Dz. U. of 2011 No 63, item. 322

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ACT

of 25 February 2011

on the chemical substances and their mixtures[1], [2]

1 This Act amends: Act of 26 June 1974 – Labour Code, Act of 14 March 1985 on the State Sanitary Inspection, Act of 20 July 1991 on the Environmental Protection Inspection, Act of 15 December 2000 on the Trade Inspection, Act of 30 March 2001 on Cosmetics, Act of 27 April 2001 – the Environmental Protection Law, Act of 11 May 2001 on Packaging and Packaging Waste, Act of 6 September 2001 – Pharmaceutical Law, Act of 13 September 2002 on Biocidal Products, Act of 28 October 2002 on Liability of Collective Entities for acts prohibited by penalty, Act of 17 October 2003 on Underwater Work, Act of 12 December 2003 on the General Safety of Products, Act of 18 December 2003 on Plant Conservation, Act of 20 April 2004 on the substances that deplete the ozone layer, Act of 20 January 2005 on the recycling of end of life vehicles, Act of 21 January 2005 on experiments on animals, Act of 29 July 2005 on counteracting drug addiction, Act of 29 July 2005 on waste electrical and electronic equipment, Act of 13 April 2007 on prevention of damage to the environment and its remediationand Act of 27 August 2009 on the Customs Service.

2 This Act regulates the implementation of the following directives:

1) Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to classification, packaging and labelling of dangerous substances (OJ L 196 of 16.08.1967, p. 1, with subsequent amendments; OJ, Special Polish Edition, Chapter 13, v. 1, p. 27),

2) Directive 92/58/EEC of 24 June 1992 on the minimum requirements for the provision of safety and/or health signs at work (the ninth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC) (OJ L 245, 26.08.1992, p. 23, with subsequent amendments; OJ, Special Polish Edition, Chapter 5, v. 2, p. 89),

3) Directive 1999/45/EC of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to classification, packaging and labelling of dangerous preparations (OJ L 200, 30.07.1999, with subsequent amendments; OJ, Special Polish Edition, Chapter 13, v. 24, p. 109),

4), Directive 2004/9/EC of 11 February 2004 on the inspection and verification of good laboratory practice (GLP) (OJ L 50, 20.02.2004, p. 28, with subsequent amendments; OJ, Special Polish Edition, Chapter 15, v. 8, p. 65),

5) Directive 2004/10/EC of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (OJ L 50, 20.02.2004, p. 44, with subsequent amendments; OJ, Special Polish Edition, Chapter 15, v. 8, p. 82),

6) Directive 2008/112/WE of 16 December 2008 amending Council Directives 76/768/EEC, 88/378/EEC, 1999/13/EC and Directives 2000/53/EC, 2002/96/EC and 2004/42/EC of the European Parliament and of the Council in order to adapt them to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (OJ L 345, 23.12.2008, p. 68).

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 689/2008 of the European Parliament and of the Council of 17 June 2008 on the export and import of dangerous chemicals (OJ L 204, 31.07.2008, p. 1), hereinafter referred to as "Regulation No 689/2008".

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 No1272/2008".

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 transport.

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) feeding stuffs within the meaning of the provisions concerning feeding stuffs,

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 and30, Articles from 36 to 40, Article 43(2), Articles 49 and50, 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 labeling 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 organizational 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 No1272/2008;

28) Export – it means export pursuant to Article 3(14)of Regulation No689/2008;

29) Delivery – it means import pursuant to Article 3(15)of Regulation No689/2008;

30) Chemicals – it means chemicals pursuant to Article 3(1)of Regulation No689/2008.

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 following 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 issuesfrom 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 office;

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[3]), 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 CodeAct 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.

[3]The amendments of the above Act has been published in the Dz. U. of 1971 No 27, item 252, of 1976 No 19, item 122, of 1982 No 11, item 81, No 19, item 147 and No 30, item 210, of 1984 No 45, item 242, 1985 No 22, item 99, of 1989 No 3, item 11, of 1990 No 34, item 198, No 55, item 321 and No 79, item 464, of 1991 No 107, item 464 and No 115, item 496, of 1993 No 17, item 78, of 1994 No 27, item 96, No 85, item 388 and No 105, item 509, of 1995 No 83, item 417, of 1996 No 114, item 542, No 139, item 46 and No 149, item 703, of 1997 No 43, item 272, No 115, item 741, No 117, item 751 and No 157, item 1040, of 1998 No 106, item 668 and No 117, item 758, of 1999 No 52, item 532, of 2000 No 22, item 271, No 74, item 855 and 857, No 88, item 983 and No 114, item 1191, of 2001 No 11, item 91, No 71, item 733, No 130, item 1450 and No 145, item 1638, of 2002 No 113, item 984 and No 141, item 1176, of 2003 No 49, item 408, No 60, item 535, No 64, item 592 and No 124, item 1151, of 2004 No 91, item 870, No 96, item 959, No 162, item 1692, No 172, item 1804 and No 281, item 2783, of 2005 No 48, item 462, No 157, item 1316 and No 172, item 1438, of 2006 No 133, item 935 and No 164, item 1166, of 2007 No 80, item 538, No 82, item 57 and No 181, item 1287, of 2008 No 116, item 731, No 163, item 1012, No 220, item 1425 and 1431 and No 228, item 1506, of 2009 No 42, item 341, No 79, item 662 and No 131, item 1075 and of 2010 No 40, item 222 and No 155, item 1037.

