ACT ON PROTECTION FROM THE HARMFUL IMPACT OF THE CHEMICAL SUBSTANCES AND MIXTURES (TITLE AMEND. - SG 114/03, IN FORCE FROM 31.01.2004; AMEND. – SG 63/10, IN FORCE FROM 13.08.2010)

Prom. SG. 10/4 Feb 2000, amend. SG. 91/25 Sep 2002, amend. SG. 86/30 Sep 2003, amend. SG. 114/30 Dec 2003, amend. SG. 100/13 Dec 2005, amend. SG. 101/16 Dec 2005, amend. SG. 30/11 Apr 2006, amend. SG. 34/25 Apr 2006, amend. SG. 95/24 Nov 2006, amend. SG. 82/12 Oct 2007, amend. SG. 110/30 Dec 2008, amend. SG. 63/13 Aug 2010, amend. SG. 98/14 Dec 2010, amend. SG. 84/2 Nov 2012, amend. SG. 61/25 Jul 2014, amend. and suppl. SG. 102/29 Dec 2015, amend. and suppl. SG. 12/3 Feb 2017, amend. SG. 58/18 Jul 2017, amend. and suppl. SG. 53/26 Jun 2018, amend. and suppl. SG. 98/27 Nov 2018, ***amend. and suppl. SG. 17/26 Feb 2019***

Chapter one.
GENERAL PROVISIONS

Art. 1. (amend. SG 114/03; amend. – SG 82/07) (1) This act shall set:

1.(amend. – SG 63/10, in force from 13.08.2010) the rights and obligations of natural persons and legal entities, producing, launching at the market, using, storing and exporting chemical substances on their own or in mixtures or in articles and mixtures, with objective of protection of the health and protection of the environment;

2. (amend. – SG 63/10, in force from 13.08.2010) powers of state authorities, implementing control over the production, launching at the market, use, storage and export of chemical substances on their own , in mixtures or in articles and mixtures;

3.(amend. – SG 63/10, in force from 13.08.2010) measures to apply:

a) Regulation (EC) No. 1907/2006 of the European Parliament and the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemical Agency, amending Directive 1999/45/EEC and repealing Regulation (EEC) No. 793/93 of the Council and Regulation (EC) No. 1488/94 of the Commission, as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC , hereinafter 'Regulation (EC) No 1907/2006 (REACH)';

b) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packing of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC and amending Regulation (EC) No 1907/2006 (OB L 353/1 of 31 December 2008), hereinafter 'Regulation (EC) No 1272/2008 (CLP)';

c) (suppl. – SG 102/15) Regulation (EC) No 648/2004 of 31 March 2004of the European Parliament and of the Council on detergents, hereinafter 'Regulation (EC) 684/2004" and Regulation (EU) No. 259/2012 of the European Parliament and of the Council of 14 March 2012 amending Regulation (EC) No 648/2004 as regards the use of phosphates and other phosphorus compounds in consumer laundry detergents and consumer automatic dishwasher detergents (OJ, L 94/16 pf 30 March 2012) herein after referred to as "Regulation (EU) No.259/2012";

d) (amend. – SG 102/15) Regulation (EC) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of dangerous chemicals (OJ L 201/60 of 27 July 2012), hereinafter 'Regulation (EC) No 649/2012";

e) Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117 EEC, hereinafter 'Regulation (EC) No 850/2004';

f) (amend. – SG 102/15) Delegated Regulation (EU) No 1062/2014 of the Commission of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ, L 294/1 of 10 October 2014), hereinafter referred to as “Delegated Regulation (EU) No 1062/2014”;

g) (new – SG 102/15) Regulation (EU) No. 528/20012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, herein after referred to as “Regulation (EU) No. 528/2012” and Regulation (EU) No. 334/2014 of the European Parliament and of the Council of 11 March 2014 amending Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, with regard to certain conditions for access to the market (OJ, L 103/22 of 5 April 2014);

(h) (new – SG 102/15) Delegated Regulation (EU) No. 492/2014 of 7 March 2014 supplementing Regulation (EU) No 528/2012 of the European Parliament and of the Council as regards the rules for the renewal of authorisations of biocidal products subject to mutual recognition (OJ, L 139/1 of 14 March 2014), herein after referred to as “Delegated Regulation (EU) No. 492/2014”;

i) (new – SG 102/15) Regulation (EU) No. 98/2013 of the European Parliament and of the Council of 14 January 2013 on the marketing and use of explosives precursors (OJ, L 39/1 of 9 February 2013), herein after referred to as “Regulation (EU) No. 98/2013”;

j) (new - SG 53/18, in force from 26.06.2018) Regulation (EU) 2017/852 of the European Parliament and of the Council of 17 May 2017 on mercury, and repealing Regulation (EC) No 1102/2008 hereinafter referred to as "Regulation (EC) 2017/852";

4. (new – SG, 84/2012, in force from 02.01.2013) the restriction of the use of harmful substances in electricity and electronic equipment (EEE) in view to protection of human health and environment, including ecologic use and waste decontamination from EEE and the related to this obligations of the economic operators of EEE;

5. (new – SG 102/15) the requirements for provision, introduction, owning and use of chemical substances and compounds which are explosives precursors and for reporting of suspicious transactions included these chemical substances and compounds.

Art. 2. (amend. SG 114/03; amend. – SG 63/10, in force from 13.08.2010, shall be applied to 31.05.2015, revoked - SG 53/18, in force from 26.06.2018)

Art. 3. (amend. SG 114/03; amend. – SG 82/07; amend. – SG 63/10, in force from 13.08.2010) (1) (amend. - SG 53/18, in force from 26.06.2018) Chapter Four shall not be applied to:

1. (amend. SG 114/03; amend. – SG 82/07) the following mixture in ready for the end customer state:

a) the medicinal products in the humanitarian medicine and the veterinary medical products;

b) the cosmetic products;

c) the foods and the additives in the foods designated for people and animals;

d) medical articles;

2. waste as per the Waste Management Act;

3. the radioactive substances and nuclear materials as per the Act on the Safe Use of Nuclear Energy;

4. the chemical substances and preparations transported transit through the territory of the Republic of Bulgaria which are not subject to customs control and are not treated or processed;

5. transportation of dangerous substances or mixtures by railway, domestic-water , sea or air

transport.

(2) (revoked - SG 53/18, in force from 26.06.2018)

(3) (amend. and suppl. – SG 102/15) Measures for implementation of Regulation (EC) No 648/2004 and Regulation (EU) No. 259/12, introduced by Chapters Three, Seven and Eight, shall be applied as per Article 1 and Article 3(1) of Regulation (EU) No. 648/2004.

(4) Measures for implementation of Regulation (EC) No 1907/2006 (REACH), introduced by Chapters Five, Seven and Eight, shall be applied as per Article 2, Article 15, Article 16, Article 56 (3), (4), and (5), Article 67 and Article 68 (1) of the Regulation.

(5) Measures for implementation of Regulation (EC) No 1272/208 (CLP), introduced by Chapters Five, Seven and Eight, shall be applied as per Article 2 of the Regulation.

(6) (amend. – SG 102/15) Measures for implementation of Regulation (EC) No 649/2012, introduced by Chapters Six, Seven and Eight, shall be applied as per Article 2 of the Regulation.

(7) Measures for implementation of Regulation (EC) No 850/2004, introduced by Chapters Six, Seven and Eight, shall be applied as per Article 1 and Article 4 of the Regulation.

(8) (new – SG 102/15) The measures for the implementation of Regulation (EU) No. 528/2012, introduced by Chapters Four, Seven and Eight shall be applied subject to compliance with Art. 2 and 3 of the same Regulation.

(9) (new – SG 102/15) The measures for the implementation of Regulation (EU) No. 98/2013, introduced by Chapters Six “a” shall be applied subject to compliance with Art. 2 of the same Regulation.

(10) (new - SG 53/18, in force from 26.06.2018) The implementing measures for Regulation (EC) 2017/852 introduced in chapters two, seventh and eighth, shall be implemented in accordance with Art. 1, 3 - 5 and Art. 7 to 9 of said Regulation as the provisions of Art. 4 (1) and (4), Art. 11, 12, 13 and 14 of that Regulation shall not be implemented on mercury waste and Art. 10 of the same Regulation on dental amalgam.

Art. 3a. (new - SG 53/18, in force from 26.06.2018) Natural and legal persons may be exempted from obligations for registration, authorisation and/or restriction in accordance with Title II, III, VI, VII, VIII and / or IX of Regulation (EC) No 1907/2006 (REACH) for certain chemicals on their own, in mixtures or un the products of interest to the defense, in one or more of the following circumstances:

1. the provision of information on production, use or placing on the market for defense purposes of a chemical on its own, in the composition of a mixture or in an article could lead to a threat to national security;

2. the lack of alternative chemicals or technologies may lead to loss of ability to manufacture, maintain, repair or modernize a defensive product as well as disturbing the long-term security of supplies for the purpose of the manufacture, maintenance, repair or modernization of such a product;

3. the ability of the Armed Forces of the Republic of Bulgaria to fulfill its task may be impaired;

4. the obligation of the Republic of Bulgaria may be violated to restrict the disclosure of information in the field of defense;

5. it is necessary to ensure the fulfillment of obligations of the Republic of Bulgaria arising from its participation in international organizations or political-military alliances for collective defense.

Art. 4. (amend. SG 114/03; amend. – SG 95/06, in force from 24.11.2006; previous text of Art. 4 – SG 63/10, in force from 13.08.2010, amend. - SG 12/17) The advertising of dangerous chemical substances without pointing out in the advertisement their category of danger according to Regulation (EC) No 1272/2008 (CLP) shall be prohibited.

(2) (new- SG 63/10, in force from 13.08.10, suppl. - SG 53/18, in force from 26.06.2018) Any advertising of a mixture, classified as dangerous or containing a substance, classified as dangerous in

accordance with Regulation (EC) No 1272/2008 (CLP), which allows the mass consumer to conclude purchase contract without seeing the label before it, shall point out the category or categories of danger as pointed on the label.

Art. 4a. (new – SG 95/06, in force from 24.11.2006; amend. – SG 82/07; amend. – SG 63/10, in force from 13.08.2010) Persons, envisaged in Art. 1. Para 1 shall be obliged to:

1.produce, place on the market, use, keep and export chemical substances on their own, in mixtures or in articles and/or mixtures in a manner, which prevents or restricts their harmful impact on the human health and the environment, as per provisions of this Act, the secondary legislation on its application, as well as of regulations, envisaged in Art. 1, item 3.

2.provide free access of the bodies as per Art. 7, Para 2 and 2 to the undertakings and sites, where production, place on the market, use, storing and export of chemical substances on their own, in mixtures or in article and/or mixtures is carried out;

3.maintain and upon request, submit to the bodies envisaged in Art. 27, Para 1, information and documents about:

a) production, placing on the market, use, storage and export of chemical substances on their own, in mixtures or in articles and/or in mixtures, including about their quantities and components;

b) identity of their direct suppliers or customers of chemical substances and mixtures.

Art. 4b. (new – SG 95/06, in force from 24.11.2006; amend. – SG 63/10, in force from 13.08.2010) (1) Procedure and manner of storage of dangerous chemical substances and mixtures shall be determined by an ordinance of the Council of Ministers.

(2) Procedure and manner of restriction of manufacturing, use and placing on the market of certain dangerous chemical substances, mixtures and articles by Annex VII of Regulation (EC) No 1907/2006 (REACH) shall be determined by an ordinance of the Council of Ministers.

Art. 4c. (new – SG 95/06, in force from 24.11.2006; revoked - SG 63/10, in force from 13.08.2010, new - SG 98/18, in force from 27.11.2018) (1) Laboratory tests for determination of toxicological and ecotoxicological properties shall be carried out in accordance with the principles of Good Laboratory Practice.

(2) The observance of the principles of Good Laboratory Practice by the laboratories shall be certified by the Executive Agency "Bulgarian Accreditation Service" under the conditions and by the order of the ordinance under para. 3 or by the national authorities of the Member States of the European Union and of the European Economic Area notified to the European Commission.

(3) Principles, inspection and certification of Good Laboratory Practice shall be determined by an ordinance of the Council of Ministers.

Art. 4d. (new – SG 95/06, in force from 24.11.2006; revoked - SG 63/10, in force from 13.08.2010)

Chapter two.
MEASURES FOR IMPLEMENTATION OF THE REGULATION (EU) 2017/852 (TITLE AMEND.

SG 114/03; AMEND. – SG 63/10, IN FORCE FROM 13.08.2010, AMEND. - SG 53/18, IN FORCE FROM 26.06.2018)

Chapter two.

CLASSIFICATION, PACKING AND LABELLING OF THE DANGEROUS CHEMICAL SUBSTANCES AND MIXTURES (title amend. SG 114/03; AMEND. – SG 63/10, IN FORCE FROM 13.08.2010)

Art. 5. (amend. SG 114/03, amend. - SG 53/18, in force from 26.06.2018) The Minister of Environment and Waters is a competent authority within the meaning of Art. 17 of Regulation (EC) 2017/852 with the exception of the provisions of Art. 10 of that Regulation related to the protection of human health from mercury, mercury compounds and mixtures of mercury including those related to dental amalgam for which the Minister of Health is the competent authority.

Art. 5a. (new – SG 114/03, amend. SG 101/05; revoked– SG 95/06, in force from 24.11.2006)

Art. 5b. (new – SG 95/06, in force from 24.11.2006, revoked – SG 63/10, in force from 13.08.2010)

Art. 6. (amend. – SG 63/10, in force from 13.08.2010, revoked - SG 12/17, new - SG 53/18, in force from 26.06.2018) (1) Imports of mercury and mercury mixtures pursuant to Annex I to Regulation (EC) 2017/852 for use authorized in the country shall be carried out with the agreement of the Minister of Environment and Waters or an official authorized by him / her.

(2) The importer under para. 1 or a person authorized by him shall submit to the Minister of Environment and Water a form for granting consent for import in an established format according to Art. 6 of Regulation (EC) 2017/852.

(3) To the form under para. 2 the information according to Art. 4 (1) of Regulation (EC) 2017/852 shall be attached.

(4) In the event of inconsistencies or incompleteness in the form under para. 2 or in the information under para. 3 the Minister of Environment and Water or an official authorized by him/her shall notify the importer or the person authorized by him within 10 days from the date of submission of the import form. In such cases, the term under para. 6 stops running.

(5) The importer or the person authorized by him shall remedy any inconsistencies or incompleteness in the form under para. 2 or the information under para. 3 within 10 days from the date of receipt of the notification under para. 4.

(6) The Minister of Environment and Waters or an official authorized by him/her shall grant consent for importation within 30 days of receipt of the form under para. 2.

(7) The Minister of Environment and Waters or an official authorized by him/her refuses to grant consent for importation when, after evaluation of the information under para. 2 and 3 it was found that:

1. the inconsistencies and incompleteness have not been remedied, or

2. the term under para. 5 has not been met.

(8) The refusal under para. 7 may be appealed in accordance with the Administrative Procedure Code.

(9) For the processing of the form under para. 2 the importer pays a fee according to the tariff under Art. 72 of the Environmental Protection Act.

Art. 7. (amend. SG 114/03; revoked – SG 63/10, in force from 13. 08.2010, new - SG 53/18, in force from 26.06.2018) (1) Any natural or legal person intending to manufacture or place on the market a new product containing mercury or to use a new production process involving the use of mercury or mercury compounds shall submit to the Minister of Environment and Water a notification containing the contact details of the person and the information under Art. 8 (3) of Regulation (EC) 2017/852.

(2) The notification and the information under Art. 8 (3) of Regulation (EC) 2017/852 shall be filed in a single copy in Bulgarian in hard copy and in electronic form and in a single copy in English in hard copy and in electronic form.

Art. 7a. (new – SG 114/03; amend. – SG 82/07; amend. – SG 63/10, in force from 13.08.2010; revoked – SG 61/14, in force from 25.07.2014, new - SG 53/18, in force from 26.06.2018) (1) The Minister of Environment and Water shall issue an order of the expert council under Art. 21 for evaluating the information under Art. 8 (3) of Regulation (EC) 2017/852 with a view to drawing up an opinion on the fulfillment of the criteria under Art. 8 (6) of Regulation (EC) 2017/852.

(2) Where inconsistencies or incompleteness are established in the information under Art. 8 (3) of Regulation (EC) 2017/852, the Minister of Environment and Water or an official authorized by him/her it shall notify the applicant within 30 days of the date of the submission of the notification. In such cases, the term under para. 5 stops running.

(3) The applicant shall correct any inconsistencies or incompleteness found within 30 days from the date of receipt of the notification under para. 2.

(4) The Minister of Environment and Waters or an official authorized by him within two weeks shall pronounce by decision terminating the procedure and notifying the person under Art. 7, para. 1, when it is established that:

1. the inconsistencies and incompleteness have not been remedied, or

2. the term under para. 3 has not been met.

(5) The Expert Council under Art. 21 shall consider the notification and the information under Art. 8 (3) of Regulation (EC) 2017/852 and within 6 months from the date of submission of the information, after consulting the competent authorities, draws up an opinion on fulfillment of the criteria under Art. 8 (6) of Regulation (EC) 2017/852.

(6) For making an opinion, the person under Art. 7, para. 1 pays a fee according to the tariff under Art. 72 of the Environmental Protection Act.

(7) In fulfilling the criteria under Art. 8 (6) of Regulation (EC) 2017/852 the Minister of Environment and Water or an official authorized by him/her shall send to the European Commission the notification and the information under Art. 8 (3) of Regulation (EC) 2017/852, accompanied by the opinion referred to in para. 5.

(8) The Minister of Environment and Water or an official authorized by him/her shall inform the European Commission and the person under Art. 7, para. 1 in case of non-fulfillment of the criteria under Art. 8 (6) of Regulation (EC) 2017/852, by sending the opinion under para. 5.

(9) The decision under para. 4 may be appealed in accordance with the Administrative Procedure Code.

