Please note that this is only unofficial working translation. According to Polish law, only acts promulgated in the Journal of Laws of the Republic of Poland (*Dziennik Ustaw*) can be considered as a source of law. The act in Polish, as published in Dziennik Ustaw, can be found here: Act on chemical substances and their mixtures (in Polish).

ACT

of 25 February 2011

on the chemical substances and their mixtures

Chapter 1

General Provisions

Article 1. The Act determines the competence of the authorities within the scope of executing administrative tasks and duties resulting from:

1) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1, with subsequent amendments), hereinafter referred to as "Regulation No 1907/2006";

2) Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (OJ L 104, 08.04.2004, p. 1, with subsequent amendments; OJ, Special Polish Edition, chapter 13, vol. 34, p. 48, with subsequent amendments), hereinafter referred to as "Regulation No 648/2004";

3) Regulation (EC) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of dangerous chemicals (OJ L 201, 27.07.2012, p. 60, with subsequent amendments), hereinafter referred to as "Regulation No 649/2012";

4) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006(OJ L 353, 31.12.2008, p. 1), hereinafter referred to as "Regulation No 1272/2008".

2. This Act regulates the conditions or the bans of manufacturing, placing on the market or use of chemical substances, hereinafter referred to as "substances", on their own, as ingredients in mixtures or in articles, within the scope unregulated by the provisions of the Regulations referred to in paragraph 1.

3. This Act does not apply to the conditions of transport of substances and mixtures, including also the conditions of transit movements under customs supervision where they are not in the course of processing or repacking during the transit.

4. The provisions of this Act do not apply to:

1) substances and mixtures being radioactive sources, within the scope laid down in separate provisions;

2) waste within the meaning of the provisions on waste;

3) substances and mixtures in the form of finished products intended for final users, being:

a) medicinal products within the meaning of the provisions of the pharmaceutical law,

b) foodstuffs within the meaning of the provisions concerning safety of food and nutrition,

c) feedingstuffs within the meaning of the provisions concerning feedingstuffs,

d) plant protection products within the meaning of the provisions concerning plant protection, with the exception of the provisions concerning classification of these products with respect to their risks, studies of their physical and chemical properties, toxicity and ecotoxicity, packaging and its labelling, provisions issued by virtue of Article 26(1), provisions of Articles 36, 41, 43 and 46 and penal provisions for incompliance with the regulations laid down in paragraph 1 items 1, 3 and 4,

e) cosmetics within the meaning of the provisions concerning cosmetics, with the exception of Articles 29 and 30, Articles from 36 to 40, Article 43(2), Articles 49 and 50, Articles from 57 to 60 and Article 64, and provisions issued pursuant to Article 16(15), Article 17(4) and Article 26,

f) invasive medical devices, within the meaning of the provisions concerning medical devices, or medical devices intended for use in direct contact with the human body, where these provisions identify their classification and labelling ensuring the same level of information and protection for human health and the environment as the provisions of the Act, with the exception of Articles 29 and 30, Articles from 36 to 40, Article 43(2), Articles 49 and 50, Articles from 57 to 61 and Article 64 and provisions issued pursuant to Article 26

– unless special provisions provide otherwise;

4) substances and mixtures imported to the territory of the Republic of Poland, where their quantity and type indicate that they are exclusively intended for private purposes.

Article 2. Whenever the Act mentions:

1) Substances – it means substances pursuant to Article 3(1) of Regulation No 1907/2006;

2) Mixtures – it means mixtures or solutions pursuant to Article 3(2) of Regulation No 1907/2006;

3) Article – it means an object pursuant to Article 3(3) of Regulation No 1907/2006, unless the Act provides otherwise;

4) Detergent – it means a substance or mixture pursuant to Article 2(1) of Regulation No 648/2004;

5) Surfactant – it means a substance or mixture pursuant to Article 2(6) of Regulation No 648/2004;

6) Registrant – it means a person pursuant to Article 3(7) of Regulation No 1907/2006;

7) Manufacturing – it means processes pursuant to Article 3(8) of Regulation No 1907/2006;

8) Manufacturer – it means a person pursuant to Article 3(9) of Regulation No 1907/2006, unless the Act provides otherwise;

9) Producer of an Article – it means a person pursuant to Article 3(4) of Regulation No 1907/2006;

10) Import - it means the physical introduction pursuant to Article 3(10) of Regulation No 1907/2006;

11) Importer - it means a person pursuant to Article 3(11) of Regulation No 1907/2006;

12) Downstream user - it means a person pursuant to Article 3(13) of Regulation No 1907/2006;

13) Distributor - it means a person pursuant to Article 3(14) of Regulation No 1907/2006;

14) Supplier of a substance or mixture – it means a person pursuant to Article 3(32) of Regulation No 1907/2006;

15) Supplier of an article– it means a person pursuant to Article 3(33) of Regulation No1907/2006;

16) Recipients of a substance or a mixture – it means a person pursuant to Article 3(34) of Regulation No 1907/2006;

17) Recipient of an article – it means a person pursuant to Article 3(35) of Regulation No 1907/2006;

18) Actor in the supply chain – it means a person pursuant to Article 3(17) of Regulation No 1907/2006;

19) Placing on the market – it means processes pursuant to Article 3(12)of Regulation No 1907/2006, unless the Act provides otherwise;

20) Use - it means processes pursuant to Article 3(24) of Regulation No 1907/2006;

21) Restriction – it means a restriction pursuant to Article 3(31) of Regulation No 1907/2006;

22) Safety data sheet – it means a safety data sheet pursuant to Article 31 of Regulation No 1907/2006;

23) Agency – it means the European Chemicals Agency as established by Regulation No 1907/2006;

24) Alternative generic name - it means a generic name which does not identify a substance in detail on the grounds of keeping trade secret;

25) Good Laboratory Practice – it means a quality system concerning the organisational process and conditions of

planning, conducting and monitoring of non-clinical studies of substances and mixtures with respect to human health and the natural environment, and recording, archiving and reporting their results;

26) Hazard class – it means a hazard class pursuant to Article 2(1) of Regulation No 1272/2008;

27) Hazard category – it means a hazard category pursuant to Article 2(2) of Regulation No 1272/2008;

28) Export – it means export pursuant to Article 3(16) of Regulation No 649/2012;

29) Importation – it means import pursuant to Article 3(17) of Regulation No 649/2012;

30) Chemicals – it means chemicals pursuant to Article 3(1) of Regulation No 649/2012.

Article 3. 1. In case of certain substances, on their own, or as ingredients in a mixture or in articles, where necessary for the needs of the State's defence, exemptions from application of Regulation No 1907/2006 shall be allowed, exclusive of the provisions laid down in Title IV of this Regulation.

2. In case of certain substances, on their own, or as ingredients in a mixture, where necessary for the needs of the State's defence, exemptions from application of Article 40 of Regulation No 1272/2008 shall be allowed.

3. The exemptions referred to in paragraphs 1 and 2, shall be granted in the form of a decision by the Minister of the National Defence, in consultation with the ministers in charge of health and economy issues.

Article 4. 1. The dangerous substances and mixtures are the substances and mixtures classified under at least one of the following categories:

1) Substances and mixtures with explosive properties;

2) Substances and mixtures with oxidising properties;

3) Extremely flammable substances and mixtures;

4) Highly flammable substances and mixtures;

5) Flammable substances and mixtures;

6) Very toxic substances and mixtures;

7) Toxic substances and mixtures;

8) Harmful substances and mixtures;

9) Corrosive substances and mixtures;

10) Irritant substances and mixtures;

11) Sensitising substances and mixtures;

12) Carcinogenic substances and mixtures;

13) Mutagenic substances and mixtures;

14) Reprotoxic substances and mixtures;

15) Substances and mixtures hazardous to the environment.

2. The hazardous substances and hazardous mixtures are these substances and mixtures classified under at least one of the hazard categories listed in Parts from 2 to 5 of Annex I to Regulation No 1272/2008.

Chapter 2

Inspector for Chemical Substances

Article 5. A central authority of the government administration competent for the matters of substances and their mixtures, i.e. the Inspector for Chemical Substances, hereinafter referred to as the "Inspector", is established.

Article 6. 1. The Inspector is appointed by the Minister in charge of health issues from among candidates selected through an open and competitive recruitment process, following consultation with the ministers in charge of economy and environment issues.

