

Act on Chemical Substances and Mixtures Thereof

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In this paper we would like to indicate the major changes introduced by the new Act on Chemical Substances and Mixtures Thereof (Dz.U. No.63, item 322 of 25 February 2011). This Act became effective on 8 April this year and has replaced the former Act on Chemical Substances and Preparations of 11 January 2001, subsequently amended. The new Act is more elaborate, which is described further below, although it retains the logic and arrangement of its predecessor. The change that at first seemingly appears to be fundamental is the general clause of article 1, which defines the competence of the authorities within the scope of executing administrative tasks and duties resulting from European Union regulations: Regulation (EC) No.1907/2006 (REACH), Regulation (EC) No.648/2004 on detergents, Regulation (EC) No.689/2008 - implementing the Rotterdam Convention in international trade and Regulation (EC) No.1272/2008 (CLP). In fact, however, the only novelty is the definition of the competence of the authorities within the scope of executing administrative tasks and duties resulting from the CLP Regulation. That competence related to the other regulations was already defined in the previous act. The new act maintains the duties resulting from the old act, including:

- the duty to notify the Inspector about the manufacture or marketing of a dangerous mixture or a hazardous mixture in Poland (Art.15)
- the requirement to hold special qualifications by the persons who market defined types of dangerous substances and dangerous mixtures or hazardous substances and hazardous mixtures (Art.23)
- imposing restrictions on the manufacture, marketing and use of dangerous or hazardous substances and mixtures, which cause an unjustified risk to human health or to the environment - by implementing appropriate executive regulations (Art.26); granting the Inspector for Chemical Substances the right to temporarily prohibit marketing a mixture, which is believed to constitute an unacceptable risk to human health or to the environment (Art.27.1)
- granting the Inspector for Chemical Substances (following an opinion issued by the Chief Sanitary Inspector or by the Chief Environmental Protection Inspector) a similar right related to imposing and lifting a ban on marketing a detergent for a specified period of time (up to 6 months) (Art.27.2). A motion to impose such ban can be put forward by the Office for Competition and Consumer Protection (UOKiK), the Chief Inspector for Environmental Protection (GIOŚ) and the Chief Sanitary Inspector (GIS).

The Act on Chemical Substances and Mixtures Thereof includes information regarding:

- which groups of substances and mixtures are considered dangerous or hazardous (Art.4.1, 4.2)
- the tasks of the new central governmental body with regard to substances and mixtures thereof – Inspector for Chemical Substances (Art.12)
- the authorities supervising the enforcement of compliance with the provisions of the Act and the scope of such supervision (Art.29, 30)
- conditions of providing information on dangerous or hazardous mixtures (Art.15)

- conditions of classification, labelling and packaging of substances and mixtures, as well as of marketing and use thereof (Art.18÷28). A few changes were introduced in definitions:
- Detergent and surfactant were defined pursuant to Regulation (EC) No.648/2004
- Supplier of an article was defined pursuant to Regulation (EC) No.1907/2006 (REACH)
- Import and export of chemicals were defined pursuant to Regulation (EC) No.689/2008
- Hazard class and category were defined pursuant to Regulation (EC) No.1272/2008 (CLP).

Classification and labelling

The substances listed in Table 3.2 of Annex VI to the Regulation (EC) No.1272/2008 (CLP) are classified in accordance with this table, provided that the classification for the individual items in this table applies to the hazard category defined under these items. All other hazards posed by such substance (if any) are indicated by the manufacturer or importer. The classification of substances not listed in Table 3.2 of Annex VI to the Regulation (EC)

No.1272/2008 (CLP) and of mixtures is done according to rules set out in the ordinance concerning the criteria and manner of classification (the regulation valid at present is the Ordinance of the Minister of Health of 2 September 2003 on the criteria and manner of classifying chemical substances and preparations (Dz.U. 2003, No.171) item 1666, as amended)). **IMPORTANT!!!** This Ordinance must be amended because of the coming into force of the new Act on Chemical Substances and Mixtures Thereof. Likewise, the ordinance on labelling of packaging must also be amended (current regulation: Ordinance of the Minister of Health of 5 March 2009 on the labelling of packaging of hazardous substances and hazardous preparations and of certain chemical preparations (Dz.U. 2009, No.53, item 439).

In our discussion here we leave out the changes in regulations concerning the central body competent in substances and mixtures, as these are mainly of importance in defining mutual relations between the central body and institutions responsible for direct supervision and control over compliance with the requirements of chemical legislation. Of importance to the recipients of law is:

1. the new name of the body and of the person at the head: Bureau for Chemical Substances and Inspector for Chemical Substances, respectively, which is important for proper addressing of correspondence (valid since the date of coming into force of the Act, that is since 8 April 2011) and
2. indicating the Inspector as the body responsible for motions concerning harmonised classification and enforcement of the provisions of the Regulation (EC).

