Protection Against the Harmful Impact of Chemical Substances and Mixtures Act
(Title amended, SG No. 114/2003, SG No. 63/2010, effective 13.08.2010)

Promulgated, State Gazette No. 10/4.02.2000, effecftive 5.02.2002, amended, SG No. 91/25.09.2002, SG No. 86/30.09.2003, amended and supplemented, SG No. 114/30.12.2003, effective 31.01.2004, SG No. 100/13.12.2005, effective 14.01.2006, SG No. 101/16.12.2005, amended, SG No. 30/11.04.2006, effective 12.07.2006, SG No. 34/25.04.2006, effective 1.01.2008 (*)(**), amended and supplemented, SG No. 95/24.11.2006, effective 24.11.2006, amended and supplemented, SG No. 82/12.10.2007, amended, SG No. 110/30.12.2008, amended and supplemented, SG No. 63/13.08.2010, effective 13.08.2010, amended, SG No. 98/14.12.2010, effective 1.01.2011, amended and supplemented, SG No. 84/2.11.2012, effective 2.01.2013, amended, SG No. 61/25.07.2014, effective 25.07.2014, amended and supplemented, SG No. 102/29.12.2015, SG No. 12/3.02.2017, amended, SG No. 58/18.07.2017, effective 18.07.2017, amended and supplemented, SG No. 53/26.06.2018, effective 26.06.2018, SG No. 98/27.11.2018, effective 27.11.2018, SG No. 17/26.02.2019, effective 26.02.2019, supplemented, SG No. 19/5.03.2021, effective 5.03.2021, amended, SG No. 102/23.12.2022, effective 1.01.2023

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*Note: An update of the English text of this Act is being prepared following the amendments in SG No. 102/8.12.2023, effective 12.12.2023, SG No. 23/19.03.2024, effective 23.03.2024

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(*) effective 1.07.2007 - amended, SG No. 80/3.10.2006, effective 3.10.2006
(**) effective 1.01.2008 - amended, SG No. 53/30.06.2007, effective 30.06.2007

Text in Bulgarian: Закон за защита от вредното въздействие на химичните вещества и смеси

CHAPTER ONE
GENERAL PROVISIONS

Article 1. (Amended, SG No. 114/2003, supplemented, SG No. 95/2006, amended, SG No. 82/2007) This Act shall regulate:
1. (amended, SG No. 63/2010, effective 13.08.2010) the rights and obligations of individuals and legal entities manufacturing, releasing on the market, using, storing and exporting chemical substances on their own, in mixtures or in articles for the purpose of protecting human health and the environment;
2. (amended, SG No. 63/2010, effective 13.08.2010) the powers of the state authorities exercising control over the manufacture, release on the market, use, storage and export of chemical substances on their own, in mixtures or in articles;
3. (amended, SG No. 63/2010, effective 13.08.2010) the measures implementing:
(a) Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, hereinafter referred to as 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 packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No. 1907/2006 (OJ, L 353/1 of 31 December 2008), hereinafter referred to as Regulation (EC) No. 1272/2008(CLP);
(c) (Supplemented, SG No. 102/2015) Regulation (EC) No. 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents, hereinafter referred to as "Regulation (EC) No. 648/2004" 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, 30 March 2012), hereinafter referred to as "Regulation (EU) No. 259/2012";
(d) (Amended, SG No. 102/2015) Regulation (EU) No. 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals (OJ, L 201/60, 27 July 2012), hereinafter referred to as "Regulation (EU) 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 referred to as Regulation (EC) No. 850/2004;
(f) (Amended, SG No. 102/2015) Commission Delegated Regulation (EU) No. 1062/2014 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, 10 October 2014), hereinafter referred to as "Delegated Regulation (EU) No. 1062/2014";
(g) (New, SG No. 102/2015) Regulation (EU) No. 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ, L 167/1, 27 June 2012), hereinafter 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 (OB, L 103/22, 5 April 2014);
(h) (New, SG No. 102/2015) Commission 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 (OB, L 139/1, 14 May 2014), hereinafter referred to as "Delegated Regulation (EU) No. 492/2014";
(i) (New, SG No. 102/2015) Regulation (EU) No. 98/2013 of the European Parliament and of the Council of 15 January 2013 on the marketing and use of explosives precursors (OJ, L 39/1, 9 February 2013), hereinafter referred to as "Regulation (EU) No. 98/2013";
(j) (new, SG No. 53/2018, effective 26.06.2018) Regulation (EC) 2017/852 of the European Parliament and of the Council of 17 may 2017 on the mercury and repealing Regulation (EC) No. 1102/2008 (OJ, L 137/1 of 24 may 2017), hereinafter referred to as "Commission Regulation (EU) 2017/852";
4. (new, SG No. 84/2012, effective 2.01.2013) the restriction of the use of hazardous substances in electrical and electronic equipment (EEE) with a view to the protection of human health and the environment, including the environmentally sound recovery and disposal of waste EEE and the obligations of EEE economic operators relating thereto;
5. (new, SG No. 102/2015) the requirements for making available, introduction, possession and use of chemical substances or mixtures which are explosives precursors, and for reporting of suspicious transactions involving such chemical substances or mixtures.

Article 2. (Amended, SG No. 114/2003, SG No. 63/2010, effective until 31.05.2015, repealed, SG No. 53/2018, effective 26.06.2018).

Article 3. (Amended, SG No. 114/2003, SG No. 82/2007, SG No. 63/2010, effective 13.08.2010) (1) (Amended, SG No. 53/2018, effective 26.06.2018) Chapter Four shall not apply to:
1. the following mixtures in the finished state intended for the final user:
(a) medicinal products for human or veterinary use;
(b) cosmetic products;
(c) foodstuffs intended for humans and animals;
(d) medical devices;
2. waste within the meaning of the Waste Management Act;
3. radioactive substances and nuclear materials within the meaning of the Safe Use of Nuclear Energy Act;
4. chemical substances and mixtures transported across the territory of the Republic of Bulgaria as transit goods which are subject to customs control and are not treated or processed;
5. transportation of dangerous chemical substances and dangerous mixtures by rail, road, inland waterways, sea or air;
(2) (Repealed, SG No. 53/2018, effective 26.06.2018).
(3) (Amended and supplemented, SG No. 102/2015) The measures implementing Regulation (EC) No. 648/2004 and Regulation (EU) No. 259/2012, as introduced in Chapters Three, Seven and Eight, shall apply in accordance with Article 1 and Article 3 (1) of Regulation (EC) No. 648/2004.
(4) The measures implementing Regulation (EC) No. 1907/2006 (REACH), as introduced in chapters Five, Seven and Eight, shall apply in accordance with Article 2, Article 15, Article 16, Article 56 (3), (4) and (5), Article 67 and Article 68 (1) of the Regulation.
(5) The measures implementing Regulation (EC) No. 1272/2008 (CLP), as introduced in Chapters Five, Seven and Eight, shall apply in accordance with Article 2 of the Regulation.
(6) (Amended, SG No. 102/2015) The measures implementing Regulation (EU) No. 649/2012, as introduced in chapters Six, Seven and Eight, shall apply in accordance with Article 2 of the Regulation.
(7) The measures implementing Regulation (EC) No. 850/2004, as introduced in chapters Six, Seven and Eight, shall apply in accordance with Article 1 and Article 4 of the Regulation.
(8) (New, SG No. 102/2015) The measures for implementation of Regulation (EU) No. 528/2012 provided for in Chapters Four, Seven and Eight shall be applied in accordance with Articles 2 and 3 of that Regulation.
(9) (New, SG No. 102/2015) The measures for implementation of Regulation (EU) No. 98/2013 provided for in Chapter Six "a" shall be applied in accordance with Article 2 of that Regulation.
(10) (New, SG No. 53/2018, effective 26.06.2018) The measures for implementation of Regulation (EU) 2017/852 introduced in chapters Two, Seven and Eight, shall be applied in accordance with Articles 1, 3 - 5 and Articles 7 - 9 of that Regulation, and the provisions of Article 4 (1) and (4), Articles 11, 12, 13 and 14 of that Regulation shall not apply to mercury waste and of Article 10 of that Regulation – to dental amalgam.

Article 3a. (New, SG No. 53/2018, effective 26.06.2018) Natural and legal persons may be exempted from the obligations for registration, authorisation and/or restriction pursuant to Titles II, III,VI,VII,VIII and/or IX of Regulation (EC) No. 1907/2006 (REACH) for certain substances, on their own, in a preparation or in an article, where necessary in the interests of defence, where one or more of the following circumstances are present:
1. the disclosure of information on the manufacture, use or placing on the market for defence purposes of a chemical substance on its own, in a preparation, or in an article may lead to a threat to national security;
2. the lack of alternative chemical substances or technologies may result in a loss of capacity for production, maintenance, repair or upgrade of a defence product, as well as to a disruption in the long-term steadiness of supplies for the purposes of production, maintenance, repair or upgrade of such a product;

3. the capacity of the armed forces of the Republic of Bulgaria to perform their task may be disrupted;
4. an obligation of the Republic of Bulgaria to limit the disclosure of information in the field of defence may be violated;
5. it is necessary to ensure the performance of the obligations of the Republic of Bulgaria arising from its participation in international organizations or political and military alliances for collective defence.

Article 4. (Amended, SG No. 114/2003, SG No. 95/2006) (1) (Previous text of Article 4, SG No. 63/2010, effective 13.08.2010, amended, SG No. 12/2017) Advertising of dangerous chemical substances without explicit indication of their category of danger as referred to in Regulation (EC) No. 1272/2008 (CLP) shall be prohibited.
(2) (New, SG No. 63/2010, effective 13.08.2010, supplemented, SG No. 53/2018, effective 26.06.2018) Any advertisement of a mixture classified as dangerous or containing a substance classified as dangerous according to Regulation (EC) 1272/2008 (CLP) which allows the general consumer to enter into a purchase transaction without having seen the label first shall indicate the category or categories of danger marked on the label.

Article 4a. (New, SG No. 95/2006, amended, SG No. 82/2007, SG No. 63/2010, effective 13.08.2010) Those referred to in Article 1, Item 1 shall be required to:
1. manufacture, place on the market, use, store and export chemical substances on their own, in mixtures or in articles and/or mixtures in a manner preventing or limiting their harmful effect on human health and the environment in accordance with the requirements of this Act, the acts of secondary legislation concerning its implementation and the Regulations listed in Article 1, Item 3;
2. ensure that the authorities referred to in Article 27, Paragraphs 1 and 2 have free access to the enterprises and sites manufacturing, placing on the market, using, storing or exporting chemical substances on their own, in mixtures or in articles and/or mixtures;
3. maintain and, upon request, provide to the authorities referred to in Article 27, Paragraph 1 and 2 information and documents concerning:
(a) the manufacture, placing on the market, use, storage and export of chemical substances on their own, in mixtures or in articles and/or of mixtures, including the quantities and composition thereof;
(b) the identity of their direct suppliers and buyers of chemical substances and mixtures.

Article 4b. (New, SG No. 95/2006, amended, SG No. 63/2010, effective 13.08.2010) (1) The storage procedures and methods for dangerous chemical substances and mixtures shall be laid down in an ordinance by the Council of Ministers.
(2) The procedures and methods to restrict the manufacture, use or placing on the market of certain dangerous chemical substances, mixtures and articles listed in Annex XVII of Regulation (EC) No. 1907/2006 (REACH) shall be laid down in an ordinance by the Council of Ministers.

Article 4c. (New, SG No. 95/2006, repealed, SG No. 63/2010, effective 13.08.2010, new, SG No. 98/2018, effective 27.11.2018) (1) Laboratory tests to determine toxicological and ecotoxicological properties shall be carried out in compliance with the principles of Good Laboratory Practice.
(2) Adherence to the principles of Good Laboratory Practice by the laboratories shall be attested to by the Bulgarian Accreditation Service Executive Agency under the conditions and in accordance with the procedure established by the ordinance referred to in Paragraph 3, or by the national authorities of the EU Member States and EEA member states notified to the European Commission.
(3) The principles, the inspection and the certification of good laboratory practice shall be determined with a regulation issued by the Council of Ministers.

Article 4d. (New, SG No. 95/2006, effective from the date of entry into force of the Republic of Bulgaria's EU Accession Treaty, repealed, SG No. 63/2010, effective 13.08.2010).

CHAPTER TWO
MEASURES FOR IMPLEMENTING REGULATION (EU) NO. 2017/852
(Title amended, SG No. 114/2003, SG No. 63/2010, effective 13.08.2010, SG No. 53/2018, effective 26.06.2018)

Article 5. (Amended, SG No. 114/2003, SG No. 95/2006, SG No. 63/2010, effective until 31.05.2015, SG No. 53/2018, effective 26.06.2018) The Minister of Environment and Water shall be the competent authority within the meaning of Article 17 of Regulation (EU) 2017/852, except for the provisions of Article 10 of that Regulation relating to the protection of human health from mercury, mercury compounds and mixtures of mercury, including the measures to address dental amalgam, for which the Minister of Health is the competent authority.

Article 5a. (New, SG No. 114/2003, amended, SG No. 101/2005, repealed, SG No. 95/2006, effective from the date of entry into force of the Republic of Bulgaria's EU Accession Treaty).

Article 5b. (New, SG No. 95/2006, effective from the date of entry into force of the Republic of Bulgaria's EU Accession Treaty, repealed, SG No. 63/2010, effective 13.08.2010).

Article 6. (Amended and supplemented, SG No. 114/2003, amended, SG No. 63/2010, effective 13.08.2010, repealed, SG No. 12/2017, new, SG No. 53/2018, effective 26.06.2018) (1) The import of mercury and mixtures of mercury pursuant to Annex I to Regulation (EU) 2017/852 for a use allowed in the country shall be carried out with the consent of the Minister of Environment and Water or an official authorised by the Minister.
(2) The importer pursuant to Paragraph 1 or a person authorised by the importer shall submit to the Minister of Environment and Water a form requesting consent for import in the format specified pursuant to Article 6 of Regulation (EU) 2017/852.
(3) The form referred to in Paragraph 2 shall be accompanied by the information referred to in Article 4(1) of Regulation (EU) 2017/852.
(4) In case of discrepancies or deficiencies in the form referred to in Paragraph 2 or in the information referred to in Paragraph 3, the Minister of Environment and Water or an official authorised by the Minister shall notify the importer or the person authorised by the importer within 10 days of the date of submission of the import form. In such cases, the deadline referred to in Paragraph 6 shall be suspended.
(5) The importer or the person authorised by the importer shall amend the discrepancies or deficiencies in the form referred to in Paragraph 2 or the information referred to in Paragraph 3 within 10 days of receiving the notification under Paragraph 4.
(6) The Minister of Environment and Water or an official authorised by the Minister shall issue the consent for import within 30 days of receiving the form under Paragraph 2.
(7) The Minister of Environment and Water or an official authorised by the Minister shall refuse to issue consent for import where, following assessment of the information referred to in Paragraphs 2 or 3, it is found that:
1. the identified discrepancies or deficiencies have not been amended, or
2. the deadline referred to in paragraph 5 has not been observed.
(8) The refusal under Paragraph 7 shall be subject to appeal pursuant to the Administrative Procedure Code.
(9) For the processing of the form referred to in Paragraph 2 the importer shall pay a fee in accordance with the tariff under Article 72 of the Environmental Protection Act.

Article 7. (Amended, SG No. 114/2003, repealed, SG No. 63/2010, effective 13.08.2010, new, SG No. 53/2018, effective 26.06.2018) (1) Any natural or legal person intending to manufacture or place on the market a new mercury-added product, or to use a new manufacturing process involving the use of mercury or mercury compounds, shall submit to the Minister of Environment and Water a notification containing contact details and the information pursuant to Article 8 (3) of Regulation (EU) 2017/852.
(2) The notification and the information referred to in Article 8(3) of Regulation (EU) 2017/852 shall be submitted in Bulgarian in one paper copy and one copy in electronic format, and in English in one paper copy and one copy in electronic format.

Article 7a. (New, SG No. 114/2003, amended, SG No. 82/2007, SG No. 63/2010, effective 13.08.2010, repealed, SG No. 61/2014, effective 25.07.2014, new, SG No. 53/2018, effective 26.06.2018) (1) The Minister of Environment and Water shall by order require that the Expert Council referred to in Article 21 assess the information under Article 8(3) of Regulation (EU) 2017/852 with a view to issuing an opinion regarding the compliance with the criteria referred to in Article 8(6) of Regulation (EU) 2017/852.
(2) In case of discrepancies or deficiencies in the information referred to in Article 8(3) of Regulation (EU) 2017/852, the Minister of Environment and Water or an official authorised by the Minister shall notify the applicant thereof within 30 days of the date of submission of the notification.In such cases, the deadline referred to in Paragraph 5 shall be suspended.
(3) The applicant shall amend the discrepancies or deficiencies within 30 days of the date of receipt of the notification under Paragraph 2.
(4) The Minister of Environment and Water or an official authorised by the Minister shall, within two weeks, issue a resolution to terminate the procedure and shall notify the person referred to in Article 7, Paragraph 1, where it is found that:
1. the identified discrepancies or deficiencies have not been amended, or
2. the deadline referred to in Paragraph 3 has not been observed.
(5) The Expert Council referred to in Article 21 shall examine the notification and the information under Article 8(3) of Regulation (EU) 2017/852 and shall, within 6 months of the date of submission of information, following coordination with the competent authorities, issue an opinion on the compliance with the criteria under Article 8(6) of Regulation (EU) 2017/852.
(6) For issue of the opinion the person referred to in Article 7(1) shall pay a fee in accordance with the tariff under Article 72 of the Environmental Protection Act.
(7) In case the criteria referred to in Article 8(6) of Regulation (EU) 2017/852 are fulfilled, the Minister of Environment and Water or an official authorised by the Minister shall forward to the European Commission the notification and the information under Article 8(3) of Regulation (EU) 2017/852, along with the opinion referred to in Paragraph 5.
(8) The Minister of Environment and Water or an official authorised by the Minister shall inform the European Commission and the person referred to in Article 7, Paragraph 1 in case the criteria under Article 8(6) of Regulation (EU) 2017/852 are not fulfilled and shall send them the opinion referred to in Paragraph 5.
(9) The resolution referred to in Paragraph 4 shall be subject to appeal pursuant to the Administrative Procedure Code.

Article 7b. (New, SG No. 114/2003, amended, SG No. 95/2006, SG No. 82/2007, SG No. 63/2010, effective until 31.05.2015, SG No. 53/2018, effective 26.06.2018) Information on the decisions adopted by the European Commission in accordance with Article 8(6) of Regulation (EU) 2017/852 shall be published on the website of the Ministry of Environment and Water.

Article 7c. (New, SG No. 114/2003, supplemented, SG No. 95/2006, amended, SG No. 63/2010, effective until 31.05.2015, SG No. 53/2018, effective 26.06.2018) (1) The Minister of Environment and Water may develop a draft National Plan for Implementation of the Minamata Convention on Mercury signed in Kumamoto, Japan, on 10 October 2013 (ratified by an act, SG

No. 71/2016) (SG No. 61/2017), hereinafter referred to as "the Convention", in accordance with Article 20 of this Convention, as well as to propose updates the plan.
(2) The plan referred to in Paragraph 1 shall be adopted by the Council of Ministers and shall be forwarded to the European Commission and to the Secretariat of the Convention by the Minister of Environment and Water.