2. The Minister in charge of health issues supervises the Inspector.

3. The Minister in charge of health issues recalls the Inspector, following consultation with the ministers in charge of economy and environment issues.

Article 7. The position of the Inspector may be held by a person that:

1) holds the professional title of Master or equivalent;

2) is the Polish national;

3) enjoys full civil rights;

4) has not been convicted of an intentional offence or intentional fiscal offence by a judgment which has the force of res iudicata;

5) holds managerial competence;

6) has been in full-time employment for at least 6 years, including at least 3 years of full-time employment at a managerial position;

7) holds experience and knowledge in the field of issues covered by the competence of the Inspector.

Article 8. 1. The information on recruitment concerning the position of the Inspector is published by placing an ad in the place that is accessible to the general public in the premises of the Bureau for Chemical Substances, hereinafter referred to as the "Bureau", and in the Public Information Bulletin and the Public Information Bulletin of the Office of the President of the Council of Ministers. The ad should include:

1) the name and address of the Bureau;

2) the job description;

3) the requirements related with the position, which result from the rules of law;

4) the scope of the tasks performed under the position;

5) the list of required documents;

6) the deadline and place of submitting these documents;

7) the information on the recruitment methods and techniques.

2. The deadline stipulated in paragraph 1(6), may not be shorter than 10 days following the publication of the ad in the Public Information Bulletin of the Office of the President of the Council of Ministers.

Article 9. 1. Recruitment concerning the position of the Inspector is conducted by a team, hereinafter referred to as the "Team", appointed by the Minister in charge of health issues composed of at least 3 persons whose knowledge and experience guarantee that the best candidates are selected.

2. During the recruitment process, the candidate's professional experience,

knowledge necessary to carry out the tasks related with the position for which the recruitment process is conducted, and managerial competence, are assessed.

3. The knowledge and managerial competence referred to in paragraph 2, may be appraised by a person not being the team member and holding relevant qualifications necessary to conduct this appraisal, and who has been commissioned by the team.

4. A member of the team and the person referred to in paragraph 3, are obliged to keep confidential the information concerning persons applying for this position that has been obtained during the recruitment process.

5. Within the recruitment process, the team selects no more than 3 candidates to be presented to the minister in charge of health issues.

Article 10. 1. The team drafts a report from the recruitment process, which should include the following information:

1) the name and address of the Bureau;

2) the description of the position for which the recruitment process has been conducted and the number of the candidates;

3) the first and last names and addresses, within the meaning of the provisions of the Civil Code Act of 23 April 1964 (Dz. U. No 16, item 93, with subsequent amendments), of no more than 3 best candidates ranked according to the level at which they have met the requirements listed in the ad, or the information that no candidate has been selected;

4) the information of the recruitment methods and techniques applied;

5) the justification of the selection made or reasons why no candidate has been selected;

6) the composition of the Team: the first and last name, job position held, work telephone number and electronic mail address at work.

2. The result of the recruitment process is published without delay by placing information in the Public Information Bulletin of the Bureau and the Public Information Bulletin of the Office of the President of the Council of Ministers. The information on the conclusion of the recruitment process should contain:

1) the name and address of the Bureau;

2) the description of the position for which the recruitment process has been conducted;

3) the first and last names of the candidates selected and their places of residence within the meaning of the provisions of the Civil Code Act of 23 April 1964 or the information that no candidate has been selected.

3. Publication of the result of the job ad in the Public Information Bulletin of the Office of the President of the Council of Ministers is free of charge.

Article 11. The provisions of the Administrative Code Act of 14 June 1960 (Dz. U. of 2000 No 98, item 1071, with subsequent amendments) are applicable for the decisions and resolutions issued by the Inspector, however the minister in charge of health issues is an appellate authority in relation to the Inspector.

Article 12. 1. The tasks of the Inspector include:

1) Gathering data concerning dangerous mixtures or hazardous mixtures, and information on substances received from the Agency;

2) Providing medical and emergency services with the data on dangerous substances and dangerous mixtures or hazardous substances and hazardous mixtures;

3) Performing the function:

a) of the competent authority designated to execute administrative tasks laid down in the European Union regulations in the field of export and import of dangerous chemicals, and cooperate in this field with other member states of the European Union and the European Commission,

b) of the competent authority designated to execute administrative tasks laid down in the European Union regulations in the field of detergents, and cooperate in this field with other member states of the European Union, Swiss Confederation or member states of the European Free Trade Association (EFTA) – parties to the Agreement on the European Economic Area and the European Commission,

c) of the competent authority laid down in Article 8 of Regulation No 648/2004, in Article 121 of Regulation No 1907/2006, in Article 43 of Regulation No 1272/2008, and of the designated national authority laid down in Article 4 of Regulation No 649/2012,

d) of the competent authority designated to execute tasks in the field of making registration laid down in Article 3(6) of Regulation No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors (OJ L 047 of 18.02.2004, with subsequent amendments);

4) Establishing in the Bureau and running the National Helpdesk pursuant to Article 124 of Regulation No 1907/2006 and Article 44 of Regulation No 1272/2008;

5) Cooperation with international organisations in the field of substances and mixtures;

6) Executing tasks laid down in the regulations concerning drug prevention;

7) Executing other tasks delegated by the minister in charge of health issues;

8) Dissemination of knowledge on harmful impact of chemical substances and their mixtures on human health and on the environment, and knowledge on prevention of such impact;

9) Annual submission to the European Commission and to the Organisation for Economic Co-operation and Development (OECD), hereinafter referred to as "OECD", not later than by 31 March of the next year, of the information for the previous year in the field of functioning of Good Laboratory Practice within the territory of the Republic of Poland.

2. The Inspector implements his/her tasks with assistance of the Bureau,

which he/she manages and represents before third parties.

Article 13. 1. Detailed tasks of the Inspector, organisation of the Bureau and principles of his/her cooperation with the European Commission and the OECD, in the field of Good Laboratory Practice are laid down in the Statute of the Bureau.

2. The minister in charge of health issues grants the Statute of the Bureau by virtue of a decree, having regard to appropriate implementation of the tasks delegated to the Inspector.

Article 14. The ministers in charge of health, economy, labour and environment issues, each one of them within the scope of their competence, may indicate research institutes or other subordinate entities appropriate for cooperation with the Inspector when executing his/her tasks related to the evaluation of substances and their mixtures provided for in this Act.

Chapter 3

Informing about dangerous or hazardous mixtures

Article 15. 1. A natural or legal person that manufactures a dangerous mixture or hazardous mixture in the territory of the Republic of Poland and places such a mixture on the market, and a natural or legal person that brings such a mixture to the territory of the Republic of Poland, shall inform the Inspector of this mixture. This information is submitted through data transmission in the form of an electronic document from the system that uses software whose compliance with the requirements specified by the Bureau pursuant to Article 13(2), item 2, letter a of the Act on the informatization of activities undertaken by entities fulfilling public tasks of 17 February 2005 (Dz. U. of 2014 item 1114) has been confirmed in the way laid down in Articles 21 and 22 of this Act. This information is submitted in the case of manufacturing of the mixture in the territory of the Republic of Poland on the date of placing it on the market at the latest, and In the case the mixture is brought to the territory of the Republic of Poland, on the date it is brought at the latest.

2. The information referred to in paragraph 1 shall include:

1) The first and last name and address of the place of conducting business activity or name (business name) and address of the registered office, as well as the telephone number and electronic address of the entity submitting this information;

2) The trade name of the mixture;

3) The application of the mixture;

4) The date of submission of this information or updating thereof;

5) The information on substances contained in the mixture:

   a) The detailed information permitting the identification in accordance with Article 18(2) of Regulation No 1272/2008,

   b) the information on the concentrations of the substances in the mixture in accordance with section 3.2 of Annex II to Regulation No 1907/2006;

6) Classification of the mixture in accordance with Article 19 or the provisions of Regulation No 1272/2008;

7) The safety data sheet for the mixture or where there is no obligation to deliver the safety data sheet, where it has not been compiled, the information laid down in sections 2 and 3 of Annex II to Regulation No 1907/2006.