No.1272/2008 (CLP), which is a requirement specified in Art.43 of this Regulation (the other were already specified in the previous act).

We are also not looking into the changes concerning the testing of substances, as these changes consist in more precise specification of the principles of Good Laboratory Practice (GLP) and of the manner of inspection and verification of compliance with the principles of Good

Laboratory Practice by the test facilities, and they do not alter the essence of previous provisions (Art. 16 and 1). We would, however, like to focus on the **new provisions concerning the responsibilities of entrepreneurs.**

Notification: change in the date for notifying about the manufacture or import of a dangerous or hazardous mixture – this should now be the date of manufacture/import (Art. 15.2). Previously it was the date of marketing.

Information in the supply chain: in case of the lack of the obligation to submit a safety data sheet, information specified under items 2 and 3 of Annex II to the Regulation (EC) No. 1907/2006 REACH should be submitted, that is information on the risks and components of the mixture.

Classification: classification of substances and mixtures is the responsibility of:

- the person marketing the substance or mixture (*as previously*).
- the registrant (**novelty in relation to previous regulations**) in the case of substances which have not been placed on the market, but which are subject to obligatory registration.

the person making this submission (**novelty**) in the case of substances of very high concern (SVHC) that are not placed on the market but are included in products (Art. 7(2) of the REACH Regulation) and substances for Product and Process Orientated Research and Development (PPORD) (Art. 9(2) of the REACH Regulation). **Special qualifications:** the requirement to hold special qualifications by the persons who market substances and mixtures and the manner of verifying these qualifications has been extended to include both dangerous and hazardous substances and mixtures.

Keeping a record: the list of dangerous and hazardous substances and mixtures is maintained by the manufacturer, importer and downstream user (Art. 25), (previously it was the marketing entity). **The new act provides a much broader list (Art. 31-64) of penal provisions concerning noncompliance with the requirements of chemical regulations. And thus:**

- A number of acts are specified, which were not listed in the previous Act . These include acts resulting from failure to observe the Regulation (EC) No. 1272/2008 (CLP) (Art. 44.(1) and (2), Art. 46. (2), Art. 51(1)-(3), Art. 61.(1) and (2))
- The penalties provided are much stricter. The acts deemed to produce the most grave effects, specified in Art. 31 to 34, are now penalized pursuant to the provisions of the Act on Liability of Collective Entities for Prohibited Acts (Art. 74).

It should be noted that no direct penalty is envisaged for the non-registration of a substance with the European Chemicals Agency (ECHA). The consequence of not registering is the suspension of manufacture/marketing pursuant to Article 5 of the Regulation (EC) 1907/2006 (REACH) titled “No data, no market” and to the provisions of the amended Article 27b.2 of the Act of 14 March 1985 on the State Sanitary Inspection (Dz.U. 2006, No. 122, item 851, as amended (Chapter 8 of the said Act titled “Amendments to the binding provisions”)). The present wording is as follows:

“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 on the market of this chemical substance, its mixture or article be suspended, and where necessary, this chemical substance, its mixture or article be withdrawn from the market, and shall immediately notify the Inspector for Chemical Substances.”

It is the failure to comply with the decision issued that is punishable under this Act.

Changes in other acts

Changes in the Act on the State Sanitary Inspection have been indicated above in connection with the consequences of not registering a substance.

The new Act on Chemical Substances and Mixtures Thereof introduces amendments to a number of other regulations in force (Art. 65÷84). These amendments are related to the following acts:

- Act of 27 August 2009 on Customs Service (Dz.U. 2009, No. 168, item 1323 and No. 201, item 1540, 2010, No. 182, item 1228) - Art. 84
- Act of 13 April 2007 on prevention of damage to the environment and its remediation (Dz.U. 2007, No. 75, item 493, 2008, No. 138, item 865 and No. 199, item 1227) - Art. 83
- Act of 29 July 2005 on waste electrical and electronic equipment (Dz.U. 2005, No. 180, item 1495, 2008, No. 223, item 1464, 2009, No. 79, item 666 and No. 215, item 1664) - Art. 82
- Act of 29 July 2005 on counteracting drug addiction (Dz.U. 2005, No. 179, item 1485, as amended) - Art. 81
- Act of 21 January 2005 on experiments on animals (Dz.U. 2005, No. 33, item 289, 2006, No. 171, item 1225 and No. 220, item 1600, 2009, No. 18, item 97) - Art. 80
- Act of 20 January 2005 on the recycling of end of life vehicles (Dz.U. 2005, No. 25, item 202, as amended) - Art. 79
- Act of 20 April 2004 on the substances that deplete the ozone layer (Dz.U. 2004, No. 121, item 1263, 2005, No. 175, item 1458 and No. 203, item 1683, 2009, No. 215, item 1664) - Art. 78
- Act of 18 December 2003 on plant protection products (Dz.U. 2004, No. 11, item 94, as amended) - Art. 77
- Act of 12 December 2003 on general safety of products (Dz.U. 2003, No. 229, item 2275, as amended) - Art. 76
- Act of 17 October 2003 on underwater work (Dz.U. 2003, No. 199, item 1936, as amended) - Art. 75
- Act of 28 October 2002 on Liability of Collective Entities for acts prohibited by penalty (Dz.U. 2002, No. 197, item 1661, as amended) - Art. 74
- Act of 13 September 2002 on biocidal products (Dz.U. 2002, No. 175, item 1433, as amended) - Art. 73
- Act of 6 September 2001 – Pharmaceutical Law (Dz.U. 2001, No. 126, item 1381, as amended) - Art. 72
- Act of 11 May 2001 on packaging and packaging waste (Dz.U. 2001, No. 63, item 638, as amended) - Art. 71
- Act of 27 April 2001 - the Environmental Protection Law (Dz.U. 2001, No. 62, item 627, as amended) - Art. 70
- Act of 30 March 2001 on cosmetics (Dz.U. 2001, No. 42, item 473, as amended) - Art. 69
- Act of 15 December 2000 on the Trade Inspection (Dz.U. 2001, No. 4, item 25, as amended) - Art. 68
- Act of 20 July 1991 on the State Inspection for Environmental Protection (Dz.U. 1991, No. 77, item 335, as amended) - Art. 67
- Act of 14 March 1985 on the State Sanitary Inspection (Dz.U. 1985, No. 12, item 49 - Art. 66
- Act of 26 June 1974 - the Labour Code (Dz.U. 1974, No. 24, item 141) - Art. 65
- and to a number of executory provisions to the Act discussed.

Those interested in details of the duties imposed by the new Act on Chemical Substances and Mixtures Thereof are invited to visit the Website of the Centre for REACH and CLP of the Industrial Chemistry Research Institute (<http://www.ichp.pl/centrum-reach-clp>; <http://www.ichp.pl/reach-kontakt>), as well as the Website of the Helpdesk (<http://reach-info.pl>).

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400 thousand visitors of the Copernicus Science Centre in Warsaw

Within 167 days from the opening, 400 thousand people have already visited the Warsaw Copernicus Science Centre (CNK). The 400 thousand visitor entered the Copernicus on May 31. As of November 2010, visitors of the Centre can conduct experiments in five permanent exhibitions: "Roots of Civilization," "Lightzone", "On the Move", "Humans and the Environment" and a special gallery for children "Buzzz!". In March, the Centre opened sixth gallery, "Re: Generation." Scheduled for June 19 is the opening of the planetarium "The Heavens of Copernicus" and later the "Discovery Park" on the roof. The Centre construction cost amounted to PLN 365 million, of which PLN 207 million came from the European Union. CNK is a joint initiative of the City of Warsaw, the Ministry of Science and Higher Education and the Ministry of National Education.

(<http://www.naukawpolsce.pap.pl>, 13.07.2011)

Scientists are developing soluble material to facilitate bone reconstruction

Material, which after being injected into a tooth socket will dissolve and facilitate the growth bone necessary for durable placement of dental implants, is being developed by PhD student at the Warsaw University of Technology Martyna Kucharska and colleagues. The work on the material is funded by the Foundation for Polish Science, which has awarded Kucharska a grant from the Ventures programme. The programme rewards young scientists, whose research can be applied in business and the economy. The material is made of biodegradable polymers, i.e. those which decompose inside the human body, but will also be absorbed. The whole process of material dissolution and bone growth will last six to nine months. After this time, an appropriate tooth implant can be placed. The author explains that developed material should offer an alternative to autologous grafts, which consist in collecting the patient's own bone and implanting it in a place that needs to be rebuilt. She noted that materials already available on the market are usually specially prepared animal materials. She assured that researchers intend to develop other materials that could have bone-forming applications. In her opinion, such procedure could be performed by a dental surgeon. Martyna Kucharska works on developing the material with Eng. Grzegorz Bubak, Dr. Tomasz Ciach, Witold Bojar, MD and Łukasz Koperski, MD. The researchers have already tested the sensitizing, irritating and toxic properties of the material. The project, funded by the Foundation for Polish Science, will run until the end of February 2012.

(<http://www.naukawpolsce.pap.pl>/23.07.2011)