Article 7d. (New, SG No. 114/2003, amended, SG No. 30/2005, supplemented, SG No. 95/2006, amended, SG No. 63/2010, effective until 31.05.2015, SG No. 53/2018, effective 26.06.2018) The Minister of Environment and Water or an official authorised by the Minister shall, in performance of the requirements referred to in Article 18 of Regulation (EU) 2017/852, prepare and submit to the European Commission reports on the implementation of that Regulation.

Article 7e. (New, SG No. 114/2003, supplemented, SG No. 95/2006, amended, SG No. 63/2010, effective until 31.05.2015, SG No. 53/2018, effective 26.06.2018, SG No. 102/2022, effective 1.01.2023) The Minister of Agriculture, 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 President of the State Agency for Metrology and Technical Surveillance and the President of the Consumer Protection Agency shall, upon request by the Minister of Environment and Water or an official authorised by the Minister, provide information in the established format for the purposes of reporting pursuant to Article 18 of Regulation (EU) 2017/852.

Article 7f. (New, SG No. 114/2003, supplemented, SG No. 95/2006, SG No. 82/2007, amended, SG No. 63/2010, effective until 31.05.2015, SG No. 53/2018, effective 26.06.2018) The Minister of Health shall submit to the Minister of Environment and Water or to an official authorised by the Minister:
1. information for the purposes of reporting pursuant to Article 18 of Regulation (EU) 2017/852;
2. summary information on the health aspects related to the use of mercury and mercury compounds, as well as the results from the control over the implementation of Regulation (EU) 2017/852 - upon request.

CHAPTER THREE
(Repealed, SG No. 82/2007, effective 1.06.2008, new, SG No. 63/2010, effective 13.08.2010)
MEASURES IMPLEMENTING REGULATION (EC) No. 648/2004 AND REGULATION (EU) No. 259/2012
(Title supplemented, SG No. 102/2015)

Article 8. (Amended, SG No. 114/2003, SG No. 30/2006, repealed, SG No. 82/2007, effective 1.06.2008, new, SG No. 63/2010, effective 13.08.2010, supplemented, SG No. 102/2015) The Minister of Environment and Water shall be a competent authority within the meaning of Article 8 (1) of Regulation (EC) No. 648/2004 and Regulation (EU) No. 259/2012.

Article 9. (Amended, SG No. 114/2003, repealed, SG No. 82/2007, effective 1.06.2008, new, SG No. 63/2010, effective 13.08.2010) (1) Derogation from the requirements of Annex III of Regulation (EC) No. 648/2004 on the ultimate aerobic biodegradability of surfactants and of detergents containing surfactants shall be granted as provided for by Article 5 and Article 6 of Regulation (EC) No. 648/2004.
(2) Manufacturers of detergents for industrial and institutional purposes which contain surfactants and/or of surfactants intended for detergents for industrial and institutional purposes meeting the primary biodegradability criteria under Annex II of Regulation (EC) No. 648/2004 but not meeting

the ultimate aerobic biodegradability criteria under Annex III shall be entitled to apply for derogation under Paragraph 1.
(3) The entities referred to in Paragraph 2 shall submit to the Minister of Environment and Water and to the European Commission an application for derogation which shall include a technical file in accordance with Article 5 of Regulation (EC) No. 648/2004.
(4) In case of errors or omissions in the documents referred to in Paragraph 3, the Minister of Environment and Water or an official authorised by the Minister shall notify the applicant thereof within 30 days after the date when the documents were submitted and shall set a deadline by which such errors or omissions are to be rectified.
(5) The technical file shall be evaluated in terms of its completeness and its compliance with the conditions for derogation referred to in Article 6 (1) of Regulation No 648/2004.
(6) The Minister of Environment and Water or an official authorised by the Minister shall send the findings of the evaluation to the European Commission within the time limits laid down in Article 5 (3) of Regulation (EC) No. 648/2004.

Article 10. (Amended, SG No. 114/2003, repealed, SG No. 82/2007, effective 1.06.2008, new, SG No. 63/2010, effective 13.08.2010) (1) The Bulgarian Accreditation Service Executive Agency shall, upon request by the Minister of Environment and Water, provide a list of the laboratories accredited to test surfactants in accordance with Article 7 of Regulation (EC) No. 648/2004.
(2) The Minister of Environment and Water or an official authorised by the Minister shall send the information referred to in Paragraph 1 to the European Commission and to the Member States in accordance with Article 8 (2) of Regulation (EC) No. 648/2004.

Article 10a. (New, SG No. 114/2003, repealed, SG No. 82/2007, effective 1.06.2008).

Article 10b. (New, SG No. 114/2003, repealed, SG No. 82/2007, effective 1.06.2008).

Article 10c. (New, SG No. 114/2003, repealed, SG No. 82/2007, effective 1.06.2008).

Article 10d. (New, SG No. 114/2003, repealed, SG No. 82/2007, effective 1.06.2008).

Article 11. (Amended, SG No. 114/2003, repealed, SG No. 82/2007, effective 1.08.2008, new, SG No. 63/2010, effective 13.08.2010) The packaging of general-use liquid detergents placed on the market may not feature graphic images of fruit which are likely to mislead the final user as to the use for which the liquid detergents are intended.

Article 12. (Amended, SG No. 114/2003, repealed, SG No. 82/2007, effective 1.08.2008).

Article 12a. (New, SG No. 114/2003, repealed, SG No. 82/2007, effective 1.08.2008).

Article 12b. (New, SG No. 114/2003, repealed, SG No. 82/2007, effective 1.08.2008).

Article 12c. (New, SG No. 114/2003, repealed, SG No. 82/2007, effective 1.08.2008).

Article 13. (Amended, SG No. 114/2003, repealed, SG No. 82/2007, effective 1.08.2008).

CHAPTER FOUR
(Repealed, SG No. 91/2002, new, SG No. 114/2003, repealed, new, SG No. 95/2006, repealed, new, SG No. 102/2015)

MEASURES FOR IMPLEMENTING REGULATION (EU) No. 528/2012 AND FOR MAKING AVAILABLE ON THE

MARKET OF BIOCIDAL PRODUCTS CONTAINING EXISTING ACTIVE SUBSTANCES LISTED IN ANNEX II TO DELEGATED REGULATION (EU) No. 1062/2014

Article 14. (New, SG No. 95/2006, amended, SG No. 82/2007, repealed, new, SG No. 102/2015) The Minister of Health shall be the competent authority within the meaning of Article 81, (1) of Regulation (EU) No. 528/2012.

Article 14a. (New, SG No. 95/2006, repealed, new, SG No. 102/2015) Biocidal products shall be made available on the market and used when authorised pursuant to this Act or in accordance with Regulation (EU) No. 528/2012.

Article 14b. (New, SG No. 95/2006, amended, SG No. 63/2010, effective 13.08.2010, repealed, new, SG No. 102/2015) Only treated articles meeting the requirements of Regulation (EU) No. 528/2012 shall be placed on the market.

Article 14c. (New, SG No. 95/2006, repealed, SG No. 102/2015).

Article 14d. (New, SG No. 95/2006, amended, SG No. 82/2007, repealed, SG No. 102/2015).

Article 14e. (New, SG No. 95/2006, repealed, SG No. 102/2015).

Article 14f. (New, SG No. 63/2010, effective 1.06.2015, amended, SG No. 98/2010, effective 1.01.2011, repealed, SG No. 102/2015).

Article 15. (New, SG No. 95/2006, repealed, new, SG No. 102/2015) (1) The Minister of Health shall issue an order to establish an Expert Council on Biocidal Products.
(2) The Council referred to in Paragraph 1 shall consist of representatives of the Ministry of Health, the Ministry of Environment and Water, the National Centre of Public Health and Analyses and the National Centre of Infectious and Parasitic Diseases.
(3) The Minister of Health may, where necessary, involve in the operation of the Council referred to in Paragraph 1 other experts in toxicology, ecotoxicology, chemistry, biology, microbiology, virusology, parasitology and veterinary medicine.
(4) The Council referred to in Paragraph 1 shall make proposals to the Minister of Health for:
1. issue of an opinion allowing or prohibiting research and development under Article 56(2) and (3) of Regulation (EU) No. 528/2012;
2. granting a national authorisation for making available on the market of a biocidal product or a biocidal product family, or refusal, or termination of the procedure set out in Articles 29 and 30 of Regulation (EU) No. 528/2012;
3. renewal of a national authorisation for making available on the market of a biocidal product under Article 31 of Regulation (EU) No. 528/2012;
4. granting an authorisation for making available on the market of a biocidal product or a biocidal product family under the simplified procedure, or refusal, or termination of the procedure set out in Articles 25 and 26 of Regulation (EU) No. 528/2012;
5. granting an authorisation for making available on the market of a biocidal product or a biocidal product family through mutual recognition under Articles 33 and 34 of Regulation (EU) No. 528/2012, or refusal, or modification of an existing authorisation under Articles 35 – 37 of Regulation (EU) No. 528/2012;
6. renewal of an authorisation for making available on the market of a biocidal product through mutual recognition pursuant to Delegated Regulation (EU) No. 492/2014;
7. granting an authorisation for making available on the market of a biocidal product or a biocidal product family through mutual recognition under Article 39 of Regulation (EU) No. 528/2012;

8. cancellation or amendment of a national authorisation for making available on the market of a biocidal product under Articles 48 – 50 of Regulation (EU) No. 528/2012 and Chapters II and III of Commission Implementing Regulation (EU) No. 354/2013 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, 19 April 2013), hereinafter referred to as "Implementing Regulation (EU) No. 354/2013";
9. evaluation of the applications for granting an authorisation for the European Union, hereinafter referred to as "Union authorisation" for making available on the market of a biocidal product or a biocidal product family, or termination of the procedure set out in Article 43 (1), (3) and (4) and in Article 44 (1) and (2) of Regulation (EU) No. 528/2012;
10. evaluation of the applications for renewal of a Union authorisation for making available on the market of a biocidal product under Article 46 (1) and (2) of Regulation (EU) No. 528/2012;
11. granting an authorisation for parallel trade in a biocidal product, or refusal, or cancellation of an authorisation for parallel trade in a biocidal product under Article 53 of Regulation (EU) No. 528/2012;
12. evaluation of the applications for approval of an active substance for inclusion in the European Union list of approved active substances or termination of the procedure set out in Articles 7 and 8 of Regulation (EU) No. 528/2012;
13. evaluation of the applications for renewal of the approval of an active substance for inclusion in the European Union list of approved active substances under Article 14 of Regulation (EU) No. 528/2012;
14. granting provisional authorisation and extension of the period referred to in Article 55 (1) and (2) of Regulation (EU) No. 528/2012;
15. granting an authorisation for a same biocidal product or refusal under Articles 3 and 5 of Commission Implementing Regulation (EU) No. 414/2013 of 6 May 2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No. 528/2012 of the European Parliament and of the Council (OJ, L 125/4, 7 May 2013), hereinafter referred to as "Implementing Regulation (EU) No. 414/2013";
16. granting an authorisation under Article 18c, Paragraph 5 or termination of the procedure set out in Article 18c, Paragraph 4;
17. amendment of an authorisation under Article 18d, Paragraph 1 or cancellation of an authorisation under Article 18e, Paragraph 1;
18. granting a new authorisation for making available on the market of a biocidal product, amendment or cancellation of already granted authorisations in the cases referred to in Article 18g, Paragraphs 1 and 2.

Article 15a. (New, SG No. 95/2006, repealed, new, SG No. 102/2015) (1) The meetings of the Council referred to in Article 15, Paragraph 1 shall be considered properly held if attended by more than half of its members.
(2) The Council referred to in Article 15, Paragraph 1 shall make the proposals referred to in Article 15, Paragraph 4 based on resolutions adopted by a majority of more than half of the members present.
(3) The members of the Council referred to in Article 15, Paragraph 1 shall be obliged not to disclose the information that has become known to them in the course of or with relation to the performance of their official duties, where such information constitutes industrial or commercial secret. They shall sign a declaration of confidentiality to this effect.
(4) The operation of the Council referred to in Article 15, Paragraph 1 shall be financed from the budget of the Ministry of Health.
(5) The Minister of Health shall issue rules of operation of the Council referred to in Article 15, Paragraph 1.

(6) The rules of operation under Paragraph 5 shall also specify the requirements concerning the educational background and qualifications of the members of the Council referred to in Article 15, Paragraph 1.

Article 15b. (New, SG No. 95/2006, repealed, SG No. 102/2015).

Article 15c. (New, SG No. 95/2006, amended, SG No. 63/2010, effective 13.08.2010, repealed, SG No. 102/2015).

Article 15d. (New, SG No. 95/2006, repealed, SG No. 102/2015).

Article 16. (New, SG No. 95/2006, repealed, new, SG No. 102/2015) A national information desk shall be set up and administered within the Ministry of Health in accordance with Article 81(2) of Regulation (EU) No. 528/2012 with a view to providing advice to persons placing biocidal products on the market as regards their responsibilities and obligations for implementing the Regulation.

Article 17. (New, SG No. 95/2006, repealed, new, SG No. 102/2015) (1) The Minister of Health shall issue an opinion on carrying out research and development under Article 56 of Regulation (EU) No. 528/2012 involving experiments or tests with unauthorised biocidal products or non-approved active substances in which a biocidal product or an active substance is released or may be released into the environment.
(2) The person intending to carry out the experiment or test referred to in Paragraph 1 shall first notify in writing the Minister of Health, attaching the following to the notification:
1. the information referred to in Article 56 (2) of Regulation (EU) No. 528/2012;
2. document evidencing payment of the fee referred to in Article 19, Paragraph 1, item 1.

Article 17a. (New, SG No. 95/2006, repealed, new, SG No. 102/2015) (1) The Minister of Health shall grant a national authorisation for making available on the market of a biocidal product or a biocidal product family under Articles 29 and 30 of Regulation (EU) No. 528/2012.
(2) For issue of the authorisation referred to in Paragraph 1 the applicant or his representative shall submit an application in Bulgarian, attaching the following thereto:
1. information about the standard identification code under Article 23 of the Commercial Register Act or a document evidencing equivalent registration in accordance with the legislation of another European Union member state, or in accordance with the legislation of a country which is party to the Agreement on the European Economic Area;
2. the documents referred to in Article 20 (1)(a) of Regulation (EU) No. 528/2012, except in the cases under Article 21 of Regulation (EU) No. 528/2012;
3. document evidencing payment of the fee referred to in Article 19, Paragraph 1, item 2.

Article 17b. (New, SG No. 95/2006, repealed, new, SG No. 102/2015) (1) The Minister of Health shall grant an authorisation for making available on the market of biocidal products or a biocidal product family under the simplified procedure pursuant to Article 26 of Regulation (EU) No. 528/2012, if they meet the conditions laid down in Article 25 of Regulation (EU) No. 528/2012.
(2) For issue of the authorisation referred to in Paragraph 1 the applicant or his representative shall submit an application in Bulgarian, attaching the following thereto:
1. information about the standard identification code under Article 23 of the Commercial Register Act or a document evidencing equivalent registration in accordance with the legislation of another European Union member state, or in accordance with the legislation of a country which is party to the Agreement on the European Economic Area;
2. the documents referred to in Article 20 (1)(b) of Regulation (EU) No. 528/2012, except in the cases under Article 21 of Regulation (EU) No. 528/2012;
3. document evidencing payment of the fee referred to in Article 19, Paragraph 1, item 3.

Article 17c. (New, SG No. 95/2006, repealed, new, SG No. 102/2015) (1) The Minister of Health shall renew the national authorisation under Article 17a, where the conditions laid down in Article 19 of Regulation (EU) No. 528/2012 are met.
(2) For renewal of the authorisation referred to in Paragraph 1 the authorisation holder or his representative shall submit an application in Bulgarian, attaching the following thereto:
1. information about the standard identification code under Article 23 of the Commercial Register Act or a document evidencing equivalent registration in accordance with the legislation of another European Union member state, or in accordance with the legislation of a country which is party to the Agreement on the European Economic Area;
2. the documents referred to in Article 31 (3) of Regulation (EU) No. 528/2012;
3. document evidencing payment of the fee referred to in Article 19, Paragraph 1, item 4.

Article 17d. (New, SG No. 95/2006, repealed, new, SG No. 102/2015) (1) The Minister of Health shall grant authorisation for making available on the market of a biocidal product or a biocidal product family through mutual recognition in sequence of a national authorisation pursuant to Article 33 of Regulation (EU) No. 528/2012.
(2) For issue of the authorisation referred to in Paragraph 1 the applicant or his representative shall submit to the Ministry of Health an application in Bulgarian, attaching the following thereto:
1. the authorisation issued by the European Union Member State where the biocidal product was authorised for the first time, accompanied by a translation thereof in Bulgarian made by a translator who has been contracted by the Ministry of Foreign Affairs;
2. document evidencing payment of the fee referred to in Article 19, Paragraph 1, item 5.

Article 17e. (New, SG No. 95/2006, amended, SG No. 63/2010, effective 13.08.2010, repealed, new, SG No. 102/2015) (1) The Minister of Health shall grant an authorisation for making available on the market of a biocidal product or a biocidal product family through mutual recognition in parallel, where the Republic of Bulgaria is the reference Member State under Article 34 (1) of Regulation (EU) No. 528/2012.
(2) For issue of the authorisation referred to in Paragraph 1 the applicant or his representative shall submit to the Ministry of Health an application in Bulgarian, attaching the following thereto:
1. the documents referred to in Article 34 (1)(a) and (b) of Regulation (EU) No. 528/2012;
2. document evidencing payment of the fee referred to in Article 19, Paragraph 1, item 6.
(3) The Minister of Health shall grant an authorisation for making available on the market of a biocidal product or a biocidal product family through mutual recognition in parallel, where the Republic of Bulgaria is the Member State concerned under Article 34(1)(b) of Regulation (EU) No. 528/2012.
(4) For issue of the authorisation referred to in Paragraph 3 the applicant or his representative shall submit to the Ministry of Health an application in Bulgarian, attaching the following thereto:
1. the documents referred to in Article 34 (2)(a) and (b) of Regulation (EU) No. 528/2012;
2. document evidencing payment of the fee referred to in Article 19, Paragraph 1, item 7.
(5) The authorisations referred to in Paragraphs 1 and 3 shall be granted pursuant to Article 34 of Regulation (EU) No. 528/2012 for a biocidal product or a biocidal product family which have not yet been authorised in accordance with Article 17 of Regulation (EU) No. 528/2012.