3. Provision of paragraph 1 is also applicable in the case of changing the trade name of the mixture.

4. Where the information laid down in paragraph 1 has been amended, the persons referred to in paragraph 1 are obliged to submit this information to the Inspector within the deadline of 14 days following the date of its update.

5. The information laid down in paragraph 1, which is beyond the scope of the information required to compile the safety data sheet for a mixture, stipulated in Annex II to Regulation No 1907/2006, is a business secret and may only be used for medical purposes to prevent risks posed by these mixtures and to provide medical treatment particularly in the event of an emergency, or for statistical purposes to conduct an analysis to identify the areas which may require implementation of improved risk control measures.

6. Where the Inspector decides that there are justifiable grounds that allow to consider that the mixture constitutes an unacceptable risk to human health or to the environment, he/she may request in a decision, the person referred to in paragraph 1 to disclose the detailed chemical composition of the mixture.

Chapter 4

Tests of substances and preparations

Article 16. 1. Where the provisions issued pursuant to this Act, provisions of the regulations listed in Article 1(1) or separate provisions require that substances or their mixtures should be tested in accordance with the principles of Good Laboratory Practice, such tests shall be conducted by entities which conduct tests of substances or their mixtures, and hold a certificate of Good Laboratory Practice, and have been registered in the register of the Good Laboratory Practice certified test facilities, hereinafter referred to as the "certified test facilities".

2. The inspection and verification whether an entity which tests substances and their mixtures, hereinafter referred to as the "test facility", complies with the principles of Good Laboratory Practice in order to grant it a Good Laboratory Practice certificate and register it in the register of the certified test facilities shall be conducted at a request of this facility.

3. The Bureau is a competent authority for the inspection and verification of compliance with the principles of Good Laboratory Practice by the test facilities. The inspection and verification of compliance with the principles of Good Laboratory Practice by the test facilities are conducted by Good Laboratory Practice inspectors, who are each time designated by the Inspector from among employees of the Bureau and for whom the Inspector ensures periodical training, including the training organized by the OECD. In justifiable cases, where it is required by the nature of a test facility or of the tests it conducts, other persons designated by the Inspector may take part in the inspection and verification.

4. At a request of the Good Laboratory Practice inspectors, the Inspector confirms in a decision that the test facility complies or does not comply with the principles of Good Laboratory Practice. The Inspector confirms the compliance with the principles of Good Laboratory Practice by issuing a Good Laboratory Practice certificate and registering the facility in the register of the certified test facilities. The certificate and the register entry of the certified test facilities specify the scope of the tests conducted by the certified test facility in accordance with the principles of Good Laboratory Practice.

4a. The certificate referred to in paragraph 4 also includes:

1) the number of the certificate;

2) the reference to the legal basis to carry out the inspection and verification;

3) the date on which the inspection and verification were conducted;

4) the name of the certified test facility;

5) the date on which the certificate was issued;

6) the first and last names of the Good Laboratory Practice inspectors who have conducted the inspection and verification as well as their signatures;

7) the first and last name of the Inspector and his/her signature.

5. The Inspector publishes the up-to-date register of the certified test facilities and the National Good Laboratory Practice Compliance Monitoring Programme, which is referred to in Directive No 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice (GLP) (Official Journal L 50 of 20.02.2004, p. 28, with subsequent amendments; Official Journal, Special Edition in Polish, Chapter 15, V. 8, p. 65), in the Bureau's Public Information Bulletin.

6. Where a test facility is registered outside of the territory of the Republic of Poland, it shall be recognized that this facility complies with the principles of Good Laboratory Practice following the submission of a valid certificate or another appropriate document granted to this facility by a competent authority responsible for the inspection and verification of compliance with the principles of Good Laboratory Practice in member states of the OECD or other states in which such authorities have been established in agreement with the OECD.

7. The certified test facilities are subject to periodical or *ad hoc* inspections and verifications of compliance with the principles of Good Laboratory Practice for which the provisions pursuant to paragraph 3 and paragraph 4 shall apply. The inspection and verification may also be organized at a request of the competent authorities responsible for the inspection and verification of compliance with the principles of Good Laboratory Practice in the countries referred to in paragraph 6, or competent authorities responsible for Good Laboratory Practice at the European Commission and the OECD.

8. Where a certified test facility does not comply with the principles of Good Laboratory Practice, the Inspector shall revoke in a decision the certificate granted and delete this facility from the register of the certified test facilities.

8a. Where it is established that a specific test or tests were performed in a manner incompliant with the principles of Good Laboratory Practice, the Inspector shall confirm in a decision that the principles of Good Laboratory Practice were not complied with in terms of the specific test or tests.

9. The inspection and verification of compliance with the principles of Good Laboratory Practice pursuant to paragraphs 2 and 7 are conducted based on a written authorisation issued by the Inspector, which should include:

1) the first and last name, and the number of a document which confirms identity of the Good Laboratory Practice inspector or the person referred to in paragraph 3 who will conduct the inspection and verification;

2) the name of test facility or certified test facility, where the inspection and verification are conducted.

3) the date of performance of the inspection and verification, description of their scope and envisaged duration.

10. Good Laboratory Practice inspectors and the persons referred to in paragraph 3 conducting the inspection and verification shall be authorised to:

1) enter the property, facilities and premises of the test facility or certified test facility where the inspection and verification are conducted, on the normal working days and during the normal working hours of this facility;

2) have access to the documentation, including raw data, and request information and explanations concerning the tests of substances or their mixtures carried out by this test facility or certified test facility.

11. The inspection and verification are conducted in presence of an authorised representative of the test facility or certified test facility where the inspection and verification are conducted.

11a. Prior to commencing their duties, Good Laboratory Practice inspectors and other persons designated by the Inspector to conduct the inspection and verification, shall submit a written statement in which they declare that there are no connections between them and the inspected test facility or certified test facility, or entity that have contracted the test facility or certified test facility that could impact impartiality of their assessment. Good Laboratory Practice inspectors and other persons designated by the Inspector to conduct the inspection and verification, shall inform the Inspector of arising circumstances that could impact impartiality of their assessment, also in the case where such circumstances have occurred in the course of the proceedings.

11b. Where the Good Laboratory Practice inspectors or other persons designated by the Inspector to conduct the inspection and verification have during the inspection and verification access to the information which constitutes a business secret of an enterprises in the meaning of article 11(4) of the Act of 16 April 1993 on combating unfair competition (Dz. U. of 2003 No 153, item 1503, with subsequent amendments), such information may not be disclosed. Where such information is included in a protocol from the completed inspection and verification, the protocol may be disclosed upon a request of appropriate national authorities, the European Commission, test facilities or certified test facilities which have

undergone the inspection and verification, and where it concerns a specific test – the entity contracting this test.

12. A protocol from the completed inspection and verification is drafted and submitted for signature of the authorised representative of the test facility or certified test facility where the inspection and verification have been conducted. The protocol from the inspection and verification of the certified test facility may include post-inspection recommendations.

13. Within the deadline of 14 days following the receipt of the protocol, the test facility or certified test facility may submit its reservations with regard to the protocol including explanation thereof. The Inspector shall consider the reservations within the deadline of 30 days following the receipt of these reservations and rule on the issue raised. The Inspector's ruling is final and is delivered, including the justification, to the test facility or certified test facility.

14. The certified test facility for which the post-inspection recommendations have been presented in the protocol from the inspection and verification is obliged to implement them, otherwise the certificate shall be revoked and the relevant entry in the register of the certified test facilities deleted.

15. The minister in charge of health issues in consultation with the minister in charge of economy issues, the minister in charge of environment and the minister in charge of agriculture issues shall lay down in a regulation:

1) the principles of Good Laboratory Practice,

2) the way of conducting the inspection and verification referred to in paragraphs 2 and 7,

3) the procedure of granting and withdrawing the Good Laboratory Practice certificate and deleting the certified test facilities from the register of the certified test facilities

– having regard to the relevant binding provisions of the European Union and the OECD and in order to guarantee adequate quality of tests.

Article 17. 1. The inspection and verification of compliance with the principles of Good Laboratory Practice by test facilities in the case referred to in:

1) Article 16(2) – are subject to a one-time fee whose proof of payment the test facility submits with an application to grant the certificate and entry in the register of the certified test facilities;

2) Article 16(7) – are subject to a fixed annual fee.

