulation (EU) No 528/2012.
[45]) Article 17 paragraph 1 of the Regulation (EU) No 528/2012.
[46]) Article 80 paragraph 2 of the Regulation (EU) No 528/2012.
[47]) Annex Tariffs of administrative charges, Part VIII, item 153a, to the Act No 145/1995 Coll. on administrative charges, as amended by the Act No 319/2013 Coll.
[48]) For example, Article 7 paragraph 4, Article 26 paragraph 4, Article 43 paragraph 4 of the Regulation (EU) No 528/2012.
[49]) For example, Article 65 paragraph 2(a) to (d) of the Regulation (EU) No 528/2012.
[50]) Article 69 of the Regulation (EU) No 528/2012.
[51]) Article 3 paragraph 1(y) of the Regulation (EU) No 528/2012.
[52]) Article 72 of the Regulation (EU) No 528/2012.
Article 48 of the Regulation (EC) No 1272/2008.
[53]) Article 62 paragraph 2, Articles 63 and 64, Article 65 paragraph 2 and Article 68 of the Regulation (EU) No 528/2012.
[54]) Article 47 paragraph 1 of the Regulation (EU) No 528/2012.
[55]) Article 58 paragraph 2 of the Regulation (EU) No 528/2012.
[56]) Article 58 paragraphs 3 to 6 of the Regulation (EU) No 528/2012.
[57]) Article 3 letter a) of the Act No 587/2004 Coll. on the Environmental Fund, amending certain acts, as subsequently amended.
[58]) Act No 71/1967 Coll. on administrative proceedings (Administrative Code), as subsequently amended.
[59]) For example, Article 8 paragraph 2, Article 14 paragraph 1, Article 26 paragraphs 3 and 4, Article 29 paragraphs 3 and 5, Article 30, Article 31 paragraphs 5 and 6, Article 33 paragraph

4, Articles 34 to 36, Article 40, Articles 44 to 46, Article 48 paragraph 1, Article 53 of the Regulation (EU) No 528/2012.
[60]) Article 3 paragraph 1(i) of the Regulation (EU) No 528/2012.
[61]) Article 89 paragraph 2 of the Regulation (EU) No 528/2012.
[62]) Article 3 paragraph 1(d) of the Regulation (EU) No 528/2012.
[63]) 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), as amended.
[64]) Articles 17 and 20 of the Regulation (EU) No 528/2012.
[65]) Article 34 of the Regulation (EU) No 528/2012.
[66]) Article 9 paragraph 1(b) of the Regulation (EU) No 528/2012.
Article 4 of the regulation (EC) No 1451/2007, as amended.
[67]) Article 3 paragraph 1(j) of the Regulation (EU) No 528/2012.
[68]) Annex V to the Regulation (EU) No. 528/2012.
[69]) For example, Article 90 paragraph 2, Article 91 of the Regulation (EU) No 528/2012.