Art. 7b. (new – SG 114/03; amend. – SG 82/07; shall be applied till 31.05.2015, amend. - SG 53/18, in force from 26.06.2018) Information on the decisions issued by the European Commission under Art. Article 8 (6) of Regulation (EC) 2017/852 shall be published on the website of the Ministry of

Environment and Waters.

Art. 7c. (new – SG 114/03l shall be applied till 31.05.2010, amend. - SG 53/18, in force from 26.06.2018) (1) The Minister of Environment and Water may prepare a draft National Plan for Implementation of the Minamas Convention on Mercury, signed in Kumamoto, Japan on October 10, 2013 (ratified by an Act - SG, issue 71 of 2016) (SG - 61/17) hereinafter referred to as "the Convention", according to Art. 20 of it, and to offer its update.

(2) The plan under par. 1 shall be adopted by the Council of Ministers and shall be sent to the European Commission and to the Secretariat of the Convention by the Minister of Environment and Waters.

Art. 7d. (new – SG 114/03; shall be applied till 31.05.2015, amend. - SG 53/18, in force from 26.06.2018) (1) The Minister of Environment and Waters or an official authorized by him in fulfillment of the requirements of Art. 18 of Regulation (EC) 2017/852 draws up and provides reports to the European Commission on the implementation of that Regulation.

Art. 7e. (new – SG 114/03; suppl. – SG 95/06, in force from 24.11.2006, amend. - SG 53/18, in force from 26.06.2018) The Minister of Agriculture, Food and Forestry, the Director of the Customs Agency, the Executive Director of the National Revenue Agency, the President of the National Statistical Institute, the Executive Director of the Executive Environment Agency, the Executive Director of the Bulgarian Drug Agency, the Chairman of the State Agency for Metrology and Technical Surveillance and the Chairman of the Commission for Consumer Protection shall provide, upon request by the Minister of Environment and Water or by an official authorized by him/her in an established format for the purposes of reporting under Art. 18 of Regulation (EC) 2017/852.

Art. 7f. (new – SG 114/03, in force from 31.01.2004, amend. - SG 53/18, in force from 26.06.2018) The Minister of Health shall provide the Minister of Environment and Water or an official authorized by him:

1. information for the purpose of reporting under Art. 18 of Regulation (EC) 2017/852;

2. summary information on health aspects, related to the use of mercury and mercury compounds, as well as the results of controls on the implementation of Regulation (EU) 2017/852 on request.

Chapter three.
MEASURES FOR THE APPLICATION OF REGULATION (EC) 684/2004 AND REGULATION (EU) No. 259/2012 (CHAPTER THREE ‘NOTIFICATION OF NEW CHEMICAL SUBSTANCES’ – REVOKED SG 82/07, IN FORCE FROM 01.08.2008; NEW – SG 63/10, IN FORCE FROM 13.08.2010; TITLE SUPPL. – SG 102/15)

Chapter three.
MEASURES FOR THE APPLICATION OF REGULATION (EC) 684/2004 (CHAPTER THREE ‘NOTIFICATION OF NEW CHEMICAL SUBSTANCES’ – REVOKED SG 82/07, IN FORCE FROM 01.08.2008; NEW – SG 63/10, IN FORCE FROM 13.08.2010)

Art. 8. (amend. SG 114/03; revoked – SG 82.07, in force from 01.06.2008, new – SG 63/10, in force from 13.08.2010; suppl. – SG 102/15) Minister of Environment and Water shall be the competent

authority referred to in Article 8 (1) of Regulation (EC) No 648/2004 and Regulation (EU) No. 259/2012.

Art. 9. (amend. SG 114/03; revoked – SG 82.07, in force from 01.06.2008; new – SG 63/10, in force from 13.08.2010) Exemption (derogation) from the requirements of Annex III to Regulation (EC) 648/2004 for ultimate biodegradability in aerobic conditions of surfactants and detergents, containing surfactants, shall be carried out under the procedure of Articles 5 and 6 of Regulation (EC) No 648/2004.

(2) Manufacturers of detergents for industrial and institutional purposes, containing surfactants and/or surfactants, intended for industrial or institutional detergents, which meet requirements for primary biodegradability as per Annex II of Regulation (EC) No 648/2004, but not meet the requirements for ultimate aerobic biodegradability under Annex III, shall be entitled to apply for exemption(derogation) under Para 1.

(3) Persons referred to in Para 2 shall submit to the Minister of Environment and Water and to the European Commission request for derogation , accompanied with the technical file as per Article 5 of Regulation (EC) No 648/2004.

(4) In case of errors or incompleteness in the documents envisaged in Para 3, Minister of Environment and Water or an empowered by him/her official shall notify of this the applicant within 30-days from the date on which the documents were submitted and shall determine a term for removal of the imperfectness.

(5) Technical file shall be assessed for completeness and compliance with the conditions for granting derogation stipulated in Article 6(1) of Regulation (EC) 648/2004.

(6) Minister of Environment and Water or an empowered by him/her official shall send conclusions from the carried out assessment to the European Commission, according to the terms specified in Article 5(3) of Regulation (EC) No 648/2004.

Art. 10. (amend. SG 114/03; revoked – SG 82.07, in force from 01.06.2008; new – SG 63/10, in force from 13.08.2010) The Executive Agency ‘Bulgarian Accreditation Service’ shall provide, upon request of the Minister of Environment and Water, a list of the laboratories, accredited to conduct testing of surfactants in accordance to Article 7 of Regulation (EC) No 648/2004.

(2) Minister of Environment and Water, or an empowered by him/her official, shall send the information envisaged in Para 1 to the European Commission and to the Member States according to Article 8(2) of Regulation (EC) 648/2004.

Art. 10a. (new – SG 114/03; revoked – SG 82.07, in force from 01.06.2008)

Art. 10b. (new – SG 114/03) The Ministry of Environment and Waters shall preserve the notification documents for 10 years after the last registration of the notified chemical substance.

Art. 10c. (new – SG 114/03; revoked – SG 82.07, in force from 01.06.2008)

Art. 10d. (new – SG 114/03; revoked – SG 82.07, in force from 01.06.2008)

Art. 11. (amend. SG 114/03; revoked – SG 82.07, in force from 01.06.2008; new – SG 63/10, in force from 13.08.2010) Graphical image of fruits on the packaging of liquid detergents, released on the market for mass usage, and which might mislead the end consumer regarding the purpose of the liquid detergents, shall not be admitted.

Art. 12. (amend. SG 114/03; revoked – SG 82.07, in force from 01.06.2008)

Art. 12a. (new – SG 114/03; revoked – SG 82.07, in force from 01.06.2008)

Art. 12b. (new – SG 114/03; revoked – SG 82.07, in force from 01.06.2008)

Art. 12c.

Art. 13. (amend. SG 114/03; revoked – SG 82.07, in force from 01.06.2008)

Chapter four.
MEASURES FOR THE APPLICATION OF REGULATION (EU) No. 528/2012 AND FOR THE RPOVISION ON THE MARKET OF BIOCIDES, CONTAINING EXISTING ACTIVE SUBSTANCES, INCLUDED IN APPENDIX II TO DELEGATED REGULATION (EU) No. 1062/2014 (revoked – SG 91/12, new – SG 114/03, the previous Chapter four shall be revoked, new – SG 95/06, in force from 24.11.2006; revoked, new – SG 102/15)

Art. 14. (new – SG 102/15) The Minister of Health is a competent body within the meaning of Art. 81(1) of Regulation (EU) No. 528/2012.

Art. 14a. (new – SG 102/15) The Minister of Health is a competent body within the meaning of Art. 81(1) of Regulation (EU) No. 528/2012.

Art. 14b. (new – SG 102/15) Treated products meeting the requirements of Regulation (EU) No. 528/2012 shall be released on the market.

Art. 15. (new – SG 102/15) (1) The Minister of Health shall establish Expert biocide council by an order.

(2) In the council referred to in par. 1 shall participate representatives of the Ministry of Health, of the Ministry of Environment and Waters, of the National Centre of Public Health and of National Center for Contagious and Parasitic Diseases.

(3) The Minister of Health may draw in other experts in toxicology, eco-toxicology, chemistry, biology, microbiology, virology, parasitology and veterinary medicine in the work of the Council under par. 1, where necessary.

(4) The council under par. 1 shall make a proposal to the Minister of Health for:

1. issuing an opinion on carrying out or prohibition to carry out research and development works under Art. 56, (2) and (3) of Regulation (EU) No. 528/2012;

2. issuing of a national permit for the provision on the market on a biocide or a group of biocides or for termination of the procedure under Art. 29 and 30 of Regulation (EU) No. 528/2012;

3. renewal of a national permit for provision on the market of a biocide under Art. 31 of Regulation (EU) No. 528/12;

4. issuing of a permit for the provision on the market on a biocide or a group of biocides according to a summary procedure or a refusal or for termination of the procedure under Art. 25 and 26 of Regulation (EU) No. 528/2012;

5. issuing of a permit for the provision on the market on a biocide or a group of biocides by mutual recognition under Art. 33 and 34 of Regulation (EU) No. 528/2012 or for a refusal, or for modification of the terms and conditions of an issued permit under Art. 35 – 37 of Regulation (EU) No. 528/2012;

6. renewal of a permit for provision on the market of a biocide by mutual recognition following the procedure of Delegated Regulation (EU) No. 492/2014;

7. issuing of a permit for the provision on the market on a biocide or a group of biocides by mutual recognition under Art. 39 of Regulation (EU) No. 528/2012;

8. amendment of a national permit for the provision on the market of a biocide under Art. 48 – 50 of Regulation (EU) No. 528/2012 and under Chapters II and III of Implementing Regulation (EU) No. 354/2013 of the Commission of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ, L 109/4 of 19 April 2013), herein after referred to as “Implementing Regulation (EU) No. 354/2013”;

9. assessment of applications for granting of a European Union permit, herein after referred to as “Union permit” for provision on the market of a biocide or of a group of biocides or for termination of the procedure under Art. 43 (1), (3) and (4) and under Art. 44 (1) and (2) of Regulation (EU) No. 528/2012;

10. assessment of applications for renewal of a Union permit for provision on the market of a biocide under Art. 46 (1) and (2) of Regulation (EU) No. 528/2012’

11. issue of a permit for parallel trade of a biocide of for a refusal or withdrawal of a permit for parallel trade of a biocide under Art. 53 of Regulation (EU) No. 528/2012;

12. assessment of applications for approval of an active substance for its inclusion in the List of approved active substances in the European Union or for termination of the procedure under Art. 7 and 8 of Regulation (EU) No. 528/2012;

13. assessment of applications for renewal of an approval of an active substance for its inclusion in the List of approved active substances in the European Union or for termination of the procedure under Art. 14 of Regulation (EU) No. 528/2012;

14. issue of a provisional permit and extension of the term under Art. 55 (1) and (2) of Regulation (EU) No. 528/2012;

15. issue of a permit for an identical biocide or for refusal under Art. 3 and 5 of Commission Implementing Regulation (EU) No. 414/2013 specifying a procedure for the authorization of same biocidal products in compliance with Regulation (EU) No. 528/212 of the European Parliament and of the Council (OJ, L 125/4 of 7 May 2013), herein after referred to as “Implementing Regulation (EU) No. 414/2013”;

16. issue of authorisation under Art. 18c, par. 6 or for termination of the procedure under Art. 17c, par. 4;

17. amending an authorization under Art. 18d, par. 1 or for withdrawal of a permit under Art. 18e, par. 1;

18. issue of a new authorization for provision on the market of a biocide, for amendment or withdrawal of issued permits in cases under Art. 18g, par. 1 and 2.

Art. 15a. (new – SG 102/15) (1) The sessions of the council under Art. 15, par. 1 shall be

considered regularly conducted in case more than half of its members are present.

(2) The Council under Art. 15, par. 1 shall make the proposals under Art. 15, para 3 on the grounds of decisions, taken by a majority of more than the half of the attending members.

(3) The members of the Council under Art. 15, par. 1 shall be obliged not to disclose the information which has become known to them at or on occasion of carrying out their duties, representing production or commercial secret. They shall sign declaration of confidentiality of the data.

(4) The activity of the Council under Art. 15, par. 1 shall be secured by resources from the budget of the Ministry of Health.

(5) The Minister of Health shall issue a Regulation for the organisation and the activity of the Council under Art. 15, par. 1.

(6) Education and qualification requirements to the members of the Council under Art. 15, par. 1 are also set out by the Regulation under par. 5.

Art. 16. (new – SG 102/15) In the Ministry of Health information bureau shall be set up and administered subject to compliance with the provision of Art. 81 (2) of Regulation (EU) No. 528/12 for provision of consultancy to persons providing on the market biocides regarding their obligations for the implementation of the Regulation.

Art. 17. (new – SG 102/15) (1) The Minister of Health shall issue an opinion on research and development activity under Art. 56 of Regulation (EU) No. 528/2012, including trials or tests with biocides or non-approved active substances with which a biocide or an active substance is being released or can be released into the environment.

(2) The person who will carry out the trial or the test under par. 1 shall notify in advance in writing the Minister of Health, with attached thereto:

1. the information referred to in Art. 56 (2) of Regulation (EU) No. 528/2012;

2. a document of a paid fee under rt. 19, par. 1, item 1.

Art. 17a. (new – SG 102/15) (1) The Minister of Health shall issue a national authorization for provision on the market of a biocide or a group of biocides under Art. 29 and 30 of Regulation (EU) No. 528/2012.

(2) For issuing of the authorization under par. 1 the applicant or their representative shall file to the Ministry of Health an application in Bulgarian language with attached thereto:

1. information about the Unified Identification Code under Art. 23 of the Trade Register Act or a document of equivalent registration according to the laws of another European Union Member State or according to the law of another state which is a party to the European Economic Area Agreement;

2. documents under Art. 20 (1), sub-item “a” of Regulation (EU) No. 528/2012, except for the cases under Art. 21 of Regulation (EU) No. 528/2012;

3. a document of a paid fee under rt. 19, par. 1, item 1.

Art. 17b. (new – SG 102/15) (1) The Minister of Health shall issue an authorisation for provision on the market of a biocide or a group of biocides under a summary procedure subject to compliance with the provision of Art. 26 of Regulation (EU) No. 528/2012 if they meet the conditions under Art. 25 of Regulation (EU) No. 528/2012.

(2) For the issue of the authorization under par. 1 the applicant or their representative shall file an application in Bulgarian language with attached thereto:

1. information about the Unified Identification Code under Art. 23 of the Trade Register Act or a document of equivalent registration according to the laws of another European Union Member State or according to the law of another state which is a party to the European Economic Area Agreement;

2. documents under Art. 20 (1), sub-item “b” of Regulation (EU) No. 528/2012, except for the cases under Art. 21 of Regulation (EU) No. 528/2012;

3. a document of a paid fee under rt. 19, par. 1, item 3.

Art. 17c. (new – SG 102/15) (1) The Minister of Health shall renew the national authorisation under Art. 17a, where the conditions under Art. 19 of Regulation (EU) No. 528/2012 are available.

(2) For renewal of the authorization under par. 1 the authorization holder or their representative shall file an application in Bulgarian language with attached thereto:

1. information about the Unified Identification Code under Art. 23 of the Trade Register Act or a document of equivalent registration according to the laws of another European Union Member State or according to the law of another state which is a party to the European Economic Area Agreement;

2. documents under Art. 31 (3) of Regulation (EU) No. 528/2012, except for the cases under Art. 21 of Regulation (EU) No. 528/2012;

3. a document of a paid fee under rt. 19, par. 1, item 4.

Art. 17d. (new – SG 102/15) (1) The Minister of Health shall issue an authorisation for provision on the market of a biocide or a group of biocides through subsequent mutual recognition of a national authorization subject to compliance with the procedure of Art. 33 of Regulation (EU) No. 528/2012.

(2) For the issue of the authorization under par. 1 the authorization holder or their representative shall file an application in Bulgarian language with attached thereto:

1. the permit issued by the respective European Union Member State where the biocide has been permitted initially, with attached translation into Bulgarian language thereof, made by a translator having got a contract with the Ministry of Foreign Affairs;

2. a document of a paid fee under rt. 19, par. 1, item 5.

Art. 17e. (new – SG 102/15) (1) The Minister of Health shall issue an authorisation for provision on the market of a biocide or a group of biocides through parallel mutual recognition where Republic of Bulgaria is selected as a reference country under Art. 34 (1) of Regulation (EU) No. 528/2012.

(2) For the issue of the authorization under par. 1 the applicant or their representative shall file to the Ministry of Health an application in Bulgarian language with attached thereto:

1. the documents under Art. 34 (1), sub-items “a” and “b” pf Regulation (EU) No. 528/2012;

2. a document of a paid fee under rt. 19, par. 1, item 7.

(3) The Minister of Health shall issue an authorisation for provision on the market of a biocide or a group of biocides through parallel mutual recognition where Republic of Bulgaria is selected as a reference country under Art. 34 (1), sub-item “b” of Regulation (EU) No. 528/2012.

(4) For the issue of the authorization under par. 3 the applicant or their representative shall file to the Ministry of Health an application in Bulgarian language with attached thereto:

1. the documents under Art. 34 (2), sub-items “a” and “b” pf Regulation (EU) No. 528/2012;

2. a document of a paid fee under rt. 19, par. 1, item 7.

(5) The authorizations under par. 1 and 3 shall be issued subject to compliance with the provision of Art. 34 of Regulation (EU) No. 528/2012 for a biocide or a group of biocides which are still not permitted in compliance with Art. 17 of Regulation (EU) No. 528/2012.

Art. 17f. (new – SG 102/15) (1) The Minister of Health upon request of official or research authorities engaged in pest control or public health protection, shall issue an authorization for provision on the market of a biocide or a group of biocides permitted in another European Union Member State through mutual recognition of the authorization.