2. Where a test facility receives the certificate and entry in the register of the certified test facilities, the one-time fee referred to in paragraph 1(1) shall become its annual fee referred to in paragraph 1(2) for the year in which the test facility has received the certificate.

3. The fees referred to in paragraph 1 may not exceed the actual costs incurred by the Bureau with respect to delivery of the relevant inspection or verification, or the issue of the certificate.

3a. Where the fixed annual fee referred to in paragraph 1(2) has not been paid, the Inspector in a decision shall revoke the granted certificate and delete the

certified test facility from the register referred to in Article 16(4).

4. The minister in charge of health issues shall lay down in a regulation the amount and way of making the payment referred to in paragraph 1, in particular having regard to the scope of actions conducted by the Good Laboratory Practice inspectors and employees of the Bureau in relation to the inspection and verification of compliance with the principles of Good Laboratory Practice by the test facilities, or to the issue of the certificate.

Chapter 5

Classification, labelling, packaging, placing on the market and use of substances and their mixtures

Article 18. Manufacturers, importers and distributors of substances that have not been listed in table 3.2 of Annex VI to Regulation No 1272/2008, are obliged to gather reliable information concerning potential risks to human health or to the environment resulting from their intrinsic physical, chemical and biological properties, and to provide access to such information for recipients of such substances in accordance with the principles set out in Regulation No 1907/2006.

Article 19. 1. Substances and mixtures are subject to the classification procedure in order to establish their eligibility to be classified under the categories pursuant to Article 4(1). In case of plant protection products causing risk to human health or to the environment, the statements indicating the type of risk shall also be assigned.

2. Classification shall be carried out in case of:

1) substances or mixtures being placed on the market – the person implementing this placement;

2) substances that have not been placed on the market, and Article 6, Article 7(1) or (5),Article 17 or Article 18 of Regulation No 1907/2006 provides the obligation to register the substance – the registrant;

3) substances that have not been placed on the market, and Article 7(2) or Article 9(2) of Regulation No 1907/2006 envisages the obligation of submitting information – the person making this submission.

3. Substances listed in table 3.2 of Annex VI of Regulation No 1272/2008 shall be classified in accordance with this table, with a reservation that the classification performed for the specific items presented in this table concerns hazard categories specified in these items. Any other hazards caused by such a substance, if applicable, shall be identified on the basis of the classification performed in accordance with the provisions issued pursuant to paragraph 5.

4. Classification of the substances that are not listed in table 3.2 of Annex VI to Regulation No 1272/2008 and mixtures shall be performed in accordance with the provisions issued pursuant to paragraph 5.

5. The minister in charge of health issues in consultation with the ministers in charge of economy, environment, labour and agriculture issues shall lay down in a regulation:

1) the criteria and the way of performing the classification of substances and mixtures based on their physico-chemical properties, toxicity, analysis

of specific effects on human health and analysis of specific effects of impacts on the environment,

2) the way of performing classification of mixtures based on the contents of dangerous ingredients,

3) the concentration of dangerous substances in a mixture which requires that these substances should be included in the classification of this mixture,

4) (repealed),

5) the phrases indicating the type of risk (R-Phrases) and their numbers,

6) (repealed)

– having regard to the provisions binding in the European Union and having regard to the protection of human health and the environment.

6. The provisions of paragraphs from 1 to 5 shall apply in accordance with Article 61(1-5) of Regulation No 1272/2008, with a reservation that references to Directives 67/548/EEC and 1999/45/EC in this Regulation shall mean the references to paragraphs from 1 to 4 of the provisions issued pursuant to paragraph 5 and to Article 4(1).

Article 20. 1. Packaging of dangerous substances and dangerous mixtures and of certain mixtures placed on the market must be adequately labelled.

2. Labelling of the packaging containing a dangerous substance or dangerous mixture shall contain:

1) the name that will enable conclusive identification of the dangerous substance or dangerous mixture;

2) the name, the address of registered office and telephone number of the operator, and in case of a natural person, the first and last name, address of his/her business, and the telephone number of the person placing this substance or mixture on the market;

3) in the case of dangerous mixtures:

a) the name of dangerous substances,

b) the alternative generic names of dangerous substances

– if applicable;

4) the danger symbol or symbols and phrases explaining their meaning;

5) the phrase of phrases indicating a type of risk (R-Phrases), and in the case of plant protection products, additional statements indicating a specific type of risk to human health or the environment placed in accordance with the provisions concerning the classification of substances and their mixtures;

6) the phrase or phrases of safe use (S-Phrases), and in the case of plant protection products, additional statements indicating the conditions of their safe use.

3. (repealed).

4. In case of certain types or categories of dangerous substances or dangerous mixtures, and certain types of packaging, the packaging labelling need not include all the elements referred to in paragraph 2.

5. In case of dangerous mixtures made available to the general public, the packaging labelling shall contain

information on the nominal quantity of the mixture in the package, unless this information is specified elsewhere on the package.

6. In case of a substance listed in table 3.2 of Annex VI to Regulation No 1272/2008, the packaging labelling shall contain the EC number, if it has been assigned to a given substance, and the wording "EC Labelling".

7. Packaging labelling of a dangerous substance or dangerous mixture shall have adequate dimensions depending on the volume of the packaging.

8. Packaging labelling of a dangerous substance or dangerous mixture placed on the market in the territory of the Republic of Poland should be in Polish, in accordance with the requirements specified in the provisions concerning the Polish language.

9. Packaging of dangerous substances and dangerous mixtures must not bear any markings indicating that such a substance or such a mixture is not dangerous.

10. In case of certain mixtures, including the ones not classified as dangerous, the packaging labelling shall contain additional wording that will be of relevance to the user.

11. The minister in charge of health issues in consultation with the ministers in charge of economy, labour, agriculture and environment issues shall lay down in a regulation:

1) the way of packaging labelling of dangerous substances and dangerous mixtures,

2) the way of forming the name that will enable a conclusive identification of the dangerous substance or dangerous mixture,

3) the categories of dangerous substances whose names are placed on the labelling of the packaging of dangerous mixtures,

4) (repealed).

5) the templates of danger symbols and wording explaining their meaning, and the criteria of displaying these symbols on the labelling of packaging of dangerous substances and dangerous mixtures,

6) the wording of phrases of safe use (S-Phrases), and additional statements indicating conditions of safe use displayed on the labelling of the packaging of plant protection products, and the criteria of assigning these statements,

7) the types and categories of dangerous substances and dangerous mixtures, and the types of packaging whose label need not contain all the elements referred to in paragraph 2, including specification of these elements,

8) the contents of additional statements, and also the criteria of displaying them on the labelling of the packaging of certain mixtures,

9) the dimensions of the label depending on the volume of the package

– having regard to the protection of human health and the environment.

12. Provisions laid down in paragraphs from 1 to 11 shall apply in accordance with Article 61(1–5) of

Regulation No 1272/2008, with a reservation that the references to Directives 67/548/EEC and 1999/45/EC in this Regulation shall mean the references to paragraphs from 1 to 10 of the provisions issued pursuant to paragraph 11 and to Article 4(1).

Article 21. 1. Containers and tanks intended for storage of hazardous substances or hazardous mixtures, and containers and tanks for working with these substances or mixtures, pipes containing hazardous substances or hazardous mixtures intended for their transport, and sites where significant quantities of hazardous substances or hazardous mixtures are stored, should be properly labelled, including the danger symbols to be displayed.

2. It is possible to waive the labelling referred to in paragraph 1, where the containers and tanks are used to work with the substances and mixtures classified in accordance with Regulation 1272/200***8*** as hazardous due to their risks to health or due to physical properties for a short time duration or where the contents of a container or tank is frequently changed.

3. The minister in charge of health issues in consultation with the ministers in charge of economy, labour and environment issues shall lay down in a regulation:

1) the way of labelling the containers and tanks intended for storage of hazardous substances or hazardous mixtures and containers and tanks for working with these substances or mixtures, pipes containing hazardous substances or hazardous mixtures intended for their transport, and sites where significant quantities of hazardous substances or hazardous mixtures are stored,

2) the conditions in which the labelling may be waived as laid down in paragraph 2

– having regard to ensuring the safety and health at the workplace.