Article 11. The provisions of the Administrative Code Act of 14 June 1960 (Dz. U. of 2000 No 98, item 1071,with subsequent amendments[4]) 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 121of 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 689/2008;

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

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

6) Receiving and gathering data on the precursors of category 2 laid down in the regulations concerning drug prevention;

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

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

[4]The amendments of the consolidated text of this Act have been published in the Dz. U. of 2001 No 49, item 509, of 2002 No 113, item 984, No 153, item 1271 and No 169, item 1387, of 2003 No 130, item 1188 and No 170, item 1660, of 2004 No 162, item 1692, of 2005 No 64, item 565, No 78, item 682 and No 181, item 1524, of 2008 No 229, item 1539, of 2009 No 195, item 1501 and No 216, item 1676, of 2010 No 40, item 230, No 167, item 1131, No 182, item 1228 and No 254, item 1700 and of 2011 No 6, item 18 and No 34, item 173.

which he/she manages and represents before third parties.

Article 13. 1. Detailed tasks of the Inspector and organization of the Bureau and principles of his/her cooperation with the European Commission and the Organization for Economic Cooperation and Development (OECD), hereinafter referred to as 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 organizational entities appropriate for cooperation with the Inspector when executing his/her tasks related with 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 a natural or legal person that brings such a mixture to the territory of the Republic of Poland, shall notify the Inspector of this mixture.

2. The notification referred to in paragraph 1 shall be submitted on the date of manufacturing of this mixture or exporting thereof to the territory of the Republic of Poland at the latest. This information should include:

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

2) the trade name of this mixture;

3) the safety data sheet for this mixture.

3. In case of the lack of the obligation to submit the safety data sheet for a mixture, where it has not been drafted, the persons referred to paragraph 1 shall submit the information stipulated in items 2 and 3 of Annex II to Regulation 1907/2006.

4. Where the safety data sheet has been amended or the information pursuant to paragraph 3 has been amended, the persons referred to paragraph 1 are obliged to submit this information to the Inspector within the deadline of 14 days following the date of this amendment.

5. 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 that the detailed chemical composition of the mixture should be disclosed. This information is a business secret and may only be used for medical purposes to prevent and treat.

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 organizational entities which conduct tests of substances or their mixtures, 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 organizational 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 carried out 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 carried out 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 justified 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.

5. The Inspector publishes the up-to-date list of the certified test facility 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 consultation 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 provision pursuant to paragraph

3 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 states 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.

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 authorization issued by the Inspector, which should include:

1) the first and last name, and 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 authorized 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 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 this test facility or certified test facility conducts.

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

12. A protocol from the completed inspection and verification is drafted and submitted for signature of the authorized 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 findings.

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 decide on the issue raised. The Inspector’s decision is final and is delivered, including the justification, to the test facility or certified test facility.

14. The test facility or certified test facility for which the post-inspection findings 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 ministers 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 Unionand 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.

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 natural 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

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) the criteria of assigning statements informing of a specific risk to human health or to the environment, caused by plant protection products,

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

6) the additional statements indicating a specific type of risk to human health or to the environment, caused by plant protection products, and their numbers

– 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 warning marking or markings 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. The use of alternative generic name requires the consent of the Inspector. At the request of a person placing a dangerous mixture on the market, in his/her decision the Inspector consents or refuses to consent to use the alternative generic name for the dangerous substances contained in the mixture. The Inspector refuses to consent to use the alternative generic name for the dangerous substances contained in the mixture where the substance does not comply with the conditions laid down in the provisions issued pursuant to paragraph 11.

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 an 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) the way of receiving the consent of the Inspector to use an alternative generic name for certain dangerous substances contained in dangerous mixtures, and the conditions which the dangerous substance needs to comply with for the Inspector to grant this consent, and the way of forming the alternative generic name,

5) the templates of warning markings and wording explaining their meaning, and the criteria of displaying these markings 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 No1272/2008, 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.Vessels and tanks intended for storage of dangerous substances or dangerous mixtures, and vessels and tanks for working with these substances or mixtures, pipework containing dangerous substances or dangerous mixtures intended for their transport, and sites where significant quantities of dangerous substances or dangerous mixtures are stored, should be properly labelled, including the warning markings to be displayed.

2. It is possible to waive the labelling referred to in paragraph 1, where the vessels and tanks are used in a workplace for a short time duration or where the contents of a vessel 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 vessels and tanks intended for storage of dangerous substances or dangerous mixtures and vessels and tanks for working with these substances or mixtures, pipework containing dangerous substances or dangerous mixtures intended for their transport, and sites where significant quantities of dangerous substances or dangerous mixtures are stored,

2) the conditions in which the labelling may be waved as laid down in paragraph 1, where the vessels and tanks are used in a workplace for a short time duration or where the contents of a vessel or tank is frequently changed.

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

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 a hazard, irrespective of its capacity.

4. The child-resistant fastening or tactile warning of a hazard 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 organizational 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 them 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 a hazard,

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 labeled 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 of the Chief Inspector for the Environmental Inspection.

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 fulfill 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 Article37(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 Actor 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 delivery of dangerous chemicals referred to in Regulation No 689/2008,

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 the mode 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) or Article 28(1) places on the market a mixture that causes unacceptable risk to human health or to the environment, 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 by deprivation of liberty for up to 2 years.

Article 32. 1. Any person who contrary to the provisions of Article 14(2)of Regulation No 689/2008 exports chemicals or an article, within the meaning of Article 3(3) of the regulation, listed in Annex V to this Regulation,

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

2. Any person who contrary to the provisions of Article 13(6) of Regulation No 689/2008 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, shall be subject to the same penalty.