(2) For the issue of the authorization under par. 1 the applicant or their representative shall submit

to the Ministry of Health an application in Bulgarian language with attached thereto:

1. the authorization issued by the respective European Union member state, where the biocide has been issued initially, with attached thereto translation into Bulgarian language made by a translator having got a contract with the Ministry of Foreign Affairs;

2. a document of a paid fee under Art. 19, par. 1, item 8.

(3) The permits under par. 1 shall be issued according to the provision of Art. 33 of Regulation (EU) No. 528/2012.

Art. 17g. (new – SG 102/15) (1) The Minister of Health shall renew an authorization for provision on the market of a biocide or a group of biocides under Art. 17d and 17e according to Delegated Regulation (EU) No. 492/2014.

(2) The Minister of Health shall renew an authorization for provision on the market of a biocide or a group of biocides through subsequent or parallel mutual recognition, where Republic of Bulgaria is selected as a reference Member State.

(3) For the renewal of the authorization under par. 2 the applicant or their representative shall submit to the Ministry of Health an application in Bulgarian language with attached thereto:

1. the documents referred to in Art. 2 of Delegated Regulation (EU) No. 492/2014;

2. a document of a paid fee under Art. 19, par. 1, item 9.

(4) The Minister of Health shall renew an authorization for provision on the market of a biocide or a group of biocides through subsequent or parallel mutual recognition, where Republic of Bulgaria is selected as an interested Member State.

(3) For the issue of the authorization under par. 4 the applicant or their representative shall submit to the Ministry of Health an application in Bulgarian language with attached thereto:

1. the documents referred to in Art. 2 of Delegated Regulation (EU) No. 492/2014;

2. a document of a paid fee under Art. 19, par. 1, item 10.

Art. 17h. (new – SG 102/15) (1) The Minister of Health shall revoke or amend issued authorizations under Art. 17a, 17b, 17d and 17e upon request of the authorization holder subject to compliance with the requirements of Art. 49 and 50 of Regulation (EU) No. 528/2012.

(2) For the amendment of the issued authorization under Art. 17a, 17d or 17e the authorization holder or their representative shall submit an application in Bulgarian language with attached thereto:

1. information about the Unified Identification Code under Art. 23 of the Trade Register Act or a document of equivalent registration according to the laws of another European Union Member State or according to the law of another state which is a party to the European Economic Area Agreement;

2. relevant documents under Art. 5 - 8 of Implementing Regulation (EU) No. 354/2013;

3. a document of a paid fee under rt. 19, par. 1, item 11.

(3) For the amendment of the issued authorization under Art. 17b the authorization holder or their representative shall submit a notification in Bulgarian language subject to compliance with the requirements of Art. 9 of Implementing Regulation (EU) No. 354/2013.

(4) The Minister of Health shall revoke or amend issued authorizations under Art. 17a, 17b, 17d and 17e in cases under Art. 48 (1) of Regulation (EU) No. 528/2012 subject to compliance with the requirements of Art. 48 (2) and (3) of Regulation (EU) No. 528/2012.

Art. 17i. (new – SG 102/15) (1) The Minister of Health shall issue an authorization for provision on the market of the same biocide under Art. 2, 3 and 5 of Commission Implementing Regulation (EU) No. 414/2013.

(2) For issuing of authorization under par. 1 the applicant or their representative shall file an application in Bulgarian language with attached thereto:

1. the documents under Art. 2 of Implementing regulation (EU) No. 414/2013;

2. a document of a paid fee under Art. 19, par. 1, item 12.

Art. 17j. (new – SG 102/15) (1) The Minister of Health shall issue an authorization for parallel trading of a biocide which is permitted in another European Union Member State and the same biocide permitted in Republic of Bulgaria under Art. 53 of Regulation (EU) No. 528/2012.

(2) For issuing of authorization under par. 1 the applicant or their representative shall file an application in Bulgarian language with attached thereto:

1. the documents under Art. 53 (4) of Regulation (EU) No. 528/2012;

2. a document of a paid fee under Art. 19, par. 1, item 13.

Art. 17k. (new – SG 102/15) The Minister of Health shall assess the applications for issuing or renewal of Union authorisation for provision on the market of a biocide or a group of biocides under Art. 43 (1), (3) and (4), Art. 44 (1) and (2) and Art. 46 (1) and (2) of Regulation (EU) No. 528/2012.

(2) The assessment under par. 1 shall be done upon preliminary written consent by the Minister of Health to the applicant.

(3) For carrying out the assessment under par. 1 the applicant shall pay a fee under Art. 19, par. 1, item 14.

Art. 17l. (new – SG 102/15) (1) The Minister of Health shall assess the applications for approval of a certain active substance to be included in the List of approved active substances in the European Union under Art. 9 (2) of Regulation (EU) No. 528/2012 or for subsequent amendments of the terms and conditions for approval of a certain active substance under Art. 8 of Regulation (EU) No. 528//2012.

(2) The assessment under par. 1 shall be done upon preliminary written consent by the Minister of Health to the applicant.

(3) For carrying out the assessment under par. 1 the applicant shall pay a fee under Art. 19, par. 1, item 15.

Art. 17m. (new – SG 102/15) The Minister of Health shall issue a provisional authorisation for provision on the market of a biocide or a group of biocides under Art. 55 (2) of Regulation (EU) No. 528/2012 following an assessment of the application under Art. 17l.

(2) For issuing of the authorization under par. 1 the applicant shall file to the Ministry of Health an application in Bulgarian language, with a document of a paid fee under Art. 19, par. 1, item 16 attached thereto.

Art. 17n. (new – SG 102/15) (1) The Minister of Health upon applicant’s proposal and after having confirmed to the applicant in writing, shall assess the applications for renewal of the approval of a certain active substance to be included in the List of approved active substances in the European Union under Art. 9 (2) of Regulation (EU) No. 528/2012.

(3) For carrying out the assessment under par. 1 the applicant shall pay a fee under Art. 19, par. 1, item 17.

Art. 17o. (new – SG 102/15) (1) The applications and documents for the procedures under Art. 17a – 17n shall be filed to the Minister of Health through the Biocides Register under rt. 71 of Regulation (EU) No. 528/2012.

Art. 17p. (new – SG 102/15) Biocides provided on the market subject to compliance with the

provisions of Art. 17a – 17n shall be classified, packed and labeled in compliance with the provisions of Art. 69 Regulation (EU) No. 528/2012 in Bulgarian language.

Art. 18. (new – SG 102/15) (1) The Minister of Health may issue authorization for provision on the market of a biocide or of a group of biocides containing:

1. an existing active substance/ existing active substances which are assessed according to Delegated Regulation (EU) No. 1062/2014 but are not approved yet for this product type;

2. an existing active substance/ existing active substances which are currently being assessed according to Delegated Regulation (EU) No. 1062/2014 but are not approved yet for this product type;

3. a combination of active substances referred to in items 1 and 2 and for active substances approved according to Regulation (EU) No. 528/2012.

(2) In cases of par. 1 the biocides shall be permitted where:

1. the existing active substances contained in the biocides are included in Appendix II of Delegated Regulation (EU) No. 1062/2014 and there is no a decision of the European Commission for their non-inclusion in the List of approved active substances in the European Union under Art. 9 (2) of Regulation (EU) No. 528/2012;

2. the product type is included in Appendix II of Delegated Regulation (EU) No. 1062/2014 and there is no a resolution of the European Commission on its non-inclusion in the List of Approved active substances in the European Union under Art. 9 (2) of Regulation (EU) No. 528/2012;

3. the person is based in the territory of the European Union and produces or imports active substance – independent or in the content of a biocide, or produces or provides on the market a biocide, which consists, contains or generated this substance which is included in the list of the European Chemicals Agency under Art. 95 (2) of Regulation (EU) No. 528/2012 for the product type to which the biocide belongs.

(3) Biocides meeting the criteria under Art. 19 (4) of Regulation (EU) No. 528/2012 are not permitted for mass use.

Art. 18a. (new – SG 102/15) Biocides under Art. 18 shall be classified, packed and labeled according to the provisions of Regulation (EU) No. 1272/2008 (CLP) and of Art. 69 of Regulation (EU) No. 528/2012 in Bulgarian language.

Art. 18b. (new – SG 102/15) (1) For issuing of an authorization under Art. 18 the person releasing on the market the biocide or their representative shall file to the Ministry of Health an application in Bulgarian language with attached thereto:

1. information about the Unified Identification Code under Art. 23 of the Trade Register Act or a document of equivalent registration according to the laws of another European Union Member State or according to the law of another state which is a party to the European Economic Area Agreement;

2. relevant documents under Art. 95 of Regulation (EU) No. 528/2012, which can be access letters within the meaning of Art. 3 (1), sub-item “u” of Regulation No. 528/2012, contracts, invoices, etc.;

3. technical file of the biocide;

4. (amend. - SG 53/18, in force from 26.06.2018) safety information sheet under the Annex II to Regulation (EC) No 1907/2006 (REACH);

5. a document of paid fee under Art. 19, par. 1, item 18.

(2) The documents under par. 1, items 3 and 4 shall be submitted in Bulgarian language, one printed copy and three electronic copies with attached thereto declaration of identity of the provided information on a hard and electronic copy.

Art. 18c. (new – SG 102/15) (1) Within 45 days after the date of receipt of documents referred to in

Art. 18b, par. 2 the completeness of information contained therein shall be reviewed.

(2) In case of identified blanks in the submitted documents, the Minister of Health shall advise the applicant thereof and shall fix a term for their removal.

(3) The Minister of Health can extend only once the term under par. 2 where the applicant submits a justified request thereof.

(4) Where the applicant fails to repair all identified blanks in the documents within the term under par. 2 or 3, the procedure of issue of authorization shall be terminated.

(5) The Minister of Health shall issue an authorization for provision on the market of a biocide or of a group of biocides within 60 days after the date of submission of the documents referred to in Art. 18bm par. 2, respectively after the date of receipt of the information under par. 2 or 3.

Art. 18d. (new – SG 102/15) (1) The Minister of Health shall reconsider the issued authorisation under Art. 18, in case of:

1. availability of new information about the effects of the active substance or of the biocide on humans or the environment;

2. a request by the applicant;

3. change in the commercial registration of the person, who places on the market a biocide;

4. change of the packing.

(2) In the cases referred to in para 1 the Minister of Health may require additional information and amend the terms of the authorisation issued.

(3) Amendment of the authorisation shall be carried out in observance of the requirements as per Art. 18 and upon payment of a fee under Art. 19, par. 1, item 19.

(4) In case of amendment of the issued authorization for provision on the market of a biocide the Minister of Health may fix time for storage, use or distribution of available quantities of a biocide.

Art. 18e. (new – SG 102/15) (1) The Minister of Health shall revoke the issued authorisation under Art. 18, where:

1. the applicant has submitted incorrect and/or misleading data for the issue of the authorisation;

2. the active substance is prohibited for placing on the market and for use in the European Union;

3. a grounded request has been submitted by the holder of the authorisation;

(2) The Minister of Health shall inform the holder of the authorisation prior to the repeal of the authorisation under para 1.

(3) In case of withdrawal of the issued authorisation for provision on the market of a biocide or of a group of biocides the Minister of Health can fix a term for storage, use and distribution of the available quantities of biocide.

Art. 18f. (new – SG 102/15) (1) The Minister of Health shall approve by an Order lists of active substances for which there is a decision of the European Commission as to the active substance is not approved to be included in the List of approved active substances in the European Union under Art. 9 (2) of Regulation (EU) No. 528/2012.

(2) The Order under par. 1 shall be promulgated in State Gazette and shall be published on the Internet page of the Ministry of Health.

Art. 18g. (new – SG 102/15) (1) Where there is a decision of the European Commission on approval of an active substance to be included in the List of approved active substances in the European Union under Art. 9 (2) of Regulation (EU) No. 528/2012 the Minister of Health shall issue a new decision for provision on the market of a biocide, shall amend or revoke the issued authorization under Art. 18.

(2) Where there is a decision of the European Commission that an active substance is not approved

to be included in the List of approved active substances in the European Union under Art. 9 (2) of Regulation (EU) No. 528/2012 for certain or for all notified product types the Minister of Health shall amend or revoke the issued authorization under Art. 18 in compliance with Delegated Regulation (EU) No. 1062/2014 and Art. 89 (2) of Regulation (EU) No. 528/2012.

(3) Issue of a new authorization, amendment or withdrawal of the issued authorization under Ar.t 18 shall be done in compliance with the decision on the approval or non-approval of inclusion of an active substance in the List of approved active substances in the European Union under Art. 9 (2) of Regulation (EU) No. 528/2012.

Art. 18h. (new – SG 102/15) An ordinance of the Council of Ministers shall determine the form and the content of:

1. the technical file and documents to be submitted by the applicant for issue of an authorization for providing on the market of a biocide or of a group of biocides under Art. 18;

2. the issued authorizations for providing on the market of a biocide or of a group of biocides under Art. 18.

Art. 18i. (new – SG 102/15) (1) A register of permitted biocides under Art. 18 shall be maintained in the Ministry of Health. The register shall be public and contains:

1. number and date of the authorization for provision on the market of the biocide;

2. validity period of the issued authorization, where applicable;

3. information about the person providing on the market the biocide – name, main office and registered address;

4. name of the biocide;

5. designation and concentration of the active substance(s) contained in the biocide;

6. type of biocide and field of application;

7. category of use;

8. date of withdrawal of the authorization;

9. changes in the particulars under items 1 – 7.

(2) (*) In the register under par. 1 a separate section shall be provided, where following the order of submission the persons having filed an application for issuing of an authorization for provision on the market of a biocide shall be registered and the number and the type of the attached to the application documents shall be described. In this section the proceeding of the file opened under the application shall be indicated.

(3) The ordinance under Art. 18h shall set out the terms and conditions and the procedure of maintenance of the register under par. 1.

Art. 19. (new – SG 102/15) (1) By the tariff of Art. 46 of the Health Act, the Council of Ministers shall determine governmental fees for:

1. issue of an opinion for carrying out research and development works under Art. 17;

2. issue of a national authorization for provision on the market of a biocide or of a group of biocides or a group of biocides under Art. 17a;

3. issue of an authorization for provision on the market of biocide or of a group of biocides under a summary procedure under Art. 17b;

4. renewal of a national authorization for provision on the market of a biocide or of a group of biocides under Art. 17c;

5. issue of an authorization for provision on the market of biocide or of a group of biocides through subsequent mutual recognition under Art. 17d;

6. issue of an authorization for provision on the market of biocide or of a group of biocides through

parallel mutual recognition under Art. 17e;

7. issue of an authorization for provision on the market of biocide or of a group of biocides through parallel mutual recognition under Art. 17e, par. 3;

8. issue of an authorization for provision on the market of biocide or of a group of biocides through mutual recognition under Art. 17f;

9. renewal an authorization for provision on the market of biocide or of a group of biocides under Art. 17d and 17e, where Republic of Bulgaria is selected as a reference member state;

10. renewal an authorization for provision on the market of biocide or of a group of biocides under Art. 17d and 17e, where Republic of Bulgaria is selected as an interested member state;

11. amendment of an authorization for provision on the market of biocide or of a group of biocides under Art. 17a, 17d and 17e;

12. issue of an authorization for provision on the market of the same biocide under Art. 17i;

13. issue of an authorization for parallel marketing of a biocide under Art. 17j;

14. assessment of applications for issuing or renewal of Union authorization for provision on the market of a biocide or a group of biocides under Art. 17k;

15. assessment of applications for approval of an active substance under Art. 17l;

16. issue of a provisional authorization for provision on the market of a biocide or a group of biocides under Art. 17m;

17. assessment of applications for renewal of the approval of an active substance under Art. 17n;

18. issue of an authorization for provision on the market of a biocide or a group of biocides under Art. 18;

19. amendment of an authorization for provision on the market of a biocide or a group of biocides under Art. 18;

20. issue of an authorization under Art. 30, par. 5.

(2) The resources from the charges under para 1 shall be deposited as an income to the budget of the Ministry of Health.

Art. 19a. (new – SG 102/15) Ministry of Health shall send a report on the application of Regulation (EU) No. 528/2012 to the European Commission in compliance with Art. 65(3) of the said Regulation.

Chapter five.
MEASURES ON IMPLEMENTATION OF REGULATION (EC) No 1907/2008 (REACH) AND REGULATION (EC) No 1272/2008 (CLP) (new – SG 82/07; title amended – SG 63/10, in force from 13.08.2010)

Art. 20. (new – SG 82/07; amend. – SG 63/10, in force from 13.08.2010) The Minister of Environment and Water shall be the competent body pursuant to Article 121 of Regulation (EC) No 1907/2006 (REACH) and Article 43 of Regulation (EC) No 1272/2008 (CLP).

Art. 20a. (new - SG 53/18, in force from 26.06.2018) (1) Exemption from the application of Title II, III, VI, VII, VIII and / or IX of Regulation (EC) No 1907/2006 (REACH) under Art. 3a shall be carried out on the basis of an authorization issued.

(2) Competent authority for issuing the authorization under para. 1 is the Interdepartmental Council for Defense Industry and Security of Supply to the Council of Ministers, hereinafter referred to as "Interdepartmental Council".

(3) The conditions, the order and the terms of issuance, revocation, amendment, termination and withdrawal of the authorization under para. 1, requirements to prevent or limit harmful effects on human

health and the environment as well as the information under Art. 20e, item 2 shall be determined by an ordinance of the Council of Ministers.

(4) The authorization under para. 1 shall be issued for a period not exceeding three years and applies only to the mentioned therein cases, types and quantities of chemicals chemical substances on their own, in mixtures or in articles and their uses.

(5) In the authorization under para. 1 shall be indicated the measures that the person should apply to prevent or limit the harmful effects on human health and the environment.

(6) The rights under the authorization may not be transferred or ceded including the transformation under Art. 261 of the Commerce Act, unless the legal form of the entity changes.

Art. 20b. (new - SG 53/18, in force from 26.06.2018) For the issuance of the authorization under Art. 3a in the Interdepartmental Council an application shall be filed in a form with the attached documents according to the ordinance under Art. 20a, para. 3.