Article 22. 1. Packaging of dangerous substances and dangerous mixtures placed on the market:

1) should have a construction that will prevent any incidental escape of the contents from the packaging; this requirement is not applicable where the specific technical safety devices are required;

2) should be made of the materials resistant to damaging impacts of its contents and preventing formation of dangerous substances resulting from impact of the contents on the packaging material;

3) should maintain tightness in the conditions of loads and tensions impacting the packaging in the course of its normal handling;

4) in case of packaging fitted with replaceable fastening devices – they should ensure that their tightness shall be maintained in the course of repeated opening and closing operations in the conditions of normal handling;

5) in case of packaging containing dangerous mixtures intended for sale to consumers, it shall not have:

a) a shape or a graphic design likely to attract or arouse the curiosity of children or to mislead consumers,

b) a similar presentation or a marking used for foodstuff or animal feeding stuff or medicinal or cosmetic products.

2. If the transport packaging satisfies the requirements of the rules on the transport of dangerous goods it shall be deemed to be equivalent to satisfying the requirements referred to in paragraph 1 (1–3).

3. The packaging of certain dangerous substances or dangerous mixtures offered or sold to consumers shall be fitted with child-resistant fastening or tactile warning of danger, irrespective of its capacity.

4. The child-resistant fastening or tactile warning of danger shall meet the requirements of the standards laid down in the provisions issued pursuant to paragraph 7.

5. Compliance with the standards referred to in paragraph 4 may only be confirmed by entities which meet the requirements of the EN 45 000 series standard, or by equivalent entities, by granting a certificate.

6. Conducting tests of the child-resistant fastenings provided for in the standards referred to in paragraph 4 is not obligatory if it seems obvious that the packaging is sufficiently safe for children as it is not possible to open it without tools. In any other cases, and if there are concerns that the packaging of a dangerous substance or dangerous mixture for which the child-resistant fastening is required is not sufficiently safe for children, the competent enforcement bodies may require the person responsible for placing the product on the market to present the certificate issued by the entity referred to in paragraph 5 that confirms the following details:

1) the type of fastening is such that conducting tests verifying the child-resistant fastenings fitted in reclosable packages or in non-reclosable packages is unnecessary, or

2) the fastening has been tested and it has been confirmed that it complies with the standards referred to in paragraph 4.

7. The minister in charge of health issues in consultation with the minister in charge of economy issues shall lay down in a regulation:

1) the categories of dangerous substances and dangerous mixtures whose packaging shall be fitted with child-resistant fastenings and tactile warning of danger,

2) the requirements concerning fastenings and warnings referred to in item 1, and the standards to be met by such fastenings and tactile warnings

- in order to ensure the protection of human health and the environment and the relevant binding provisions of the European Union.

8. The provisions of paragraphs from 1 to 7 shall apply in accordance with Article 61 (1–4) of Regulation No 1272/2008, with a reservation that the references to Directives 67/548/EEC and 1999/45/EC in this Regulation shall mean the references to paragraphs from 1 to 6 and provisions issued pursuant to paragraph 7.

Article 23. Where it is decided that trade of specific categories of dangerous substances and dangerous mixtures or hazardous substances and hazardous

mixtures may cause unacceptable risk to the general public, the minister in charge of health issues in consultation with the minister in charge of economy issues may lay down in a regulation:

1) the categories of these dangerous substances and dangerous mixtures or hazardous substances and hazardous mixtures,

2) the requirements concerning qualifications to be held by the persons who place such dangerous substances and dangerous mixtures or hazardous substances and hazardous mixtures on the market within the territory of the Republic of Poland,

3) the method of confirming the qualifications provided for in item 2 held by nationals of the European Union member states and member states of the European Free Trade Association (EFTA) – parties to the Agreement on the European Economic Area or the Swiss Confederation

- having regard to the need for the protection of human health and the environment from the risks caused by these dangerous substances and dangerous mixtures or hazardous substances and hazardous mixtures.

Article 24. 1. Advertising a dangerous substance without declaring the hazard category under which this substance has been classified shall be prohibited.

2. Any advertisement for a dangerous mixture or a mixture that is required to be labelled pursuant to the provisions issued by virtue of Article 20(11) and which allows consumers to purchase such a mixture without first having sight of the label placed on the packaging shall mention the type or types of risks indicated on the label.

Article 25. The manufacturer, importer and downstream user are obliged to assemble, keep and update on the ongoing-basis a list of dangerous substances and dangerous mixtures or hazardous substances and hazardous mixtures they manufacturer, import or use.

Article 26. 1. Where it has been established that the manufacturing, placing on the market or use of a dangerous substance, dangerous mixture, hazardous substance or hazardous mixture cause an unjustified risk to human health or to the environment, or where it results from international agreements, the minister in charge of economy issues, at a request of the ministers in charge of health, environment and agriculture issues, shall lay down in a regulation the following restrictions:

1) manufacturing, placing on the market or use of such a substance or mixture,

2) placing on the market or use of articles containing such a substance or mixture

– in particular having regard to the use of such a substance or mixture, use in the concentration or proportions exceeding the specific level, the presence in the specific concentrations or quantities in specific articles.

2. In cases specified in Annex XVII to Regulation No 1907/2006, the minister in charge of economy issues may lay down in a regulation the way of using the restrictions specified in the Annex, having regard to the objectives of these restrictions.

Article 27. 1. Where there are justifiable grounds to believe that a mixture constitutes an unacceptable risk to human health or to the environment, even if the person placing this mixture on the territory of the Republic of Poland complies with all the requirements of the Act, the Inspector may prohibit in a decision placing this mixture on the market in the territory of the Republic of Poland for a specified period of time which however will not exceed 3 months, or prescribe conditions that must be fulfilled during placing this mixture on the market.

2. The decision referred to in paragraph 1 may also be issued at a request of the Chief Sanitary Inspector or of the Chief Inspector for the Environmental Inspection.

Article 27a. Where a downstream user of a substance on its own or in a mixture, contrary to the provisions of Article 37(4) of Regulation No 1907/2006 does not prepare the required chemical safety report, the Inspector may ban, at a request of a (district) public sanitary inspector submitted through the Chief Sanitary Inspector or at a request of the Chief Inspector for the Environmental Inspection, in a decision, placing this substance on the market or using it in the territory of the Republic of Poland until such chemical safety report is prepared, or prescribe the deadline, after which this decision shall be issued where the required chemical safety report is not prepared within the deadline prescribed.

Article 28. 1. Where there are justifiable grounds to believe that a detergent constitutes a risk to safety or health of humans or a risk to the environment, although complying with the requirements of Regulation No 648/2004, following the receipt of an opinion of the Chief Sanitary Inspector and an opinion of the Chief Inspector for Environmental Protection, the Inspector may prohibit in a decision placing this detergent on the market in the territory of the Republic of Poland for a specified period of time which however will not exceed 6 months, or prescribe conditions that must be fulfilled during placing it on the market, and which at the same time fulfil the requirements laid down in Article 15(1) of Regulation No 648/2004.

2. The Inspector in a decision shall lift the prohibition referred to in paragraph 1 or extend it by another 6 months accordingly with the results of the consultations provided for in Article 15(2) of Regulation 648/2004.

3. The Inspector shall lift the prohibition referred to in paragraph 1 pursuant to his/her decision taken following the decision provided for in Article 15(2) of Regulation No 648/2004.

4. The decision referred to in paragraph 1 may also be issued at a request of the Chief Sanitary Inspector, the Chief Inspector for Environmental Protection or the President of the Office for Competition and Consumer Protection.