Article 17f. (New, SG No. 95/2006, repealed, new, SG No. 102/2015) (1) The Minister of Health, at the request of official or scientific bodies involved in pest control activities or the protection of public health, shall grant an authorisation for making available on the market of a biocidal product or a biocidal product family authorised in another Member State under the mutual recognition procedure.
(2) For issue of the authorisation referred to in Paragraph 1 the applicant or his representative shall submit to the Ministry of Health an application in Bulgarian, attaching the following thereto:

1. the authorisation issued by the European Union Member State where the biocidal product was authorised for the first time, accompanied by a translation thereof in Bulgarian made by a translator who has been contracted by the Ministry of Foreign Affairs;
2. document evidencing payment of the fee referred to in Article 19, Paragraph 1, item 8.
(3) The authorisations referred to in Paragraph 1 shall be granted pursuant to Article 33 of Regulation (EU) No. 528/2012.

Article 17g. (New, SG No. 95/2006, repealed, new, SG No. 102/2015) (1) The Minister of Health shall renew the authorisation for making available on the market of a biocidal product or a biocidal product family under Articles 17d and 17e pursuant to Delegated Regulation (EU) No. 492/2014.
(2) The Minister of Health shall renew an authorisation for making available on the market of a biocidal product or a biocidal product family through mutual recognition in sequence or in parallel, where the Republic of Bulgaria is the reference Member State.
(3) For renewal of the authorisation referred to in Paragraph 2 the applicant or his representative shall submit to the Ministry of Health an application in Bulgarian, attaching the following thereto:
1. the documents referred to in Article 2 of Delegated Regulation (EU) No. 492/2014;
2. document evidencing payment of the fee referred to in Article 19, Paragraph 1, item 9.
(4) The Minister of Health shall renew an authorisation for making available on the market of a biocidal product or a biocidal product family through mutual recognition in sequence or in parallel, where the Republic of Bulgaria is the Member State concerned.
(5) For issue of the authorisation referred to in Paragraph 4 the applicant or his representative shall submit to the Ministry of Health an application in Bulgarian, attaching the following thereto:
1. the documents referred to in Article 2 of Delegated Regulation (EU) No. 492/2014;
2. document evidencing payment of the fee referred to in Article 19, Paragraph 1, item 10.

Article 17h. (New, SG No. 95/2006, repealed, new, SG No. 102/2015) (1) The Minister of Health shall cancel or amend authorisations granted under Articles 17a, 17b, 17d and 17e at the request of the authorisation holder, subject to the requirements laid down in Articles 49 and 50 of Regulation (EU) No. 528/2012.
(2) For amendment of the authorisation granted under Articles 17a, 17d or 17e the authorisation holder or his representative shall submit an application in Bulgarian, attaching the following thereto:
1. information about the standard identification code under Article 23 of the Commercial Register Act or a document evidencing equivalent registration in accordance with the legislation of another European Union member state, or in accordance with the legislation of a country which is party to the Agreement on the European Economic Area;
2. the relevant documents referred to in Articles 5 – 8 of Implementing Regulation (EU) No. 354/2013;
3. document evidencing payment of the fee referred to in Article 19, Paragraph 1, item 11.
(3) For amendment of the authorisation granted under Article 17b the authorisation holder or his representative shall submit a notification in Bulgarian, subject to the requirements laid down in Article 9 of Implementing Regulation (EU) No. 354/2013.
(4) The Minister of Health shall cancel or amend authorisations granted under Articles 17a, 17b, 17d and 17e in the cases referred to in Article 48 (1) of Regulation (EU) No. 528/2012, subject to the requirements laid down in Article 48 (2) and (3) of Regulation (EU) No. 528/2012.

Article 17i. (New, SG No. 95/2006, supplemented, SG No. 82/2007, amended, SG No. 63/2010, effective 13.08.2010, repealed, new, SG No. 102/2015) (1) The Minister of Health shall grant an authorisation for making available on the market of a same biocidal product under Articles 2, 3 and 5 of Implementing Regulation (EU) No. 414/2013.
(2) For issue of the authorisation referred to in Paragraph 1 the applicant or his representative shall submit an application in Bulgarian, attaching the following thereto:

1. the documents referred to in Article 2 of Implementing Regulation (EU) No. 414/2013;
2. document evidencing payment of the fee referred to in Article 19, Paragraph 1, item 12.

Article 17j. (New, SG No. 95/2006, amended, SG No. 63/2010, effective 13.08.2010, repealed, new, SG No. 102/2015) (1) The Minister of Health shall grant an authorisation for parallel trade in a biocidal product which is authorised in another EU Member state and is same as a biocidal product authorised in the Republic of Bulgaria under Article 53 of Regulation (EU) No. 528/2012.
(2) For issue of the authorisation referred to in Paragraph 1 the applicant or his representative shall submit an application in Bulgarian, attaching the following thereto:
1. the documents referred to in Article 53 (4) of Regulation (EU) No. 528/2012;
2. document evidencing payment of the fee referred to in Article 19, Paragraph 1, item 13.

Article 17k. (New, SG No. 95/2006, repealed, new, SG No. 102/2015) (1) The Minister of Health shall evaluate the applications for granting or renewal of a Union authorisation for making available on the market of a biocidal product or a biocidal product family under Article 43(1), (3) and (4), Article 44(1) and (2) and Article 46(1) and (2) of Regulation (EU) No. 528/2012.
(2) The evaluation referred to in Paragraph 1 shall be carried out after the Minister of Health has sent prior written consent to the applicant.
(3) For the evaluation referred to in Paragraph 1 the applicant shall pay the fee under Article 19, Paragraph 1, item 14.

Article 17l. (New, SG No. 95/2006, repealed, new, SG No. 102/2015) (1) The Minister of Health shall evaluate the applications for approval of an active substance for inclusion in the European Union list of approved active substances under Article 9 (2) of Regulation (EU) No. 528/2012 or for subsequent amendments to the conditions of approval of an active substance under Article 8 of Regulation (EU) No. 528/2012.
(2) The evaluation referred to in Paragraph 1 shall be carried out after the Minister of Health has sent prior written consent to the applicant.
(3) For the evaluation referred to in Paragraph 1 the applicant shall pay the fee under Article 19, Paragraph 1, item 15.

Article 17m. (New, SG No. 95/2006, repealed, new, SG No. 102/2015) (1) The Minister of Health shall grant a provisional authorisation for making available on the market of a biocidal product or a biocidal product family under Article 55 (2) of Regulation (EU) No. 528/2012 after evaluation of the application under Article 17l.
(2) For issue of the authorisation referred to in Paragraph 1 the applicant shall submit to the Ministry of Health an application in Bulgarian, attaching thereto a document evidencing payment of the fee referred to in Article 19, Paragraph 1, item 16.

Article 17n. (New, SG No. 95/2006, amended, SG No. 63/2010, effective 13.08.2010, repealed, new, SG No. 102/2015) (1) The Minister of Health, upon a proposal by the applicant and having sent prior written consent to the applicant, shall carry out an evaluation of the applications for renewal of the approval of an active substance for inclusion in the European Union list of approved active substances under Article 9 (2) of Regulation (EU) No. 528/2012.
(2) For the evaluation referred to in Paragraph 1 the applicant shall pay the fee under Article 19, Paragraph 1, item 17.

Article 17o. (New, SG No. 102/2015) The applications and documents for the procedures laid down in Articles 17a – 17n shall be submitted to the Ministry of Health via the Register for Biocidal Products referred to in Article 71 of Regulation (EU) No. 528/2012.

Article 17p. (New, SG No. 102/2015) Biocidal products which are made available on the market pursuant to Articles 17a – 17o, shall be classified, packaged and labelled in Bulgarian in accordance with the provisions of Article 69 of Regulation (EU) No. 528/2012.

Article 18. (New, SG No. 95/2006, repealed, new, SG No. 102/2015) (1) The Minister of Health may grant an authorisation for making available on the market of a biocidal product or a biocidal product family containing:
1. an existing active substance/existing active substances which have been evaluated under Delegated Regulation (EU) No. 1062/2014, but which have not yet been approved for that product-type;
2. an existing active substance/existing active substances which are being evaluated under Delegated Regulation (EU) No. 1062/2014, but which have not yet been approved for that product-type;
3. a combination of active substances referred to in items 1 and 2, and for active substances approved in accordance with Regulation (EU) No. 528/2012.
(2) In the cases referred to in Paragraph 1 the biocidal product shall be authorised where:
1. the existing active substances contained in the biocidal product are listed in Annex II to Delegated Regulation (EU) No. 1062/2014 and the European Commission has not issued a decision not to include them in the European Union list of approved active substances under Article 9 (2) of Regulation (EU) No. 528/2012;
2. the product-type is listed in Annex II to Delegated Regulation (EU) No. 1062/2014 and the European Commission has not issued a decision not to include it in the European Union list of approved active substances under Article 9 (2) of Regulation (EU) No. 528/2012;
3. the person is established within the European Union and manufactures or imports an active substance – on its own or in biocidal products, or manufactures or makes available on the market a biocidal product consisting of, containing or generating that substance which is included in the European Chemicals Agency list under Article 95 (2) of Regulation (EU) No. 528/2012, for the product-type to which the biocidal product belongs.
(3) Biocidal products which meet the criteria set out in Article 19 (4) of Regulation (EU) No. 528/2012 shall not be authorised for use by the general public.

Article 18a. (New, SG No. 95/2006, repealed, new, SG No. 102/2015) The biocidal products referred to in Article 18 shall be classified, packaged and labelled in Bulgarian in accordance with the provisions of Regulation (EC) No. 1272/2008 (CLP) and of Article 69 of Regulation (EU) No. 528/2012.

Article 18b. (New, SG No. 95/2006, repealed, new, SG No. 102/2015) (1) For issue of an authorisation under Article 18 the person placing the biocidal product on the market or his representative shall submit to the Ministry of Health an application in Bulgarian, attaching the following thereto:
1. information about the standard identification code under Article 23 of the Commercial Register Act or a document evidencing equivalent registration in accordance with the legislation of another European Union member state, or in accordance with the legislation of a country which is party to the Agreement on the European Economic Area;
2. documents evidencing compliance with Article 95 (2) of Regulation (EU) No. 528/2012, such as letters of access within the meaning of Article 3(1)(t) of Regulation (EU) No. 528/2012, contracts, invoices, etc.;
3. technical dossier of the biocidal product;
4. (amended, SG No. 53/2018, effective 26.06.2018) safety data sheet pursuant to Annex II to Regulation (EC) No. 1907/2006 (REACH);
5. document evidencing payment of the fee referred to in Article 19, Paragraph 1, item 18.
(2) The documents referred to in Paragraph 1, items 3 and 4 shall be submitted in Bulgarian – one paper copy and three copies in electronic format, accompanied by a declaration that the information submitted on paper is identical to the information submitted in electronic format.

Article 18c. (New, SG No. 95/2006, repealed, new, SG No. 102/2015) (1) Within 45 days of the date of receipt of the documents referred to in Article 18b, Paragraph 2 they are reviewed for completeness of the data contained therein.
(2) Where the documents submitted are found to be incomplete, the Minister of Health shall inform the applicant thereof and set a time limit for submitting the additional information.
(3) The Minister of Health may grant one extension of the time limit referred to in Paragraph 2, provided that the applicant has submitted a reasoned request to this effect.
(4) Should the applicant fail to submit all required additional information within the time limit referred to in Paragraphs 2 or 3, the authorisation procedure shall be terminated.
(5) The Minister of Health shall grant an authorisation for making available on the market of a biocidal product or a biocidal product family within 60 days of the date of submission of the documents referred to in Article 18b, Paragraph 2, respectively of the date of receipt of the information referred to in Paragraphs 2 or 3.

Article 18d. (New, SG No. 95/2006, amended, SG No. 63/2010, effective 13.08.2010, repealed, new, SG No. 102/2015) (1) The Minister of Health shall review the authorisation granted under Article 18 in case of:
1. availability of new data on the adverse effects of the active substance or biocidal product for humans or the environment;
2. a request made by the applicant;
3. a change in the commercial registration of the person placing a biocidal product on the market;
4. a change in packaging.
(2) In the cases referred to in Paragraph 1 the Minister of Health may request additional information and amend the terms and conditions of the authorisation.
(3) An authorisation shall be amended subject to the requirements of Article 18 and after the fee referred to in Article 19, Paragraph 1, item 19 has been paid.
(4) When amending an authorisation for making available on the market of a biocidal product the Minister of Health may determine a time limit for storage, use or distribution of the available quantities of the biocidal product.

Article 18e. (New, SG No. 95/2006, amended, SG No. 63/2010, effective 13.08.2010, repealed, new, SG No. 102/2015) (1) The Minister of Health shall cancel the authorisation granted under Article 18 where:
1. the applicant submitted false and/or misleading information when applying for authorisation;
2. the making available on the market and the use of the active substance are prohibited within the European Union;
3. the authorisation holder has made a reasoned request.
(2) Prior to cancelling the authorisation referred to in Paragraph 1 the Minister of Health shall notify the authorisation holder.
(3) When cancelling an authorisation for making available on the market of a biocidal product or a biocidal product family the Minister of Health may determine a time limit for storage, use or distribution of the available quantities of the biocidal product.

Article 18f. (New, SG No. 95/2006, repealed, new, SG No. 102/2015) (1) The Minister of Health shall issue an order containing the lists of active substances for which the European Commission has issued a decision stating that they are not endorsed for inclusion in the European Union list of approved active substances under Article 9 (2) of Regulation (EU) No. 528/2012.
(2) The order referred to in Paragraph 1 shall be promulgated in the State Gazette and published on the website of the Ministry of Health.

Article 18g. (New, SG No. 95/2006, repealed, new, SG No. 102/2015) (1) Where the European Commission has issued a decision approving an active substance for inclusion in the European Union list of approved active substances under Article 9 (2) of Regulation (EU) No.

528/2012, the Minister of Health shall grant a new authorisation for making available on the market of a biocidal product, amend or cancel the authorisation granted under Article 18.
(2) Where the European Commission has issued a decision that the active substance is not endorsed for inclusion in the European Union list of approved active substances under Article 9 (2) of Regulation (EU) No. 528/2012 for certain or all notified product-types, the Minister of Health shall amend or cancel the authorisation granted under Article 18 in accordance with Delegated Regulation (EU) No. 1062/2014 and Article 89 (2) of Regulation (EU) No. 528/2012.
(3) The granting of new authorisation, the amendment or the cancellation of an authorisation granted under Article 18 shall be carried out in accordance with the decision endorsing or not endorsing the inclusion of the active substance in the European Union list of approved active substances under Article 9 (2) of Regulation (EU) No. 528/2012.

Article 18h. (New, SG No. 102/2015) A Council of Ministers ordinance shall establish the format and contents of:
1. the technical dossier and the documents submitted by the applicant when applying for authorisation for making available on the market of a biocidal product or a biocidal product family under Article 18;
2. the authorisations granted for making available on the market of a biocidal product or a biocidal product family under Article 18.

Article 18i. (New, SG No. 102/2015) (1) The Ministry of Health shall keep a register of authorised biocidal products under Article 18. The register shall be public and contain the following information:
1. number and date of the authorisation for making available on the market of the biocidal product;
2. expiry date of the authorisation, where available;
3. information on the person placing a biocidal product on the market – name, registered address and management address;
4. name of the biocidal product;
5. name(s) and concentration of the active substance/active substances contained in the biocidal product;
6. type of the biocidal product and field of application;
7. category of use;
8. date of cancellation of the authorisation;
9. changes in the circumstances referred to in 1 to 7 above.
(2) The register referred to in Paragraph 1 shall contain a separate section listing by order of submission the persons who have applied for authorisation for making available on the market of a biocidal product and stating the number and type of documents attached to the application. Information about the status of the application processing shall also be recorded in this section.
(3) The ordinance referred to in Article 18h shall lay down the terms and procedure for keeping the register referred to in Paragraph 1.

Article 19. (New, SG No. 95/2006, repealed, new, SG No. 102/2015) (1) With the tariff referred to in Article 46 of the Health Act the Council of Ministers shall set the state fees for:
1. issue of an opinion for carrying out research and development under Article 17;
2. granting of a national authorisation for making available on the market of a biocidal product or a biocidal product family or a biocidal product family under Article 17a;
3. granting an authorisation for making available on the market of a biocidal product or a biocidal product family under the simplified procedure pursuant to Article 17b;
4. renewal of a national authorisation for making available on the market of a biocidal product or a biocidal product family under Article 17c;
5. granting an authorisation for making available on the market of a biocidal product or a biocidal product family through mutual recognition in sequence under Article 17d;

6. granting an authorisation for making available on the market of a biocidal product or a biocidal product family through mutual recognition in parallel under Article 17e, Paragraph 1;
7. granting an authorisation for making available on the market of a biocidal product or a biocidal product family through mutual recognition in parallel under Article 17e, Paragraph 3;
8. granting an authorisation for making available on the market of a biocidal product or a biocidal product family through mutual recognition under Article 17f;
9. renewal of an authorisation for making available on the market of a biocidal product or a biocidal product family under Articles 17d and 17e, where the Republic of Bulgaria is the reference Member State;
10. renewal of an authorisation for making available on the market of a biocidal product or a biocidal product family under Articles 17d and 17e, where the Republic of Bulgaria is the Member State concerned;
11. amendment of an authorisation for making available on the market of a biocidal product or a biocidal product family under Articles 17a, 17d and 17e;
12. granting an authorisation for making available on the market of a same biocidal product under Article 17i;
13. granting an authorisation for parallel trade in a biocidal product under Article 17j;
14. evaluation of the applications for granting or renewal of a Union authorisation for making available on the market of a biocidal product or a biocidal product family under Article 17k;
15. evaluation of the applications for approval of an active substance under Article 17l;
16. granting a provisional authorisation for making available on the market of a biocidal product or a biocidal product family under Article 17m;
17. evaluation of the applications for renewal of the approval of an active substance under Article 17n;
18. granting an authorisation for making available on the market of a biocidal product or a biocidal product family under Article 18;
19. amendment of an authorisation for making available on the market of a biocidal product or a biocidal product family under Article 18;
20. granting an authorisation under Article 30, Paragraph 5.
(2) The proceeds from the fees referred to in Paragraph 1 shall be paid into the budget of the Ministry of Health.

Article 19a. (New, SG No. 95/2006, repealed, new, SG No. 102/2015) The Minister of Health shall submit to the European Commission a report on the implementation of Regulation (EU) No. 528/2012 in accordance with Article 65 (3) of that Regulation.

Article 19b. (New, SG No. 95/2006, repealed, SG No. 102/2015).

Article 19c. (New, SG No. 95/2006, repealed, SG No. 102/2015).

Article 19d. (New, SG No. 95/2006, repealed, SG No. 102/2015).

Article 19e. (New, SG No. 95/2006, repealed, SG No. 102/2015).

Article 19f. (New, SG No. 95/2006, amended, SG No. 63/2010, effective 13.08.2010, repealed, SG No. 102/2015).

Article 19g. (New, SG No. 95/2006, repealed, SG No. 102/2015).

Article 19h. (New, SG No. 95/2006, repealed, SG No. 102/2015).

Article 19i. (New, SG No. 95/2006, repealed, SG No. 102/2015).

Article 19j. (New, SG No. 95/2006, repealed, SG No. 102/2015).