Art. 20c. (new - SG 53/18, in force from 26.06.2018) (1) The Interdepartmental Council shall issue an authorization when an exemption under Art. 3a and the applicant meets the conditions for authorization defined in the Ordinance under Art. 20a, para. 3.

(2) The Interdepartmental Council shall refuse to issue an authorization when:

1. no exemption under Art. 3a is allowed;

2. the applicant does not meet some of the conditions for authorization;

3. the information in the application or the documents attached thereto is false;

4. the information in the application or in the documents attached thereto is incomplete and has not been provided within 7 days of the date of notification.

(3) The Interdepartmental Council shall amend the authorization in case of:

1. the necessity to change a measure or the addition of a new measure in the authorization under Art. 20a, para. 5;

2. extension of the initial authorization under Art. 20a, para. 4.

(4) The Interdepartmental Council shall terminate the authorization at the written request of the person to whom the authorization has been issued.

(5) The Interdepartmental Council shall revoke the authorization when the ground for exemption under Art. 3a.

(6) The Interdepartmental Council shall immediately notify the Ministry of Defense, The Ministry of Environment and Water, the Ministry of Health and the Customs Agency in any event, the issue, refusal, amendment, termination or revocation of an authorization and provide a copy of the authorization issued.

(7) The decisions of the Interdepartmental Council may be appealed in accordance with the Administrative Procedure Code. The appeal does not stop the execution of the contested act.

Art. 20d. (new - SG 53/18, in force from 26.06.2018) (1) The Interdepartmental Council shall establish and maintain a register of issued permits which shall not be public.

(2) The register shall contain:

1. number and date of authorization;

2. name, seat, representation and registered address of the entity to which the authorization has been issued;

3. grounds for and date of amendment, termination and/or revocation of the authorization;

4. comments on the recorded circumstances;

Art. 20e. (new - SG 53/18, in force from 26.06.2018) Persons to whom the permits have been issued are obliged to:

1. comply with the requirements and measures to prevent or mitigate harmful effects on human health and the environment, defined in the Ordinance under Art. 20a, para. 3 and in the permit under Art. 20a, para. 5;

2. maintain and annually, by 31 January, provide the Interdepartmental Council with the information specified in the ordinance under Art. 20a, para. 3.

Art. 21. (new – SG 82/07) (1) The Minister of Environment and Waters with an order shall set Expert council for assessment of priority substances pursuant to Art. 45 with reference to Art. 46, 47 and 48 of Regulations 1907/2006, herein after referred to as "Expert council".

(2) (amend. – SG 63/10, in force from 13.08.2010; amend. – SG 102/15) Representatives of the Ministry of Environment and Water, of the Ministry of Health, National Centre for Public Health and analyses and Environment Executive Agency.

(3) The Minister of Environment and Waters shall issue Rules of organization and operation of the expert council.

(4) (amend. – SG 63/10, in force from 13.08.2010, suppl. - SG 53/18, in force from 26.06.2018) The Minister of Environment and Water, where appropriate, may involve in the operation of the expert council also experts in chemistry, physics chemistry, eco-toxicology, toxicology, biology, labour medicine, economics and other experts following a procedure, set in the Rules envisaged in Para 3.

(5) In cases of Art. 45 (4) of Regulations 1907/2006 the Minister of Environment and Waters shall assign by an order to the expert council accomplishment of an assessment of priority substances, included in the Detailed action plan of the Community under Art. 44 (2) of the Regulations.

(6) (amend. – SG 63/10, in force from 13.08.2010) Within the term of Art. 46 (4) of Regulation 1907/2006 the expert council shall carry out an assessment and shall present to the Minister of Environment and Waters detailed report with conclusions of the carried out assessment, accompanied with a draft decision, pursuant to Article 48 of Regulation (EC) No 1907/2006 (REACH).

(7) (amend. – SG 63/10) On the base of results obtained from the accomplished assessment, the expert council may submit to the Minister of Environment and Water reasoned proposal for:

1. harmonized classification and labelling of the substances as per Article 37(1) of Regulation (EC) No 1272/2008 (CLP);

2. identification of the substance as per Article 59(3) of Regulation (EC) No 1907/2006 (REACH);

3. restriction of the substance as per Article 69(4) of Regulation (EC) No 1907/2006 (REACH);

4. (new – SG, 84/2012, in force from 02.01.2013) restriction of the use of a substance or group of substances in EEE;

5. (new - SG 53/18, in force from 26.06.2018) opinion on the fulfillment of the criteria under Art. 8 (6) of Regulation (EC) 2017/852.

(8) (new – SG 63/10, in force from 13.08.2010, amend. - SG 53/18, in force from 26.06.2018) Minister of Environment and Water or an empowered by him/her official:

1. shall notify the European Chemicals Agency of the accomplished assessment as per Article 48 of Regulation (EC) No 1907/2006 (REACH);

2. submit to the European Chemicals Agency a dossier on the proposals under para. 7, items 1 to 3;

3. submit to the European Chemicals Agency a dossier on the proposals under para. 7, items 4.

(9) (new – SG 63/10, in force from 13.08.2010) The expert council shall consider proposals for change of harmonised classification and labelling of dangerous substances, placed on the market in Bulgaria, made by manufacturers, importers and downstream users, following procedure, envisaged in Article 37(6) of Regulation No 1272/2008 (CLP).

(10) (new – SG 63/10, in force from 13.08.2010; amend. – SG 102/15) Work of the expert council shall be ensured:

1. for carrying out an assessment within the meaning of par. 6 - with funds from the European Chemicals Agency as per Article 14(1) of the Commission Regulation (EC) No 340/2008 of 16 April 2008

on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No 1907/2006 (REACH) (OJ, L 107/6 of 17 April 2008) of the European Parliament and of the Council concerning the registration, evaluation, authorization and restriction of chemicals (REACH) (OJ, L 107/6 of 17 April 2008);

2. for drawing up a justified proposal and consideration of proposals within the meaning of par. 7 – 9 – with funds from the budget of the Ministry of Environment and Waters.

Art. 21a. (new – SG 82/07) (1) (amend. - SG 63/10, in force from 13.08/2010) Minister of Environment and Water or an official, empowered by him/her, shall prepare reports under Article 117 (1) of Regulation (EC) No 1907/2006 (REACH) and sent them to the European Commission and reports under Article 46(2) of Regulation (EC) No 1272/2008 (CLP) to the European Chemicals Agency, following the procedure, set for collaboration of the institutions of the European Union.

(2) (amend. - SG 63/10, in force from 13.08.2010) The Minister of Health, the Executive Director of the Executive Agency "General Labour Inspection Office", the Director of the Agency "Customs", the Executive Director of the National Revenue Agency and the Chairperson of the National Statistics Institute shall submit upon request of the Minister of Environment and Water or of an empowered by him/her official the information as per Art. 127 of Regulation (EC) No. 1907/2006 (REACH) for the purposes of reporting under Article 117 (1) of the same Regulation.

(3) (new – SG 63/10, in force from 13.08.2010) The Minister of Health shall submit upon request of the Minister of Environment and Water, or by an empowered by him/her official, summary information on the results from the control on the execution of Regulation (EC) No 1272/2008 (CLP) for the purposes of reporting under Article 46(2) of the same Regulation.

Art. 21b. (new – SG 63/10, in force from 13.08.2010) (1) National Information Bureau for provision of advises to the manufacturers, importers, downstream users and distributors of chemical substances on their own, in mixtures and in articles and/or mixtures regarding their obligations on the execution of the two Regulations shall be established and administered to the Ministry of Environment and Water, as per Article 124 of Regulation No 1907/2006 (REACH) and Article 44 of Regulation (EC) No 1272/2008 (CLP).

(2) (amend. – SG 102/15) At the execution of its obligation, the National Information Bureau shall be assisted by the Ministry of Health and by the National Centre for Public Health and Analyses.

Art. 21c. (new – SG 63/10, in force from 01.06.2015) (1) (suppl. – SG 102/15, amend. - SG 98/18, in force from 27.11.2018) Importers and downstream users who place on the market mixtures, including biocides, classified as dangerous on the base of their effects on the health or their physical effects as per Regulation (EC) No 1272/2008 (CLP), shall submit to the Toxicology Clinic to the Multi- profile Hospital for Active Treatment "N. I. Pirogov" information on the chemical composition of these mixtures, including on the chemical identity of the substances in the mixtures, about which using alternative chemical nomination is allowed, following the procedure stipulated in Article 24 of Regulation (EC) No 1272/ 2008 (CLP).

(2) Toxicology Clinic to the Multi-profile Hospital for Active Treatment and Emergency Medicine ‘N.I. Pirogov" shall be the competent body in the meaning of Article 45 of Regulation (EC) No 1272/2008 (CLP).

(3) (amend. – SG 102/15) Information envisaged in Para 1 shall be provided before the first launching on the market of chemical mixtures by all importers and downstream users.

(4) Form to submit the information envisaged in Para 1 shall be established in accordance with Article 45(1) of Regulation (EC) No 1272/2008 (CLP).

(5) (amend., - SG 98/10, in force from 01.01.2011) Medical establishments shall send to the body envisaged in Para 2 and to the regional health inspectorates information regarding the cases of intoxication or doubt about intoxication with mixtures, classified as dangerous on the base of their effects on the health or physical effects.

(6) (suppl. – SG 102/15) Body, envisaged in Para 2 shall send annually till 30th of April to the Ministry of Health summary report on the previous year regarding the cases of intoxication or doubt about intoxication with mixtures, including with biocides, classified as dangerous on the base of their effects on the health or physical effects, as well as a list of the persons, who have submitted information under Para 1.

Art. 21d. (new – SG 63/10, in force from 13.08.2010, amend. - SG 98/18, in force from 27.11.2018) Observation of the good laboratory practice principles by the laboratories, where eco-toxicological and doxological testing and analyses of chemical substances for the purposes of Regulation (EC) 1907/2006 (REACH) and Regulation (EC) No 1272/2006 are carried out, shall be certified by the Executive Agency ‘Bulgarian Accreditation Service" pursuant to the Ordinance envisaged in Art. 4c, Para 3.

Chapter five "a".
RESTRICTION OF DANGEROUS SUBSTANCES IN ELECTRIC AND ELECTRONIC EQUIPMENT. (new – SG 84/2012, IN FORCE FROM 02.01.2013)
Chapter five "a".

Art. 21e. (new – SG, 84/2012, in force from 02.01.2013) (1) The conditions and procedure for placing on the market EEE in relation to restriction for use of certain dangerous substances shall be determined by a Council of Ministers ordinance.

(2) The ordinance under Para. 1 shall determine:

1. the obligations of the economic operators for provision of compliance with the restriction for use of dangerous substances in EEE placing on the market;

2. the conditions for provision, renewal or withdrawal of exemption from restriction for use of certain dangerous EEE;

3. (revoked – SG 102/15);

4. dangerous substances, whose use in EEE is subject to restriction and the limit admissible values of their weight concentration in homogeneous materials, contained in EEE;

5. the marking and indicating requirements on EEE;

6. the procedure of compliance assessment with the restriction for use of dangerous substances in EEE and the contents of the compliance declaration.

(3) (new – SG 102/15) Minister of Environment and Waters shall approve by an order the cases of exemption from the restrictions for use of hazardous substances in certain materials and components in EEE.

(4) (new – SG 102/15) The orders under par. 3 shall be promulgated in State Gazette and shall be published on the Internet page of the Ministry of Environment and Waters.

Art. 21f. (new – SG, 84/2012, in force from 02.01.2013) (1) The EEE, placed on the market shall not contain dangerous substances above the limit admissible concentrations, determined by the ordinance under Art. 21e, Para. 1.

(2) Para. 1 shall apply to the following categories EEE, including cables and spare parts for its

repair, its second use, updating its functional characteristics or increasing its capacity:

1. large household appliances;

2. small household appliances;

3. information and telecommunication equipment;

4. consumer equipment;

5. lighting equipment;

6. electric and electronic instruments;

7. play toys and equipment for amusement and sport purposes;

8. medicine items under Art. 2, Para. 1, p. 1 and 3 of the Act on Medicinal Items;

9. appliances for control and direction, including industrial appliances for control and direction;

10. automatic machines;

11. other EEE, which is not included in the categories of p. 1 – 10.

(3) Para. 1 shall not apply to:

1. equipment, which is needed for protecting the basic interest of the Republic of Bulgaria, related to the national security, including guns, ammunitions and military products, especially intended for military use;

2. equipment, intended for sending into the cosmic space;

3. equipment, which is especially designed and is installed as a part of other type of equipment, which is excluded from or does not fall into the scope of this Chapter, which may serve its purpose only as a part of this equipment and may be replaced only by the same specially designed equipment;

4. large units stationary industrial equipment;

5. large immovably mounted installations;

6. transport means for passengers or goods with exception of electric two-wheel motor vehicles, which have not received type approval;

7. mobile installations, which have not been intended for movement on the roads, provided exclusively for professional use;

8. active implanting medicinal items under art. 2, Para. 1, p. 2 of the Act on Medicinal Items;

9. photovoltaic panels, intended for use in a system, which has been designed, created and installed by specialists for permanent exploitation at a certain place for production of energy form solar light for public, trade, industrial and household needs;

10. equipment, especially designed only for the purposes of a scientific and development activity and provided only on the principle of the connected economic systems;

11. (new - SG 17/19, in force from 26.02.2019) musical pipe organs.

Art. 21g. (new – SG, 84/2012, in force from 02.01.2013) (1) The producer of EEE shall assess the compliance of the product with the provision of Art. 21f, Para. 1 and shall certify it with CE marking and a declaration for compliance under the requirements of the ordinance under Art. 21e, Para. 1.

(2) CE marking shall be placed in compliance with the general principles, determined by Art. 30 of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ. L 218/30 of 13 August 2008), called hereinafter "Regulation (EC) N 765/2008".

(3) Where on EEE is placed CE marking, it shall be considered that this EEE does not contain dangerous substances in its homogeneous materials above the limited admissible weight concentrations, determined by the ordinance under Art. 21e, Para. 1, unless there is proof about the opposite.

Art. 21h. (new – SG, 84/2012) in force from 02.01.2013) (1) The EEE and the materials and components of EEE, which have passed successfully tests or measurements, proving compliance with the provision of Art. 21f, Para. 1 or have been assessed under harmonized standards, whose names and number have been published in Official Journal of the EU is considered that they meet the restrictions for use of dangerous substances.

(2) Where it is established that a certain harmonized standard under Para. 1 does not provided complete compliance with the requirements of Art. 21. f, Para. 1, the State Agency for metrological and Technical Supervision, and in the cases of EEE under Art. 21f, Para. 2, p 8 – the Executive Medicines Agency shall inform the Committee, established under Art. 5 of Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations.

Art. 21i. (new – SG, 84/2012, in force from 02.01.2013) (1) The Minister of Environment and Waters or an official authorized by him/her shall make a proposal to the European Commission for restriction of a substance or of a group of substances in EEE, on the grounds of:

1. an assessment of priority substances, made in compliance with Art. 45 of Regulation (EC) N 1907/2006 REACH and under Art. 21 or other EU Member State of another state – party of the EEA Agreement;

2. identification of dangerous substances under Art. 59, Para. 3 of Regulation (EC) N 1907/2006 REACH;

3. restriction of dangerous substances under Art. 69, Para. 4 of Regulation (EC) N 1907/2006 REACH.

(2) The proposal of Para. 1 shall contain:

1. exact and clear formulation of the proposed restriction;

2. information and scientific evidence about the proposed restriction;

3. information for use of the proposed substance or group of substances in EEE;

4. information about the harmful consequences and exposure to dangerous impact, more-precise during the activities of waste management from EEE;

5. information about availability and reliability of possible substitutes and other alternatives;

6. grounds for the need of imposing restrictions at EU level as the most appropriate measure;

7. social-economic assessment of the proposed restriction.

Art. 21j. (new – SG, 84/2012, in force from 02.01.2013) (1) Yearly by 31 March the chairperson of the State Agency for metrological and Technical Supervision and the executive director of the Executive Medicines Agency or officials, authorized by them shall produce to the Minister of Environment and Waters a summarized information about the performed control on the application of the provisions of this Chapter and of the ordinance under Art. 21e, Para. 1.

(2) The information under Para. 1 shall be used for preparation of an assessment on application of this Chapter and of the ordinance under Art. 21e, Para. 1.

Art. 21k. (new – SG, 84/2012, in force from 02.01.2013) The provision of this Chapter shall apply without contradicting the requirements of Regulation (EC) N 1907/2006 (REACH), Regulation (EC) N 850/2004 and the requirements in the area of safety and health and waste management.

Chapter six.
MEASURES ON APPLICATION OF REGULATION (EC) No 649/2012 AND REGULATION (EC) No 850/2004 (TITLE AMEND. – SG 114/2003, IN FORCE FROM 31.01.2004; AMEND. – SG 82/07; AMEND. – SG 63/10, IN FORCE FROM 13.08.2010; AMEND. – SG 102/15)

Chapter six.
MEASURES ON APPLICATION OF REGULATION (EC) No 689/2008 AND REGULATION (EC) No 850/2004 (TITLE AMEND. – SG 114/2003, IN FORCE FROM 31.01.2004; AMEND. – SG 82/07; AMEND. – SG 63/10, IN FORCE FROM 13.08.2010)

Art. 22. (amend. – SG 82/07; amend. – SG 63/10, in force from 13.08.2010; amend. – SG 102/15) The Minister of Environment and Water shall be the competent body pursuant to Article 4 of Regulation (EC) 649/2012 and Article 15 of Regulation (EC) No 850/2004.

Art. 22a. (new – SG 114/03; amend. – SG 82/07; amend. – SG 102/15) (1) Before the first in the year export of a hazardous chemical substance in an independent form or in a mixture pursuant to Article 8(2) of Regulation (EC) No 649/2012 or in the content of a product according to Art. 15 (1) of Regulation (EI) No. 649/2012, the exporter shall submit to the Ministry of Environment and Water an export notification electronically through the data base of the European Chemical Agency in compliance with the deadlines and in the format determined in Art. 8(2) of Regulation (EU) No. 649/2012.