Article 33. 1. Any person who contrary to the provisions of Article 7(2) of Regulation No 689/2008 does not notify the Inspector of the export of chemicals listed in Part 1 of Annex I to this regulation, no later than 30 days prior to the first export and no later than 15 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 provision of Article 9(1) of Regulation No 689/2008 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 provision of Article 16 of Regulation No

689/2008 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 by deprivation of liberty for up to 2 years.

2. Any person whocontrary 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.

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 Regulationdoes 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 by deprivation of liberty for up to 2 years.

2. Any person who contrary to theprovisions 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 Article26(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 by deprivation of liberty 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 No1907/2006,

shall be subject to the penalty by fine, penalty by restricted liberty or penalty by deprivation of liberty 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. 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 ofArticle 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 fulfill 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 requiring a specific labelling, without the labeling 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 vessels and tanks intended for storage of dangerous substances or dangerous mixtures and working with them, pipework containing dangerous substances or dangerous mixtures or used for their transport,and sites where significant quantities of dangerous substances or dangerous 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 by deprivation of liberty 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)(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 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 fulfill 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 labeling 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 No 1907/2006does 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, Authorization 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.

Article 64. Judgment with respect to the offences referred to in Article 35, Articles 41–49 and Articles 52–63, shall be delivered pursuant the provisions of the Act of 24 August 2001 – the Petty Offences Procedure Code(Dz. U. of 2008 No 133, item 848, with subsequent amendments[5]).

[5]Amendments to the consolidated text of this Act were published in the Dz. U. of 2008 No 214, item 1344 and No 237, item 1651, of 2009 No 178, item 1375, No 190, item 1474 and No 206, item 1589 and of 2010 No 182, item 1228, No 197, item 1307 and No 225, item 1466.

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[6])the following amendments are introduced:

1) Article 220 § 3 shall be replaced by the following:

„§ 3. Provisions of § 2 are not applicable to chemical substances and their mixtures.";

2) Article 221 § 1–4 shall be replaced by the following:

„§ 1. The use of chemical substances and their mixtures that have not been labeled in a visible way to enable their identification shall be prohibited.

§ 2. The use of a dangerous substance, dangerous mixture, hazardous substance or hazardous mixture without holding an updated list of these substances and mixtures, safety data sheets, as well as packaging preventing from their hazardous impacts, fire or explosion shall be prohibited.

§ 3 The use of a dangerous substance, dangerous mixture, hazardous substance or hazardous mixture shall be allowed provided that the measures protecting health and life of workers are used.

§ 4. The principles of classification of chemical substances and their mixtures concerning risks they cause to health or life, the list of dangerous chemical substances, the requirements concerning safety data sheets and the way of their labeling are provided for in separate provisions.";

3) Article 222 shall be replaced by the following:

„Article 222 § 1. In case of employing employees in the conditions of exposure to chemical substances, their mixtures, agents or technological processes causing carcinogenicity or mutagenicity, the employer shall replace these chemical substances, their mixtures, agents or technological processes with less harmful to health, or use other available measures reducing the extent

[6]Amendments to the consolidated text of this Act were published in the Dz. U. of 1998 No 106, item 668 and No 113, item 717, of 1999 No 99, item 1152, of 2000 No 19, item 239, No 43, item 489, No 107, item 1127 and No 120, item 1268, of 2001 No 11, item 84, No 28, item 301, No 52, item 538, No 99, item 1075, No 111, item 1194, No 123, item 1354, No 128, item 1405 and No 154, item 1805, of 2002 No 74, item 676, No 135, item 1146, No 196, item 1660, No 199, item 1673 and No 200, item 1679, of 2003 No 166, item 1608 and No 213, item 2081, z 2004 r. No 96, item 959, No 99, item 1001, No 120, item 1252 i No 240, item 2407, z 2005 r. No 10, item 71, No 68, item 610, No 86, item 732 and No 167, item 1398, of 2006 No 104, item 708 and 711, No 133, item 935, No 217, item 1587 i No 221, item 1615, z 2007 r. No 64, item 426, No 89, item 589, No 176, item 1239, No 181, item 1288 and No 225, item 1672, of 2008 No 93, item 586, No 116, item 740, No 223, item 1460 and No 237, item 1654, of 2009 No 6, item 33, No 56, item 458, No 58, item 485, No 98, item 817, No 99, item 825, No 115, item 958, No 157, item 1241 and No 219, item 1704, of 2010 No 105, item 655, No 135, item 912, No 182, item 1228, No 224, item 1459, No 249, item 1655 and No 254, item 1700 and of 2011 No 36, item 181.

of this exposure having regard to the achievements of science and technology.

§ 2. The employer shall register all types of work which include contact chemical substances, their mixtures, agents or technological processes causing carcinogenicity or mutagenicity, and specified in the list referred to in § 3, as well as keep a register of the workers employed to conduct this work.