Article 19k. (New, SG No. 95/2006, repealed, SG No. 102/2015).

Article 19l. (New, SG No. 95/2006, repealed, SG No. 102/2015).

Article 19m. (New, SG No. 95/2006, repealed, SG No. 102/2015).

Article 19n. (New, SG No. 95/2006, effective until 14.05.2010, amended, SG No. 82/2007, repealed, SG No. 102/2015).

Article 19o. (New, SG No. 95/2006, effective until 14.05.2010, repealed, SG No. 102/2015).

Article 19p. (New, SG No. 95/2006, effective until 14.05.2010, repealed, SG No. 102/2015).

Article 19q. (New, SG No. 95/2006, effective until 14.05.2010, amended, SG No. 63/2010, effective 13.08.2010, repealed, SG No. 102/2015).

Article 19r. (New, SG No. 95/2006, effective until 14.05.2010, repealed, SG No. 102/2015).

Article 19s. (New, SG No. 95/2006, amended and supplemented, SG No. 82/2007, repealed, SG No. 102/2015).

Article 19t. (New, SG No. 95/2006, amended, SG No. 82/2007, repealed, SG No. 102/2015).

Article 19u. (New, SG No. 95/2006, amended, SG No. 82/2007, repealed, SG No. 102/2015).

Article 19v. (New, SG No. 95/2006, amended, SG No. 82/2007, repealed, SG No. 102/2015).

Article 19w. (New, SG No. 95/2006, repealed, SG No. 102/2015).

Article 19x. (New, SG No. 95/2006, repealed, SG No. 102/2015).

Article 19y. (New, SG No. 95/2006, amended, SG No. 82/2007, repealed, SG No. 102/2015).

CHAPTER FIVE
(Amended, SG No. 86/2003, repealed, SG No. 114/2003, new, SG No. 82/2007)
MEASURES IMPLEMENTING REGULATION (EC) No. 1907/2006 (REACH) AND REGULATION (EC) No. 1272/2008 (CLP)
(Title amended, SG No. 63/2010 effective 13.08.2010)

Article 20. (Repealed, SG No. 114/2003, new, SG No. 82/2007, amended, SG No. 63/2010, effective 13.08.2010) The Minister of Environment and Water shall be the competent authority within the meaning of Article 121 of Regulation (EC) No. 1907/2006 (REACH) and Article 43 of Regulation (EC) No. 1272/2008 (CLP).

Article 20a. (New, SG No. 53/2018, effective 26.06.2018) (1) An exemption from the application of Titles II, III, VI, VII, VIII and/or IX of Regulation (EC) No. 1907/2006 (REACH) pursuant to Article 3a shall be granted based on an issued authorisation.
(2) The competent authority for issuing the authorisation under Paragraph 1 shall be the Interinstitutional Council on Defence Industry and Security of Supplies with the Council of Ministers, hereinafter referred to as "the Interinstitutional Council".

(3) The terms, procedure and deadlines for issue, refusal, amendment, termination and withdrawal of the authorisation referred to in Paragraph 1, the requirements for preventing or limiting the harmful effect on human health and the environment, as well as the information referred to in Article 20e, Item 2, shall be laid down with an ordinance of the Council of Ministers.
(4) The authorisation referred to in Paragraph 1 shall be issued for a period not longer than three years and shall apply only to the cases, types and quantities of chemical substances on their own, in mixtures or in articles, and their uses. The validity of the authorisation may be extended once for a period not longer than the initial period of validity upon its issue.
(5) The authorisation referred to in Paragraph 1 shall contain the measures which the person is to apply for preventing or limiting the harmful effect on human health and the environment.
(6) The rights granted under the authorisation may not be transferred or assigned, including in case of transformation pursuant to Article 261 of the Commerce Act, except in case of change of the person's legal form.

Article 20b. (New, SG No. 53/2018, effective 26.06.2018) For issue of the authorisation referred to in Article 3a, an application in standard format shall be submitted to the Interinstitutional Council, accompanied by the documents required the ordinance referred to in Article 20a, Paragraph 3.

Article 20c. (New, SG No. 53/2018, effective 26.06.2018) (1) The Interinstitutional Council shall issue an authorisation where an exemption pursuant to Article 3a is admissible and the applicant meets the requirements for issue of an authorisation laid down with the ordinance referred to in Article 20a, Paragraph 3.
(2) The Interinstitutional Council shall refuse to issue an authorisation where:
1. exemption pursuant to Article 3a is not admissible;
2. the applicant does not meet any of the requirements for issue of an authorisation laid down with the ordinance referred to in Article 20a, Paragraph 3;
3. the information contained in the application or in the documents attached is incorrect;
4. the information contained in the application or in the documents attached to it is incomplete or has not been submitted within 7 days of the date of notification thereof;
(3) The Interinstitutional Council shall amend the authorisation in the following cases:
1. it has been found that a measure needs to be amended or that a new measure needs to be added to the authorisation pursuant to Article 20a, Paragraph 5;
2. the validity of the initial authorisation is extended pursuant to Article 20a, Paragraph 4.
(4) The Interinstitutional Council shall terminate the validity of the authorization upon the written request by the person to whom the authorization was issued.
(5) The Interinstitutional Council shall withdraw the authorisation when the grounds for exemption pursuant to Article 3a no longer exist.
(6) The Interinstitutional Council shall immediately notify the Ministry of Defence, the Ministry of Environment and Water, the Ministry of Health and the Customs Agency of any case of issue, refusal, amendment, termination or withdrawal of an authorisation, and shall provide them with a copy of the authorisation issued.
(7) The decisions of the Interinstitutional Council shall be appealable pursuant to the Administrative Procedure Code. An appeal shall not stay the execution of the appealed act.

Article 20d. (New, SG No. 53/2018, effective 26.06.2018) The Interinstitutional Council shall set up and maintain a register of issued authorisations; this register shall not be public.
(2) The register shall contain:
1. number and date of the authorisation;
2. name, registered office, representation and management address of the authorisation holder;
3. date and grounds for amendment, termination, and/or withdrawal of the authorisation;
4. any notes to the recorded circumstances.

Article 20e. (New, SG No. 53/2018, effective 26.06.2018) Authorisation holders shall be obliged to:
1. comply with the requirements and measures for preventing or limiting the harmful effect on human health and the environment set out with the ordinance referred to in Article 20a, Paragraph 3, and the authorisation pursuant to Article 20a, Paragraph 5;
2. maintain and submit to the Interinstitutional Council on an annual basis the information required by the ordinance referred to in Article 20a, Paragraph 3.

Article 21. (Repealed, SG No. 114/2003, new, SG No. 82/2007) (1) The Minister of Environment and Water shall issue an order setting up an Expert Council on the evaluation of priority substances within the meaning of Article 45 and in connection with Articles 46, 47 and 48 of Regulation 1907/2006, hereinafter referred to as "the Expert Council".
(2) (Amended, SG No. 63/2010, effective 13.08.2010, SG No. 102/2015) The Expert Council shall include representatives of the Ministry of Environment and Water, the Ministry of Health, the National Centre of Public Health and Analyses and the Executive Environment Agency.
(3) The Ministry of Environment and Water shall issue regulations on the organization and activities of the Expert Council.
(4) (Amended, SG No. 63/2010, effective 13.08.2010, supplemented, SG No. 53/2018, effective 26.06.2018) If necessary, the Minister of Environment and Water may involve experts in chemistry, physicochemistry, ecotoxicology, toxicology, biology, occupational medicine, economics, etc. in the operation of the Expert Council in accordance with a procedure laid down in the rules of operation referred to in Paragraph 53.
(5) In the cases referred to in Article 45 (4) of Regulation 1907/2006, the Minister of Environment and Water shall issue an order charging the Expert Council with the conduct of an evaluation of priority substances included in the Community Rolling Action Plan referred to in Article 44 (2) of the Regulation.
(6) (Amended, SG No. 63/2010, effective 13.08.2010) The Expert Council shall perform an evaluation and submit a detailed report including the conclusions of the evaluation performed, with a draft decision enclosed in accordance with Article 48 of Regulation (EC) No. 1907/2006 (REACH), to the Minister of Environment and Water within the time limit referred to in Article 46 (4) of Regulation 1907/2006.
(7) (Amended, SG No. 63/2010, effective 13.08.2010) Based on the results of the evaluation, the Expert Council may submit to the Minister of Environment and Water a substantiated proposal for:
1. harmonised classification and labelling of a substance in accordance with Article 37 (1) of Regulation (EC) No. 1272/2008 (CLP);
2. identification of the substance in accordance with Article 59 (3) of Regulation (EC) No. 1907/2006 (REACH);
3. restriction of the substance in accordance with Article 69 (4) of Regulation (EC) No. 1907/2006 (REACH);
4. (new, SG No. 84/2012, effective 2.01.2013) restriction of the use of a substance or a group of substances in EEE;
5. (new, SG No. 53/2018, effective 26.06.2018) opinion regarding the compliance with the criteria referred to in Article 8(6) of Regulation (EU) 2017/852.
(8) (New, SG No. 63/2010, effective 13.08.2010, amended, SG No. 53/2018, effective 26.06.2018) The Minister of Environment and Water or an official authorised by the Minister:
1. shall inform the European Chemicals Agency of the results from the evaluation pursuant to Article 48 of Regulation (EC) No. 1907/2006 (REACH);
2. shall submit to the European Chemicals Agency a dossier for the proposals pursuant to Paragraph 7, items 1 - 3;
3. shall submit to the European Commission a dossier for the proposal pursuant to Paragraph 7, item 4.

(9) (New, SG No. 63/2010, effective 13.08.2010) The Expert Council shall consider, as provided for by Article 37 (6) of Regulation (EC) No. 1272/2008 (CLP), proposals by manufacturers, importers or downstream users for changing the harmonised classification and labelling of dangerous substances placed on the market in Bulgaria.
(10) (New, SG No. 63/2010, effective 13.08.2010, amended, SG No. 102/2015) The operation of the Expert Council shall be financed, as follows:
1. the evaluations within the meaning of Paragraph 6 – with funding from the European Chemicals Agency, in accordance with Article 14 (1) of 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 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ, L 107/6, 17 April 2008);
2. the preparation of substantiated proposals and the review of proposals within the meaning of Paragraphs 7 and 9 – with funding from the budget of the Ministry of Environment and Water.

Article 21a. (New, SG No. 82/2007) (1) (Amended, SG No. 63/2010, effective 13.08.2010) The Minister of Environment and Water or an official authorised by the Minister shall draft and send reports to the European Commission under Article 117 (1) of Regulation (EC) No. 1907/2006 (REACH) and to the European Chemicals Agency under Article 46 (2) of Regulation (EC) No. 1272/2008 (CLP) in accordance with the established procedure for communicating with the European Union institutions.
(2) (Amended, SG No. 63/2010, effective 13.08.2010) The Minister of Health, the Executive Director of the General Labour Inspectorate Executive Agency, the Director of the Customs Agency, the Executive Director of the National Revenue Agency and the President of the National Statistical Institute shall, upon request by the Minister of Environment and Water or by an official authorised by the Minister, provide information under Article 127 of Regulation (EC) No. 1907/2006 (REACH) for the reporting purposes referred to in Article 117 (1) of the Regulation.
(3) (New, SG No. 63/2010, effective 13.08.2010) The Minister of Health shall, upon request by the Minister of Environment and Water or by an official authorised by the Minister, provide summarised information on the results of the enforcement control regarding Regulation (EC) No. 1272/2008 (CLP) for the reporting purposes referred to in Article 46 (2) of the Regulation.

Article 21b. (New, SG No. 63/2010, effective 13.08.2010) (1) A national helpdesk shall be established and administered at the Ministry of Environment and Water in accordance with Article 124 of Regulation (EC) No. 1907/2006 (REACH) and Article 44 of Regulation (EC) No. 1272/2008 (CLP) to advise manufacturers, importers, downstream users and distributors of chemical substances on their own, in mixtures and in articles and/or of mixtures concerning their obligations to apply both Regulations.
(2) (Amended, SG No. 102/2015) In discharging its duties under Paragraph 1, the national helpdesk shall be supported by the Ministry of Health and by the National Centre of Public Health and Analyses.

Article 21b[1]. (New, SG No. 19/2021, effective 5.03.2021) (1) Effective from 5 January 2021, each supplier of a product according to the definition under Article 3, item 33 of Regulation (EC) 1907/2006 upon first delivery shall provide electronically in the database of the European Chemicals AgencyEuropean Chemicals Agency the information under Article 33 (1) of Regulation (EC) 1907/2006, using for this purpose the form and instruments provided by the European Chemicals Agency.
(2) The information under paragraph 1 shall be provided for the following delivery of a product after the inclusion of a substance in the list under Article 59 (1) of Regulation (EC) 1907/2006, contained in an product with concentration greater than 0.1 weight percent.
(3) Paragraph 1 shall not apply to products necessary for the purposes of national security and defence, which shall be certified with documents for the purpose of the product.

Article 21c. (New, SG No. 63/2010, effective 1.06.2015) (1) (Supplemented, SG No. 102/2015, amended, SG No. 98/2018, effective 27.11.2018) Importers and downstream users placing on the market mixtures, including biocidal products, classified as dangerous based on their effects on health or physical effects pursuant to Regulation (EC) No. 1272/2008 (CLP) shall provide the Toxicology Clinic of N. I. Pirogov Multi-Profile Hospital for Active Treatment and Emergency Medicine with information on the chemical composition of such mixtures, including the chemical identity of substances in mixtures for which a request for use of an alternative chemical name has been accepted under Article 24 of Regulation (EC) No. 1272/2008 (CLP).
(2) The Toxicology Clinic of N. I. Pirogov Multi-Profile Hospital for Active Treatment and Emergency Medicine shall be a competent authority within the meaning of Article 45 of Regulation (EC) No. 1272/2008 (CLP).
(3) (Amended, SG No. 102/2015) The information referred to in Paragraph 1 shall be provided before the first placing on the market of the chemical mixtures by all importers or downstream users.
(4) The format for the submission of the information referred to in Paragraph 1 shall be established in accordance with Article 45 (4) of Regulation (EC) No. 1272/2008 (CLP).
(5) (Amended, SG No. 98/2010, effective 1.01.2011) Medical establishments shall send to the authority referred to in Paragraph 2 and to the regional health inspectorates information on the cases of poisoning or suspected poisoning by mixtures classified as dangerous based on their effects on health or physical effects.
(6) (Supplemented, SG No. 102/2015) The authority referred to in Paragraph 2 shall, on an annual basis by the 30th day of April, send to the Ministry of Health, a summary report on the cases of poisoning or suspected poisoning by mixtures, including by biocidal products, classified as dangerous based on their effects on health or physical effects in the pat year and a list of the entities which have provided information under Paragraph 1.

Article 21d. (New, SG No. 63/2010, effective 13.08.2010, amended, SG No. 98/2018, effective 27.11.2018) Observance of the principles of Good Laboratory Practices by laboratories while performing ecotoxicological and toxicological tests and analyses of chemical substances for the purposes of Regulation (EC) No. 1907/2006 (REACH) and Regulation (EC) No. 1272/2008 (CLP) shall be certified by the Bulgarian Accreditation Service Executive Agency in accordance with the ordinance referred to in Article 4c, Paragraph 3.

CHAPTER FIVE "A"
(New, SG No. 84/2012, effective 2.01.2013)
RESTRICTION OF HAZARDOUS SUBSTANCES IN ELECTRICAL AND ELECTRONIC EQUIPMENT

Article 21e. (New, SG No. 84/2012, effective 2.01.2013) (1) The terms and conditions for placing on the market of EEE with relation to the restrictions on the use of certain hazardous substances shall be laid down in an ordinance issued by the Council of Ministers.
(2) The ordinance referred to in Paragraph 1 shall lay down:
1. the obligations of economic operators to ensure compliance with the restrictions on the use of hazardous substances in EEE placed on the market;
2. the conditions for granting, renewing or revoking an exemption from the restrictions on the use of certain hazardous substances in EEE;
3. (repealed, SG No. 102/2015);
4. the hazardous substances whose use in EEE is subject to restriction and the maximum concentration values by weight in homogeneous materials contained in EEE;
5. the requirements to EEE marking and identification;

6. the procedure for assessing conformity with the restrictions on the use of hazardous substances in EEE and the contents of the declaration of conformity.
(3) (New, SG No. 102/2015) The Minister of Environment and Water shall issue an order stipulating the cases of exemption from the restrictions on the use of hazardous substances in certain materials and components in EEE.
(4) (New, SG No. 102/2015) The orders referred to in Paragraph 3 shall be promulgated in the State Gazette and published on the website of the Ministry of Environment and Water.

Article 21f. (New, SG No. 84/2012, effective 2.01.2013) (1) EEE placed on the market must not contain hazardous substances exceeding the maximum concentration values laid down in the ordinance referred to in Article 21e, Paragraph 1.
(2) Paragraph 1 shall apply to the following categories of EEE, including cables and spare parts for its repair, its reuse, updating of its functionalities or upgrading of its capacity:
1. large household appliances;
2. small household appliances;
3. IT and telecommunications equipment;
4. consumer equipment;
5. lighting equipment;
6. electrical and electronic tools;
7. toys, leisure and sports equipment;
8. medical devices as referred to in Article 2, Paragraph 1, items 1 and 3 of the Medical Devices Act;
9. monitoring and control instruments, including industrial monitoring and control instruments;
10. automatic dispensers;
11. other EEE not included in the categories listed in items 1 to 10 above.
(3) Paragraph 1 shall not apply to:
1. equipment which is necessary for the protection of the essential interests of the national security of the Republic of Bulgaria, including arms, munitions and war material intended for specifically military purposes;
2. equipment designed to be sent into space;
3. equipment which is specifically designed, and is to be installed, as part of another type of equipment that is excluded or does not fall within the scope of this Chapter, which can fulfil its function only if it is part of that equipment, and which can be replaced only by the same specifically designed equipment;
4. large-scale stationary industrial tools;
5. large-scale fixed installations;
6. means of transport for persons or goods, excluding electric two-wheel vehicles which are not type-approved;
7. non-road mobile machinery made available exclusively for professional use;
8. active implantable medical devices as referred to in Article 2, Paragraph 1, item 2 of the Medical Devices Act;
9. photovoltaic panels intended to be used in a system that is designed, assembled and installed by professionals for permanent use at a defined location to produce energy from solar light for public, commercial, industrial and residential applications;
10. equipment specifically designed solely for the purposes of research and development only made available on a business-to-business basis;
11. (new, SG No. 17/2019, effective 26.02.2019) musical pipe organ.

Article 21g. (New, SG No. 84/2012, effective 2.01.2013) (1) The EEE manufacturer shall assess the product's conformity with the provisions of Article 21f, Paragraph 1 and shall verify this with the CE marking and a declaration of conformity pursuant to the requirements of the ordinance referred to in Article 21e, Paragraph 1.