(2) To the notification of para 1 shall be attached a safety information sheet of the chemical substance or mixture drawn up in compliance with Appendix II of Regulation (EU) No. 1907/2006 (REACH) and with Art. 17(4) of Regulation (EU) No. 649/2012.

(3) In case of existing errors or diminution in the notification under par. 1, the Minister of Environment and Waters or an official empowered by him/her shall notify thereof the exporter through the data base of the European Chemicals Agency within 5 days from the date of submission of the information under Art. 8 (2) of Regulation (EU) No. 649/2012.

(4) Exporter shall repair the existing errors or diminutions within 5 days after the date of receipt of the notification under par. 3.

(5) The export of chemicals envisaged in Parts 2 and 3 of Annex I to the Regulation (EC) No 649/2012 shall be subject to mutual consent in written by the competent bodies of the States of destination.

(6) For the processing of the notification under par. 1 the exporter shall pay a fee on the grounds of Art. 8 (8) of Regulation (EU) No. 649/2012 according to the tariff under Art. 72 of the Environment Protection Act.

Art. 22b. (new – SG 114/03; amend. – SG 82/07; revoked – SG 102/15)

Art. 22c. (new – SG 114/03; amend. – SG 82.07; amend. – SG 63/10, in force from 13.08.2010; revoked – SG 102/15)

Art. 22d. (new – SG 114/03; amend. – SG 82/07) (1) (amend. – SG 63/10, in force from 13.08.2010; amend. – SG 102/15) The Minister of Environment and Water, or an official empowered by him/her, shall draft and submit a report on implementation of Regulation (EC) No 649/2012 following the

procedure of Article 22(1) of the same Regulation.

(2) (amend. – SG 102/15) For reporting purposes under par. 1 the Agency "Customs" shall present upon request by the Minister of Environment and Water or by a person empowered by him/her information pursuant to Article 18 of Regulation (EC) No 649/2012.

(3) The information under par. 2 shall include data about:

1. (amend. – SG 63/10, in force from 13.08.2010; amend. – SG 102/15) exported from and imported to the customs territory of the Republic of Bulgaria chemical substances and preparations of Annex I to Regulation (EC) No 649/2012 in the reported period;

2. (amend. – SG 63/10, in force from 13.08.2010) identity of the exporter and/or the importer of chemical substances and/or mixtures under item 1;

3. (amend. – SG 63/10, in force from 13.08.2010; amend. – SG 102/15) registered cases of inconformity with the provisions of Article 8 and of Article 14 (6) of the Regulation (EC) No 649/2012 in case of export of chemical substances and mixtures of Annex I to the Regulation.

Art. 22e. (new – SG 114/03; revoked – SG 82/07; new – SG 63/10, in force from 13.08.2010; amend. – SG 102/15, suppl. - SG 12/17) Every year till 31st of March, the exporters and importers of dangerous chemical substances on their own, in mixtures and in articles as enlisted in Annex I to Regulation (EC) No 649/2012 shall submit to the Ministry of Environment and Water through the database of the European Chemicals Agency information about the exported and imported during the previous year chemicals pursuant to Article 9 of Regulation (EC) No 649/2012.

Art. 22f. (new – SG 114/03; revoked – SG 82/07; new – SG 63/10, in force from 13.08.2010)(1) Minister of Environment and Water shall prepare and update the National Action Plan on management of the stable organic pollutants and shall send of to the European Commission and to the Member States pursuant to Article 8 of Regulation (EC) No 850/2004.

(2) The envisaged in Para 1 plan shall be adopted by the Council of Ministers.

Art. 22g. (new – SG 114/03; revoked – SG 82/07; new – SG 63/10, in force from 13.08.2010)(1) The Minister of Environment and Water, or an empowered by him/her official, shall prepare and present reports on execution of Regulation (EC) No 850/2004 to the European Commission.

(2) (amend. – SG 58/17, in force from 18.07.2017) The Minister of Agriculture, Foods and Forestry, the Minister of Health, the Director of Customs Agency, the Executive Director National Revenue Agency and the Chairperson of the National Statistics Institute shall present, upon a request by the Minister of Environment and Water, or by an empowered by him/her official, information in the established form for the purposes of reporting under Article 12 of Regulation (EC) No 850/2004.

(3) (new – SG 102/15) The holder of stock in an amount exceeding 50 kg of hazardous substances of Appendix I and/or Appendix II of Regulation (EU) No. 850/2004 the use of which is permitted, shall provide to the Minister of Environment and Waters information about the type and quantity of this stock and the measures of its safe storage in the terms determined in Art. 5(2) of Regulation (EU) No. 850/2004.

Art. 22h. (new – SG 114/03; revoked – SG 82/07)

Art. 22i. (new – SG 114/03; revoked – SG 82/07)

Art. 22j. (new – SG 114/03; revoked – SG 82/07)

Chapter six "a".
MEASURES ON APPLICATION OF REGULATION (EC) No 98/2013 (NEW - SG 102/15)

Art. 23. (amend. SG 114/03; revoked – SG 82/07 – in force from 01.06.2009; new – SG 102/15) Precursors of explosive substances under restriction within the meaning of Art. 3, item 10 of Regulation (EU) No. 98/2013 shall not be provided, introduced, owned or used by mass consumers.

Art. 24. (amend. SG 114/03; amend. – SG 95/06, in force from 24.11.2006; revoked – SG 63/10, in force from 13.08.2010; new – SG 102/15) According to Art. 5 of Regulation (EU) No. 98/2013 economic operators shall ensure, either by affixing an appropriate label or by verifying that an appropriate label is affixed, that the packaging clearly indicates that the acquisition, possession or use of that restricted explosives precursor by members of the general public is subject to a restriction.

Art. 24a. (new – SG 114/03; amend. – SG 82/07; revoked – SG 63/10, in force from 13.08.2010; new – SG 102/15) (1) The Ministry of Interior is the national contact point within the meaning of Art. 9(2) of Regulation (EU) No. 98/2013.

(2) Economic operators shall report to the national contact point under par. 1 all suspicious transaction or attempted transactions and significant disappearances and thefts of the substances listed in Annex I and Annex II of Regulation (EU) No. 98/2013 in compliance with the provisions of Art. 9 (3) and (4) of the same Regulation.

(3) (amend. - SG 17/19) Reporting under par. 2 shall be done subject to compliance with the requirements of personal data protection.

Art. 24b. (new – SG 102/15) The obligations under Art. 9(6) of Regulation (EU) No. 98/2013 shall be fulfilled by provision of access to the guidelines on the application by the European Commission of the same Regulation on the Internet pages of the Ministry of Health and of the Ministry of Interior.

Chapter seven.
CONTROL OVER THE CHEMICAL SUBSTANCES ON THEIR OWN, IN MIXTURES AND IN PRODUCTS (title amend. SG 114/03, in force from 31.04.2004, amend. – SG 63/10, in force from 13.08.2010; amend. – SG 102/2015)
Chapter seven.
CONTROL OVER THE CHEMICAL SUBSTANCES AND MIXTURES (title amend. SG 114/03, in force from 31.04.2004, amend. – SG 63/10, in force from 13.08.2010)

Art. 25. (1) (amend. SG 114/03; amend. – SG 63/10, in force from 13.08.2010, prev. text of Art. 25 - SG 53/18, in force from 26.06.2018) Subject to control shall be the implementation of requirements for:

1. (revoked - SG 53/18, in force from 26.06.2018)

2. classification, labelling and packing of chemical substances, mixtures and specific Articles as per Regulation (EC) No 1272/2008 (CLP);

2a. (new – SG 102/15) labeling of explosive substances precursors under restriction according to Regulation (EU) No. 98/13;

3. notification to the European Chemicals Agency of classification and labelling of the released on the market dangerous chemical substances on their own and in mixtures as per Regulation (EC) No 1272/2008 (CLP);

4. registration of chemical substances on their own, in mixtures and in Articles as per Regulation (EC) No 1907/2006 (REACH);

5. information exchange about substances and avoidance of unnecessary testing as per Regulation (EC) No 1907/2006 (REACH);

6. downstream users as per Regulation (EC) No 1907/2006 (REACH);

7. (suppl. - SG 53/18, in force from 26.06.2018) downstream provision of information, including safety data sheet, about delivery of chemical substances on their own, in mixtures and in Articles as per Regulation (EC) No 1907/2006 (REACH);

8. permission of certain dangerous chemical substances as per Regulation (EC) No 1907/2006 (REACH);

9. restriction of manufacturing, placing on the market and usage of certain dangerous chemical substances, mixtures and articles as per Regulation (EC) No 1907/2006 (REACH) and the ordinance envisaged in Art. 46, Para 2 for the purposes of environment preservation;

10. restriction of place on the market and usage of certain dangerous chemical substances, mixtures and Articles as per Regulation (EC) No 1907/2006 (REACH) and the ordinances envisaged in Art. 46, Para 2 for the purposes of human health protection;

11. granting access to information about the chemical substances and mixture for persons who work with dangerous chemical substances as per Art. 35 of Regulation (EC) No 1907/2006 (REACH) and implementation measures for control over the exposition in the working environment, as stated in the safety data sheet ;

12. (amend. – SG 102/15, suppl. - SG 53/18, in force from 26.06.2018) export and import of dangerous chemical substances on their own, in mixtures or in article within the range of Regulation (EU) No 649/2012 and under Art. 3 to 5 of Regulation (EC) 2017/852;

13. (amend. – SG 102/15) provision of information about the export and import of dangerous chemical substances on their own, in mixtures or in Articles within the range of Regulation (EU) No 649/2012;

14. prohibition and restriction of manufacturing, place on the market and use of the stable organic pollutants within the range of Regulation (EC) No 850/2004 ;

14a. (new – SG 102/15) prohibition for provision of restricted explosive substances precursors to the mass consumers under art. 23;

15. provision of information about the stable organic pollutants within the range of Regulation (EC) No 850/2004;

16. storage of dangerous chemical substances and mixtures pursuant to the ordinance envisaged in Art. 46, Para 1 and the conditions enlisted in the safety data sheet by the manufacturer, importer or downstream user;

17. biodegradability of surfactants and detergents, containing surfactants pursuant to Regulation (EC) No 648/2004;

17a. (new – SG 102/15) restriction of the use of phosphates and other phosphate compounds in consumers washing detergents and detergents for dish washers according to Regulation (EU) No. 259/2012;

18. labelling and packing of detergents and surfactants, intended for detergents pursuant to Regulation (EC) No 648/2004;

19. provision of information about the components of detergents pursuant to Regulation (EC) No 648/2004;

20. (amend. – SG 102/15) provision on the market and professional use of biocides;

20a. (new – SG 102/15) according to Art. 95(2) of Regulation (EU) No. 528/2012;

20b. (new – SG 102/15) releasing on the market of treated products;

21. conducting scientific research and development activity, including conducting experiments, where biocide or active substance is released or may be released into the environment;

22. (amend. – SG 102/15) provision of information about the provided on the market biocides and mixtures, classified as dangerous on the base of their effects on the health or the physical effects, for the purposes of planning of preventive measures and treatment and protection of the live and health of humans.

23. (new – SG, 84/2012, in force from 02.01.2013, suppl. - SG 53/18, in force from 26.06.2018) the EEE, placed on the market under Art. 21f, Para. 2, p. 1 – 7 and 9 – 11. determined in Chapter Five "a" and in the ordinance under Art. 21e, Para. 1 and limiting the production and placing on the market of mercury-added products under items 2 - 6 and non-electronic measuring devices which are not medical devices under item 9 of Part A and Part B of Annex II to Regulation (EC) 2017/852;

24. (new – SG, 84/2012, in force from 02.01.2013, suppl. - SG 53/18, in force from 26.06.2018) the EEE, placed on the market under Art. 21f, Para. 2, p. 8. determined in Chapter Five "a" and in the ordinance under Art. 21e, Para. 1 and limitation of the production and placing on the market of local antiseptics and medical devices respectively under items 8 and 9 of Part A of Annex II to Regulation (EC) 2017/852;

25. (new – SG 102/15) reporting of suspicious transactions or attempted transaction and of significant disappearances and thefts of the substances listed in Appendix I and Appendix II of Regulation (EU) No. 98/2013;

26. (new - SG 53/18, in force from 26.06.2018) a ban on the manufacture, placing on the market and use of cosmetic products and biocidal products with added mercury referred to in points 7 and 8 respectively and products referred to in point 9 of Part A of Annex II to Regulation (EC) No 2017/852;

27. (new - SG 53/18, in force from 26.06.2018) a ban on the manufacture of products with added mercury under items 1 to 6 and 9 of Part A of Annex II pursuant to Art. 5 of Regulation (EC) 2017/852;

28. (new - SG 53/18, in force from 26.06.2018) a ban on the use of mercury and mercury compounds in the manufacturing processes under Part I of Annex III, 7 of Regulation (EC) 2017/852 as from the dates set out in said Annex, with the exception of their use in production processes in Part II of Annex III, under the conditions set out in that Annex;

29. (new - SG 53/18, in force from 26.06.2018) environmentally friendly storage of mercury, mercury compounds and mixtures of mercury according to Art. 7, para. 3 of Regulation (EC) 2017/852;

30. (new - SG 53/18, in force from 26.06.2018) the production of new mercury-added products and new production processes involving the use of mercury or mercury compounds received authorization under Art. 8 (6) of Regulation (EC) 2017/852;

31. (new - SG 53/18, in force from 26.06.2018) a ban on artisanal and small-scale extraction and processing of gold in which mercury amalgamation is used to extract gold from ore according to Art. 9 of Regulation (EC) 2017/852;

32. (new - SG 53/18, in force from 26.06.2018) a ban on the placing on the market of mercury-added products under point 1 of Part A of Annex II to Regulation (EC) 2017/852;

33. (new - SG 53/18, in force from 26.06.2018) maintaining information under Art. 20e, item 2.

(2) In the exemption under Art. 3a the subject of control is also compliance with the requirements and measures, defined in the Ordinance under Art. 20a, para. 3 and in the permit under Art. 20a, para. 5, for:

1. preventing or limiting harmful effects on the environment;

2. preventing or limiting harmful effects on the human health.

Art. 26. (amend. – SG 63/10, in force from 13.08.2010) (1) Control, stipulated by this Act is preventive, current and following.

(2) Preventive control shall be carried out through the procedures of issuance of authorisation to place on the market biocides under provisions of Chapter Four.

(3) Current control shall be carried out by execution of :

1. planned inspections on the base of annual plan of the control activity;

2. inspections upon complaints and signals by natural and legal persons;

3. inspections in case of doubt;

4. inspections upon inquiry by the European Chemical Agency or by a competent body of another Member State of the European Union or another country – a party to the European Economic Area Agreement.

(4) Following control shall be carried out by way of monitoring the execution of prescriptions, given to the controlled persons during the monitoring and of the imposed under the procedure of this Act punitive administrative measures.

(5) Control shall be carried out by way of execution of checks of documents and on spot, by taking samples, by carrying out laboratory analyses, observations and measurement.

(6) (suppl. – SG, 84/2012, in force from 02.01.2013) Control shall be by way of separate or joint inspections carried out by bodies, envisaged in Art. 27, Para. 1, 2 and 4.

(7) Where carrying out control, bodies envisaged in Art. 27, Para 1 and 2 shall draw up protocols of findings.

(8) In the protocols under Para 7 the found facts and circumstances shall be entered and mandatory prescriptions to remove the found incompliance and offences with fixed terms and responsible for the execution persons shall be stipulated.

(9) Minister of Environment and Water, Minister of Health and Minister of Labour and Social Policy, within their competence, shall issue joint instructions on the carrying out control over the execution of this Act, of the secondary legislation on its implementation and of the Regulations referred to in Art.1, item 3.

(10) (new - SG 53/18, in force from 26.06.2018) The Ministry of Environment and Water, the Ministry of Health and the Ministry of Labor and Social Policy exchange information for the purposes of control under Art. 25, para. 1, items 2, 3 and 5 - 10.

Art. 27. (amend. SG 114/03; amend. – SG 63/10, in force from 13.08.2010) (1) (amend. – SG 102/15, amend. - SG 12/17, amend. - SG 53/18, in force from 26.06.2018) Minister of Environment and Water, the directors of the regional inspection offices of environment and waters or officials, empowered by them, shall exercise control in the cases of Art. 25, Para. 1 items 3 - 9, 13, 14, 15 - 17a, 27 - 31 and 33. as wall as Art. 25, para. 2, item 1 with the objective of environment preservation.

(2) (amend. – SG 102/15, amend. - SG 53/18, in force from 26.06.2018) The authorities of state health control under the Health Act shall exercise control in the cases of Art. 25, para. 1, item 2, 2a, 3, 7, 10, 14a, 18-22, 26 and 33 as well as Art. 25, para. 2, item 2 with the objective of preservation of the health of the population.

(3) (amend. – SG 102/15, amend. - SG 53/18, in force from 26.06.2018) Bodies of the state control under the Protection of Plants Act shall implement control over the classification, packing and labelling and over the safety data sheets for the released on the market and intended for export products for plant protection, following the procedure stipulated in the Protection of Plants Act, including prohibitions and restrictions on mercury-added pesticides under point 8 of Part A of Annex II to Regulation (EU) 2017/852.

(4) (amend. – SG 102/15, amend. - SG 53/18, in force from 26.06.2018) Customs Agency shall exercise control in the cases of Art. 25, para. 1, item 12 following the procedure of Regulation (EEC) No 2913/92 of the Council establishing Community Customs Code and the Regulation (EC) No. 2454/93 laying down provisions for the implementation of Council Regulation (EEC) No. 2913/92 establishing the Community Customs Code.