§ 3. The minister in charge of health issues in consultation with the minister in charge of labour issues, having regard to diversity of properties of chemical substances, their mixtures, agents or technological processes causing carcinogenicity or mutagenicity, their use and necessity to implement necessary measures protecting from the risks caused by their use shall lay down in a regulation:

1) the list of chemical substances their mixtures, agents or technological processes causing carcinogenicity or mutagenicity, and the way of their registration,

2) the way of keeping the register of the works whose performance requires a contact with the chemical substances, their mixtures, agents or technological processes causing carcinogenicity or mutagenicity,

3) the way of keeping the register of employees employed to perform this work,

4) the templates of the documents concerning exposure of employees to the chemical substances their mixtures, agents or technological processes causing carcinogenicity or mutagenicity and the way of storing these documents and providing them to the entities that are competent to recognize or confirm occupational diseases,

5) the detailed conditions of protecting workers from risks caused by the chemical substances, their mixtures, agents or technological processes causing carcinogenicity or mutagenicity,

6) the conditions and the way of monitoring the health condition of the workers exposed to impacts of the chemical substances their mixtures, agents or technological processes causing carcinogenicity or mutagenicity.";

4) In Article 237 11a§ 1(1)shall be replaced by the following:

„1) changing work organization and equipment of the work places, introduction of new technological processes as well as chemical substances and their mixtures, if they may cause risk to health or life of the workers,";

5) in Article 283 in § 2(5), letters b and c shall be replaced by the following:

„b) chemical substances and their mixtures that have not been labelled in a visible way to enable their identification,

c) dangerous substances, dangerous mixtures, hazardous substance or hazardous mixture without safety data sheets, as well as packaging preventing from their hazardous impacts, fire or explosion,".

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[7]

the following amendments are introduced:

1) in Article 4 (1), item 8 shall be replaced by the following:

„8) compliance by manufacturers, importers, persons placing on the market, using or exporting chemical substances, their mixtures or articles within the meaning of the provisions of the Act of 25 February 2011 on chemical substances and their mixtures (Dz. U. of 2011 No 63, item. 322) with the duties resulting from this Act and from the regulations of the European Communities listed therein;";

2) in Article 27b:

a) paragraphs 1 and 2 shall be replaced by the following:

„1. Where it is found that the chemical substances, their mixtures or articles have been placed on the market contrary to the restrictions provided for in the provisions issued pursuant to Article 26(1) of the Act of 25 February 2011on chemical substances and their mixtures or in the provisions of Annex XVII of Regulation No 1907/2006, or contrary to the conditions provided for in these provisions, the competent state sanitary inspector shall request in a decision that manufacturing or placing on the market of this substance, mixture or article shall be suspended, or where necessary, withdraw this substance, mixture or article from the market, and immediately notify the Inspector for Chemical Substances thereof.

2. Where it is found that a chemical substance on its own or in a mixture or in an article is manufactured or has been placed on the market without registration, where required, in accordance with the provisions of Titles II and III of Regulation No 1907/2006 and contrary to the deadlines provided for in Article 21 of this Regulation, the competent state sanitary inspector shall request in a decision that manufacturing or placing this chemical substance, its mixture or article shall be suspended, and where necessary, this chemical substance, its mixture or article shall be withdrawn from the market, and immediately notify the Inspector for Chemical Substances thereof.",

b) paragraph 4 shall be replaced by the following:

„4. The minister in charge of health issues shall lay down in a regulation the conditions, mode and way of withdrawing a chemical substance, its mixture or article referred to in paragraphs from 1 to 3 from the market, and the conditions and way of their storage having regard to ensuring the adequate level of protection of health and the environment",

[7] Amendments to the consolidated text of this Act were published in the Dz. U. of 2006 No 104, item 708, No 143, item 1032, No 170, item 1217, No 171, item 1225 and No 220, item 1600, of 2007 No 176, item 1238, of 2008 No 227, item 1505 and No 234, item 1570, of 2009 No 18, item 97, No 20, item 106, No 92, item 753 and No 157, item 1241 and of 2010 No 21, item 105, No 81, item 529, No 130, item 871, No 182, item 1228 and No 213, item 1396.

c) the following paragraphs 5 and 6 are inserted:

„5. In case of a justifiable suspicion that the circumstances specified in paragraphs 1 and 2 have arisen, the competent state sanitary inspector shall collect samples of the chemical substances, their mixtures and articles.

6. The minister competent for health issues shall lay down in a regulation:

1) the mode of collecting and testing samples of chemical substances, their mixtures and articles,

2) the standard protocol of sample collection,

3) the way of securing samples,

4) the standard study report,

5) the procedure of handling residues of these samples

– having regard to ensuring high quality of the studies and safety of the persons who conduct them.”;

3) Article 29 shall be replaced by the following:

„Article 29. In the cases specified in Articles 27 and28, the state sanitary inspectors are authorized to secure premises, means of transport, machinery and other equipment, foodstuffs, objects of use, materials and articles intended for contact with food, cosmetics, detergents, chemical substances, their mixtures and articles within the meaning of the provisions of the Act of 25 February 2011on chemical substances and their mixtures (Dz. U. of 2011 No 63, item. 322), as well as other articles that may affect human health. For the purpose of the security-related procedure, the provisions of the Act of 17 June 1966 on the enforcement procedure in the administration shall apply (Dz. U. of 2005 No 229, item 1954, with subsequent amendments[8]), unless otherwise provided by specific provisions.”;

4) Article 37b shall be replaced by the following:

„Article 37b. Any person who contrary to the decision of the competent state sanitary inspector manufactures, places on the market or does not withdraw a chemical substance, its mixture or article from the market, shall be subject to the penalty by fine, penalty by restricted liberty or penalty by deprivation of liberty for up to 2 years.”.

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[9])

[8]Amendments to the consolidated text of this Act were published in the Dz. U. of 2006 No 104, items 708 and 711, No 133, item 935, No 157, item 1119 and No 187, item 1381, of 2007 No 89, item 589, No 115, item 794, No 176, item 1243 and No 192, item 1378, of 2008 No 209, item 1318, of 2009 No 3, item 11, No 39, item 308, No 131, item 1075, No 157, item 1241 and No 201, item 1540 and of 2010 No 28, item 143, No 40, item 229, No 75, item 474, No 122, item 826, No 152, item 1018 and No 229, item 1497.