(2) The CE marking shall be affixed in compliance with the general principles set out in Article 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), hereinafter referred to as "Regulation (EC) No. 765/2008".
(3) Where the CE marking has been affixed to EEE, it shall be considered that said EEE does not contain hazardous substances in homogeneous materials exceeding the maximum concentration value by weight set out in the ordinance referred to in Article 21e, Paragraph 1, in the absence of the provision of proof to the contrary.

Article 21h. (New, SG No. 84/2012, effective 2.01.2013) (1) Electrical and electronic equipment and materials and components of EEE which have successfully undergone tests or measurements to prove compliance with the provisions of Article 21f, Paragraph 1 or which have been assessed according to harmonised standards whose names and numbers have been published in the Official Journal of the European Union shall be considered compliant with the restrictions on the use of hazardous substances.
(2) Where it is established that a harmonised standard referred to in Paragraph 1 does not ensure full compliance with the requirements of Article 21f, Paragraph 1, the State Agency for Metrology and Technical Surveillance, and in the cases of EEE referred to in Article 21f, Paragraph 2, item 8 - the Bulgarian Drug Agency shall notify the Committee established pursuant to Article 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 and of rules on Information Society services.

Article 21i. (New, SG No. 84/2012, effective 2.01.2013) (1) The Minister of Environment and Water or an official authorised thereby shall make a proposal to the European Commission for the restriction of a substance or a group of substances in EEE on the basis of:
1. evaluation of priority substances carried out in accordance with Article 45 of Regulation (EC) No. 1907/2006 (REACH) and pursuant to Article 21 or by another European Union member state or another state party to the Agreement on the European Economic Area;
2. identification of hazardous substances pursuant to Article 59(3) of Regulation (EC) No. 1907/2006 REACH;
3. restriction of hazardous substances pursuant to Article 69(4) of Regulation (EC) No. 1907/2006 REACH.
(2) The proposal referred to in Paragraph 1 shall contain:
1. precise and clear wording of the proposed restriction;
2. references and scientific evidence for the proposed restriction;
3. information on the use of the substance or the group of similar substances in EEE;
4. information on detrimental effects and exposure in particular during waste EEE management operations;
5. information on possible substitutes and other alternatives, their availability and reliability;
6. justification for considering a Union-wide restriction as the most appropriate measure;
7. socioeconomic assessment of the proposed restriction.

Article 21j. (New, SG No. 84/2012, effective 2.01.2013) (1) No later than 31 March of each year the president of the State Agency for Metrology and Technical Surveillance and the executive director of the Bulgarian Drug Agency or officials authorised thereby shall submit to the Minister of Environment and Water summary information on control measures exercised regarding the implementation of the provisions of this Chapter and of the ordinance referred to in Article 21e, Paragraph 1.
(2) The information referred to in Paragraph 1 shall be used to assess the implementation of this Chapter and of the ordinance referred to in Article 21e, Paragraph 1.

Article 21k. (New, SG No. 84/2012, effective 2.01.2013) The provision of this Chapter shall apply without prejudice to the requirements of Regulation (EC) No. 1907/2006 (REACH), Regulation (EC) No. 850/2004 and the requirements in the field of safety, health and waste management.

CHAPTER SIX
MEASURES IMPLEMENTING REGULATION (EU) No. 649/2012 AND REGULATION (EC) No. 850/2004 (Title amended, SG No. 114/2003, SG No. 82/2007, SG No. 63/2010, effective 13.08.2010, SG No. 102/2015)

Article 22. (1) (Amended and supplemented, SG No. 114/2003, amended, SG No. 82/2007, SG No. 63/2010, effective 13.08.2010, SG No. 102/2015) The Minister of Environment and Water shall be a competent authority within the meaning of Article 4 of Regulation (EU) No. 649/2012 and Article 15 of Regulation (EC) No. 850/2004.

Article 22a. (New, SG No. 114/2003, amended, SG No. 34/2006, SG No. 82/2007, amended and supplemented, SG No. 63/2010, effective 13.08.2010, amended, SG No. 102/2015) (1) Prior to the first export in a calendar year of a hazardous chemical on its own or in a mixture pursuant to Article 8 (2) of Regulation (EU) No. 649/2012, or in an article pursuant to Article 15 (1) of Regulation (EU) No. 649/2012 the exporter shall submit to the Ministry of Environment and Water an export notification in electronic form by means of the European Chemicals Agency Database in accordance with the time limit and the format laid down in Article 8 (2) of Regulation (EU) No. 649/2012.
(2) The notification referred to in Paragraph 1 shall be accompanied by a safety data sheet for the chemical substance or mixture drafted in accordance with Annex II to Regulation (EC) No. 1907/2006 (REACH) and Article 17 (4) of Regulation (EU) No. 649/2012.
(3) Where the notification under Paragraph 1 is found to be incomplete or containing errors, the Minister of Environment and Water or an official authorised by him shall notify the exporter thereof by means of the European Chemicals Agency Database within 5 days of the date of submission of the information referred to in Article 8 (2) of Regulation (EU) No. 649/2012.
(4) The exporter shall amend the errors and supply the missing information within 5 days of the date of receipt of the notification under Paragraph 3.
(5) The export of chemicals listed in Parts 2 and 3 of Annex I to Regulation (EU) No. 649/2012 shall be subject to written consent by the competent authorities of the countries of destination.
(6) For the processing of the notification referred to in Paragraph 1 the exporter shall pay a fee pursuant to Article 8 (8) of Regulation (EU) No. 649/2012 in accordance with the tariff under Article 72 of the Environmental Protection Act.

Article 22b. (New, SG No. 114/2003, amended, SG No. 82/2007, amended and supplemented, SG No. 63/2010, effective 13.08.2010, repealed, SG No. 102/2015).

Article 22c. (New, SG No. 114/2003, amended, SG No. 82/2007, SG No. 63/2010, effective 13.08.2010, repealed, SG No. 102/2015).

Article 22d. (New, SG No. 114/2003, amended, SG No. 82/2007) (1) (Amended, SG No. 63/2010, effective 13.08.2010, SG No. 102/2015) The Minister of Environment and Water, or an official authorised by him, shall prepare and present a report on the implementation of Regulation (EU) No. 649/2012 pursuant to Article 22 (1) of that Regulation.
(2) (Amended, SG No. 63/2010, effective 13.08.2010, SG No. 102/2015) For the purposes of the reporting referred to in Paragraph 1, the Customs Agency shall produce, on request by The Minister

of Environment and Water, or an officer empowered by him, information within the meaning of Article 18 of Regulation (EU) No. 649/2012.
(3) The information referred to in Paragraph 2 shall contain data on the following:
1. (amended, SG No. 63/2010, effective 13.08.2010, SG No. 102/2015) chemical substances and mixtures listed in Annex I of Regulation (EU) No. 649/2012 exported from and imported into the customs-regulated territory of the Republic of Bulgaria over the reporting period;
2. identity of the exporter and/or importer of the chemical substances and/or mixtures referred to in Item 1.
3. (amended, SG No. 63/2010, effective 13.08.2010, SG No. 102/2015) cases of non-compliance with the provisions of Article 8 and Article 14 (6) of Regulation (EU) No. 649/2012 for exports of chemical substances and mixtures from Annex I to the Regulation.

Article 22e. (New, SG No. 114/2003, amended, SG No. 34/2006, repealed, SG No. 82/2007, new, SG No. 63/2010, effective 13.08.2010, amended, SG No. 102/2015, supplemented, SG No. 12/2017) By the 31st day of March each year the exporters and importers of dangerous chemical substances on their own, in mixtures and in articles listed in Annex I of Regulation (EU) No. 649/2012 shall submit to the Ministry of Environment and Water via the European Chemicals Agency's database information on the chemicals exported and imported in the past year pursuant to Article 10 of Regulation (EU) No. 649/2012.

Article 22f. (New, SG No. 114/2003, repealed, SG No. 82/2007, new, SG No. 63/2010, effective 13.08.2010) (1) The Minister of Environment and Water shall draft and update a National Implementation Plan for the management of persistent organic pollutants and shall send it to the European Commission and to the Member States in accordance with Article 8 of Regulation (EC) No. 850/2004.
(2) The Plan referred to in Paragraph 1 shall be adopted by the Council of Ministers.

Article 22g. (New, SG No. 114/2003, repealed, SG No. 82/2007, new, SG No. 63/2010, effective 13.08.2010) (1) The Minister of Environment and Water or an official authorised by the Minister shall draft and present reports on the implementation of Regulation (EC) No. 850/2004 to the European Commission.
(2) (Amended, SG No. 58/2017, effective 18.07.2017, SG No. 102/2022, effective 1.01.2023) The Minister of Agriculture, the Minister of Health, the Director of the Customs Agency, the Executive Director of the National Revenue Agency and the President of the National Statistical Institute shall, upon request by the Minister of Environment and Water or an official authorised by the Minister, provide information in accordance with an established format for the reporting purposes referred to in Article 12 of Regulation (EC) No. 850/2004.
(3) (New, SG No. 102/2015) The holder of a stockpile greater than 50 kg of dangerous substances listed in Annex I and/or Annex II to Regulation (EC) No. 850/2004, and the use of which is permitted shall provide the Minister of Environment and Water with information concerning the nature and size of that stockpile and the measures for their safe storage within the deadlines set in Article 5 (2) of Regulation (EC) No. 850/2004.

Article 22h. (New, SG No. 114/2003, repealed, SG No. 82/2007).

Article 22i. (New, SG No. 114/2003, repealed, SG No. 82/2007).

Article 22j. (New, SG No. 114/2003, repealed, SG No. 82/2007).

CHAPTER SIX "A"
(New, SG No. 102/2015)
MEASURES FOR IMPLEMENTING REGULATION (EU) No. 98/2013

Article 23. (Amended, SG No. 114/2003, repealed, SG No. 82/2007, effective 1.06.2009, new, SG No. 102/2015) Restricted explosives precursors within the meaning of Article 3, item 10 of Regulation (EU) No. 98/2013 shall not be made available to, or introduced, possessed or used by, members of the general public.

Article 24. (Amended, SG No. 114/2003, SG No. 95/2006, repealed, SG No. 63/2010, effective 13.08.2010, new, SG No. 102/2015) In accordance with Article 5 of Regulation (EU) No. 98/2013 economic operators shall either affix to the packaging of a restricted explosives precursor an appropriate label or verify that an appropriate label is affixed to that packaging, indicating that the acquisition, possession or use of restricted explosives precursors by members of the general public is prohibited.

Article 24a. (New, SG No. 114/2003, amended, SG No. 82/2007, repealed, SG No. 63/2010, effective 13.08.2010, new, SG No. 102/2015) (1) The Ministry of Interior shall be the national contact point within the meaning of Article 9 (2) of Regulation (EU) No. 98/2013.
(2) Economic operators shall report to the national contact point referred to in Paragraph 1 all suspicious transactions or attempted suspicious transactions and significant disappearances and thefts of the substances listed in Annex I and Annex II to Regulation (EU) No. 98/2013, in accordance with the provisions of Article 9 (3) and (4) of that Regulation.
(3) (Amended, SG No. 17/2019) The reporting referred to in Paragraph 17 shall be carried out in compliance with the requirements for personal data protection.

Article 24b. (New, SG No. 102/2015) The obligations referred to in Article 9 (6) of Regulation (EU) No. 98/2013 shall be fulfilled by ensuring access to the European Commission guidelines for implementation of that Regulation on the websites of the Ministry of Health and the Ministry of Interior.

CHAPTER SEVEN
CONTROL OVER CHEMICAL SUBSTANCES AND MIXTURES ON THEIR OWN, IN MIXTURES AND IN ARTICLES
(Title amended, SG No. 114/2003, SG No. 63/2010, effective 13.08.2010, SG No. 102/2015)

Article 25. (1) (Amended, SG No. 114/2003, supplemented, SG No. 101/2005, amended and supplemented, SG No. 95/2006, SG No. 82/2007, amended, SG No. 63/2010, effective 13.08.2010, previous text of Article 25, SG No. 53/2018, effective 26.06.2018) The following shall be subject to compliance control:
1. (repealed, SG No. 53/2018, effective 26.06.2018);
2. the classification, labelling and packaging of chemical substances, mixtures and specific articles pursuant to Regulation (EC) No. 1272/2008 (CLP);
2a. (new, SG No. 102/2015) the labelling of restricted explosives precursors in accordance with Regulation (EU) No. 98/2013;
3. notification of the European Chemicals Agency concerning the classification and labelling of the dangerous chemical substances placed on the market on their own and in mixtures pursuant to Regulation (EC) No. 1272/2008 (CLP);
4. the registration of chemical substances on their own, in mixtures and in articles pursuant to Regulation (EC) No. 1907/2006 (REACH);
5. the exchange of information on substances and the prevention of unnecessary tests pursuant to Regulation (EC) No. 1907/2006 (REACH);
6. downstream users pursuant to Regulation (EC) No. 1907/2006 (REACH);

7. (supplemented, SG No. 53/2018, effective 26.06.2018) the downstream provision of information, including a safety data sheet, on the supply of chemical substances on their own, in mixtures and in articles pursuant to Regulation (EC) No. 1907/2006 (REACH);
7a. (new, SG No. 19/2021, effective 5.03.2021) providing information to the European Chemicals Agency pursuant to Article 21b[1] (1) from product providers;
8. the authorisation of certain dangerous chemical substances pursuant to Regulation (EC) No. 1907/2006 (REACH);
9. restricting the manufacture, placing on the market and use of certain dangerous chemical substances, mixtures and articles pursuant to Regulation (EC) No. 1907/2006 (REACH) and the ordinance referred to in Article 4b, Paragraph 2 for environmental protection purposes;
10. restricting the placing on the market and use of certain dangerous chemical substances, mixtures and articles pursuant to Regulation (EC) No. 1907/2006 (REACH) and the ordinance referred to in Article 4b, Paragraph 2 for human health protection purposes;
11. giving people working with dangerous chemical substances access to information on chemical substances and mixtures under Article 35 of Regulation (EC) No. 1907/2006 (REACH) and application of the work environment exposure control measures identified in the safety data sheet;
12. (amended, SG No. 102/2015, supplemented, SG No. 53/2018, effective 26.06.2018) the export and import of dangerous chemical substances on their own, in mixtures or in articles as covered by Regulation (EU) No. 649/2012 and pursuant to Articles 3 - 5 of Regulation (EU) 2017/852;
13. (amended, SG No. 102/2015) the provision of information on the export and import of dangerous chemical substances on their own, in mixtures or in articles as covered by Regulation (EU) No. 649/2012;
14. prohibiting and restricting the manufacture, placing on the market and use of persistent organic pollutants as covered by Regulation (EC) No. 850/2004;
14a. (new, SG No. 102/2015) prohibiting the making available of restricted explosives precursors to members of the general public pursuant to Article 23;
15. the provision of information on persistent organic pollutants as covered by Regulation (EC) No. 850/2004;
16. the storage of dangerous chemical substances and mixtures in accordance with the ordinance referred to in Article 4b, Paragraph 1 and the conditions identified in the manufacturer's, importer's or downstream user's safety data sheet;
17. the biodegradability of surfactants and detergents containing surfactants pursuant to Regulation (EC) No. 648/2004;
17a. (new, SG No. 102/2015) the limitation on the use of phosphates and other phosphorus compounds in consumer laundry detergents and consumer automatic dishwasher detergents in accordance with Regulation (EU) No. 259/2012;
18. the labelling and packaging of detergents and surfactants intended for detergents pursuant to Regulation (EC) No. 648/2004;
19. the provision of information on the ingredients of detergents pursuant to Regulation (EC) No. 648/2004;
20. (amended, SG No. 102/2015) the making available on the market and the professional use of biocidal products;
20a. (new, SG No. 102/2015) compliance with Article 95 (2) of Regulation (EU) No. 528/2012;
20b. (new, SG No. 102/2015) placing on the market of treated articles;
21. research and development, including experiments where a biocidal product or active substance is or may be released in the environment;
22. (amended, SG No. 102/2015) the provision of information on the biocidal products and mixtures made available on the market which are classified as dangerous based on their effects on health or physical effects, for the purpose of planning preventive measures and treatment to protect human life and health;

23. (new, SG No. 84/2012, effective 2.01.2013, supplemented, SG No. 53/2018, effective 26.06.2018) EEE placed on the market pursuant to Article 21f, Paragraph 2, items 1 - 7 and 9 - 11, as referred to in Chapter Five "a" and the ordinance referred to in Article 21e, Paragraph 1, and limiting the manufacturing 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 (EU) 2017/852;
24. (new, SG No. 84/2012, effective 2.01.2013, supplemented, SG No. 53/2018, effective 26.06.2018) EEE placed on the market pursuant to Article 21f, Paragraph 2, item 8, as referred to in Chapter Five "a" and the ordinance referred to in Article 21e, Paragraph 1, and limiting the manufacturing and placing on the market of topical antiseptics and medical devices, respectively under items 8 and 9 of part A of Annex II to Regulation (EU) 2017/852;
25. (new, SG No. 102/2015) reporting of suspicious transactions or attempted suspicious transactions and of significant disappearances and thefts of the substances listed in Annex I and Annex II to Regulation (EU) No. 98/2013;
26. (new, SG No. 53/2018, effective 26.06.2018) the ban on the manufacture, placing on the market and use of mercury-added cosmetic products and biocides listed in items 7 and 8, respectively, and of products listed in item 9 of part A of Annex II to Regulation (EU) 2017/852;
27. (new, SG No. 53/2018, effective 26.06.2018) the ban on the manufacture of mercury-added products under items 1 - 6 and 9 of part A of Annex II pursuant to Article 5 of Regulation (EU) 2017/852;
28. (new, SG No. 53/2018, effective 26.06.2018) prohibited use of mercury and mercury compounds in the manufacturing processes referred to in Part I of Annex III pursuant to Article 7 of Regulation (EU) 2017/852, from the dates laid down with that Annex, except their use in the manufacturing processes referred to in Part II of Annex III, subject to the conditions listed in that Annex;
29. (new, SG No. 53/2018, effective 26.06.2018) environmentally sound interim storage of mercury, mercury compounds and mixtures of mercury pursuant to Article 7(3) of Regulation (EU) 2017/852;
30. (new, SG No. 53/2018, effective 26.06.2018) the manufacturing of new mercury-added products and new manufacturing processes involving the use of mercury or mercury compounds, authorised pursuant to Article 8(6) of Regulation (EU) 2017/852;
31. (new, SG No. 53/2018, effective 26.06.2018) the ban on artisanal and small-scale gold mining and processing in which mercury amalgamation is used to extract gold from ore pursuant to Article 9 of Regulation (EU) 2017/852;
32. (new, SG No. 53/2018, effective 26.06.2018) the ban on placing on the market of mercury-added products under item 1 of part A of Annex II to Regulation (EU) 2017/852;
33. (new, SG No. 53/2018, effective 26.06.2018) availability of the information referred to in Article 20e, item 2.
(2) (New, SG No. 53/2018, effective 26.06.2018) In case of exemption pursuant to Article 3a, the compliance with the requirements and measures laid down with the ordinance referred to in Article 20a, Paragraph 3 and the authorisation referred to in Article 20a, Paragraph 5, shall also be subject to control for:
1. preventing or limiting the harmful effect on the environment;
2. preventing or limiting the harmful effect on human health.

