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REGULATION OF

THE MINISTER OF HEALTH

of 9 November 2015

on conferring the Statute to the Bureau for Chemical Substances

(Dz. U. of 25 November 2015)

Pursuant to Article 13(2) of the Act of 25 February 2011 on the chemical substances and their mixtures (Dz. U. of 2015 item 1203) it is hereby ordered as follows:

§ 1. A statute, which specifies detailed tasks of the Inspector for Chemical Substances, the organisation of the Bureau for Chemical Substances, and principles of cooperation of the Inspector for Chemical Substances with the European Commission and the Organisation for Economic Co-operation and Development (OECD) in the field of Good Laboratory Practice, which constitutes an annex to the regulation, is conferred upon the Bureau for Chemical Substances.

§ 2. Regulation of the Minister of Health of 4 April 2014 on conferring the Statute to the Bureau for Chemical Substances (Dz. U. item 384) is repealed.

§ 3. This regulation enters into force on the day following the day of its publication.

ANNEX

STATUTE OF THE BUREAU FOR CHEMICAL SUBSTANCES

Chapter 1

Detailed tasks of the Inspector for Chemical Substances

§ 1. The tasks of the Inspector for Chemical Substances, hereinafter referred to as the "Inspector", include:

1) Gathering data concerning dangerous mixtures or hazardous mixtures and information concerning substances provided by the European Chemicals Agency – establishing a register of dangerous mixtures and hazardous mixtures and a register of information concerning substances received from the European Chemicals Agency;
2) Providing medical and emergency services with the data on dangerous substances and dangerous mixtures or hazardous substances and hazardous mixtures – providing poison information centres designated by the minister in charge of health issues with the information received pursuant to Article 15 of the Act of 25 February 2011 on the chemical substances and their mixtures (Dz. U. of 2015 item 1203), hereinafter referred to as the "Act", and the information concerning substances received from the European Chemicals Agency;
3) Performing the function 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 cooperation in this field with other member states of the

European Union and the European Commission – executing obligations laid down in the provisions of Regulation No 649/2012 of the European Parliament and of the Council (EU) of 4 July 2012 concerning the export and import of hazardous chemicals (OJ L 201 of 27.07.2012, p. 60, with subsequent amendments), hereinafter referred to as "Regulation No 649/2012";

4) Performing the function of the competent authority laid down in Article 8 of Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (OJ L 104 of 08.04.2004, p. 1, with subsequent amendments; OJ special edition in Polish, Chapter 13, V. 34, p. 48, with subsequent amendments) – cooperation 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;
5) Performing the function of the competent authority laid down in Article 121 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) and 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 of 30.12.2006, p. 1, with subsequent amendments), hereinafter referred to as "Regulation No 1907/2006" - cooperation with other member states of the European Union or member states of the European Free Trade Association (EFTA) – parties to the Agreement on the European Economic Area and the European Commission, the European Commission and the European Chemicals Agency within the scope laid down in Regulation No 1907/2006 and ensuring scientific and technical support to members of the Member State Committee, the Committee for Risk Assessment, Committee for Socio-economic Analysis, laid down in Regulation No 1907/2006;
6) Performing the function of the competent authority laid down in Article 43 of Regulation No 1272/2008 of the European Parliament and of the Council (EC) of 16 December 2008 on classification, labelling and packaging of substances and mixtures - amending and repealing Directive 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353 of 31.12.2008, p. 1, with subsequent amendments), hereinafter referred to as "Regulation No 1272/2008" - cooperation with other member states of the European Union or member states of the European Free Trade Association (EFTA) – parties to the Agreement on the European Economic Area, the European Commission and the European Chemicals Agency within the scope laid down in Regulation No 1272/2008 and ensuring scientific and technical support to members of the Member State Committee, the Committee for Risk Assessment, Committee for Socio-economic Analysis, laid down in Regulation No 1907/2006;
7) Performing the function of the designated national authority laid down in Article 4 of Regulation No 649/2012 - cooperation with other member states of the European Union, parties to the Rotterdam Convention and Secretariat of this Convention and other states within the scope laid down in Regulation No 649/2012;
8) Performing the function of the competent authority designated to execute tasks in the field of making the registration laid down in Article 3(6) of Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors (OJ L 47 of 18.02.2004, p. 1, with subsequent amendments; OJ special edition in Polish, Chapter 15, V. 8, p. 46, with subsequent amendments), hereinafter referred to as "Regulation No 273/2004" – registering substances classified under category 2 in Annex I to Regulation No 273/2004;
9) Running a National Helpdesk, in accordance with Article 124 of Regulation No 1907/2006 and Article 44 of Regulation No 1272/2008 – to provide answers to questions concerning obligations resulting from these regulations and cooperation with other member states