Chapter 6

Provisions on enforcement

Article 29. Enforcement of the compliance with the provisions of this Act and the provisions of the regulations referred to in Article 1(1) is delivered by the State Sanitary Inspection, the State Sanitary Inspection of the Ministry of Internal Affairs and Administration and the Military Sanitary Inspection, within the scope of their competence, and also

1) The Inspection for Environmental Protection – as regards risks to the environment concerning:

a) correctness of safety data sheets as regards:

– procedure to apply in case of unintended release of a substance or mixture to the environment,

– storage of a substance or mixture,

– handling of waste,

– ecological information,

b) Compliance of downstream users with the obligations laid down in Article 37(5) and (6) of Regulation No 1907/2006 concerning application of risk management measures – within the scope necessary to ensure that the risk to the environment is adequately controlled,

c) Compliance with the conditions of the authorization in accordance with the provisions of Title VII of Regulation No 1907/2006 to use chemical substances specified in Annex XIV of Regulation No 1907/2006,

d) Compliance of downstream users with the provisions concerning restrictions on manufacturing, placing on the market and use of chemical substances and their mixtures in accordance with Article 26 of the on their own or in mixtures; Act or provisions laid down in Article 67 of Regulation No 1907/2006 – within the scope of its competence,

e) Compliance with the provisions of Regulation No 1907/2006 concerning recovered substances;

2) The State Labour Inspection – as regards the enforcement and inspection of compliance with the provisions of this Act - within the scope of its competence;

3) The Trade Inspection – as regards the compliance with:

a) the obligation of performing the required registration of a substance and the obligation of providing the recipient of a substance or mixture with the required safety data sheet,

b) the provisions of Article 26 of the Act the provisions of Article 67 of Regulation No 1907/2006 – within the scope of its competence,

c) the provisions of Article 11 of Regulation No 648/2004 – as regards labelling of detergents sold within wholesale and retail,

d) Article 20 and Article 22 of the Act and provisions of Titles III and IV of Regulation No 1272/2008 – with reference to wholesale and retail;

4) The State Fire Service – as regards adequate marking of the places where the substances and mixtures referred to in items from 1 to 5 of Article 4(1) of the Act and in part 2 of Annex I of Regulation No 1272/2008 are stored;

5) The customs authorities - as regards compliance with the provisions concerning:

a) export and importation of dangerous chemicals referred to in Regulation No 649/2012,

b) a substance, mixture or article whose import has been prohibited or is subject of a restriction in the field of

import, in accordance with the provisions issued pursuant to Article 26,

c) import of a substance, mixture or article referred to in Title VII of Regulation No 1907/2006,

d) import of a substance, mixture or article referred to in Annex XVII of Regulation No 1907/2006; customs authorities shall notify the competent state sanitary inspector of any cases of import of substances, mixtures or articles that raise their doubts with respect to the importers' compliance with the conditions listed in this Annex.

Article 30. The authorities listed in Article 29 shall carry out the enforcement in accordance with the principles and within their competencies specified in separate provisions.

Chapter 7

Penal provisions

Article 31. Any person who contrary to the decision of the Inspector issued pursuant to Article 27(1), Article 27a or Article 28(1) places on the market a mixture that causes unacceptable risk to human health or to the environment, or a substance without the necessary chemical safety report or a detergent that raises justifiable grounds to believe that it causes a risk to human health or to the environment,

shall be subject to the penalty by fine, penalty by restricted liberty or penalty of imprisonment for up to 2 years.

Article 32. 1. Any person who contrary to the provisions of Article 15(2) of Regulation No 649/2012 exports chemicals or an article, within the meaning of Article 3(4) of this Regulation, listed in Annex V to this Regulation,

shall be subject to the penalty by fine, penalty by restricted liberty or penalty of imprisonment for up to 2 years.

2. Any person who contrary to the provisions of Article 14(6) of Regulation No 649/2012 exports the chemicals listed in Annex I Part 2 or 3 to this Regulation without receiving the information from the Inspector that the designated national authorities of the importing Party or the competent authorities of another importing country have consented to this import or that the export may take place in accordance with the provisions of Article 14(7) of this Regulation, shall be subject to the same penalty.

Article 33. 1. Any person who contrary to the provisions of Article 8(2) of Regulation No 649/2012 does not notify the Inspector of the export of chemicals listed in Part 1 of Annex I to this regulation, no later than 35 days prior to the first export and no later than 35 days prior to the first export in any subsequent calendar year,

shall be subject to the penalty by fine.

2. Any person who contrary to the provisions of Article 10(1) of Regulation No 649/2012 does not notify the Inspector in the first quarter of each year of the quantities of exported and imported chemicals (in the form of a substance or contained in mixtures or in articles) listed in Annex I to this regulation in the previous year, shall be subject to the same penalty.

3. Any person who contrary to the provisions of Article 17 of Regulation No 649/2012 exports chemicals without labelling used in the European Union or without the required safety data sheet, shall be subject to the penalty provided for in paragraph 1.

Article 34. 1. Any person who without receiving the required consent to derogation referred to in Article 5 of Regulation No 648/2004, places on the market a surfactant intended for use in detergents or a detergent containing a surfactant not fulfilling the conditions stipulated in Article 4(3) of this Regulation,

shall be subject to the penalty by fine, penalty by restricted liberty or penalty of imprisonment for up to 2 years.

2. Any person who contrary to the conditions of the derogation granted pursuant to Article 5 of Regulation No 648/2004, places on the market or uses a surfactant intended for use in detergents or a detergent containing a surfactant, shall be subject to the same penalty.

3. Any person who contrary to the provision of Article 4a of Regulation No. 648/2004 places on the market detergents not complying with the requirements concerning the content of phosphates and of other compounds of phosphorus referred to in Annex Via to this Regulation, shall be subject to the penalty provided for in paragraph 1.

Article 35. 1. A manufacturer, within the meaning of Article 2(10) of Regulation No 648/2004, who contrary to the provisions of Article 11(2-6) of this Regulation places on the market a detergent without the required labelling or labelled incorrectly, and in particular, does not display the required information on the packaging of the detergents or in the documents accompanying detergents transported in bulk,

shall be subject to the penalty by fine.

2. A manufacturer, within the meaning of Article 2(10) of Regulation No 648/2004, who contrary to the provisions of Article 9 of this Regulation does not provide the required information at the request of the Inspector or medical personnel, shall be subject to the same penalty.

3. A manufacturer, within the meaning of Article 2(10) of Regulation No 648/2004, who contrary to the provision of Annex VII D to this Regulation, does not provide the required information on a website, shall be subject to the penalty provided for in paragraph 1.

Article 36. 1. Any person who contrary to the restrictions provided for in the provisions pursuant to Article 26(1) manufactures, places on the market or uses a dangerous substance, hazardous substance, dangerous mixture, hazardous mixture or an article containing such a substance or mixture,

shall be subject to the penalty by fine, penalty by restricted liberty or penalty of imprisonment for up to 2 years.

2. Any person who contrary to the provisions of Article 67 of Regulation No 1907/2006, manufactures, places on the market or uses a substance, on its own, in a mixture or in an article for which a restriction has been specified in Annex XVII to this Regulation, or acts in this way contrary to the restriction set out in this Annex or in the provisions issued pursuant to Article 26(2) of this Act, shall be subject to the same penalty.

Article 37. A manufacturer, importer or downstream user who contrary to the provisions of Article 56 (1-6) of Regulation No 1907/2006 or contrary to the conditions stipulated in the authorisation, places on the market or uses a substance listed in Annex XIV to this Regulation,

shall be subject to the penalty by fine, penalty by restricted liberty or penalty of imprisonment for up to one year.

Article 38. A registrant who conducts studies involving vertebrate animals or outsources their conduct contrary to the provisions of Article 26 (3) of Regulation No 1907/2006,

shall be subject to the penalty by fine, penalty by restricted liberty or penalty of imprisonment for up to one year.

Article 39. A manufacturer, importer or producer of an article who contrary to the provision of Article 9(6) of Regulation No 1907/2006 does not fulfil the conditions imposed by the Agency in accordance of Article 9(4) of this Regulation,

shall be subject to the penalty by fine.

Article 40. A downstream user who contrary to the provision of Article 37(5) of Regulation No 1907/2006 does not identify, does not use, and where suitable, does not recommend appropriate measures to control risks adequately,

shall be subject to the penalty by fine.

Article 41. A manufacturer, importer or a downstream user who contrary to the provision of Article 19(1) of this Act or Article 4(1) of Regulation No 1272/2008 who places on the market a substance or mixture without classification of this substance or mixture that has been derived in accordance with the provisions of this Act or this Regulation respectively, shall be subject to the penalty by fine.

Article 42. Any person who contrary to the provision of Article 19(2) of this Act or Article 4(2) of Regulation No 1272/2008 does not classify a substance not yet placed on the market or classifies it in the way that does not fulfil the requirements specified in the provisions of this Act or this Regulation,

shall be subject to the penalty by fine.

Article 43. 1. Any person who places on the market a dangerous substance or dangerous mixture or a mixture requiring a specific labelling, without the labelling required pursuant to the provisions of Article 20 or with the labelling that does not comply with these requirements,

shall be subject to the penalty by fine.