Article 26. (Amended, SG No. 63/2010, effective 13.08.2010) (1) The control provided for by this Act shall be preventive, on-going and follow-up control.
(2) Preventive control shall be effected through the authorisation issuance procedures pertaining to the placement of biocidal products on the market as provided for by Chapter Four.
(3) Ongoing control shall be effected through:
1. planned checks based on an annual control plan;
2. checks prompted by complaints and alerts by individuals and legal entities;

3. checks in case of suspicion;
4. checks prompted by inquiries by the European Chemicals Agency or a competent authority of another European Union Member State or another state which is a party to the European Economic Area Agreement.
(4) Follow-up control shall be effected through monitoring the implementation of the instructions given to the controlled entities during the control and of the compulsory administrative measures imposed under this Act.
(5) Control shall be effected through document and on-site checks, sampling, laboratory analyses, monitoring and measurements.
(6) (Supplemented, SG No. 84/2012, effective 2.01.2013) Control shall be effected through independent or joint checks by the authorities referred to in Article 27, Paragraphs 1, 2 and 4.
(7) The authorities referred to in Article 27, Paragraphs 1 and 2 shall draw up records of findings when effecting such control.
(8) The records referred to in Paragraph 7 shall indicate the facts and circumstances found, give mandatory instructions to rectify any non-compliance and violations found, and specify deadlines for and people in charge of the implementation of such instructions.
(9) The Minister of Environment and Water, the Minister of Health and the Minister of Labour and Social Policy, within the limits of their respective competence, shall jointly issue directions for controlling the implementation of this Act, the acts of secondary legislation concerning its implementation and the Regulations listed in Article 1, Item 3.
(10) (New, SG No. 53/2018, effective 26.06.2018) The Ministry of Environment and Water, the Ministry of Health and the Ministry of Labour and Social Policy shall exchange information for the purposes of control pursuant to Article 25, Paragraph 1, items 2, 3 and 5 - 10.

Article 27. (Amended, SG No. 114/2003, amended and supplemented, SG No. 95/2006, SG No. 82/2007, amended, SG No. 63/2010, effective 13.08.2010) (1) (Amended, SG No. 102/2015, SG No. 12/2017, SG No. 53/2018, effective 26.06.2018) The Minister of Environment and Water, the directors of the regional inspectorates of environment and water, or officials authorised by them shall exert control in the cases referred to in Article 25, Paragraph 1, items 3 - 9, 13, 14, 15 - 17a, 27 - 31 and 33, as well as Article 25, Paragraph 2, item 1, with a view to protecting the environment.
(2) (Amended, SG No. 102/2015, SG No. 53/2018, effective 26.06.2018) The government health control authorities under the Health Act shall exert control in the cases referred to in Article 25, Paragraph 1, items 2, 2a, 3, 7, 10, 14a, 18 - 22, 26 and 33, as well as Article 25, Paragraph 2, item 2, with a view to protecting public health.
(3) (Amended, SG No. 53/2018, effective 26.06.2018) The government control authorities under the Plant Protection Act shall control the classification, packaging and labelling and safety data sheets of the plant protection products placed on the market or intended for export as provided for by the Plant Protection Act, including bans and restrictions on mercury-added pesticides pursuant to item 8 of Part A of Annex II to Regulation (EU) 2017/852.
(4) (Amended, SG No. 53/2018, effective 26.06.2018) The Customs Agency shall exert control in the cases referred to in Article 25, Paragraph 1, item 12, as provided for by Council Regulation (EEC) No. 26.06.2018 establishing the Community Customs Code and Commission Regulation (EC) No. 25 laying down provisions for the implementation of Council Regulation (EEC) No. 1 establishing the Community Customs Code.
(5) (Amended, SG No. 53/2018, effective 26.06.2018) The General Labour Inspectorate Executive Agency under the Minister of Labour and Social Policy shall exert control as provided for by the Labour Code in the cases referred to in Article 25, Paragraph 1, Item 11 for the purpose of ensuring health and safety at work.
(6) (New, SG No. 84/2012, effective 2.01.2013, amended, SG No. 53/2018, effective 26.06.2018) In the cases referred to in Article 25, Paragraph 1, item 23, the president of the State Agency for Metrology and Technical Surveillance or officials authorised thereby shall carry out market

surveillance pursuant to Chapter Four of the Technical Requirements towards Products Act and in compliance with Chapter III of Regulation (EC) No. 26.06.2018.
(7) (New, SG No. 84/2012, effective 2.01.2013, amended, SG No. 53/2018, effective 26.06.2018) In the cases referred to in Article 25, Paragraph 1, item 24, the executive director of the Bulgarian Drug Agency or officials authorised thereby shall carry out market surveillance pursuant to Chapter Six of the Medical Devices Act and in compliance with Chapter III of Regulation (EC) No. 26.06.2018.
(8) (New, SG No. 102/2015, amended, SG No. 53/2018, effective 26.06.2018) In the cases referred to in Article 25, Paragraph 1, item 25 the Minister of Interior or officials authorised by him shall exert control pursuant to the Ministry of Interior Act.
(9) (New, SG No. 53/2018, effective 26.06.2018) In the cases referred to in Article 25, Paragraph 1, item 32, the President of the Consumer Protection Agency or officials authorised thereby shall exert control pursuant to the Consumer Protection Act and in accordance with Article 5 of Regulation (EU) 2017/852.

Article 28. (Amended, SG No. 114/2003, SG No. 82/2007) (1) The authorities referred to in Article 27, Paragraphs 1 and 2 shall be entitled to:
1. (amended, SG No. 63/2010, effective 13.08.2010, SG No. 12/2017) unimpeded access to enterprises and sites which manufacture, place on the market, use, store and export chemical substances on their own, as compounds in mixtures or in articles and/or mixtures;
2. (amended, SG No. 63/2010, effective 13.08.2010, SG No. 12/2017) demand information and documents and take samples for laboratory analyses related to the manufacture, placing on the market, use, storage and export of chemical substances on their own, as compounds in mixtures or in articles and/or mixtures;
3. (amended, SG No. 63/2010, effective 13.08.2010, SG No. 12/2017) demand information on the quantities of chemical substances on their own, as compounds in mixtures or in articles and/or mixtures having been manufactured, imported, exported, used and placed on the market;
4. (amended, SG No. 63/2010, effective 13.08.2010, SG No. 12/2017) demand information from manufacturers, importers, exporters, downstream users and distributors of chemical substances and mixtures on the identity of their suppliers and users in the supply chain for chemical substances on their own, as compounds in mixtures or in articles and/or mixtures.
(2) (Repealed, SG No. 63/2010, effective 13.08.2010).
(3) (Amended, SG No. 63/2010, effective 13.08.2010) The authority referred to in Article 27, Paragraph 4 shall be entitled to:
1. (amended, SG No. 102/2015) demand documents and information and take samples for laboratory analyses in connection with the import and export of dangerous chemical substances on their own and in mixtures as listed in Annex I and Annex V of Regulation (EU) No. 649/2012;
2. (amended, SG No. 102/2015) retain the goods pending a decision by the Minister of Environment and Water or by an official authorised by the Minister in cases of suspected violations of the prohibitions and/or restrictions laid down in Annex I or in Annex V of Regulation (EU) No. 649/2012, or return the substances, mixtures and/or articles at the expense of the exporter/importer or of the entity authorised to export/import in cases of established violations.
(4) The authorities referred to in Article 27 shall be obliged not to disclose any industrial or commercial information of confidential nature.
(5) (New, SG No. 63/2010, effective 13.08.2010, amended, SG No. 12/2017) If, as a result of laboratory analysis of a sample/samples of a chemical substance/chemical substances on their own, in mixtures or in articles, of a mixture/mixtures or of a biocide/biocides, the authorities referred to in Article 27, Paragraph 1 and 2 find a violation of this Act, the acts of secondary legislation concerning its implementation and the Regulations listed in Article 1, Item 3, the entities guilty of such violation shall pay the cost of the analyses performed.
(6) (New, SG No. 63/2010, effective 13.08.2010, amended, SG No. 102/2015) If it is found that a chemical substance on its own, in a mixture or in an article and/or a biocidal product placed on the

market does not comply with the provisions of this Act, the acts of secondary legislation concerning its implementation and/or of the Regulations listed in Article 1, Item 3, and such substance, mixture and/or biocidal product poses a risk to human health and safety and/or the environment, the Minister of Health and/or the Minister of Environment and Water or officials authorised by them may order that such substance, mixture and/or biocidal product be immediately and effectively recalled from the market at the expense of those responsible for its placing on the market, or seized from the final user.
(7) (New, SG No. 63/2010, effective 13.08.2010, supplemented, SG No. 102/2015) The measures referred to in Paragraph 6 shall be undertaken in case all measures undertaken have turned out to be insufficient to prevent or limit the risk to human health and/or the environment.
(8) (New, SG No. 63/2010, effective 13.08.2010) The customs authorities shall, upon request and in accordance with an established format, provide information to the authorities referred to in Article 27, Paragraphs 1 and 2 or to officials authorised by such authorities on the import of substances on their own and in mixtures which are the subject of authorisation and on the import of chemical substances and mixtures which are the subject of restriction under Regulation (EC) No. 1907/2006 (REACH).

Article 29. (Previous Article 30, Amended, SG No. 114/2003) A state authority may not ban, limit or impede the placing on the market of dangerous chemical substances and mixtures which meet the requirements of this Act.

Article 30. (Previously Article 29, Amended, SG No. 114/2003) (1) (Amended, SG No. 63/2010, effective 13.08.2010) If new information emerges that a chemical substance and/or mixture complying with the provisions of this Act, the acts of secondary legislation concerning its implementation and of the Regulations listed in Article 1, Item 3, poses an immediate and material hazard to human health and/or the environment, the authorities referred to in Article 27, Paragraphs 1 and 2 may temporarily prohibit its placing on the market and its use..
(2) (New, SG No. 95/2006) Acting within their powers, the Minister of Health and the Minister of Environment and Water may impose a temporary ban on the placing on the market of any detergent which, though complying with the requirements of Regulation (EC) No. 648/2004 of the European Parliament and of the Council, is believed to present a risk to the safety of humans and animals or to the environment, as well as imposing temporarily certain specific conditions.
(3) (New, SG No. 95/2006, amended, SG No. 63/2010, effective 13.08.2010, SG No. 102/2015) Acting within their powers, the Minister of Health and the Minister of Environment and Water may impose temporarily a ban or restrictions on the use or marketing of an authorised biocidal product which is suspected to present a risk to the health of humans and animals or to the environment.
(4) (New, SG No. 95/2006, amended, SG No. 82/2007) When imposing any of the measures referred to in Paragraphs 1, 2 and 3, the Minister of Health and the Minister of Environment and Water shall immediately notify the European Commission and the EU member states thereof, stating the reasons for their decision.
(5) (Renumbered from Paragraph 2, amended, SG No. 95/2006, SG No. 63/2010, effective 13.08.2010, SG No. 102/2015) In the emergence of immediate danger to man and/or the environment which cannot be eliminated otherwise, the Minister of Health may as an exception, following the procedure and within the time limit laid down in Article 55 (1) of Regulation (EU) No. 528/2012, authorise the making available on the market or the use of a biocidal product not meeting the requirements of Chapter Four.
(6) (New, SG No. 95/2006, amended, SG No. 63/2010, effective 13.08.2010) The authorization referred to in Paragraph 5 shall be granted on a proposal adopted by unanimity by the Expert Council on Biocidal Products based on a previous evaluation of the bioefficiency of the biocidal product and its toxicological and ecotoxicological properties.
(7) (New, SG No. 95/2006, repealed, SG No. 102/2015).
(8) (New, SG No. 95/2006, amended, SG No. 102/2015) To obtain an authorisation under Paragraph 5, the applicant shall pay the fee under Article 19, Paragraph 1, item 20.

(9) (New, SG No. 95/2006, effective from the date of entry into force of the Republic of Bulgaria's EU Accession Treaty, repealed, SG No. 102/2015).
(10) (New, SG No. 95/2006, effective from the date of entry into force of the Republic of Bulgaria's EU Accession Treaty, repealed, SG No. 102/2015).

Article 30a. (New, SG No. 102/2015) (1) The Minister of Health may, upon a proposal made by the Minister of Interior, temporarily prohibit or limit the making available, possession and use of substances not listed in Annex I and Annex II to Regulation (EU) No. 98/2013, in accordance with Article 13 (1) of that Regulation.
(2) The Minister of Health may, upon a proposal made by the Minister of Interior, limit further or prohibit the making available, possession and use of substances listed in Annex I and Annex II to Regulation (EU) No. 98/2013 in accordance with Article 13 (2) and (3) of that Regulation.
(3) When implementing a measure under Paragraph 1 and/or Paragraph 2 the Minister of Health shall immediately notify thereof the European Commission and the other Member States, stating the grounds for his decision.

Article 31. (Repealed, SG No. 91/2002, new, SG No. 102/2015) The control pursuant to Regulation (EU) No. 528/2012 shall be carried out in compliance with the requirements laid down in Regulation (EC) No. 765/2008.

CHAPTER EIGHT
ADMINISTRATIVE AND PENAL PROVISIONS

Section I
Compulsory administrative measures

Article 32. With a view to preventing and stopping the administrative violations under this Act, as well as with a view to preventing and stopping their adverse effects, the competent authorities or persons authorized by them shall apply compulsory administrative measures pursuant to Article 33.

Article 33. (Amended, SG No. 114/2003, SG No. 63/2010, effective 13.08.2010) (1) (Amended, SG No. 102/2015) The Minister of Environment and Water or officials authorised by the Minister, shall, in accordance with their respective authority, suspend the manufacture, placing on the market, use and/or export of chemical substances, mixtures and/or articles.
(2) (Amended, SG No. 102/2015) The directors of the regional health inspectorates shall, in accordance with their respective authorities, suspend the placing on the market and/or use of chemical substances, mixtures, including biocidal products and/or articles.
(3) The activities referred to in Paragraphs 1 and 2 shall be suspended until the reason causing the compulsory administrative measure is eliminated.
(4) The compulsory administrative measure shall be applied through a substantiated order by the authorities referred to in Paragraphs 1 and 2.
(5) The order referred to in Paragraph 4 shall specify the effective period of the compulsory administrative measure and the method for its application.
(6) The order referred to in Paragraph 4 shall be delivered to the entity concerned as provided for by Code of Civil Procedure.

Article 34. (Amended, SG No. 30/2006) Compulsory administrative measures may be appealed pursuant to the Administrative Procedure Code.

Section II
Administrative Violations and Penalties

Article 35. (Amended, SG No. 63/2010, effective 13.08.2010) (1) (Amended, SG No. 114/2003) A penalty shall be imposed on anyone who:
1. fails to fulfil the obligations referred to in Article 4a towards the government control authorities listed in Article 27, Paragraphs 1 and 2;
2. (amended, SG No. 12/2017) fails to implement a mandatory instruction and/or an order to suspend the production, placing on the market and/or use of chemical substances on their own, as compounds in mixtures or in articles issued by an authority referred to in Article 27, Paragraphs 1 and 2;
3. (amended and supplemented, SG No. 102/2015, amended, SG No. 12/2017) fails to fulfil the obligations referred to in Article 16 and Article 56 (1) of Regulation (EU) No. 528/2012;
4. (amended and supplemented, SG No. 102/2015) advertises a chemical substance or mixture in violation of Article 4 of this Act and Article 72 of Regulation (EU) No. 528/2012;
5. fails to store dangerous chemical substances and mixtures in accordance with the requirements, conditions and information indicated by the manufacturer, importer or downstream user in the safety data sheet;
6. (supplemented, SG No. 53/2018, effective 26.06.2018) violates the storage requirements applicable to dangerous chemical substances and mixtures under the ordinance referred to in Article 4b, Paragraph 1 and the obligations for environmentally sound interim storage of mercury, mercury compounds and mixtures of mercury pursuant to Article 7(3) of Regulation (EU) 2017/852;
7. (repealed, SG No. 53/2018, effective 26.06.2018);
8. fails to fulfil the obligations pertaining to the classification, labelling and packaging of chemical substances, mixtures and certain articles pursuant to Article 4 of Regulation (EC) No. 1272/2008 (CLP);
9. fails to fulfil the obligations pertaining to the identification and examination of the available information on the substances referred to in Article 5 and the mixtures referred to in Article 6 of Regulation (EC) No. 1272/2008 (CLP);
10. fails to fulfil the obligations to limit and prevent animal and human testing pursuant to Article 7 of Regulation (EC) No. 1272/2008 (CLP);
11. fails to fulfil the obligations to evaluate the information on the hazards and to classify substances and mixtures as provided for by Articles 9 - 15 of Regulation (EC) No. 1272/2008 (CLP);
12. fails to fulfil the obligations to provide information on the hazards posed by chemical substances and/or mixtures by means of the label as provided for by Articles 17 - 27 and Articles 30 - 33 of Regulation (EC) No. 1272/2008 (CLP);
13. fails to fulfil the obligations pertaining to the packaging of dangerous chemical substances and/or mixtures pursuant to Article 35 of Regulation (EC) No. 1272/2008 (CLP);
14. fails to fulfil the requirements pertaining to the harmonisation of a substance's classification and labelling pursuant to Article 37 (6) of Regulation (EC) No. 1272/2008 (CLP);
15. fails to fulfil the obligations to notify the European Chemicals Agency pursuant to Article 40 of Regulation (EC) No. 1272/2008 (CLP);
16. fails to fulfil the obligations to provide information under Article 45 of Regulation (EC) No. 1272/2008 (CLP);
17. fails to fulfil the requirements pertaining to the advertisement of chemical substances and mixtures pursuant to Article 48 of Regulation (EC) No. 1272/2008 (CLP);
18. fails to fulfil the obligations pertaining to information storage and provision pursuant to Article 49 of Regulation (EC) No. 1272/2008 (CLP);
19. violates the requirements of Articles 3 and 5 (2) of Regulation (EC) No. 850/2004;
20. (amended, SG No. 102/2015) makes a biocidal product available on the market without an authorisation having been issued;
21. (amended, SG No. 102/2015) is a professional user and uses a biocidal product without an authorisation;