of the European Union, the European Commission and the European Chemicals Agency to harmonise these answers at the European Union level;
10) Cooperation with international organisations in the field of substances and their mixtures – cooperation with organisations associated under the Inter-Organization Programme for the Sound Management of Chemicals;
11) Executing tasks laid down in the regulations concerning drug prevention – in relation to execution of the tasks in the field of registration laid down in Article 3(6) of Regulation No 273/2004 – issuing decisions on granting, refusing to grant, suspending or cancelling the registration, notifying the competent state district sanitary inspector of the decisions issued, and keeping the national register of registered business entities and users;
12) Dissemination of knowledge on the harmful impact of chemical substances and their mixtures on human health and on the environment, and knowledge on prevention of such impact – particularly posting the relevant information on websites of the Bureau for Chemical Substances, hereinafter referred to as the "Bureau", and organising conferences and seminars to inform of activities in the field of preventing such harmful impact, which are implemented in Poland and in the European Union;
13) Annual submission to the European Commission and to the Organization for Economic Co-operation and Development (OECD), hereinafter referred to as "OECD", not later than by 31 March of the following year, of the information for the previous year in the field of functioning of Good Laboratory Practice within the territory of the Republic of Poland – particularly submission of the up-to-date list of the certified test facilities and the facilities deleted from this list and the information on the inspections and verifications of the test facilities and certified test facilities conducted in the previous year;
14) Executing other tasks delegated by the minister in charge of health issues:
    a) Cooperation with enforcement authorities listed in Article 29 of the Act, including the State Sanitary Inspection in the field of training of the enforcement authorities,
    b) Executing, within the relevant competence, tasks resulting from the Stockholm Convention on Persistent Organic Pollutants, drafted in Stockholm on 22 May 2001 (Dz. U. of 2009 No 14, item 76), and cooperation with the minister in charge of environment issues and the Inspection for Environmental Protection in the field of implementation of provisions of this Convention.

§ 2. When executing the tasks laid down in the Act, the Inspector shall cooperate with research institutes and other organisational entities, which operate in the field of the evaluation of substances and their mixtures, in particular:
1) in the field of assessment of risk to human health – with Nofer Institute of Occupational Medicine in Lodz and other entities appointed by the minister in charge of health issues;
2) in the field of assessment of risk to the environment – with research institutes and other entities appointed by the minister in charge of environment issues;
3) in the field of assessment of threats posed by physico-chemical properties of substances and their mixtures - with research institutes and other entities appointed by the minister in charge of economy issues;
4) in the field of safety of employees using substances and their mixtures - with research institutes and other entities appointed by the minister in charge of labour issues.

§ 3. In the field of the tasks laid down in Article 16(3) of the Act and in the field of the Inspector’s cooperation with the European Commission and the OECD related to Good Laboratory Practice the Inspector shall ensure:
1) active participation of the Bureau’s employees in the activities of Good Laboratory Practice working groups at the European Commission and the OECD;
2) employment of a sufficient number of employees at the Bureau, available to the Inspector to be designated as Good Laboratory Practice inspectors to conduct the

inspection and verification of compliance with the principles of Good Laboratory Practice by test facilities, who hold appropriate qualifications and practical experience in the field of sciences that are crucial to conducting studies of physico-chemical properties, toxicity and ecotoxicity of substances and their mixtures;

3) availability of the Bureau for the purpose of the Bureau's evaluation as an entity authorised to conduct the inspections of compliance with the principles of Good Laboratory Practice by the entities competent to conduct the inspections of compliance with the principles of Good Laboratory Practice in other states of the OECD, in accordance with the programme of the inspections of such entities laid down by the OECD Secretariat.

§ 4. The Inspector shall submit annual reports on his/her activities to the minister in charge of health issues, not later than by the end of February of the following year.

Chapter 2

Organisation of the Bureau for Chemical Substances

§ 5. The Inspector manages the Bureau with assistance of the General Director and heads of organisational units referred to in § 6(1) items 1-3.

§ 6. 1. The Bureau consists of the following organisational units, shared job positions and independent job positions:

1) Department for Good Laboratory Practice;
2) Department for Risk Assessment;
3) Department for Dangerous Substances and Mixtures;
4) Independent Position for Legal Affairs;
5) Shared Position for Administrative and Human Resources Affairs;
6) Shared Position for Financial Affairs;
7) Independent Position for Internal Audit.

2. Directors manage organisational units referred to in paragraph 1(1-3).

3. The internal organisation and the detailed scope of tasks of the organisational units, shared positions and independent positions, referred to in paragraph 1, are laid down in the Bureau's regulations.