2. The same penalty shall be used for any person who contrary to Article 65 of Regulation No 1907/2006 does not include the required authorisation number on the label of the substance or mixture before placing this substance or mixture on the market.

Article 44. 1. A supplier of a substance or mixture who contrary to Article 4(4) of Regulation No1272/2008 places a hazardous substance or mixture without labelling prepared in accordance with Title III of this Regulation,

shall be subject to the penalty by fine.

2. The same penalty shall be used for any supplier of a substance or mixture, who contrary to the provision of Article 30 of Regulation No 1272/2008 does not update information contained in the label.

Article 45. Any person who contrary to the provision of Article 21 does not ensure

appropriate labelling of the containers and tanks intended for storage of hazardous substances or hazardous mixtures and working with them, pipes containing hazardous substances or hazardous mixtures or used for their transport, and sites where significant quantities of hazardous substances or hazardous mixtures are stored,

shall be subject to the penalty by fine.

Article 46. 1. Any person who contrary to the provision of Article 22 does not ensure required packaging for dangerous substances and dangerous mixtures,

shall be subject to the penalty by fine.

2. The same penalty shall be used for any supplier of a substance or mixture, who contrary to the provision of Article 4(4) of Regulation No 1272/2008 places on the market a hazardous substance or mixture without packaging that complies with the requirements of Title IV of this Regulation.

Article 47. 1. Any person who advertises a dangerous substance without declaring categories laid down in Article 4(1) under which it has been classified, shall be subject to the penalty by fine.

2. The same penalty shall be used for any person who advertises a dangerous mixture or mixture for which by virtue of the provision issued pursuant to Article 20(11) the labelling is required, if this advertisement does not contain the information about the type or types of hazards listed on the label placed on the packaging of this mixture, where this advertisement facilitates its purchase by consumers without prior examining of the label on its packaging.

Article 48. 1. Any person who advertises a hazardous substance without declaring its classes and categories of the hazards related with this substance,

shall be subject to the penalty by fine.

2. The same penalty shall be used for any person, who without declaring the type or types of hazards listed on the label advertises the hazardous mixture or mixture pursuant to Article 25(6) of Regulation No 1272/2008 facilitates its purchase by consumers without prior examining of the label.

Article 49. A registrant who contrary to the provisions of Article 22(1),(2) and (4) of Regulation No 1907/2006 does not fulfil the obligation of recording the required new information in the registration dossier and does not submit it to the Agency, or does not update the registration dossier as required,

shall be subject to the penalty by fine.

Article 50. An owner of the study results who contrary to the provisions of Article 30(1), (3) and (4) of Regulation No 1907/2006 refuses to provide within the deadline prescribed the documents that prove the expenses incurred with respect to this study or to provide within the deadline prescribed the study documentation to a participant of the Substance Information Exchange Forum (SIEF),

shall be subject to the penalty by fine of up to 50 000 PLN.

Article 51. 1. Any person who contrary to the provision of Article 7(1) of Regulation No 1272/2008 conducts new test on animals,

shall be subject to the penalty by fine, penalty by restricted liberty or penalty of imprisonment for up to one year.

2. The same penalty shall be used for any person who contrary to the provisions of Article 7(2) and (3) of Regulation No 1272/2008 conducts tests on non-human primates or tests on humans.

3. The penalty laid down in paragraph 1 shall be used to any person who conducts tests on vertebrates in order to obtain information on substances and mixtures, contrary to Article 8(1) of Regulation No 1272/2008.

Article 52. 1. A supplier of a substance or mixture who contrary to the provisions of Article 31(1) and (3-8) of Regulation No 1907/2006 does not submit the required safety data sheet developed in accordance with Annex II to this Regulation,

shall be subject to the penalty by fine.

2. The same penalty shall be used for any supplier of a substance or mixture who contrary to the provision of Article 31(9) of Regulation No 1907/2006 submits an outdated safety data sheet.

Article 53. 1. Any supplier of a substance or mixture who contrary to the provisions of Article 32 of Regulation No 1907/2006 does not submit the required information,

shall be subject to the penalty by fine.

2. The same penalty shall be used for any supplier of a substance or mixture who does not perform the required update of the information referred to in paragraph

Article 54. 1. Any supplier of an article containing a substance meeting the criteria laid down in Article 57 of Regulation No 1907/2006 and identified in accordance with Article 59(1) of this Regulation in a concentration above 0.1% weight by weight, who contrary to the provision of Article 33(1) of this Regulation does not supply the recipient of this article with the information required,

shall be subject to the penalty by fine.

2. The same penalty shall be used for any supplier of an article, who contrary to the provision of Article 33(2) of Regulation No 1907/2006 does not provide the consumer with the required information at his/her request.

Article 55. 1. Any actor in the supply chain of a substance or mixture, who contrary to the provision of Article 34 of Regulation No 1907/2006 does not communicate the required information to the next actor or distributor up the supply chain,

shall be subject to the penalty by fine.

2. The same penalty shall be used for any distributor, who contrary to the provision of Article 34 of Regulation No 1907/2006 does not communicate the information received in accordance with paragraph 1 to the next actor up the supply chain.

Article 56. 1. Any person who contrary to the provision of Article 36 of Regulation No 1907/2006 does not keep or makes available the information required of him in order to fulfil the duties resulting from the provisions of this Regulation,

shall be subject to the penalty by fine.

2. The same penalty shall be used for any person who contrary to the provision of Article 49 of Regulation No 1272/2008 does not keep or makes

available the information he/she used for the purpose of classification and labelling pursuant to the provisions of this Regulation.

Article 57. 1. Any downstream user who contrary to the provisions of Article 37(4) and (7) of Regulation No 1907/2006, does not prepare or update the required chemical safety report within the deadlines laid down in Article 39(1) of this Regulation,

shall be subject to the penalty by fine of at least 2 000 PLN.

2. The same penalty shall be used for any downstream user who contrary to the provision of Article 38 of Regulation No 1907/2006, does not communicate the required information to the Agency or does not update this information within the deadlines laid down in Article 39(2) of this Regulation.

3. Any distributor who contrary to the provision of Article 37(2) of Regulation No 1907/2006 does not communicate the required information to the next actor or distributor up the supply chain, shall be subject to the penalty referred to in paragraph 1.

Article 58. Any registrant or any downstream user who contrary to the decision of the Agency made pursuant to Article 40(3) of Regulation No 1907/2006 does not provide the Agency with the required information within the deadline prescribed,

shall be subject to the penalty by fine.

Article 59. 1. Any registrant who contrary to the decision of the Agency made pursuant to Article 41(3) of Regulation No 1907/2006 does not submit the required information within the deadline prescribed in order to ensure compliance of the registration dossier with the provisions of this Regulation,

shall be subject to the penalty by fine.

2. The same penalty shall be used for any registrant who contrary to the decision of the Agency made pursuant to Article 46(1) of Regulation No 1907/2006 does not provide the Agency with the required further information within the deadline prescribed.

Article 60. Any downstream user who contrary to the provision of Article 66(1) of Regulation No 1907/2006 and within the deadline specified in this provision does not communicate the use of the substance referred to in Article 56(2) of this Regulation to the Agency,

shall be subject to the penalty by fine.

Article 61. 1. Any person who contrary to the provisions of Article 40(1) and (3) of Regulation No 1272/2008 places on the market the substance referred to in Article 39 of this Regulation without communicating the required information to the Agency,

shall be subject to the penalty by fine.

2. The same penalty shall be used for any person who does not communicate to the Inspector the required information referred to in Article 15 of this Act, or contrary to Article 40(2) of Regulation No 1272/2008,does not update this information.

Article 62. Any person who contrary to the obligation does not ensure that his or her employees and their representatives have access to the information submitted pursuant to the provisions of Article 31 and Article 32 of Regulation No 1907/2006 with

reference to the substances or mixtures they use or they are likely to be exposed to during their work,

shall be subject to the penalty by fine.

Article 63. Any person who pays a reduced fee or charge pursuant to Articles 3 to 10 of Regulation No 340/2008 of the Commission Regulation (EC) No 340/2008 of 16 April 2008 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 107, 17.04.2008, p. 6), or uses an exemption from payment of the charge pursuant to Article 74(2) of Regulation No 1907/2006 without being entitled to do so,

shall be subject to the penalty by fine.