22. (amended, SG No. 102/2015) places on the market active substances which are not included in the European Union list of approved active substances under Article 9 (2) of Regulation (EU) No. 528/2012;
23. (amended, SG No. 102/2015) performs experiments where a biocidal product or active substance is or may be released in the environment without having submitted a notification;
24. (amended, SG No. 102/2015) places on the market a treated article which does not meet the requirements of Article 58 of Regulation (EU) No. 528/2012;
25. (amended, SG No. 102/2015) makes available on the market a biocidal product in violation of the terms and conditions of the granted authorisation;
26. (amended, SG No. 102/2015) fails to fulfil the obligations for record-keeping and reporting pursuant to Article 68 (1) of Regulation (EU) No. 528/2012;
26a. (new, SG No. 102/2015) fails to fulfil the obligations for provision of information under Article 73 of Regulation (EU) No. 528/2012;
26b. (new, SG No. 102/2015) fails to fulfil the obligations for limiting the tests on vertebrates pursuant to Article 62 of Regulation (EU) No. 528/2012;
27. violates the restrictions regarding the biodegradability of surfactants and of detergents containing surfactants pursuant to Article 4 of Regulation (EC) No. 648/2004;
27a. (new, SG No. 102/2015) violates the limitations on the use of phosphates and other phosphorus compounds in consumer laundry detergents and consumer automatic dishwasher detergents in accordance with Article 4a of Regulation (EU) No. 259/2012;
28. fails to provide information on the biodegradability of surfactants and of detergents containing surfactants pursuant to Article 9 (1) of Regulation (EC) No. 648/2004;
29. fails to provide, immediately and for free, the information referred to in Article 9 (3) of Regulation (EC) No. 648/2004;
30. fails to publish the list of ingredients for the detergents pursuant to Annex VII, section D of Regulation (EC) No. 648/2004;
31. violates the requirements pertaining to the labelling and packaging of detergents and surfactants intended for detergents pursuant to Article 11 of Regulation (EC) No. 648/2004 and Article 11 of the Act;
32. (supplemented, SG No. 53/2018, effective 26.06.2018) violates the requirements pertaining to the manufacture and placing on the market of chemical substances on their own, in mixtures and/or in articles and the placing on the market of mixtures pursuant to Article 53 of Regulation (EC) No. 2018 (REACH) and of mercury-added products pursuant to Article 5 of Regulation (EU) 2017/852;
33. fails to fulfil the obligations pertaining to:
(a) the registration of chemical substances on their own, in mixtures or in articles pursuant to 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) the preparation and delivery of safety data sheets and of information along the supply chain pursuant to Article 31 (1), (2), (3), (7) and (9), Article 32 (1) and (3), Article 33 (1), Article 34, 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) (amended, SG No. 98/2018, effective 27.11.2018) the evaluation of substances pursuant to Article 50 (4) of Regulation (EC) No. 1907/2006 (REACH);
(d) the authorisation of chemical substances on their own, in preparations and/or in articles pursuant to Article 56 (1) and (2), Article 60 (10) and Article 65 of Regulation (EC) No. 1907/2006 (REACH);
(e) restricting the manufacture, use or placing on the market of chemical substances, mixtures and/or articles pursuant to Article 67 (1) of Regulation (EC) No. 1907/2006 (REACH);
34. fails to fulfil the obligations pertaining to:
(a) the registration of chemical substances on their own, in preparations or in articles 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) data exchange and performing tests on vertebrate animals pursuant to Article 25 (1) and (2), Article 26 (1) and (3), Article 29 (3) and Article 30 (1), (2) and (6) of Regulation (EC) No. 1907/2006 (REACH);
(c) the preparation and delivery of safety data sheets 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) the evaluation of dossiers, substances and intermediates pursuant to Article 40 (4), Article 41 (4), Article 46 (2), Article 49 and Article 50 (2) and (3) of Regulation (EC) No. 1907/2006 (REACH);
(e) the authorisation of chemical substances on their own, in preparations or in articles pursuant to Article 60 (8), Article 61 (1) and Article 66 (1) of Regulation (EC) No. 1907/2006 (REACH);
(f) providing additional information to the European Chemicals Agency pursuant to Article 20 (2) and Article 21 (2) of Regulation (EC) No. 1907/2006 (REACH);
(g) (new, SG No. 53/2018, effective 26.06.2018) compliance with the requirements or measures for preventing or limiting the harmful effect on human health or the environment laid down with the ordinance referred to in Article 20a, Paragraph 3, and the authorisation referred to in Article 20a, Paragraph 5;
(h) (new, SG No. 19/2021, effective 5.03.2021) providing information to the European Chemicals Agency pursuant to Article 21b[1] (1);
35. (amended, SG No. 102/2015, supplemented, SG No. 53/2018, effective 26.06.2018) fails to fulfil the obligations to submit an export notification for dangerous chemical substances on their own, in mixtures and/or in articles pursuant to Article 8 and Article 15 (1) of Regulation (EU) No. 649/2012 and pursuant to Article 3 of Regulation (EU) 2017/852;
36. (amended, SG No. 102/2015) fails to observe the restrictions on the export of dangerous chemical substances on their own and/or in mixtures pursuant to Article 14 of Regulation (EU) No. 649/2012;
37. (amended, SG No. 102/2015, supplemented, SG No. 53/2018, effective 26.06.2018) violates the export prohibitions referred to in Article 15 (2) of Regulation (EU) No. 649/2012 and Articles 3 and 5 of Regulation (EU) 2017/852;
38. (amended, SG No. 102/2015) fails to fulfil the obligations to provide information under Articles 10, 16 and 17 of Regulation (EU) No. 649/2012;
39. (new, SG No. 84/2012, effective 2.01.2013) violates the requirements of Chapter Five "a" or of the ordinance referred to in Article 21e, Paragraph 1 relating to:
a) the restrictions on the use of hazardous substances in EEE and of cables and spare parts for its repair, its reuse, updating of its functionalities or upgrading of its capacity;
b) the assessment of conformity with the restrictions on the use of hazardous substances in EEE or the drawing up of technical documentation or of a declaration of conformity;
c) the affixing of the CE marking and the identification of EEE and of cables and spare parts for its repair, its reuse, updating of its functionalities or upgrading of its capacity;
d) collection and submission of information verifying the conformity of EEE placed on the market with the implemented restrictions on the use of hazardous substances;
40. (new, SG No. 102/2015) violates the ban on making restricted explosives precursors available to members of the general public;
41. (new, SG No. 102/2015) fails to fulfil the obligation for labelling of restricted explosives precursors under Article 24;
42. (new, SG No. 102/2015) fails to fulfil the obligation for reporting of suspicious transactions or attempted suspicious transactions and significant disappearances and thefts of the substances listed in Annex I and Annex II to Regulation (EU) No. 98/2013;

43. (new, SG No. 53/2018, effective 26.06.2018) fails to perform the obligation for maintaining the information pursuant to Article 20e, item 2;
44. (new, SG No. 53/2018, effective 26.06.2018) violates the import ban on mercury, mercury compounds, and mixtures of mercury pursuant to Article 4(1), (2) and (3) and on mercury-added products pursuant to Article 5(1) of Regulation (EU) 2017/852;
45. (new, SG No. 53/2018, effective 26.06.2018) violates the ban on manufacturing of mercury-added products pursuant to Article 5(1) and the use of mercury and mercury compounds in manufacturing processes referred to in Article 7(1) of Regulation (EU) 2017/852;
46. (new, SG No. 53/2018, effective 26.06.2018) violates the ban on manufacturing of new mercury-added products and on new manufacturing processes involving the use of mercury or mercury compounds pursuant to Article 8(1) and (2) of Regulation (EU) 2017/852, unless with an authorisation for such activities pursuant to Article 8(6) of that Regulation;
47. (new, SG No. 53/2018, effective 26.06.2018) violates the ban on using mercury in artisanal and small-scale gold mining and processing pursuant to Article 9(1) of Regulation (EU) 2017/852;
48. (new, SG No. 53/2018, effective 26.06.2018) violates the ban on placing on the market of mercury-added products pursuant to Annex II to Regulation (EU) 2017/852 and of new mercury-added products pursuant to Article 8 of that Regulation.
(2) For the violations referred to in Article 35 of Regulation (EC) No. 1907/2006 (REACH), sanctions under the Labour Code shall be imposed.
(3) For the violations referred to in Paragraph 1, the following fines or penalty payments shall be imposed on individuals or legal entities respectively:
1. (amended, SG No. 102/2015, SG No. 53/2018, effective 26.06.2018) under items 8, 19, 20, 22, 23, 32, 33, 40 and 44 - 48 – between BGN 10,000 to BGN 100,000;
2. (supplemented, SG No. 102/2015) under Items 3, 10, 11, 12, 13, 15, 16, 18, 21, 24, 26a, 26b, 34, 36 and 37 – between BGN 5,000 and BGN 50,000;
3. (amended, SG No. 84/2012, effective 2.01.2013, amended and supplemented, SG No. 102/2015, amended, SG No. 53/2018, effective 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 – between BGN 1,000 and BGN 40,000.
(4) In case of repeated violation, the fine or penalty payment referred to in Paragraph 3 shall be doubled.

Article 36. (1) (Amended, SG No. 114/2003, SG No. 84/2012, effective 2.01.2013, SG No. 102/2015, SG No. 53/2018, effective 26.06.2018) The violations referred to in Article 35, Paragraph 1, items 1 - 38, 40, 41 and 43 - 47 shall be ascertained with statements issued by government health inspectors or by officials determined by the directors of the regional inspectorates of Environment and Water in accordance with their authorities.
(2) (Amended, SG No. 114/2003, SG No. 102/2015, SG No. 53/2018, effective 26.06.2018) The penal decrees shall be issued by the director of the relevant regional health inspectorate or by the director of the relevant regional inspectorate of environment and water in accordance with their authorities.
(3) (New, SG No. 84/2012, effective 2.01.2013, amended, SG No. 53/2018, effective 26.06.2018) The statements for violations referred to in Article 35, Paragraph 1, items 39 and 48 shall be drawn up by officials appointed by the President of the State Agency for Metrology and Technical Surveillance, by the President of the Consumer Protection Agency, by the directors of the relevant regional food safety department, or by the executive director of the Bulgarian Drug Agency in accordance with their powers, while penal decrees shall be issued by the president of the State Agency for Metrology and Technical Surveillance, by the President of the Consumer Protection Agency, by the directors of the relevant regional food safety department, or by the executive director of the Bulgarian Drug Agency in accordance with their powers or by officials authorised thereby.

(4) (New, SG No. 102/2015) The statements ascertaining the violations under Article 35, Paragraph 1, item 42 shall be drawn up by officials determined by the Minister of Interior and the penal decrees shall be issued by the Minister of Interior or officials authorised by him.

Article 37. Violations shall be established, statements shall be drawn up, penal decrees shall be issued, appealed and executed pursuant to the Administrative Violations and Sanctions Act.

ADDITIONAL PROVISIONS
(Title amended, SG No. 84/2012, effective 2.01.2013)

§ 1. (Amended, SG No. 114/2003) For the purpose of this Act:

1. "Chemical substances" shall mean chemical elements and their compounds as they occur in the natural state or as produced by an industrial process which includes additives necessary for stabilization of the products and impurities occurring in the production process used but excludes any solvent which might be separated without affecting the stability of the substance or changing its composition.
2. (Amended, SG No. 63/2010, effective 13.08.2010) "Mixtures" shall mean mixtures or solutions composed of two or more substances.
3. (Amended, SG No. 95/2006, repealed, SG No. 82/2007).
4. (Repealed, SG No. 63/2010, effective 13.08.2010).
5. (Repealed, SG No. 63/2010, effective 13.08.2010).
6. (Amended, SG No. 63/2010, effective 13.08.2010, SG No. 102/2015) "Dangerous chemical substances and mixtures" shall mean the chemical substances and mixtures which are classified as dangerous in one or more hazard categories under Annex I to Regulation (EC) No. 1272/2008 (CLP).
7. (Amended, SG No. 63/2010, effective 13.08.2010) "Classification" shall mean the procedure of assessing whether the chemical substance or mixture possesses one or more hazardous properties, depending on which it is referred to a specific category.
8. (Amended, SG No. 63/2010, effective 13.08.2010) "Labelling" shall mean all texts, symbols, images and signs placed on the packaging of a chemical substance or mixture indicating the presence of a potential danger with a view to classification.
9. (Repealed, SG No. 82/2007).
10. (Repealed, SG No. 82/2007).
11. (Repealed, SG No. 82/2007).
12. "Tactile sign" shall mean a tangible sign intended for use by visually impaired persons.
13. (Amended, SG No. 63/2010, effective 13.08.2010) "Storage" shall mean any method of storing chemical substances or mixtures prior to their use, processing or transportation.
14. "Repeated violation" shall mean a violation committed within one year of the coming into force of a penal decree for a violation of the same type.
15. (Repealed, SG No. 82/2007).
16. (Supplemented, SG No. 95/2006, amended, SG No. 63/2010, effective 13.08.20) "Placing on the market" shall mean making the chemical substance or mixture available to third parties against payment or free of charge for distribution and/or use. "Import" shall be construed as "Placing on the market".
17. (Amended, SG No. 95/2006, effective from 01 January 2007, SG No. 63/2010, effective 13.08.2010) "Professional user" shall mean any Bulgarian or foreign natural or legal entity which is registered under the Commerce Act or its national legislation or which is a free lancer within the meaning of the Income Taxes on Natural Persons Act, which uses or places chemical substances and mixtures on the market.
18. "Professional use" shall mean the activities performed by the persons referred to in item 17.
19. (Amended, SG No. 63/2010, effective 13.08.2010, repealed, SG No. 102/2015).

20. "Harmful organism" shall mean any organism which has an unwanted presence or a detrimental effect for humans, their activities or the products they use or produce, or for animals or for the environment.
21. "Active substance" shall mean a chemical substance or micro-organism, including viruses or fungi, having general or specific action on or against harmful organisms.
22. (Amended, SG No. 95/2006, repealed, SG No. 82/2007).
23. (Amended, SG No. 95/2006) "Development" shall mean further research on a substance through use of pilot plants or under production trials to test the fields of its application.
24. (Amended, SG No. 101/2005, repealed, SG No. 95/2006, effective from the date of entry into force of the Republic of Bulgaria's EU Accession Treaty).
25. (Amended, SG No. 63/2010, effective 13.08.2010, repealed, SG No. 102/2015).
26. (Amended, SG No. 95/2006, repealed, SG No. 102/2015).
27. (Amended, SG No. 63/2010, effective 13.08.2010, repealed, SG No. 102/2015).
28. "Residues" shall mean quantities of one or more of the substances present in a biocidal product which remain as a result of its use, including the metabolites of such substances and products resulting from their degradation or reaction.
29. (Amended, SG No. 63/2010, effective 13.08.2010, repealed, SG No. 102/2015).
30. (Amended, SG No. 63/2010, effective 13.08.2010) "Declaration for use of information" shall mean a document signed by the owner or the owners of information which is protected as confidential by the provisions of this Act, certifying that the Ministry of Health may use this information for authorization or registration of another biocidal product.
31. "Admissible daily dose" shall mean the quantity of substance which can be consumed daily with the food during the life cycle without any risk to human health.
32. "Limit value" shall mean the average measured value of a certain chemical agent or dust in the air in the breathing field of the worker at his working place for a specified period of time.
33. (Repealed, SG No. 82/2007).
34. (Repealed, SG No. 82/2007).
35. (Repealed, SG No. 82/2007).
36. (Amended, SG No. 63/2010, effective 13.08.2010) "Exposure" shall mean exposing the human organism and the components of the environment to the effects of chemical substances, mixtures and biocidal products.
37. (New, SG No. 101/2005, repealed, SG No. 95/2006, effective from the date of entry into force of the Republic of Bulgaria's EU Accession Treaty).
38. (New, SG No. 95/2006, repealed, SG No. 82/2007).
39. (New, SG No. 95/2006, repealed, SG No. 102/2015).
40. (New, SG No. 95/2006, amended, SG No. 63/2010, effective 13.08.2010) "Persistent organic pollutants" shall mean dangerous chemical substances, either on their own or in mixtures, that travel away from their sources across international borders, persist in the environment, accumulate in organisms through the food web and pose a risk to human health and the environment.
41. (New, SG No. 84/2012, effective 2.01.2013) "Electrical and electronic equipment (EEE)" means equipment which is dependent on electric currents or electromagnetic fields in order to work properly and equipment for the generation, transfer and measurement of such currents and fields and designed for use with a voltage rating not exceeding 1000 volts for alternating current and 1500 volts for direct current.
42. (New, SG No. 84/2012, effective 2.01.2013) "Large-scale stationary industrial tools" means a large size assembly of machines, equipment, and/or components, functioning together for a specific application, permanently installed and de-installed by professionals at a given place, and used and maintained by professionals in an industrial manufacturing facility or research and development facility.
43. (New, SG No. 84/2012, effective 2.01.2013) "Large-scale fixed installation" means a large-size combination of several types of apparatus and, where applicable, other devices, which are

assembled, installed and de-installed by professionals and are intended to be used permanently at a pre-defined and dedicated location.
44. (New, SG No. 84/2012, effective 2.01.2013) "Cables" means all cables with a rated voltage of less than 250 volts that serve as a connection or an extension to connect EEE to the electrical outlet or to connect two or more EEE to each other.
45. (New, SG No. 84/2012, effective 2.01.2013) "EEE manufacturer" means any natural or legal person who manufactures an EEE or has an EEE designed or manufactured and markets it under his name or trademark.
46. (New, SG No. 84/2012, effective 2.01.2013) "Authorised representative" means any natural or legal person established within a European Union member state or another state party to the Agreement on the European Economic Area who has received a written mandate from an EEE manufacturer to act on his behalf in relation to the discharge of specific obligations pursuant to the ordinance referred to in Article 21e, Paragraph 1.
47. (New, SG No. 84/2012, effective 2.01.2013) "EEE distributor" means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes an EEE available on the market.
48. (New, SG No. 84/2012, effective 2.01.2013) "EEE importer" means any natural or legal person established within a European Union member state or another state party to the Agreement on the European Economic Area who places an EEE from a third country on the European Union market.
49. (New, SG No. 84/2012, effective 2.01.2013) "Economic operator" means the manufacturer, the importer and the distributor of EEE or the authorised representative.
50. (New, SG No. 84/2012, effective 2.01.2013) "Making available on the market" means any supply of EEE for distribution, consumption or use on the European Union market in the course of a commercial activity, whether in return for payment or free of charge.
51. (New, SG No. 84/2012, effective 2.01.2013) "Placing of EEE on the market" means the first making available of EEE on the European Union market.
52. (New, SG No. 84/2012, effective 2.01.2013) "Harmonised standard" means a standard adopted by one of the European standardisation bodies on the basis of a request made by the European Commission in accordance with Article 6 of Directive 98/34/EC.
53. (New, SG No. 84/2012, effective 2.01.2013) "CE marking" means a marking by which the manufacturer of EEE indicates that the product is in conformity with the applicable requirements set out in European Union harmonisation legislation providing for its affixing.
54. (New, SG No. 84/2012, effective 2.01.2013) "Conformity assessment" means the process demonstrating whether the requirements of Chapter Five "a" and the ordinance referred to in Article 21e, Paragraph 1 relating to an EEE, are met.
55. (New, SG No. 84/2012, effective 2.01.2013) "Homogeneous material" means one material of uniform composition throughout or a material, consisting of a combination of materials, that cannot be disjointed or separated into different materials by mechanical actions such as unscrewing, cutting, crushing, grinding and abrasive processes.
56. (New, SG No. 84/2012, effective 2.01.2013) "Medical device" means a medical device or accessory within the meaning of § 1, item 21 of the additional provisions of the Medical Devices Act, which is EEE.
57. (New, SG No. 84/2012, effective 2.01.2013) "In vitro diagnostic medical device" means a medical device within the meaning of § 1, item 12 of the additional provisions of the Medical Devices Act.
58. (New, SG No. 84/2012, effective 2.01.2013) "Active implantable medical device" means a medical device within the meaning of § 1, item 1 of the additional provisions of the Medical Devices Act.
59. (New, SG No. 84/2012, effective 2.01.2013) "Industrial monitoring and control instruments" means monitoring and control instruments designed for exclusively industrial or professional use.