[9]Amendments to the consolidated text of this Act were published in the Dz. U. of 2007 No 75, item 493, No 88, item 587 and No 124, item 859, of 2008 No 138, item 865, No 199, item 1227 and No 227, item 1505, of 2009 No 18, item 97,

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

„a) of the Act of 25 February 2011on chemical substances and their mixtures (Dz. U. of 2011 No 63, item. 322)

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:

1) in Article 3(1),item 1c shall be replaced by the following:

„1c) the inspection of chemical substances, their mixtures, articles and detergents intended for consumers, within the scope laid down in the provisions on chemical substances and their mixtures;";

2) Article 18a shall be replaced by the following:

„Article 18a. 1. Where in the course of an inspection it is established that a substance, its mixture or article has been placed on the market contrary to the restrictions provided for in the provisions issued pursuant to Article 26 of the Act of 25 February 2011 on chemical substances and their mixtures or in the provisions of Annex XVII of Regulation (EC) No 1907/2006 of the European Parliament and the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European 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, item 1, with subsequent amendments), hereinafter referred to as "Regulation No 1907/2006", the Voivodship (regional) Inspector shall prohibit in a decision further supply of this substance, its mixture or article by the entity inspected.

2. With respect to the articles that due to the risks caused by chemical substances or their mixtures contained in these articles, do not comply with the general safety requirements specified pursuant to the Act of 12 December 2003 on the general safety of products, the provisions concerning general safety of products shall apply.

3. As regards the articles not complying with the basic requirements due to the risks caused by chemical substances or their mixtures contained in these articles, the provisions concerning the compliance evaluation system shall apply.

4. President of the Office shall immediately notify the Inspector for Chemical Substances of the decision issued pursuant to the provisions concerning the compliance evaluation system for the article that does not comply with the basic requirements in relation to the

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No 31, item 206, No 79, item 666 and No 130, item 1070 and of 2010 No 182, item 1228 and No 239, item 1592.

chemical substances or their mixtures contained in this article.

5. In case where it is confirmed that there is manufacturing or placing on the market of a chemical substance on its own, in a mixture or in an article without having it registered, if it is required in accordance with the relevant provisions of Title II of Regulation No 1907/2006 and contrary to the deadlines provided for in Article 21 of this Regulation, the Regional Inspector shall immediately notify a competent state sanitary inspector of this fact.".

Article 69. In the Act of 30 March 2001 on cosmetics (Dz. U. No 42, item 473, with subsequent amendments[10]) the following amendments are introduced:

1) Article 2(1) shall be replaced by the following:

„1. Within the meaning of this Act, a cosmetic shall mean any chemical substance or mixture, intended to be placed in contact with the external parts of the human body: epidermis, hair, lips, nails, external genital organs, teeth and the mucous membranes of the oral cavity, with a view exclusively or mainly to cleaning them, keeping them in good condition, protecting them, perfuming them, changing their appearance or correcting body.";

2) in Article 3:

a) item 3 shall be replaced by the following:

„3) cosmetic ingredient – chemical substance of synthetic or natural origin or its mixture; impurities resulting from a technological process, supplementary technical materials and solvents as well as carriers of perfume and aromatic compositions shall not be regarded as cosmetic ingredients

b) the following item 3a shall be inserted:

„3a) mixture – a mixture or solution referred to in Article 3(2)Regulation (EC) No 1907/2006 of the European Parliament and the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European 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),",

c) items 7 and 8 shall be replaced by the following:

„7) perfume composition – a chemical substance of synthetic or natural origin or a mixture intended to perfume a cosmetic, 8) aromatic composition – a chemical substance

[10]Amendments to the consolidated text of this Act were published in the Dz. U. of 2003 No 73, item 659, No 189, item 1852 and No 208, item 2019, of 2004 No 213, item 2158, of 2009 No 18, item 97, No 20, item 106 and No 91, item 740 and of 2010 No 107, item 679.

of synthetic or natural origin or a mixture intended to provide a cosmetic with aroma or flavour,";

3) Article 4(3)shall be replaced by the following:

„3. The use of substances classified as carcinogenic, mutagenic or reprotoxic category 1A, 1B and 2 in cosmetics shall be prohibited pursuant to the provisions of 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 1907/20061272/2008 (OJ L 353, 31.12.2008, p. 1), hereinafter referred to as "Regulation (EC) No 1272/2008; category 2 substances may be used provided that they have been specified in the lists referred to in Article 5, paragraph 3 items 1–3.";

4) Article 4a(3)shall be replaced by the following:

„3. The prohibition referred to in paragraph 2 item 1 letter b and item 2, shall be binding from the moment when tests on animals have been replaced by one or more recognized methods listed in the Commission Regulation (EC) No 440/2008 of30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) (OJ L 142, 31.05.2008, p. 1, with subsequent amendments) or in the regulation issued pursuant to paragraph 4.";

5) In Article 11, paragraphs 2 and 2a shall be replaced by the following:

„2. The evaluation referred to in paragraph 1(4) is conducted in accordance with the principles of Good Laboratory Practice within the meaning of the provisions on chemical substances and their mixtures, where the application of the principles of Good Laboratory Practice is justifiable.