(5) (amend. – SG 102/15, amend. - SG 53/18, in force from 26.06.2018) Executive Agency "General labour inspection office" to the Minister of Labour and Social Policy shall exercise control under the procedure of Labour Code in the cases of Art. 25, para. 1, item 11 with the purpose to ensure occupational health and safety.

(6) (new – SG, 84/2012, in force from 02.01.2013, amend. – SG 102/15, amend. - SG 53/18, in force from 26.06.2018) In the cases under Art. 25, para. 1, p. 23, the chairperson of the State Agency for metrology and technical supervision or officials, authorized by him/her shall exercise supervision on the market under Chapter Four of the Act on technical Requirements to Products and incompliance with Chapter III of Regulation (EC) N 765/2008.

(7) (new – SG, 84/2012, in force from 02.01.2013, amend. - SG 53/18, in force from 26.06.2018) In the cases under Art. 25, para. 1, p. 24 the executive director of the Executive Drug Agency or officials authorized by him/her shall exercise supervision under Chapter Six of the Act on Medicinal Products in compliance with Chapter III of Regulation (EC) N 765/2008.

(8) (new – SG 102/15, amend. - SG 53/18, in force from 26.06.2018) In cases referred to in Art. 25, para. 1, item 25 the Minister of Interior or officials authorized thereby shall exercise control subject to compliance with the Ministry of Interior Act.

(9) (new - SG 53/18, in force from 26.06.2018) In the cases under Art. 25, para. 1, item 32 the Chairman of the Commission for Protection of Consumers or officials authorized by him shall exercise control under the procedure of the Consumer Protection Act and in accordance with Art. 5 of Regulation (EC) 2017/852.

Art. 28. (amend. SG 114/03; amend. – SG 82/07; amend. – SG 63/10, in force from 13.08.2010) (1) The bodies envisaged in Art. 27, Para 1 and 2 shall have the right to:

1. (amend. – SG 63/10, in force from 13.08.2010, amend. - SG 12/17) free access to the enterprises and sites, implementing production, place on the market, use, storage and export of chemical substances on their own, in the composition of mixtures or in articles and/or mixtures;

2. (amend. – SG 63/10, in force from 13.08.2010, amend. - SG 12/17) require information and documents and take samples for laboratory analyses, connected with the production, place on the market, the use, the storage and the export of chemical substances on their own, in the composition of mixtures or in articles and/or mixtures;

3. (amend. – SG 63/10, in force from 13.08.2010, amend. - SG 12/17) require information concerning quantities of produced, imported, exported, used and released on the market chemical substances on their own, in the composition of mixtures or in articles and/or mixtures;

4. (amend. – SG 63/10, in force from 13.08.2010, amend. - SG 12/17) require information from producers, importers, exporters, users along the chain and distributors of chemical substances on their own, in the composition of mixtures or in articles and/or mixtures about the identity of their suppliers and users along the supply chain of chemical substances on their own, in the composition of mixtures or in articles and/or mixtures.

(2) (revoked – SG 63/10, in force from 13.08.2010)

(3) (amend. – SG 63/10, in force from 13.08.2010) The body under Art. 27, Para 4 shall have right to:

1. (amend. – SG 102/15) require documents and information and take samples for laboratory analyses with regard to the import and export of dangerous chemical substances on their own and in mixtures of Attachments I and V of Regulation (EC) No 649/2012;

2. (amend. – SG 102/15) in case of alleged violations of prohibitions and/or restrictions, envisaged in Attachment I or in Attachment V of Regulation (EC) No 649/2012 – to detain the goods until obtaining a reference of the Minister of Environment and Waters or of an official, empowered by him/her, and in case of found violations – to sent back the substances, mixtures and/or products on the account of the

exporter/importer or of a person, authorized for the export/import.

(4) The bodies under Art. 27 shall be obliged not to disclose the information which is a manufacturing or commercial secret.

(5) (new – SG 63/10, in force from 13.08.2010, amend. - SG 12/17) Where, as a result of laboratory analysis/analyses of a chemical substance/of chemical substances on their own, in mixtures or in articles, or of a mixture/mixtures or biocide/biocides, bodies envisaged in Art. 27, Para 1 and 2 find offence of this Act, the secondary legislation on its implementation and of the Regulations, enlisted in Art. 1, item '3', the persons found guilty shall pay the expenditures for the analyses carried out.

(6) (new – SG 63/10, in force from 13.08.2010; amend. – SG 102/15) Where is found, that a released on the market chemical substance on its own, in the content of a mixture or in a product, a mixture and/or biocide do not meet provisions of this Act, of the secondary legislation on its implementation and/or of the Regulations, enlisted in Art. 1, item 3 and the substance, mixture and/or biocide presents a risk for the human health and safety and/or the environment, Minister of Health and/or the Minister of Environment and Waters or empowered thereby officials may direct immediate and effective withdrawal of the substance, mixture and/or the biocide from the market at the account of the persons liable for placing on the market or seizure from the end consumer.

(7) (new – SG 63/10, in force from 13.08.2010; suppl. – SG 102/15) Measures per Para 6 shall be undertaken in case, that all undertaken measures have not been sufficient to prevent or restrict the risk for the human health and/or for the environment.

(8) (new – SG 63/10, in force from 13.08.2010) Customs authorities shall provide information on the import of chemical substances on their own and in mixtures, which are subject to authorisation and on the import of chemical substances and mixtures, which are subject to restriction under Regulation (EC) No 1907/2006 (REACH) upon request by the bodies of Art. 27, Para 1 and 2 or by empowered by them officials and in an established form.

Art. 29. (prev. art. 30, amend. SG 114/03; amend. – SG 63/10, in force from 13.08.2010) A state body cannot prohibit, restrict or impede the placing on the market of dangerous substances and mixtures meeting the requirements of this Act.

Art. 30. (1) (prev. art. 29, amend. SG 114/03; amend. – SG 63/10, in force from 13.08.2010) Upon existence of new information, that a chemical substance and/or mixture, complying with the provisions of this Act, of the secondary legislation on its implementation and of the regulations stated in Art. 1, item 3 present an immediate and great danger for the human health and/or the environment, the bodies of Art. 27 Para 1 and 2 can temporary prohibit their place on the market.

(2) (new – SG 95/06, in force from 24.11.2006) In accordance with their powers, the Minister of Health and the Minister of Environment and Waters may temporary prohibit the placing on the market of a detergent, with respect to which there is a reason to be considered that poses a risk to human or animal health or to the environment, regardless of the fact that it meets the requirements of Regulation 648/2004 of the European Parliament and the Council, or the said ministers may temporary impose the fulfilment of specific terms.

(3) (new – SG 95/06, in force from 24.11.2006; amend. – SG 63/10, in force from 13.08.2010; amend. – SG 102/15) In accordance with their powers, the Minister of Health and the Minister of Environment and Waters may temporary prohibit or restrict the use or the trade of authorised biocide, with respect to which there are grounds to consider that pose a danger to human or animal health or to the environment.

(4) (new – SG 95/06, in force from 24.11.2006; amend. – SG 82/07) Where measure under para 1,

2 and 3 is being imposed, the Minister of Health and the Minister of Environment and Waters shall immediately notify the European Commission and the Member States of the European Union, and shall state the reasons for their decision.

(5) (prev. text of para 2, amend. – SG 95/06, in force from 24.11.2006; amend. – SG 63/10, in force from 13.08.2010; amend. – SG 102/15) Upon occurrence of immediate danger for people and/or environment, which cannot be removed by other means, the Minister of Health may by way of exception allow following the procedure and within the term provided in Art. 55(1) of Regulation (EU) No. 528/12 the provision on the market or use of a biocide, which does not meet the requirements of Chapter Four.

(6) (new – SG 95/06, in force from 24.11.2006; amend. – SG 63/10, in force from 13.08.2010) The permission pursuant to para 5 shall be issued upon proposal by the Expert biocide council on the grounds of assessments of the biological efficiency of the biocide and its toxicological and eco-toxicological properties, accepted by unanimity.

(7) (new – SG 95/06, in force from 24.11.2006; revoked – SG 102/15).

(8) (new – SG 95/06, in force from 24.11.2006) For issue of a permission under para 5 the applicant shall pay a charge according to the tariff pursuant to Art. 19y, para 1, item 26.

(9) (new – SG 95/06, in force from 24.11.2006; revoked – SG 102/15)

(10) (new – SG 95/06, in force from 24.11.2006; revoked – SG 102/15)

Art. 30a. (new – SG 102/15) (1) Minister of Health upon a proposal of the Minister of Interior can temporarily restrict or limit the provision, owning and use of substances, which are not listed in Appendix I and Appendix II of Regulation (EU) No. 98/2013 in compliance with Art. 13(1) of the same Regulation.

(2) Minister of Health upon a proposal of the Minister of Interior can additionally limit or restrict the provision, owning and use of substances, which are not listed in Appendix I and Appendix II of Regulation (EU) No. 98/2013 in compliance with Art. 13(2) and (3) of the same Regulation.

(3) For the application of a measure under par. 1 and/or par. 2 the Minister of Health shall immediately inform thereof the European Commission and the other Member States and shall provide their justification for the decision.

Art. 31. (Revoked SG 91 2002; new – SG 102/15) The control under Regulation (EU) No. 528/2012 shall be carried out subject to compliance with the requirements of Regulation (EU) No. 765/2008.

Chapter eight.
ADMINISTRATIVE PUNITIVE PROVISIONS

Section I.
Compulsory administrative measures

Art. 32. (amend. – SG 82/07) The competent bodies or persons empowered by them shall apply compulsory administrative measures by the order of art. 33 for prevention and termination of the administrative breaches under this act as well as for prevention and termination of the harmful consequences therefrom.

Art. 33. (amend. – SG 63/10, in force from 13.08.2010) (1) (amend. and suppl. – SG 102/15)

Minister of Environment and Waters or officials, empowered by him/her, shall, in compliance with their powers, stop the manufacturing, the place on the market, the use and/or the export of chemical substances, mixtures and/or products.

(2) (amend. – SG 102/15) The Directors of Regional Health Inspection offices in compliance with their powers, shall stop place on the market and/or use of chemical substances, mixtures including biocides and/or products.

(3) Activities under Para 1 and 2 shall be stopped for a time period until the reason leading to implementation of the compulsory administrative measure is removed.

(4) Implementation of the compulsory administrative measure shall be carried out by a reasoned order of the bodies envisaged in Para 1 and 2.

(5) In the order of Para 4 the period of effectiveness of the compulsory administrative measure and the manner of its implementation shall be determined.

(6) The order of Para 4 shall be served to the interested person observing the procedure stipulated in the Civil Procedure Code.

Art. 34. (amend. - SG 30/06, in force from 12.07.2006) The compulsory administrative measures can be appealed by the order of the Administrative procedure code.

Section II.
Administrative breaches and penalties

Art. 35. (amend. – SG 63/10, in force from 13.08.2010) (1) Punished shall be the person who:

1. does not fulfil his/her/its duties under Art.4a to the bodies of state control, determined in Art. 27, Para 1 and 2;

2. (amend. - SG 12/17) does not fulfil an obligatory prescription and/or an order to stop the producing, placing on the market and/or use chemical substances on their own, in the composition of mixtures or in articles, issued by a body of Art. 27, Para 1 or 2;

3. (amend. and suppl. – SG 102/15, amend. - SG 12/17) does not fulfil duties stipulated in Art.16 and Art.56 (1) of Regulation (EU) No. 528/2012;

4. (amend. and suppl. – SG 102/15) advertises a chemical substance or a mixture offending Art. 4 of this Act and Art. 72 of Regulation (EU) No. 528/2012;

5. does not store dangerous chemical substances and mixtures in accordance to the requirements, conditions and information as states by the manufacturer, importer or the downstream user in the safety data sheet;

6. (suppl. - SG 53/18, in force from 26.06.2018) violates requirements for storage of dangerous chemical substances and mixtures as per ordinance of Art. 46, Para 1 and obligations for the environmentally sound interim storage of mercury, mercury compounds and mixtures of mercury under Art. 7 (3) of Regulation (EC) 2017/852;

7. (revoked - SG 53/18, in force from 26.06.2018)

8. does not fulfil duties for classification, labelling and packing of chemical substances as per Article 4 of Regulation (EC) 1272/2008;

9. does not fulfil duties to identify and research the available data for substances under Article 5 and mixtures under Article 6 of Regulation (EC) No 1272/2008 (CLP);

10. does not fulfil duties to restrict or to avoid testing on animals and humans pursuant to Article 7 of Regulation (EC) No 1272/2008 (CLP);

11. does not fulfil duties for carrying out assessment of the information about the dangers and

classification of substances and mixtures under the procedure stipulated in Articles 9 – 15 of Regulation (EC) No1272/2008 (CLP);

12. does not fulfil duties to provide information about dangers of chemical substances and/or mixtures by labelling under the procedure stipulated in Articles 17-27 and Articles 30-33 of Regulation (EC) No 1272/2008 (CLP);

13. does not fulfil duties for packing of dangerous chemical substances and/or mixtures pursuant to Article 35 of Regulation (EC) No 1272/2008 (CLP);

14. does not fulfil the requirements for harmonization of classification and labelling of a substance pursuant to Article 37 (6) of Regulation (EC) No 1272/2008 (CLP);

15 does not fulfil obligation to notify the European Chemicals Agency pursuant Article 40 of Regulation (EC) No 1272/2008 (CLP);

16. does not fulfil obligations for provision of information pursuant to Article 45 of Regulation (EC) No 1272/2008 (CLP);

17. does not fulfil requirements for advertising of chemical substances and mixtures pursuant to Article 48 of Regulation (EC) No 1272/2008 (CLP);

18. does not fulfil obligations for storage and provision of information pursuant to Article 49 of Regulation (EC) No 1272/2008 (CLP);

19. offends the requirements of Articles 3 and 5(2) of Regulation (EC) No 850/2004;

20. (amend. – SG 102/15) provides on the market biocide without an issued permit;

21. (amend. – SG 102/15) is a professional consumer and uses a biocide without issued authorization;

22. (amend. – SG 102/15) releases on the market active substances, which are not included in the list of approved active substances in the European Union under Art. 9 (2) of Regulation (EU) No, 528/2012;

23. (amend. – SG 102/15) carries out experiments, which release or may release a biocide or an active substance, without issued notification;

24. (amend. – SG 102/15) releases on the market a treated product which does not meet the requirements of Art. 58 of Regulation (EU) No. 528/2012;

25. (amend. – SG 102/15) provides on the market a biocide in violation of the terms and conditions of the issued authorization;

26. (amend. – SG 102/15) does not fulfil their duties for keeping and provision of information according to Art. 68 (1) of Regulation (EU) No. 528/2012;

26a. (new– SG 102/15) fails to fulfill the obligation for provision of information under Art. 73 of Regulation (EU) No. 528/2012;

26b. (new – SG 102/15) fails to fulfill the obligations for limitation of tests on vertebrate animals according to Art. 62 of Regulation (EU) No. 528/2012;

27. breaches the restrictions on the biodegradability of surfactants and of detergents, containing surfactants pursuant to Article 4 of Regulation (EC) No 648/2004;

27a. (new – SG 102/15) violates the restrictions for use of phosphates and other phosphorus compounds in consumers washing detergents and consumer detergents for automatic dishwashers according to Art. 4a of Regulation (EU) No. 259/2012;

28. does not provide information about the biodegradability of surfactants and of detergents, containing surfactants, pursuant to Article 9(1) of Regulation (EC) No 648/2004;

29. does not provide immediately and free of charge the information, envisaged in Article 9(3) of Regulation (EC) No 648/2004;

30. does not publish the list of ingredients of the detergents pursuant to Annex VII, Section D to Regulation (EC) No 648/2004;

31. breaches the requirements for labelling and packing of detergents and surfactants, intended for detergents pursuant to Article 11 of Regulation (EC) No 648/2004 and Art. 11 of this Act;

32. (suppl. - SG 53/18, in force from 26.06.2018) breaches the requirements for manufacturing and

place on the market of chemical substances on their own, in mixtures and/or in articles and for the place on the market of mixtures, pursuant to Article 5 of Regulation (EC) No 1907/2006 (REACH) and of products with added mercury pursuant to Art. 5 of Regulation (EC) 2017/852;

33. fails to fulfil obligations:

a) for registration of chemical substances on their own, in mixtures or in articles under Article 6(1), (2) and (3), Article 7 (1), (2) and (5), Article 8 (2), Article 9 (6) and Article 14 (1), (6) and (7) of Regulation (EC) No 1907/2006 (REACH);

b) for preparation of documents and provision of safety data sheets and information along the supply chain pursuant Article 31 (1), (2), (3), (7) and (9), Article 32 (1) and (3), Article 33 (1), Article 34, Article 35, Article 37 (4), (5), (6) and (7), Article 38 (1), (3) and (4) and Article 39 (1) and (2) of Regulation (EC) No 1907/2006 (REACH);

c) (amend. - SG 98/18, in force from 27.11.2018) related to assessment of files and substances pursuant Article 50 (4) of Regulation (EC) No 1907/2006 (REACH);

d) related to permission of chemical substances on their own, in mixtures and/or in articles under Article 56 (1) and (2), Article 60 (10) and Article 65 of Regulation (EC) No 1907/2006 (REACH);

e) related to limitation of the production, use or place on the market of chemical substances on their own, in mixtures or in products under Article 67 (1) of Regulation (EC) No 1907/2006 (REACH);

34. fails to fulfil his/her/its obligations:

a) for registration of chemical substances on their own, in mixtures or in products pursuant to Article 7 (3), Article 8 (3), Article 9 (2), Article 11 (1) and (3), Article 12 (2), Article 13 (1), (2) and (3), Article 17 (1), Article 18 (1), Article 19 (1), Article 22 (1), (2) and (4), Article 24 (2) and Article 28 (1) and (6) of Regulation (EC) No 1907/2006 (REACH);

b) for information exchange and for carrying out tests on vertebrates pursuant to Article 25 (1) and (2), Article 26 (1) and (3) and Article 30 (1), (2) and (6) of Regulation (EC) No 1907/2006 (REACH);

c) for preparation and provision of safety data sheet and of information along the supply chain pursuant to Article 31 (5), (6) and (8), Article 32 (2), Article 33(2), Article 36 (1) and (2) and Article 37 (2) and (3) of Regulation (EC) No 1907/2006 (REACH);

d) in relation to assessment of files, substances and intermediates pursuant to Article 40 (3), Article 41 (4), Article 46 (2), Article 49 and Article 50 (2) and (3) of Regulations 1907/2006;

e) related to permission of chemical substances on their own, in mixtures or in articles pursuant to Article 61 (1) and Article 66 (1) of Regulation (EC) No 1907/2006 (REACH);

f) for provision of additional information to the European Chemicals Agency pursuant to Article 113 (1) and (3) of Regulation (EC) No 1907/2006 (REACH);

g) (new - SG 53/18, in force from 26.06.2018) to meet the requirements or measures to prevent or limit the harmful effects on human health or the environment, defined in the Ordinance under Art. 20a, para. 3 and in the permit under Art. 20a, para. 5.