2. The same penalty shall be used for any person who pays a reduced fee pursuant to Articles 3 and 4 of the Commission Regulation (EC) No 440/2010 of 21 May 2010 on the fees payable to the European Chemicals Agency pursuant to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 126, 22.05.2010, p. 1) without being entitled to do so.

Article 64. Judgment with respect to the offences referred to in Article 35, Articles 41–49 and Articles 52–63, shall be delivered pursuant to the provisions of the Act of 24 August 2001 – the Petty Offences Procedure Code (Dz. U. of 2013, item 395, with subsequent amendments).

Chapter 8

Amendments to the binding provisions

Article 65. In the Act of 26 June 1974 – the Labour Code (Dz. U. of 1998 No 21, item 94, with subsequent amendments) the following amendments are introduced: (amendments disregarded).

Article 66. In the Act of 14 March 1985 on the State Sanitary Inspection (Dz. U. of 2006 No 122, item 851, with subsequent amendments):

the following amendments are introduced: (amendments disregarded).

Article 67. In the Act of 20 July 1991 on the Inspection for Environmental Protection (Dz. U. of 2007 No 44, item 287, with subsequent amendments)

In Article 2(1) in item 12, letter a shall be replaced by the following: (amendments disregarded).

Article 68. In the Act of 15 December 2000 on the Trade Inspection (Dz. U. 2009 No 151, item 1219 and of 2010 No 182, item 1228) the following amendments are introduced: (amendments disregarded).

Article 69. In the Act of 30 March 2001 on cosmetics (Dz. U. No 42, item 473, with subsequent amendments) the following amendments are introduced: (amendments disregarded).

Article 70. In the Act of 27 April 2001 – the Environmental Protection Law (Dz. U. of 2008 No 25, item 150, with subsequent amendments) (amendments disregarded).

Article 71. In the Act of 11 May 2001 on packaging and packaging waste (Dz. U. No 63, item 638, with subsequent amendments) In Article 3(3), item 3a shall

be replaced by the following: (amendments disregarded).

Article 72. In the Act of 6 September 2001 – Pharmaceutical Law (Dz. U. of 2008 No 45, item 271, with subsequent amendments) the following amendments are introduced: (amendments disregarded).

Article 73. In the Act of 13 September 2002 on biocidal products (Dz. U. of 2007 No 39, item 252, with subsequent amendments), the following amendments are introduced: (amendments disregarded).

Article 74. In the Act of 28 October 2002 on Liability of Collective Entities for acts prohibited by penalty (Dz. U. No 197, item 1661, with subsequent amendments) In Article 16(1), in item 8 letter b shall be replaced by the following: (amendments disregarded).

Article 75. In the Act of 17 October 2003 on underwater work (Dz. U. No 199, item 1936, with subsequent amendments) In Article 2, item 19 shall be replaced by the following: (amendments disregarded).

Article 76. In the Act of 12 December 2003 on general safety of products (Dz. U. No 229, item 2275, with subsequent amendments) Article 24a shall be replaced by the following: (amendments disregarded).

Article 77. In the Act of 18 December 2003 on plant protection products (Dz. U. of 2008 No 133, item 849, with subsequent amendments) the following amendments are introduced: (amendments disregarded).

Article 78. In the Act of 20 April 2004 on the substances that deplete the ozone layer (Dz. U. No 121, item 1263, of 2005 No 175, item 1458 and No 203, item 1683 and of 2009 No 215, item 1664) Article 6(4) shall be replaced by the following: (amendments disregarded).

Article 79. In the Act of 20 January 2005 on the recycling of end of life vehicles (Dz. U. No 25, item 202, with subsequent amendments) In Article 3 in item 14, the full stop shall be replaced with the semicolon, and the following item 15 shall be inserted: (amendments disregarded).

Article 80. In the Act of 21 January 2005 on experiments on animals (Dz. U. No 33, item 289, of 2006 No 171, item 1225 and No 220, item 1600 and of 2009 No 18, item 97) In Article 16(1), item 6 shall be replaced by the following: (amendments disregarded).

Article 81. In the Act of 29 July 2005 on counteracting drug addiction (Dz. U. No 179, item 1485, with subsequent amendments), the following amendments are introduced: (amendments disregarded).

Article 82. In the Act of 29 July 2005 on waste electrical and electronic equipment (Dz. U. No 180, item 1495, of 2008 No 223, item 1464 and of 2009 No 79, item 666 and No 215, item 1664), the following amendments are introduced: (amendments disregarded).

Article 83. In the Act of 13 April 2007 on prevention of damage to the environment and its remediation (Dz. U. No 75, item 493 and of 2008 No 138, item 865 and No 199, item 1227) in Article 3(2), in item 1 letter a shall be replaced by the following: (amendments disregarded).

Article 84. In the Act of 27 August 2009 on Customs Service (Dz. U. No 168, item 1323 and No 201, item 1540 and of 2010 No 182, item 1228)

In Article 2(1) item 4 shall be replaced by the following: (amendments disregarded).

Chapter 9

Transitional and Final Provisions

Article 85. 1. On the date of entry of this Act into force, the Inspector for Chemical Substances and Preparations appointed pursuant to the previous provisions shall become the Inspector for Chemical Substances.

2. On the date of entry of this Act into force, the Bureau for Chemical Substances and Preparations established pursuant to the previous provisions shall become the Bureau for Chemical Substances.

3. On the date of entry of this Act into force, employees of the Bureau for Chemical Substances and Preparations established pursuant to the previous provisions shall become employees of the Bureau for Chemical Substances.

4. The Statute of the Bureau for Chemical Substances and Preparations established pursuant to the previous provisions shall remain effective until the date of entry into force of secondary legislation issued pursuant to Article 13(2) of the Act, however for no longer than 12 months following the date of entry of this Act into force.

Article 86. Whenever separate provisions refer to the Inspector for Chemical Substances and Preparations or the Bureau for Chemical Substances and Preparations, it shall mean the Inspector for Chemical Substances or the Bureau for Chemical Substances respectively.

Article 87. 1. The previous legislation will be applicable to the proceedings that started prior to the date of entry of this Act into force and were not completed prior to this date.

2. The fee pursuant to Article 17(1) item 2, shall be payable for the first time following the expiry of the period for which the fee charged pursuant to the previous legislation has been paid.

3. The certificates confirming that a test facility complies with the principles of Good Laboratory Practice granted by virtue of a decision by the Inspector for Chemical Substances and Preparations prior to the date of entry of this Act into force shall remain effective throughout the period for which they have been granted.

4. The first list of certified test facilities referred to in Article 16(1), covers these facilities that received the certificates confirming their compliance with the principles of Good Laboratory Practice prior to the date of entry of this Act into force.

Article 88. Secondary legislation (regulations) issued pursuant to:

1) Article 4(2), Article 24(2) and (5), Article 26, Article 27(2), Article 28(3) and Article 31 of the Act referred to in Article 89, shall remain effective until the date of entry into force of the secondary legislation issued pursuant to Article 16(15), Article 17(4), Article 19(5), Article 20(11), Article 21(3), Article 22(7)and Article 26 of this Act,

2) Article 33c of the Act referred to in Article 89, shall remain effective until the date of entry into force of the secondary legislation issued pursuant to Article 27b(6) of the Act referred to in Article 66, in the wording of this Act,

3) Article 222(3) of the Act referred to in Article 65, shall remain effective until the date of entry into force of the secondary legislation issued pursuant to Article 222 § 3 of the Act referred to in Article 65, in the wording of this Act,

4) Article 27b(4) of the Act referred to in Article 66, shall remain effective until the date of entry into force of the secondary legislation issued pursuant to Article 27b(4) of the Act referred to in Article 66, in the wording of this Act– however for no longer than 12 months following the date of entry of this Act into force.

Article 89. The Act of 11 January 2001 on chemical substances and preparations (Dz. U. of 2009 No 152, item 1222 and of 2010 No 107, item 679 and No 182, item 1228) is hereby repealed.

Article 90. The provisions of Article 20(3) and (11) item 4 are hereby repealed as of 1 June 2015.

Article 91. This Act will enter into force 14 days following its publication.