2a. Manufacturer shall ensure public access to the information concerning the composition of a cosmetic, including the quantitative data for the substances that fulfill the classification criteria for any hazard class of category listed in:

1) Part 2 in item 2.1 – 2.4, 2.6, 2.7, 2.8 (A and B Type), 2.9, 2.10, 2.12,

2.13 (category 1 and 2), 2.14 (category 1 and 2) and 2.15 (Type A–F),

2) Part 3 in items 3.1 – 3.6, 3.7 (harmful effects on sexual functions and fertility or development of offspring), 3.8 (apart from the substances fulfilling the criteria of classification due to narcotic effects), 3.9 and 3.10,
3) part 4 in item 4.1,

4) part 5 in item 5.1

– to Annex I to Regulation (EC) No 1272/2008, and to data specified in paragraph 1(5); this information must be easily accessible by appropriate means of information communication, in particular by post, telephone or electronic media.".

Article 70. In the Act of 27 April 2001 – the Environmental Protection Law (Dz. U. of 2008 No 25, item 150, with subsequent amendments[11]) In Article 147a(1),item 2 shall be replaced by the following:

„2) certified test facilities referred to in Article 16(1) of the Act of 25 February 2011 on chemical substances and their mixtures (Dz. U. of 2011 No 63, item. 322).

Article 71. In the Act of 11 May 2001 on packaging and packaging waste (Dz. U. No 63, item 638, with subsequent amendments[12]) In Article 3(3),item 3a shall be replaced by the following:

„3a) dangerous materials – shall mean:

a) chemical substances and their mixtures classified pursuant to the provisions on chemical substances and their mixtures as very toxic, toxic, carcinogenic category 1 or 2, mutagenic category 1 or 2, reprotoxic category 1 or 2, or dangerous to the environment with the N symbol assigned or

b) chemical substances and their mixtures classified pursuant to the provisions of the Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006(OJ L 353, 31.12.2008, p.1), hereinafter referred to as „Regulation (EC) No 1272/2008", in the class of acute toxicity category 1, 2 or 3, or as carcinogenic category 1A or 1B, mutagenic category 1A or 1B, reprotoxic category 1A or 1B or as hazardous to aquatic environment due to acute toxicity category 1 or due to toxicity category 1 and 2, or

c) plant protection products classified as very toxic, toxic or dangerous to aquatic environment with the N symbol assigned pursuant to the provisions on chemical substances and their mixtures or classified under the acute toxicity class category 1, 2 or 3 or as hazardous to aquatic environment due to acute toxicity category 1 or due to chronic toxicity category 1 and 2 pursuant to the provisions of Regulation (EC) No 1272/2008, or

d) plant protection products classified as toxic to bees or aquatic organisms, provided for in the provisions on plant protection,".

[11]Amendments to the consolidated text of this Act were published in the Dz. U. of 2008 No 111, item 708, No 138, item 865, No 154, item 958, No 171, item 1056, No 199, item 1227, No 223, item 1464 and No 227, item 1505, of 2000 No 19, item 100, No 20, item 106, No 79, item 666, No 130, item 1070 i No 215, item 1664, of 2010 No 21, item 104, No 28, item 145, No 40, item 227, No 76, item 489, No 119, item 804, No 152, item 1018 and 1019, No 182, item 1228, No 229, item 1498 and No 249, item 1657 and of 2011 No 32, item 159.

[12]Amendments to the consolidated text of this Act were published in the Dz. U. of 2003 No 7, item 78, of 2004 No 11, item 97 and No 96, item 959 and of 2005 No 175, item 1458.

Article 72. In the Act of 6 September 2001 – Pharmaceutical Law (Dz. U. of 2008 No 45, item 271, with subsequent amendments[13]) the following amendments are introduced:

1) Article 17(1) shall be replaced by the following:

„1. Tests referred to in Article 10(2) item 4 letter b, performed in order to assess safety of a medicinal product or a test referred to in Article 10(2b) item 6 letter b, performed in order to assess safety of a veterinary medicinal product, shall be conducted by the entities that comply with the principles of Good Laboratory Practice within the meaning of the Act of 25 February 2011 on chemical substances and their mixtures (Dz. U. of 2011 No 63, item. 322).";

2) in Article 65(10), items 2 and 2a shall be replaced by the following:

„2) research institutes and laboratories checking quality of medicines, within the scope of the tests of medicinal products provided for in paragraph 4(1–3) and paragraph 7 – having regard in particular to compliance by these entities with the principles of Good Laboratory Practice within the meaning of the provisions on chemical substances and their mixtures;

2a) laboratories checking quality of medicines specializing in tests of the products referred to in paragraph 4(4) – having regard in particular to compliance by these entities with the principles of Good Laboratory Practice within the meaning of the provisions on chemical substances and their mixtures;".

Article 73. In the Act of 13 September 2002 on biocidal products (Dz. U. of 2007 No 39, item 252, with subsequent amendments[14]), the following amendments are introduced:

1) Article 8c shall be replaced by the following:

„Article8c. Safety data sheets shall be drafted for biocidal products and active substances contained in the composition of biocidal products in accordance with the principles laid down in Regulation (EC) No 1907/2006 of the European Parliament and the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European 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) in Article 8d paragraph 1 shall be replaced by the following:

[13] Amendments to the consolidated text of this Act were published in the Dz. U. of 2008 No 227, item 1505 and No 234, item 1570, of 2009 No 18, item 97, No 31, item 206, No 92, item 753, No 95, item 788 and No 98, item 817 and of 2010 No 78, item 513 and No 107, item 679.

[14] Amendments to the consolidated text of this Act were published in the Dz. U. of 2008 No 171, item 1056, of 2009 No 20, item 106 and of 2010 No 107, item 679 and No 225, item 1464.