35. (suppl. - SG 53/18, in force from 26.06.2018) fails to fulfil his/her/its obligations to submit notification of export of dangerous chemical substances on their own, in mixtures and/or in articles pursuant to Article 7and Article 14(1) of Regulation (EC) No 689/2008 and under Art. 3 of Regulation (EC) 2017/852 and under Art. 3 and 5 of Regulation (EC) 2017/852;

36. (amend. – SG 102/15) fails to fulfil the restrictions for export of dangerous chemical substances on their own, and./or in mixtures pursuant to Article 14 of Regulation (EC) No 649/2012;

37. (amend. – SG 102/15, suppl. - SG 53/18, in force from 26.06.2018) fails to fulfil the prohibitions for export under Article 15 (2) of Regulation (EC) No 649/2012 and under Art. 3 and 5 of Regulation (EC) 2017/852;

38. (amend. – SG 102/15) fails to fulfil his/her/its obligations to provide information under Articles 10, 16 and 17 of Regulation (EC) No 649/2012

39 (new – SG, 84/2012, in force from 02.01.2013) breaches the requirements of Chapter Five "a" or the ordinance under Art. 21e, Para. 1 for:

a) restriction of the use of dangerous substances in EEE and cables and spare parts for its repairing, its second use, updating of its functional characteristics or raising its capacity;

b) compliance assessment with the restrictions for use of dangerous substances in EEE or drawing up technical documentation or compliance declaration;

c) placement of "CE" marking on EEE and on cables and spare parts for its repairing, its second use, updating of its functional characteristics or raising its capacity;

d) maintenance and provision of information for finding the compliance of the EEE placed on the market with the introduced restrictions for use of dangerous substances.

40. (new – SG 102/15) violates the prohibition for provision of limited explosive substances precursors to mass consumers;

41. (new – SG 102/15) fails to fulfill their obligation for labeling of limited explosive substances precursors under Art. 24;

42. (new – SG 102/15) fails to fulfill their obligation for reporting of suspicious transactions or attempted suspicious transactions and of significant disappearances and thefts of the substances listed in Appendix I and Appendix II of Regulation (EU) No. 98/2013.

43. (new - SG 53/18, in force from 26.06.2018) fails to fulfill its obligation to maintain information under Art. 20e, item 2;

44. (new - SG 53/18, in force from 26.06.2018) violates the ban on the import of mercury, mercury compounds and mixtures of mercury under Art. 4 (1), (2) and (3) and products with added mercury pursuant to Art. 5 (1) of Regulation (EC) 2017/852;

45. (new - SG 53/18, in force from 26.06.2018) violates the ban on the production of mercury-added products under Art. 5 (1) and the use of mercury and mercury compounds in production processes under Art. 7 (1) of Regulation (EC) 2017/852;

46. (new - SG 53/18, in force from 26.06.2018) violates the ban on the production of new products with added mercury and new production processes involving the use of mercury or mercury compounds according to Art. 8 (1) and (2) of Regulation (EC) 2017/852 unless he/she obtains permission for these activities under Art. 8 (6) of that Regulation;

47. (new - SG 53/18, in force from 26.06.2018) violates the ban on the artisanal and small-scale gold mining and processing according to Art. 9 (1) of Regulation (EC) 2017/852;

48. (new - SG 53/18, in force from 26.06.2018) violates the ban on the placing on the market of mercury-added products under the Annex II to Regulation (EC) 2017/852 and new mercury-added products under Art. 8 of that Regulation.

(2) For breaches of Article 35 of Regulation (EC) No 1907/2006 (REACH) sanctions pursuant to the Labour Code shall be imposed.

(3) For violations of Para 1, the natural persons shall be punished by a fine, and the legal persons - proprietary sanction, in the following amounts:

1. (amend. – SG 102/15, amend. - SG 53/18, in force from 26.06.2018) under items 8, 19, 20, 22, 23, 32, 33, 40 and 44 - 48 – from 10 000 to 100 000 BGN;

2. (suppl. – SG 102/15) under items 3, 10, 11, 12, 13, 15, 16, 18, 21, 24, 26a, 26b, 34, 36 and 37 – from 5 000 to 50 000 BGN;

3. (amend and suppl. – SG 102/15, amend. - SG 53/18, in force from 26.06.2018) under items 1, 2, 4, 5, 6, 9, 14, 17, 25, 26, 27, 27a, 28, 29, 30, 31, 35, 38, 39, 41, 42 and 43 – from 1 000 to 40 000 BGN.

(4) In case of a repeated violation, the fine, respectively the proprietary sanction under Para 3 shall be imposed in a double amount.

Art. 36. (1) (amend. SG 114/03, amend. – SG, 84/2012, in force from 02.01.2013, amend. – SG 102/15, amend. - SG 53/18, in force from 26.06.2018) The breaches of art. 35, Para. 1, p. 1 - 41 shall be established by acts issued by state health inspectors or by officials, nominated by the directors of the

regional inspectorates of environment and water in compliance with their authorities.

(2) (amend. SG 114/03; amend. – SG 82/07; amend. – SG 102/15, amend. - SG 53/18, in force from 26.06.2018) The punitive decrees shall be issued by the Director of the respective Regional Health Inspection Office or by the Director of the respective inspectorate of environment and waters or by officials empowered thereby in compliance with their powers.

(3) (new – SG, 84/2012, in force from 02.01.2013) The violation acts under Art. 35, Para. 1 shall be drawn up by officials, determined by the chairperson of the State agency for metrology and technical supervision, Chairman of the Commission for Consumer Protection, from the directors of the relevant District Food Safety Directorate or by the executive director of the Executive drug agency in compliance with their authorizations and the penal decrees shall be issued by the chairperson of the State agency for metrology and technical supervision, Chairman of the Commission for Consumer Protection, from the directors of the relevant District Food Safety Directorate or by the executive director of the Executive drug agency in compliance with their authorizations or by officials, authorized by them.

(4) (new – SG 102/15) The acts establishing violations under Art. 35, par. 1, item 42 shall be drawn up by officials nominated by the Minister of Interior, and the punitive decrees shall be issued by the Minister of Interior or by officials empowered thereby.

Art. 37. The establishing of the breaches, the compiling of the acts, the issuing, the appealing and the execution of punitive decrees shall be implemented by the order of the Act on the administrative breaches and penalties.

Additional provisions

§ 1. (amend. SG 114/03) In the sense of this Act:

1. "Chemical substances" are chemical elements and their compounds in natural state or obtained by production process, including also additives necessary for stabilisation of the products, and admixtures occurred at the used production process but excluding any solvent that could be separated without influencing the stability of the substance or changing its contents.

2. (amend. – SG 63/10, in force from 13.08.2010) "Mixtures" are mixtures or solutions comprised by two or more chemical substances.

3. (amend. – SG 95/06, in force from 24.11.2006; revoked – SG 82/07);

4. (revoked – SG 63/10, in force from 13.08.2010);

5. (revoked – SG 63/10, in force from 13.08.2010);

6. (amend. – SG 63/10, in force from 13.08.2010; amend. – SG 102/15) "Dangerous chemical substances and mixtures" are the chemical substances and mixtures which are classified as dangerous in one or more hazard categories, as indicated in Appendix No. I of Regulation (EU) No. 1272/2008 (CLP);

7. (amend. – SG 63/10, in force from 13.08.2010) "Classification" is the procedure by which an assessment is made whether the chemical substance and mixture has one or more dangerous properties and depending on this it is referred to certain category.

8. (amend. – SG 63/10, in force from 13.08.2010) "Labelling" are all the texts, marks, images and signs on the packing of the chemical substance and mixture, reflecting the existence of potential danger according to the classification.

9. (revoked – SG 82/07);

10. (revoked – SG 82/07);

11. (revoked – SG 82/07);

12. "Tactile mark" is a mark tangible at touching designated for blind persons.

13. (amend. – SG 63/10, in force from 13.08.2010) "Preservation" is any way of storing chemical substances or mixtures before their use, treatment, processing or transport.

14. "Repeated breach" is a breach committed in one year term after a punitive decree has entered into force with which the violator is punished for breach of the same kind.

15. (revoked – SG 82/07);

16. (suppl. – SG 95/06, in force from 24.11.2006; amend. – SG 63/10, in force from 13.08.2010) "Placing on the market" is any conceding of chemical substance or mixture against payment or gratuitously for distribution and/or use. The import shall be considered as placing on the market.

17. (amend. – SG 95/06, in force from 24.11.2006; amend. – SG 63/10, in force from 13.08.2010) "Professional use" is any Bulgarian or foreign individual or corporate body, which is registered under the Commercial Act or under his national legislation or who exercises free lance practice in the sense of the Act on Taxes on The Income of Natural Persons, who uses and/or releases on the market dangerous chemical substances and mixtures.

18. "Professional use" are the activities, implemented by the persons of item 17.

19. (amend. – SG 63/10, in force from 13.08.2010; revoked – SG 102/15).

20. "Harmful organism" is any organism, which presence is not wanted or which exercises harmful effect on people, their activities or the products they produce or use, or on animals and environment.

21. "Active substance" is chemical substance or micro-organism, including viruses and fungi, with general or specific effect on or against harmful organisms.

22. (amend. – SG 95/06, in force from 24.11.2006; revoked – SG 82/07).

23. (amend. – SG 95/06, in force from 24.11.2006) "Development activity" is follow up mixture of certain substance for investigation and the application areas.

24. (amend. SG 101/05; revoked – SG 95/06, in force from 24.11.2006);

25. (amend. – SG 63/10, in force from 13.08.2010; revoked – SG 102/15);

26. (amend. – SG 95/06, in force from 24.11.2006; revoked – SG 102/15);

27. (amend. – SG 63/10, in force from 13.08.2010; revoked – SG 102/15);

28. (amend. – SG 63/10, in force from 13.08.2010) "Residual quantities" are the quantities of one or more substances, contained in given biocide, which remain are result of its use, including the metabolites of these substances, as well as from the products of their disintegration or interaction.

29. (amend. – SG 63/10, in force from 13.08.2010; revoked – SG 102/15);

30. (amend. – SG 63/10, in force from 13.08.2010) "Declaration for using of information" is a document, signed by the owner or the owners of information, protected as confidential by the provisions of this act, certifying that the Minister of Health can use it at permitting or registration of other biocide.

31. "Admissible day dose" is the quantity of substance, which can be absorbed daily with the food during all life without risk for human life.

32. "Limit value" is the measures average value of given chemical agent or dust in the air of the breathing zone of the working person at the working place for defined period of time.

33. (revoked – SG 82/07).

34. (revoked – SG 82/07).

35. (revoked – SG 82/07).

36. (amend. – SG 63/10, in force from 13.08.2010) "Exposure" is exposing of human organism and the components of environment to the impact of chemical substances, mixtures and biocides.

37. (new – SG 101/05; revoked – SG 95/06 in force from 01.01.2007)

38. (new – SG 95/06 in force from 01.01.2007; revoked – SG 82/07).

39. (new – SG 95/06 in force from 01.01.2007, amend. – SG 63/10, in force from 13.08.2010; revoked – SG 102/15);

40. (new – SG 95/06 in force from 01.01.2007) "Stable organic pollutants" shall be dangerous chemical substances, regardless whether in individual form or in mixtures, which are being transported

through the international borders far away from their sources and are stable in the environment, and which are being accumulated in the organisms through the food chain and threaten the human health and the environment.

41. (new – SG, 84/2012, in force from 02.01.2013) EEE is an equipment, which is needed by electric currency or electric magnet fields in order to fulfil at least on of the purpose functions, as well as equipment for generation, transmission and measurement of such currency or fields and has been created for use with electric tension, which does not exceed 1000 V for variable currency and 1500 V for constant currency.

42. (new – SG, 84/2012, in force from 02.01.2013) Large Unit Stationary Industrial Equipment is a large combination of machines, equipment and/or components, functioning together with specific application, mounted and dismounted permanently by specialists at a certain place and exploited and maintained by specialists in industrial production premises or facilities for scientific and development activity.

43. (new – SG, 84/2012, in force from 02.01.2013) Large Immovable Mounted Installation is a large combination of several types of apparatus and where applicable, other facilities, mounted, and dismounted by specialists and are intended for permanent exploitation at a preliminary determined place.

44. (new – SG, 84/2012, in force from 02.01.2013) Cables are all cables with nominal tension less than 250 V, serving for connection or extension at connection of the EEE with the electric network or in connecting 2 or more EEE.

45. (new – SG, 84/2012, in force from 02.01.2013) Producer of EEE is any natural or legal persons, who produces EEE or has designed or produced EEE and offers it on the market under his name or trade mark.

46. (new – SG, 84/2012, in force from 02.01.2013) Authorised representative is any natural or legal persons, established on the territory of an EU Member State or on another state- party under the EEAA, who is authorized in writing by an EEE producer to act on his/her behalf for fulfilment of certain obligations under the ordinance of Art. 21e, Para. 1.

47. (new – SG, 84/2012, in force from 02.01.2013) EEE Distributor is any natural or legal persons on the delivery chain, different form the producer or importer, who provides EEE on the market.

48. EEE Importer is any natural or legal person, established on the territory of an EU Member State or on another state – party of the EEAA, who places on the EU market EEE from a third state.

49. (new – SG, 84/2012, in force from 02.01.2013) Economic operator is a producer, importer and distributor of EEE or an authorized representative.

50. (new – SG, 84/2012, in force from 02.01.2013) Providing EEE on the market is any paid or unpaid delivery of EEE for distribution or use on the EU market as a part of a certain trade activity.

51. (new – SG, 84/2012, in force from 02.01.2013) Placing EEE on the Market is provision of EEE on the EU market for the first time.

52. (new – SG, 84/2012, in force from 02.01.2013) Harmonized Standard is a standard, adopted by an European organization for standardization implementing a European Commission mandate in compliance with Art. 6 of Directive 98/34/EC.

53. (new – SG, 84/2012, in force from 02.01.2013) CE Marking is a marking by which the EEE producer certifies that the product complies with the applicable requirements of the EU legislative acts for harmonization, providing its placement.

54. (new – SG, 84/2012, in force from 02.01.2013) Compliance Assessment is a procedure by which it is established if the requirements of Chapter Five "a" have been observed and of the ordinance Art. 21e, Para. 1 in relation to a certain EEE.

55. (new – SG, 84/2012, in force from 02.01.2013) Homogeneous Material is a material of a homogeneous composition or material consisting of a combination of materials which cannot be broken down in different materials by mechanical actions as unwinding, cutting, breaking and abrasive technologies.

56 (new – SG, 84/2012, in force from 02.01.2013) Medical Item is a medical item in the meaning of Para. 1. p. 21 of the Additional Provision of the Act on Medicinal Items, which is EEE.

57. (new – SG, 84/2012, in force from 02.01.2013) In vitro Diagnostic medicinal Item is a medicinal item in the meaning of § 1. p. 21 of the Additional Provision of the Act on Medicinal Items.

58. (new – SG, 84/2012, in force from 02.01.2013) Active Implanting Medicinal Item is a medicinal item in the meaning of § 1. p. 1 of the Additional Provision of the Act on Medicinal Items.

59. (new – SG, 84/2012, in force from 02.01.2013) Production Appliances for Management Control are appliances for control and management, intended for the production or professional use.

60. (new – SG, 84/2012, in force from 02.01.2013) Substitute Availability is the ability of a certain substitute to be able to be produced and supplied within the frames for a reasonable term of time in comparison with the time, needed for the production and supply of the substances, determined by the ordinance under Art. 21e, Para. 1.

61. (new – SG, 84/2012, in force from 02.01.2013) Reliability of a Substitute is the possibility EEE, used as a substitute to fulfil the needed function under certain conditions and for the indicated period of time.

62. (new – SG, 84/2012, in force from 02.01.2013) Spare part for EEE is a separate part of EEE, which may replace a part of this equipment and without which it cannot function. The EEE functioning is restored or improved, where the part is replaced by a spare part.

63. (new – SG, 84/2012, in force from 02.01.2013, suppl. - SG 17/19, in force from 26.02.2019) Mobile equipment not intended for movement of road and are explicitly for professional use are machines with a board source of energy or driven by traction powered by an external power source whose functioning imposes moving or replacement between several fixed work places during operation and are explicitly for professional use.

64. (new – SG, 84/2012, in force from 02.01.2013) Interests of the Republic of Bulgaria, related to the national security are the ones, determined by § 1, p. 14 of the Additional Provision of the Act on the Classified Information Protection.

65. (new - SG 53/18, in force from 26.06.2018) "Allowed use" is any use of mercury, mixtures of mercury or mercury compounds authorized under the relevant Union or Bulgarian legislation, including the uses according to Art. 3, 4, 5, 7, 8 and 10 of Regulation (EC) 2017/852.

§ 1a. (new – SG 102/15) For the purposes of Chapter Four, Seven and Eight the definitions provided in Regulation (EU) No. 528/2012 shall apply.