60. (New, SG No. 84/2012, effective 2.01.2013) "Availability of a substitute" means the ability of a substitute to be manufactured and delivered within a reasonable period of time as compared with the time required for manufacturing and delivering the substances listed in the ordinance referred to in Article 21e, Paragraph 1.
61. (New, SG No. 84/2012, effective 2.01.2013) "Reliability of a substitute" means the probability that an EEE using a substitute will perform a required function without failure under stated conditions for a stated period of time.
62. (New, SG No. 84/2012, effective 2.01.2013) "EEE spare part" means a separate part of an EEE that can replace a part of an EEE. The EEE cannot function as intended without that part of the EEE. The functionality of EEE is restored or is upgraded when the part is replaced by a spare part.
63. (New, SG No. 84/2012, effective 2.01.2013, supplemented, SG No. 17/2019, effective 26.02.2019) "Non-road mobile machinery made available exclusively for professional use" means machinery with an on-board power source or with traction powered by an external power source, the operation of which requires either mobility or continuous or semi-continuous movement between a succession of fixed working locations while working, and is made available exclusively for professional use.
64. (New, SG No. 84/2012, effective 2.01.2013) "Interests of the Republic of Bulgaria relating to national security" shall have the meaning defined in § 1, item 14 of the additional provisions of the Classified Information Protection Act.
65. (New, SG No. 53/2018, effective 26.06.2018) "Allowed use" shall mean any use of mercury, mixtures of mercury, or mercury compounds which is allowed pursuant to the relevant European Union legislation or Bulgarian legislation, including the types of use pursuant to Articles 3, 4, 5, 7, 8 and 10 of Regulation (EU) 2017/852.

§ 1a. (New, SG No. 102/2015) (1) For the purposes of Chapters Four, Seven and Eight the definitions of Regulation (EU) No. 528/2012 shall apply.
(2) For the purposes of Chapter Six "a" the definitions of Regulation (EU) No. 98/2013 shall apply.

§ 1b. (New, SG No. 84/2012, effective 2.01.2013, previously § 1a, SG No. 102/2015, supplemented, SG No. 17/2019, effective 26.02.2019) This Act implements 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 1.7.2011) and 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 (OJ, L 305/8 of 21.11.2017).

TRANSITIONAL AND FINAL PROVISIONS

§ 2. The persons performing activities referred to in Article 1 for which registration pursuant to Chapter Four is required, shall submit an application for registration within six months after the coming into force of this Act.

§ 3. (Amended, SG No. 114/2003) The Minister of Health and the Minister of Environment and Water may consign their functions, rights and obligations under this Act to their deputies and to other officials within the structure of the respective ministries.

§ 4. The Act shall become effective two years after its promulgation in the State Gazette.

§ 5. (Amended, SG No. 114/2003, SG No. 63/2010, effective 13.08.2010) The enforcement of this Act shall be assigned to the Minister of Health and the Minister of Environment and Water.

§ 6. (New, SG No. 82/2007) The Minister of Environment and Water, the Minister of Health and the Minister of Labour and Social Policy shall, each within their competence, provide

guidelines on the implementation of Regulation 1907/2006, Regulation 304/2003, Regulation 850/2004 and Regulation (EC) No. 1451/2007.

TRANSITIONAL AND FINAL PROVISIONS
to the Act Amending and Supplementing the Protection Against
the Harmful Impact of Chemical Substances and Preparations Act
(SG No. 114/2003, effective 31.01.2004)

§ 40. The Council of Ministers shall adopt the regulations referred to in Articles 11, 13 and Article 16, Paragraph 1 within one year from the date of promulgation of this Act in the State Gazette

§ 42. (1) This Act shall enter into force one month after its promulgation in the State Gazette, save for the provisions of Chapter Four, Section I "Conditions and procedure for placing active substances and biocide products on the market", which shall become effective as of 1 January 2007.
(2) The provisions of Chapter Four, Section II "Conditions and procedure for placing of biocide products on the market", shall apply until 1 January 2007.

TRANSITIONAL PROVISION
to the Act Amending and Supplementing the Protection Against
the Harmful Impact of Chemical Substances and Preparations Act
(SG No. 101/2005)

§ 5. The Council of Ministers shall adopt the ordinance under Article 5a within three months of entry into force of this act.

(*) ACT to Amend the Commercial Register Act
(SG No. 80/2006, effective 3.10.2006)

§ 1. In § 56 of the Transitional and Final Provisions the words "1 October 2006" shall be replaced by "1 July 2007".
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TRANSITIONAL AND FINAL PROVISIONS to the Act Amending and Supplementing the Protection Against Harmful Impact of Chemical Substances and Preparations Act
(SG No. 95/2006, effective 24.11.2006, amended and supplemented, SG No. 82/2007, amended, SG No. 63/2010, effective 13.08.2010)

§ 22. The Council of Ministers shall adopt the ordinance under Article 14 within three months of entry into force of this Act.

§ 23. (1) (Amended, SG No. 82/2007) The Minister of Health shall cancel or modify an authorisation for placing a biocidal product on the market granted before the entry into force of this Act in compliance with Article 4 (2) of Regulation (EC) No. 1451/2007.
(2) (Amended, SG No. 82/2007) By cancelling an authorisation under Paragraph 1, the Minister of Health shall lay down time limits for storage, use or distribution of the available quantities of the biocidal product.

§ 24. (Supplemented, SG No. 82/2007) The provisions of Article 19n, Paragraph 3, Article 19s, Article 19t and Section XVIII of the new Chapter Four shall apply to biocidal products authorised before the entry into force of this Act, save in the cases referred to in § 23.

§ 25. The definitions given in Article 2 of Regulation (EC) No. 648/2004 of the European Parliament and of the Council shall apply to detergents and surfactants as of the date of entry into force of the Republic of Bulgaria's EU Accession Treaty.

§ 26. This Act shall enter into force on the date of its promulgation in the State Gazette, save for § 4 with regard to Article 4d, § 6, § 7, § 11, Item 2 with regard to Paragraph 5 of Article 7d, § 15 with regard to the new Chapter Four, Sections III - XVI, § 19, Item 3 with regard to Paragraphs 9 and 10 of Article 30, § 20, Item 1 "c" with regard to Items 20 and 21 of Article 35, Paragraph 1 and § 21, Items 4 and 6 with regard to Items 24 and 37 of § 1 of the Supplementary Provision, which shall become effective as of the date of entry into force of the Republic of Bulgaria's EU Accession Treaty.

§ 27. (Amended, SG No. 63/2010, effective 13.08.2010) (1) The provisions of Section XVII of Chapter Four shall apply until 14 May 2014.
(2) Where the Commission has passed a decision to include an active substance in the lists referred to in Article 14, Paragraph 4, Items 1 or 2 wherein the date set for application is later than 14 May 2014the provisions of Article 19v, section XVII of Chapter Four shall apply to biocidal products containing the active substance until such date.

TRANSITIONAL AND FINAL PROVISIONS
to the Income Taxes on Natural Persons Act
(SG No. 95/2006, effective 01.01.2007)

.....

§ 12. In § 1, Item 17 of the Supplementary Provision of the Protection Against the Harmful Impact of Chemical Substances and Preparations Act (promulgated, SG No. 10/2000; amended, SG No. 91/2002, Nos. 86 and 114/2003, Nos. 100 and 101/2005, Nos. 30 and 34/2006), the words "the Personal Income Tax Act" shall be replaced by the words "the Income Taxes on Natural Persons Act".

.....

§ 21. This Act shall enter into force on 01 January 2007, save for § 10, which shall become effective as of the date of promulgation of this Act in the State Gazette.

(**) ACT to Amend the Commercial Register Act
(SG No. 53/2007, effective 30.06.2007)

§ 1. In § 56 of the Transitional and Final Provisions the words "1 July 2007" shall be replaced by "1 January 2008".

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ACT to Amend and Supplement the Protection Against
the Harmful Impact of Chemical Substances and Preparations Act
(SG No. 82/2007)

.....

Supplementary provision

§ 40. Throughout the text, the words "authorised" or "the authorised" shall be replaced by the words "empowered" or "the empowered", and the words "the Minister of Agriculture and Forestry" shall be replaced by the words "the Minister of Agriculture and Food Supply".

Transitional and final provisions

§ 41. The certificates of registration applying to the exports of dangerous chemical substances and preparations issued under Article 22, Paragraph 4 shall remain valid until 31 December 2007.

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§ 43. The provisions of § 8, Item 3, § 9, § 32, Item 1 and § 36, Item 1 "a" shall become effective on 1 June 2008.

§ 44. The provision of § 10 shall become effective on 1 August 2008.

§ 45. The provisions of § 29, § 32, Item 2 and § 36, Item 1 "c" shall become effective on 1 June 2009.

ACT to Amend and Supplement the Protection Against
the Harmful Impact of Chemical Substances and Preparations Act
(SG No. 63/2010)

.....

Supplementary Provisions

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

§ 46. Everywhere in Chapter Four the words "the biocidal preparations", "biocidal preparation", "biocidal preparations", "the biocidal preparation", "the preparations", "the preparation", "the biocidal preparation", "preparation" and "preparations" shall be replaced by "the biocidal products", "biocidal product", "biocidal products", "the biocidal product", "the biocidal products", "the biocidal product", "the biocidal product", "biocidal product" and "biocidal products".

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

§ 48. This Act transposes the provisions of Directive 2009/107/EC of the European Parliament and of the Council of 16 September 2009 amending Directive 98/8/EC concerning the placing of biocidal products on the market as regards the extension of certain time periods (OJ, L 262/40 of 6 October 2009).

Transitional and Final Provisions

§ 49. The Council of Ministers shall adopt the ordinances referred to in Article 4b within 9 months after this Act's entry into force.

§ 50. The authorisations to place biocidal preparations on the market issued prior to this Act's entry into force shall remain valid.

§ 51. Article 2, Article 5, Paragraphs 1 - 3 and Paragraph 5 and Articles 7b - 7f shall apply until 31 May 2015

§ 52. This Act shall enter into force on the date of its promulgation in the State Gazette, save for § 14 and 24, which shall take effect as of 1 June 2015.

TRANSITIONAL AND FINAL PROVISIONS
to the Act Amending and Supplementing the Protection Against
Harmful Impact of Chemical Substances and Mixtures Act
(SG No. 84/2012, effective 2.01.2013, amended and supplemented,
SG No. 17/2019, effective 26.02.2019)

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§ 12. The provisions of Article 21f, Paragraph 1 shall not apply to:
1. medical devices placed on the market before 22 July 2014;
2. monitoring and control instruments placed on the market before 22 July 2014;
3. in vitro diagnostic medical devices placed on the market before 22 July 2016;
4. industrial monitoring and control instruments placed on the market before 22 July 2017;

5. (new, SG No. 17/2019, effective 26.02.2019) any other EEE that is placed on the market before 22 July 2019 and is not covered by items 1 to 10 of Article 21f(2);
6. (renumbered from item 5, SG No. 17/2019, effective 26.02.2019) cables or spare parts for the repair, the reuse, the updating of functionalities or upgrading of capacity of the following:
a) electrical and electronic equipment placed on the market before 1 July 2006;
b) medical devices placed on the market before 22 July 2014;
c) monitoring and control instruments placed on the market before 22 July 2014;
d) in vitro diagnostic medical devices placed on the market before 22 July 2016;
e) industrial monitoring and control instruments placed on the market before 22 July 2017;
f) electrical and electronic equipment which benefited from an exemption and which was placed on the market before that exemption expired as far as that specific exemption is concerned;
g) (new, SG No. 17/2019, effective 26.02.2019) any other EEE that is placed on the market before 22 July 2019 and is not covered by items 1 to 10 of Article 21f(2);
7. (renumbered from item 6, amended, SG No. 17/2019, effective 26.02.2019) reused spare parts, recovered from EEE, provided that reuse of spare parts takes place in closed-loop business-to-business return systems subject to audits and that the reuse of parts is notified to the consumer, if the following conditions have been fulfilled:
a) the spare parts used have been recovered from an EEE placed on the market before 1 July 2006 and have been used in an EEE placed in the market before 1 July 2016;
b) the spare parts used have been recovered from medical devices referred to in items 1 and 3 of Article 2(1) of the Medical Devices Act or from industrial monitoring and control instruments placed on the market before 2 July 2014 and have been used in an EEE placed on the market before 22 July 2024;
c) the spare parts used have been recovered from in vitro diagnostic medical devices placed on the market before 22 July 2016 and have been used in an EEE placed in the market before 22 July 2026;
d) the spare parts used have been recovered from industrial monitoring and control instruments placed on the market before 22 July 2017 and have been used in an EEE placed in the market before 22 July 2027;
e) the spare parts used have been recovered from another EEE placed on the market before 22 July 2019 and have been used in an EEE placed in the market before 22 July 2029 and not covered by items 1 to 10 of Article 22f(2).

§ 13. (Repealed, SG No. 17/2019, effective 26.02.2019).

§ 14. The Council of Ministers shall adopt the ordinance referred to in Article 21e, Paragraph 1 within three months of the promulgation of this Act in the State Gazette.

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TRANSITIONAL AND FINAL PROVISIONS
to the Act Amending and Supplementing the Protection Against the Harmful Impact of Chemical Substances and Mixtures Act
(SG No. 102/2015)

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§ 32. (1) Authorisations for making available on the market of biocidal products issued prior to the entry into force of this Act pursuant to the repealed Article 19d, Paragraph 1 shall remain valid until the expiry of the period for which they were granted, subject to compliance with the conditions for authorisation.
(2) The persons holding authorisations other than those referred to in Paragraph 1 shall, within one month of the entry into force of this Act, submit to the Ministry of Health documents proving that the supplier of the active substances or of the biocidal product is included in the European Chemicals Agency list under Article 95 (1) of Regulation (EU) No. 528/2012 for the product-types

to which the biocidal product belongs, such as letters of access within the meaning of Article 3 (1)(t) of that Regulation, contracts, invoices, etc.
(3) If within one month of the entry into force of this Act the persons other than those referred to in Paragraph 1 fail to submit the documents referred to in Paragraph 2 or if the documents submitted do not prove that the supplier of the active substances or of the biocidal product is included in the European Chemicals Agency list under Article 95 (1) of Regulation (EU) No. 528/2012, the Minister of Health shall cancel the authorisation for making available on the market of a biocidal product.
(4) Authorisations for making available on the market of biocidal products issued prior to the entry into force of this Act other than those referred to in Paragraph 1, for which the documents referred to in Paragraph 2 have been submitted shall remain valid until the expiry of the period for which they were granted, subject to compliance with the conditions for authorisation.

§ 33. (1) The persons holding authorisations for making available on the market of biocidal products constituting mixtures within the meaning of Regulation (EC) No. 1272/2008 (CLP) and classified in accordance with the requirements of the ordinance referred to in Article 5, Paragraph 2 prior to the entry into force of this Act shall submit to the Ministry of Health an application for amendment of the authorisation no later than 1 June 2017, attaching the following thereto:
1. proposal for classification and labelling of the biocidal product pursuant to Regulation (EC) No. 1272/2008 (CLP);
2. summary of the reasons for the proposed classification and labelling of the biocidal product, including the methods, data, calculations, criteria, etc. used;
3. documents confirming all data about the chemical constituents and the biocidal product stated in the summary, including test records, safety data sheets under Annex II to Regulation (EC) No. 1907/2006, etc.;
4. declaration that the chemical composition and all other data relating to the biocidal product are identical to the chemical composition and data on the basis of which the first authorisation was granted;
5. design of the label of the biocidal product in Bulgarian;
6. safety data sheet of the biocidal product in Bulgarian in accordance with the requirements of Annex II to Regulation (EC) No. 1907/2006.
(2) The documents referred to in Paragraph 1 shall be submitted in Bulgarian – one paper copy and three copies in electronic format, accompanied by a declaration that the information submitted on paper is identical to the information submitted in electronic format.
(3) Authorisations issued prior to the entry into force of this Act for which applications for amendment have been submitted within the time limit referred to in Paragraph 1, shall remain valid, subject to compliance with the conditions for authorisation.
(4) The Minister of Health shall cancel the authorisations issued prior to the entry into force this Act for which applications for amendment were not submitted within the time limit referred to in Paragraph 1.
(5) The Minister of Health shall review the authorisations granted under Paragraph 1 in the cases referred to and following the procedure referred to in Article 18d.

§ 34. The provisions of Article 18i, Paragraph 2 shall apply after the necessary technical and organisational conditions have been put in place.

§ 35. Within three months of the entry into force of this Act the Council of Ministers shall bring the ordinance referred to in Article 21e, Paragraph 1 in compliance with it.

TRANSITIONAL AND FINAL PROVISIONS
to the Act to Amend and Supplement the Protection Against
the Harmful Impact of Chemical Substances and Mixtures Act
(SG No. 53/2018, effective 26.06.2018)

§ 25. (1) By 1 July 2019, the Council of Ministers shall, on a proposal by the Minister of Health, adopt a national plan concerning the measures for phasing down the use of dental amalgam pursuant to Article 10 (3) of Regulation (EU) 2017/852.
(2) The national plan referred to in Paragraph 1 shall be published on the website of the Ministry of Health and, within one month of its adoption, shall be forwarded to the European Commission.

§ 26. Within one year of the entry into force of this Act, the Council of Ministers shall adopt the ordinance referred to in Article 20a, Paragraph 3 on a proposal by the Minister of Environment and Water, the Minister of Defence, and the Minister of Economy.

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FINAL PROVISIONS
to the Act to Amend and Supplement the Protection Against
the Harmful Impact of Chemical Substances and Mixtures Act
(SG No. 17/2019, effective 26.02.2019)

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§ 5. This Act shall enter into force on the day of its promulgation in the State Gazette, except for § 4, which shall enter into force as of 1st August 2016.

TRANSITIONAL AND FINAL PROVISIONS
to the Act to Amend and Supplement
the Agricultural Producers Support Act
(SG No. 102/2022, effective 1.01.2023)

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§ 62. In the Protection Against the Harmful Impact of Chemical Substances and Mixtures Act (SG No. 10/2000; amended, SG No. 91/2002, SG No. 86 and 114/2003, SG No. 100 and 101/2005, SG No. 30, 34, 80 and 95/2006, SG No. 53 and 82/2007, SG No. 110/2008, SG No. 63 and 98/2010, SG No. 84/2012, SG No. 61/2014, SG No. 102/2015, SG No. 12 and 58/2017, SG No. 53 and 98/2018, SG No. 17/2019 and SG No. 19/2021) everywhere the words "The Minister of Agriculture, Food and Forestry" shall be replaced by "The Minister of Agriculture".

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