„1. Studies of physico-chemical properties, toxicological and ecotoxicological studies and supplementary studies referred to in Article 20(2), shall be performed with an aid of the methods laid down in Article 13 of Regulation No 1907/2006, and where relevant, in accordance with the principles of Good Laboratory Practice within the meaning of the provisions on chemical substances and their mixtures.”;

3) Article 16 shall be replaced by the following:

„Article 16. Authorizations for a biocidal product:

1) classified pursuant to the provisions on chemical substances and their mixtures at least as toxic, very toxic or carcinogenic category 1 or 2 or mutagenic category 1 or 2 or reprotoxic category 1 or 2, or

2) classified pursuant to the provisions of 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), at least in the class of acute toxicity under category 1, 2 or 3 or as carcinogenic under category 1A or 1B or mutagenic under category 1A or 1B or as reprotoxic category 1A or 1B

– also defines the scope of placing it on the market and its use, excluding permissibility of retail or general use.”;

4) in Article 24a (2), item 3 shall be replaced by the following:

„3) the name and contents of an active substance in this product, as well as the name and contents of any dangerous substance within the meaning of the provisions on chemical substances and their mixtures;”;

5) w Article 27(1), item 2 shall be replaced by the following:

„2) has been classified, packed and labelled in accordance with the provisions on chemical substances and their mixtures;”;

6) Article 29 shall be replaced by the following:

„Article29. The minister in charge of health issues shall refuse to submit the application referred to in Article 28, if an active substance intended for use in low risk biocidal products:

1) has been classified in accordance with the provisions on chemical substances and their mixtures as carcinogenic, mutagenic, reprotoxic, sensitizing or

2) in accordance with the criteria specified in the provisions on chemical substances and their mixtures, it does not decompose easily or it bioaccummulates in the environment.”;

7) Article 44(1)shall be replaced by the following:

„1. Biocidal products should be classified and labelled, subject to paragraphs from 2 to 4, in accordance with the provisions on chemical substances and their mixtures.”.

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[15]) In Article 16(1), in item 8 letter b shall be replaced by the following:

„b) Articles from 31 to 34 of the Act of 25 February 2011 on chemical substances and their mixtures(Dz. U. of 2011 No 63, item. 322)".

Article 75. In the Act of 17 October 2003 on underwater work (Dz. U. No 199, item 1936, with subsequent amendments[16]) In Article 2, item 19 shall be replaced by the following:

„19) particularly dangerous underwater work – actions conducted under water surface with the use of explosive or pyrotechnic materials, involving contamination caused by dangerous or hazardous substances or their dangerous or hazardous mixtures, involving application of hydraulic and pneumatic equipment, involving searching for mines or ammunition, moving and discharging them, as well as testing new diving equipment or testing new technologies of underwater work.".

Article 76. In the Act of 12 December 2003 on general safety of products (Dz. U. No 229, item 2275, with subsequent amendments[17]) Article 24a shall be replaced by the following:

„Article24a. An enforcement body shall inform the Inspector for Chemical Substances of the decisions made pursuant to Article 24(1-2) and (4), in case where these decisions concern risks caused by products containing chemical substances or their mixtures within the meaning of the provisions on chemical substances and their mixtures.".

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

1) in Article 38(1), item 5 shall be replaced by the following:

[15]Amendments to the consolidated text of this Act were published in the Dz. U. of 2004 No 93, item 889, No 191, item 1956 and No 243, item 2442, of 2005 No 157, item 1316, No 178, item 1479, No 180, item 1492 and No 183, item 1538, of 2006 No 120, item 826, of 2007 No 75, item 492 and No 166, item 1172, of 2008 No 214, item 1344, of 2009 No 20, item 106, No 62, item 504, No 166, item 1317 and No 201, item 1540 and of 2010 No 81, item 530 and No 127, item 857.

[16]Amendments to the consolidated text of this Act were published in the Dz. U. of 2004No 273, item 2703, of 2005 No 155, item 1298, of 2007 No 64, item 428 and of 2008 No 180, item 1112.

[17]Amendments to the consolidated text of this Act were published in the Dz. U. of 2007 No 35, item 215, of 2008 No 157, item 976 and of 2009 No 18, item 97 and No 20, item 106.

[18]Amendments to the consolidated text of this Act were published in the Dz. U. of 2008 No 227, item 1505, of 2009 No 20, item 106, No 31, item 206 and No 98, item 817 and of 2010 No 47, item 278.

„5) labelling and packaging of plant protection products have been prescribed in accordance with the provisions on chemical substances and their mixtures;”;

2) Article 39(5) shall be replaced by the following:

„5. Studies of a plant protection product, excluding the studies on efficacy of a plant protection product, and studies of active substance contained in this product referred to in paragraph 4(3) and (4), shall be conducted:

1) in accordance with the principles of Good Laboratory Practice provided for in the provisions on chemical substances and their mixtures;

2) in test facilities complying with the principles of Good Laboratory Practice in accordance with the provisions on chemical substances and their mixtures;

3) with an aid of the methods specified pursuant to Article 13 of Regulation No 1907/2006.”;

3) Article 45(2) shall be replaced by the following:

„2. Classification of plant protection products referred to in paragraph 1(4), shall be derived in accordance with the provisions on chemical substances and their mixtures, however the classification with respect to risks to bees shall not be derived for the plant protection products whose scope and method of application exclude possibility of having direct contact with bees.”;

4) In Article 47a(2):

a) in item 2, letter a shall be replaced by the following:

„a) classified in accordance with the provisions of the European Union concerning labelling and classification of chemical substances and mixtures,”,

b) item 4 shall be replaced by the following:

„4) labelling and packaging of plant protection products have been prescribed in accordance with the provisions on chemical substances and their mixtures.”;

5) in Article 58(2), item 1 shall be replaced by the following:

„1) names and contents of active substances and names of dangerous substances within the meaning of the provisions on chemical substances and their mixtures;”;

6) Article 118 shall be replaced by the following:

„Article118. Where the studies referred to in Article 39(4), items 3 and 4, have been conducted prior to the date of entry of this Act into force or if methods of these studies have not been provided for in the provisions on chemical substances and their mixtures, the minister in charge of agricultural issues may approve in a decision the studies, where they have been conducted with an aid of the methods recognized by international organizations.”.