(2) For the purposes of Chapter Six “a” the definitions provided in Regulation (EU) No. 98/2013 shall apply.

§ 1b. (new – SG, 84/2012, in force from 02.01.2013; prev. § 1a – SG 102/15, suppl. - SG 17/19, in force from 26.02.2019) This act shall introduce the requirements of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ, L 174/88 of 1 June 2011) and of Directive (EU) 2017/2102 of the European Parliament and of the Council of 15 November 2017 amending Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Transitional and concluding provisions

§ 2. The persons implementing activities of art. 1 for which registration by the order of chapter four is required shall submit application for registration in six months term after the act enters into force.

§ 3. (amend. SG 114/03) The Minister of Health and the Minister of Environment and Waters can concede their functions, rights and obligations under this act to their deputies or to other officials in the system of the corresponding ministries.

§ 4. The act shall enter into force two years after its promulgation in State Gazette.

§ 5. (amend. SG 114/03; amend. – SG 63/10, in force from 2010) The implementation of the Act shall be assigned to the Minister of Health and the Minister of Environment and Water.

§ 6. (new – SG 82/07; amend. – SG 63/10, in force from 13.08.210) The Minister of Environment and Water, the Minister of Health and the Minister of Labour and Social Policy within the scope of their competency shall give instructions on the implementation of Regulations 1907/2006, Regulations 304/2003, Regulations 850/2004 and of Regulation (EC) No 1451/2007.

…….

This Act was adopted by the XXXVIII National Assembly on 20 January 2000 and was the official seal of the National Assembly was attached.

Transitional and concluding provisions
(SG 114/03)

§ 40. The Council of Ministers shall approve the ordinances of art. 11, 13 and art. 16, para 1 in one year term after the day of promulgation of this act on State Gazette.

§ 42. (1) This act shall enter into force one month after its promulgation in State Gazette except the provisions of chapter four, section I "Conditions and order for releasing on the market active substances and biocide preparations", which shall enter into force on January 1, 2007.

(2) The provisions of chapter four, section II "Conditions and order for releasing on the market biocide preparations" shall be implemented till January 1, 2007.

The act was adopted by the 38th National Assembly on January 20, 2000 and was affixed with the official seal of the National Assembly.

Transitional and concluding provisions

TO THE ADMINISTRATIVE PROCEDURE CODE

(PROM. – SG 30/06, IN FORCE FROM 12.07.2006)

§ 142. The code shall enter into force three months after its promulgation in State Gazette, with the exception of:

1. division three, § 2, item 1 and § 2, item 2 – with regards to the repeal of chapter third, section II "Appeal by court order", § 9, item 1 and 2, § 15 and § 44, item 1 and 2, § 51, item 1, § 53, item 1, § 61, item 1, § 66, item 3, § 76, items 1 – 3, § 78, § 79, § 83, item 1, § 84, item 1 and 2, § 89, items 1 - 4§ 101, item 1, § 102, item 1, § 107, § 117, items 1 and 2, § 125, § 128, items 1 and 2, § 132, item 2 and § 136, item 1, as well as § 34, § 35, item 2, § 43, item 2, § 62, item 1, § 66, items 2 and 4, § 97, item 2 and § 125, item 1 – with regard to the replacement of the word "the regional" with the "administrative" and the replacement of the word "the Sofia City Court" with "the Administrative court - Sofia", which shall enter into force from the 1st of May 2007;

2. paragraph 120, which shall enter into force from the 1st of January 2007;

3. paragraph 3, which shall enter into force from the day of the promulgation of the code in State Gazette.

Transitional and concluding provisions
TO THE COMMERCIAL REGISTER ACT

(PROM. – SG 34/06, IN FORCE FROM 01.10.2006)

§ 56. This act shall enter into force from the 1st of October, with the exception of § 2 and § 3, which shall enter into force from the day of the promulgation of the act in State Gazette.

Transitional and concluding provisions
TO THE ACT OF AMENDMENT AND SUPPLEMENT OF THE ACT ON PROTECTION FROM THE HARMFUL IMPACT OF THE CHEMICAL SUBSTANCES AND MIXTURES

(PROM. – SG 95/06, IN FORCE FROM 24.11.2006; amend. – SG 82/07, amend. – SG 63/10, in force from 13.08.2010)

§ 22. The Council o9f Ministers shall adopt the ordinance pursuant to Art. 14a in three-month term from the entry into force of this Act.

§ 23. (1) (amend. – SG 82/07) The Minister of health shall repeal or amend the issued prior to enforcement of this act authorization for placing on the market of biocide preparation in compliance with Art. 4 (2) of Regulations 2032/2003.

(2) (amend. – SG 82/07) By the repeal of the authorisation under para 1 the Minister of Health shall fix a term for storage, use or distribution of the available quantities of biocide preparation.

§ 24. (suppl. – SG 82/07) Apart from the cases referred to in § 23, to the biocide preparations authorised prior to the entry into force of this Act shall be applied the provisions of Art. 19n, par. 3, Art. 19t, Art. 19u and section XVIII of the new Chapter four.

§ 25. From the date of coming into effect of the Treaty of Accession of the Republic of Bulgaria to the European Union with respect to the detergents and the surfactants shall be applied the definitions pursuant to Art. 2 of Regulation No 648/2004 of the European Parliament and the Council.

§ 26. This Act shall enter into force from the day of its promulgation in State Gazette, except for § 4 regarding Art. 4d, § 6, § 7, § 11, item 2 regarding para 5 of Art. 7d, § 15 regarding the new Chapter four, sections III through XVI, § 19, item 3 regarding para 9 and 10 of Art. 30, § 20, item 1, letter "c" regarding item 20 and 21 of Art. 35, para 1 and § 21, items 4 and 6 regarding items 24 and 37 of § 1 of the Additional provisions, which shall enter into force from the date of coming into effect of the Treaty of Accession of the Republic of Bulgaria to the European Union.

§ 27. (amend. – SG 63/10, in force from 13.08.2010) Provisions of Section XVII of Chapter Four shall be applied till the 14th of May 2014.

(2) In cases, where, by a decision of the Commission to include an active substance in the lists of Art. 14, Para 4, items 1 and 2, a later date than 14th of May 2014 is determined for the implementation of Provisions stipulated in Art. 19v, Section XVIII of Chapter Four shall be applied to the biocides, containing the active substance up, to that date.

Transitional and concluding provisions
TO THE ACT ON TAXES ON THE INCOME OF NATURAL PERSONS

(PROM. – SG 95/06, IN FORCE FROM 24.11.2006)

§ 21. The act shall enter into force from the 1st of January 2007, except for § 10, which shall enter into force from the date of promulgation of the Act in the State Gazette.

Transitional and concluding provisions
TO THE ACT OF AMENDMENT AND SUPPLEMENT OF THE ACT ON PROTECTION FROM THE HARMFUL IMPACT OF THE CHEMICAL SUBSTANCES AND PREPARATIONS

(PROM. – SG 82/07)

§ 40. Everywhere in the act the words "authorized" and "the authorized" shall be replaced respectively with "empowered" and "the empowered", and the words "the Minister of Agriculture and Forests" shall be replaced with "the Minister of Agriculture and Food Supplies"

……

§ 41. The issued pursuant to the provisions of Art. 22, par. 4 certificates of registration of export of dangerous chemical substances and preparations shall be valid till 31 December 2007.

……..

§ 43. The provisions of § 8, item 3, § 9, § 32, item 1 and §36, item 1, item "a" shall enter into force from 1 June 2008.

§ 44. The provision of § 10 shall enter into force from 1 August 2008.

§ 45. The provisions of § 29, § 32, item 2 and §36, item 1, item "c" shall enter into force from 1 June 2009.

Additional provisions
TO THE ACT ON AMENDMENT AND SUPPLEMENT OF THE ACT ON PROTECTION FROM THE HARMFUL IMPACT OF THE CHEMICAL SUBSTANCES AND MIXTURES

(PROMULAGTED – SG 63/10, IN FORCE FROM 13.08.2010)

§ 45. In the titles of Chapters Two and Seven, as well as everywhere in Chapters One, Two, Six, Seven and Eight words "preparation" and "preparations" shall be replaced respectively with "mixture" and "mixtures".

§ 46. In Chapter Four everywhere words "biocide preparation", "biocide preparations", "preparation" and "preparations" shall be replaced respectively with "biocide" and "biocides".

§ 47. Everywhere in this Act the words "Regulations 2032/2003" shall be replaced with "Regulation (EC) No 1451/2007".

§ 48. This Act introduces the stipulations of Directive 2009/107/EC of the European Parliament and of the Council of 16 September 2006 amending Directive 98/8/EC concerning the placing of biological products on the market as regards the extension of certain time periods (OJ, L 262/40 of 06.10.2009).

Transitional and concluding provisions
TO THE ACT ON AMENDMENT AND SUPPLEMENT OF THE ACT ON PROTECTION FROM THE HARMFUL IMPACT OF THE CHEMICAL SUBSTANCES AND MIXTURES

(PROMULAGTED – SG 63/10, IN FORCE FROM 13.08.2010)

§ 49. Council of Ministers shall adopt the ordinances specified in Art. 4b within nine - months term from the moment of entering of this Act into force.

§ 50. Permits to place on the market biocide preparations, issued before this Act shall enter into force, shall stay effective.

§ 51. Art. 2, Art. 5, Para 1-3- and Para 5, and Art. 7b – 7f shall be applied till 31 May 2015.

§ 52. This Act shall enter in force from the day of its promulgation in the State Gazette, except for § 14 and § 24, which shall enter into force from 1 June 2015.

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE ACT ON PROTECTION OF HAZARDEOUS IMPACT OF THE CHEMICAL SUBSTANCES AND MIXTURES

(PUBL. – SG. 84/2012, IN FORCE FROM 02.01.2013, AMEND. AND SUPPL. - SG 17/19, IN FORCE FROM 26.02.2019)

§ 12. The provision of art. 21f, Para. 1 shall not apply to:

1. medicinal items, placed on the market before 22 July 2014;

2. control and management appliances , placed on the market before 22 July 2014;

3. in vitro diagnostic medicinal items, placed on the market before 22 July 2016;

4. production control and management appliances, placed on the market before 22 July 2017;

5. (new - SG 17/19, in force from 26.02.2019) any other EEE that is placed on the market before 22 July 2019 and which is not covered by Art. 21e, para. 2, items 1-10;

6. (prev. item 5 - SG 17/19, in force from 26.02.2019) cables or spare parts for repairs, second use, updating the functional characteristics or raising the capacity of:

a) EEE, placed on the market before 1 July 2006;

b) medicinal items, placed on the market before 22 July 2014;

c) control and management appliances placed on the market before 22 July 2014;

d) in vitro diagnostic medicinal items, placed on the market before 22 July 2016;

e) industrial control and management appliances placed on the market before 22 July 2017;

f) EEE, for which is used the right to liberation and which was placed on the market before the term of liberation, insofar this refers the relevant liberation;

g) (new - SG 17/19, in force from 26.02.2019) any other EEE that is placed on the market before 22 July 2019 and which is not covered by Art. 21e, para. 2, items 1-10;

7. (prev. item 6, amend. - SG 17/19, in force from 26.02.2019) second used spare parts, restored from EEE, provided that the reuse of spare parts is carried out in auditable closed linked return systems between business entities and the consumer is notified of this reuse if the following conditions are met:

a) used spare parts are recovered from EEE placed on the market before 1 July 2006 and consumed in EEE placed on the market before 1 July 2016;

b) used spare parts are recovered from medical devices under Art. 2, para. 1, item 1 and 3 of the

Medical Devices Act or from industrial control devices placed on the market before 2 July 2014 and used in EEE placed on the market before 22 July 2024;

c) used spare parts are recovered from in vitro diagnostic medical devices placed on the market before 22 July 2016 and used in EEE placed on the market before 22 July 2026;

d) used spare parts have been recovered from industrial control devices placed on the market before 22 July 2017 and consumed in EEE placed on the market before 22 July 2027;

e) used spare parts are recovered from other EEE placed on the market before 22 July 2019 and used in EEE placed on the market before 22 July 2029 and which is not covered by Art. 21e, para. 2, items 1-10.

§ 13. (revoked - SG 17/19, in force from 26.02.2019)

§ 14 The Council of Ministers shall adopt the ordinance under Art. 21e, Para. 1 within 3-month term from the publication of this act in the State Gazette.

§ 15. This act shall come into force from 2 January 2013.

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE CONSUMER PUROTECTION ACT

(PUBL. – SG 61/2014, IN FORCE FROM 25.07.2014)

§ 91. The act shall enter into force on the day of its promulgation in State Gazette.

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE ACT ON PROTECTION FROM THE HARMFUL IMPACT OF THE CHEMICAL SUBSTANCES AND MIXTURES

(PUBL. – SG 102/15)

§ 32. (1) Authorizations for releasing on the market of biocides issued before entering of this act into force according to the provisions of the revoked Art. 19d, par. 1 shall keep their validity until the expiration of the term for which they are issued subject to compliance with the authorization terms and conditions.

(2) The persons holding authorizations, beyond those under par. 1, shall submit within one month after entering of this act into force to the Ministry of Health documents, substantiating that the active substances supplier or the biocide supplier is included in the list of the European Chemicals Agency under Art. 95 (1) of Regulation (EU) No. 528/2012 on the product types to which the biocide belongs, which can be access letters within the meaning of Art. 3 (1), sub-item “t” of the said Regulation, agreements, invoices, etc.

(3) If within one month after entering of this act into force the persons beyond those under par. 1,

fail to file the documents under par. 2 or the filed document do not prove that the substances supplier or the biocide supplier is included in the list of the European Chemicals Agency under Art. 95 (1) of Regulation (EU) No. 528/2012 the Minister of Health shall withdraw the issued authorization for releasing on the market of a biocide.

(4) Authorizations for releasing on the market of biocides issued prior to entering of this act into force beyond these under par. 1, for which documents under par. 2 are filed, shall keep their validity until the expiration of the term for which they are issued subject to compliance with the authorization terms and conditions.

§ 33. (1) The persons holding authorizations for releasing on the market of biocides which are mixtures within the meaning of Regulation (EC) No. 1272/2008 (CLP) and classified according to the requirements of the ordinance referred to in Art. 5, par. 2 shall file to the Ministry of Health an application for amendment of the authorization by 1 June 2017 at the latest with attached thereto:

1. proposal for biocide classification and labeling according to Regulation (EC) No. 1272/2008 (CLP);

2. summarized justification of the proposed biocide classification and labelling, including applied methods, data, calculations, criteria, etc.;

3. documents confirming all data regarding chemical ingredients and the biocide, provided in the summary, including test reports, safety information sheets according to Appendix II of Regulation (EC) No. 1907/2006, etc.;

4. declaration of identity of chemical composition and of all other biocide data with the composition and data based on which the first authorization has been issued;

5. a design of biocide label in Bulgarian language;

6. biocide safety information sheet in Bulgarian language according to the requirements of Appendix II of Regulation (EC) No. 1907/2006.

(2) The documents under par. 1 shall be submitted in Bulgarian language; one hard copy and three copies on an electronic storage device with an attached declaration of identity of provided information – both on a hard copy and on an electronic storage device.

(3) Authorizations issued before entering of this act into force for which within the term under par. 1 applications for amendment of the authorization have been filed, shall keep their validity subject to compliance with authorization terms and conditions.

(4) Minister of Health shall withdraw all authorizations issued before entering of this act into force for which no applications for amendment have been issued within the term under par. 1.

(5) Minister of Health shall review the issued authorizations under par. 1 in cases and subject to compliance with the provision of Art. 18d.

§ 34. The provision of Art. 18i, par. 1 shall apply after the provision of the required technical and organizational conditions.

§ 35. Within three months after entering of this act into force the Council of Ministers shall bring the ordinance under Art. 21e, par. 1 in compliance herewith.

Concluding provisions
TO THE ACT AMENDING THE ACT ON BULGARIAN FOOD SAFETY AGENCY

(PROM. - SG 58/17, IN FORCE FROM 18.07.2017)

§ 76. This Act shall enter into force on the day of its promulgation in the State Gazette.

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE ACT ON PROTECTION FROM THE HARMFUL IMPACT OF THE CHEMICAL SUBSTANCES AND MIXTURES

(PROM. - SG 53/18, IN FORCE FROM 26.06.2018)

§ 25. (1) The Council of Ministers shall, at the proposal of the Minister of Health, adopt a national plan by 1 July 2019 on measures to phase out the use of dental amalgam according to Art. 10 (3) of Regulation (EC) 2017/852.

(2) The national plan under para. 1 shall be published on the website of the Ministry of Health and shall be forwarded to the European Commission within one month of its adoption.

§ 26. Within one year from the entry into force of this Act, the Council of Ministers shall adopt the ordinance under Art. 20a, para. 3 at the proposal of the Minister of Environment and Water, the Minister of Defense and the Minister of Economy.

……..

§ 29. The Act shall enter into force on the day of its promulgation in the State Gazette.

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE ENVIRONMENTAL PROTECTION ACT

(PROM. - SG 98/18, IN FORCE FROM 27.11.2018)

§ 49. The Act shall enter into force on the day of its promulgation in the State Gazette with the exception of:

1. paragraph 3, items 1 and 3 concerning Art. 94 para. 1, item 9 and para. 4, § 4, item 2, § 5, 6, § 7, item 2, § 8, 10-12, § 15, item 2, § 16, 17, 21 - 26, 30 and 31, which shall enter into force nine months after its promulgation;

2. paragraph 40, item 24, which shall enter into force on 11 August 2006.

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE ACT ON PROTECTION FROM THE HARMFUL IMPACT OF THE CHEMICAL SUBSTANCES AND MIXTURES

(PROM. - SG 17/19, IN FORCE FROM 26.02.2019)

§ 5. The Act shall enter into force on the day of its promulgation in the State Gazette with the exception of § 4, which shall enter into force on 1 August 2016.