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:

„4. Within the scope unregulated by this Act, the provisions on chemical substances and their mixtures shall be applicable for labelling of the vessels containing controlled substances.”.

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[19]) In Article 3 in item 14, the full stop shall be replaced with the semicolon, and the following item 15 shall be inserted:

„15) dangerous substance – shall mean any substance fulfilling the classification criteria for any classes or categories of risk stipulated in:

a) part 2 in items 2.1 – 2.4, 2.6, 2.7, 2.8 (A and B Type), 2.9, 2.10, 2.12, 2.13 (category 1 and 2), 2.14 (category 1 and 2) and 2.15 (A–F Type),

b) part 3 in items 3.1 – 3.6, 3.7 (harmful effects on sexual functions and fertility or development of offspring), 3.8 (apart from the substances fulfilling the criteria of classification due to narcotic effects), 3.9 and 3.10,

c) part 4 in item 4.1,

d) part 5 in item 5.1

– Annex I to the Regulation 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).”.

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:

„6) organizational entities holding specialist laboratories that conduct tests of medicinal products, foodstuffs, chemical substances and their mixtures, plant protection products, biocidal products and genetically modified organisms, where the obligation of conducting such tests results from separate provisions, in particular, the provisions on: pharmaceutical law, chemical substances and their mixtures, plant protection, biocidal products, and the provisions on genetically modified organisms.”.

[19] Amendments to the consolidated text of this Act were published in the Dz. U. of 2005 No 175, item 1458, of 2007 No 176,item 1236, of 2009 No 79, item 666, No 92, item 753 and No 215, item 1664 and of 2010 No 28, item 145 and No 76, item 489.

Article 81. In the Act of 29 July 2005 on counteracting drug addiction (Dz. U. No 179, item 1485, with subsequent amendments[20]), the following amendments are introduced:

1) in Article 3, item 2 shall be replaced by the following:

„2) chemical substances and their mixtures being precursors within the scope unregulated in the provisions on chemical substances and their mixtures.";

2) Article 44(4)shall be replaced by the following:

„4. The Inspector for Chemical Substances shall keep a register of manufacturers, importers and other entities placing category 2 precursors on the market, having regard to the data referred to in Article 3(6) of Regulation No 273/2004, and notify the competent state district sanitary inspector of the application.".

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:

1) in Article 3(1), item 7 shall be replaced by the following:

„7) dangerous ingredient – a dangerous mixture within the meaning of Article 4(1) of the Act of 25 February 2011 on chemical substances and their mixtures(Dz. U. of 2011 No 63, item. 322)

or a substance fulfilling the classification criteria for any classes or categories of risks stipulated in:

a) part 2 in item 2.1 – 2.4, 2.6, 2.7, 2.8 (A and B Type), 2.9, 2.10, 2.12,

2.13 (category 1 and 2), 2.14 (category 1 and 2) and 2.15 (A–F Type),

b) part 3 in item 3.1 – 3.6, 3.7 (harmful effects on sexual functions and fertility or development of offspring), 3.8 (apart from the substances fulfilling the criteria of classification due to narcotic effects), 3.9 and 3.10,

c) part 4 in item 4.1,

d) part 5 in item 5.1

– Annex I to 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 (EC) No 1272/2008".";

2) In Annex No 2 to the Act:

[20]Amendments to the consolidated text of this Act were published in the Dz. U. of 2006 No 66, item 469 and No 120, item 826, of 2007 No 7, item 48 and No 82, item 558, of 2009 No 18, item 97, No 63, item 520, No 92, item 753 and No 98, item 817 and of 2010 No 28, item 146, No 143, item 962, No 213, item 1396 and No 228, item 1486.

a) in paragraph 1, item 13 shall be replaced by the following:

„13) components containing fire-proof ceramic fibres specified in table 3.2 of Annex VI to Regulation (EC) No 1272/2008,”,

b) in paragraph 2, the introduction to the list shall be replaced by the following:

„Collected waste electrical and electronic equipment from which substances and mixtures as well as the components specified in paragraph 1 have been removed, should be processed in the following way:”.

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:

„a) dangerous substances and dangerous mixtures or hazardous substances or hazardous mixtures within the meaning of the provisions on chemical substances and their mixtures,”.

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:

„4) recognizing, detecting, preventing and counteracting crimes and offences involving infringements of the provisions concerning delivery to the territory of the Republic of Poland and export from the territory of the Republic of Poland the goods subject to restrictions or bans on placing them on the market due to safety and public order, or international safety, which in particular include waste, chemical substances and their mixtures, nuclear and radioactive materials, abusive (intoxicating) substances and psychotropic substances, weapons, ammunition, explosives and goods and technologies of strategic importance;”.

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 is hereby repealedas of 1 June 2015.

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

President of Polish Republic

Bronisław Komorowski