„Harmonisation of Polish regulations according to European legislation – marketing and using of chemical substances and preparations”

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In 1994, Poland signed the EU Association Treaty which has obliged our country to adjust the legal regulations on the conditions of marketing and use of chemical substances and preparations to the relevant EU law.

Heretofore, there was no system of, or criteria for, classifying chemical products marketed in Poland. The Nofer Institute of Occupational Medicine in Lodz has been committed by the Ministry of Health and Social Welfare to draft the Chemical Substances and Preparations Act aimed at setting conditions of marketing and use of chemical substances and preparations.

The Act lays down conditions, bans and/or restrictions of production, placing on the market and/or use of chemical substances and preparations in order to protect human health and/or the environment against the harmful impact of these substances and preparations.

Within the meaning of this Act dangerous substances and dangerous preparations are substances and preparations belonging to at least one of the following categories:

1) explosive substances and preparations,
2) oxidising substances and preparations,
3) extremely flammable substances and preparations,
4) highly flammable substances and preparations,
5) flammable substances and preparations,
6) highly toxic substances and preparations,
7) toxic substances and preparations,
8) harmful substances and preparations,
9) corrosive substances and preparations,
10) irritant substances and preparations,
11) sensitising substances and preparations,
12) carcinogenic substances and preparations,
13) mutagenic substances and preparations,
14) substances and preparations harmful for reproduction,
15) substances and preparations dangerous for the environment

The authority of Inspector for Chemical Substances and Preparations, hereinafter referred to as the "Inspector" is hereby established.

The Inspector is competent to issue decisions in situations identified by the Act.

The duties of the Inspector shall include:

1) receiving notifications on new substances required by the Act in order to assess the risk posed by such substances,

2) collecting data on dangerous substances and dangerous preparations,

3) providing data on dangerous substances and dangerous preparations to medical and rescue services,

4) exchanging information on new substances with the European Commission and relevant authorities of the states referred to in Article 2 paragraph 1 subparagraph 6,

5) co-operation with international organisations concerning chemical substances and preparations,

6) executing other tasks imposed by the minister in charge of health.

2. Inspector exercises his/her tasks with the assistance of the Office for Chemical Substances and Preparations, hereinafter referred to as the "Office", which he heads and represents in external relations.

Any new substance:

1) manufactured on the territory of The Republic of Poland,

2) imported into the territory by an importer established on the territory of The Republic of Poland,

3) manufactured outside of the territory by a manufacturer who has established a sole representative in The Republic of Poland,

shall be notified to the Inspector prior to its placing on the market either on its own or in a preparation.

The obligation to notify falls upon:

1) a manufacturer who places a new substance on the market either on its own or in a preparation in the case of substances manufactured on the territory of The Republic of Poland,

2) an importer who places a new substance on the market either on its own or in a preparation if he/her is established in The Republic of Poland, or upon a sole representative of the manufacturer established on the territory of The Republic of Poland in the case of new substances manufactured outside of the territory

3). Obligation to notify shall not apply if the person made a prior notification in one of the Member States of the European Union or the territory of Iceland, Liechtenstein and Norway, according to provisions binding in these states.

The obligation to notify not apply to:

1) polymers, except those containing in combined form at least 2% of a new substance,

2) multimolecular compounds, products of polymerisation and polycondensation and polyadducts, except products containing at least 2% of a new substance in combined form which were placed on the market between 18 September, 1981 and 30 October, 1993,

3) new substances used exclusively as food additives, in the meaning of health provisions for foodstuffs and nutrition,

4) new substances used exclusively as feedingstuff additives, in the meaning of provisions on the control over certain products used for feeding animals,

5) new substances used exclusively as active substances, in the meaning of provisions on pharmaceuticals, medical materials, pharmacies, pharmaceutical wholesalers and pharmaceutical supervision,

6) new substances used exclusively as biologically active substances in the meaning of provisions on the protection of cultivated plants,

7) new substances the turnover of which does not exceed 10 kilograms annually,

8) new substances placed on the market exclusively for scientific research and development in R&D units and other laboratories if the turnover does not exceed 100 kilograms annually and a manufacturer or an importer keeps written information on the substance in question concerning its identification, labelling, quantities placed on the market and the list of customers.

The person placing a dangerous substance or a dangerous preparation on the market on the territory of The Republic of Poland is obliged to provide the safety data sheet to the recipient of this substance or preparation free of charge not later than on the day of the first supply.

Importers or distributors marketing European Union products in the Polish market experience problems in preparing the Safety Data Sheets.

The problems are primarily due to the fact that the sheet must be in Polish and must comply to the national laws and any other national measures on the protection of human and environmental health if such laws and measures are applicable to the substance or preparation, for example:

- limitations on sale and use
- classification of waste
- specific control parameters such as occupational exposure limit values (MAC, STEL, TLV-C), biological limit values
- recommended monitoring procedures
- ecological limit values
- regulations on handling of dangerous materials

They should be included in the Safety Data Sheet in the most comprehensive manner and accompanied by references to relevant law.

Safety Data Sheet translated into Polish are usually encumbered with one fundamental formal defect: they refer to the regulations on safety (in its broad sense) which are valid in the manufacturer's country.

The person responsible for marketing the dangerous foreign product should:

- make sure that the sheet has all required 16 items
- unequivocally identify the dangerous component
- make sure that the manufacturer's classification is correct
- adjust the contents to the requirements of the relevant polish law
- use correct terminology and wording as required by relevant regulations, it is necessary to use terminology specified in the ordinances accompanying the act and, in particular, preserve the wording of the R and S phrases
- amend the safety data sheet when new information is made available which may require reassessment of heath risk and workplace or environmental safety, and also in cases when legal regulations are modified

Before a dangerous preparation may be marketed in the territory of the Republic of Poland, the Inspector must receive a relevant information comprising:

- name, address and telephone number of the person marketing the dangerous preparation
- commercial name of the dangerous preparation
- safety data sheet

Labelling of a packaging of a dangerous substance and a dangerous preparation shall show a name allowing for unequivocal identification of a substance or a preparation, identification of a person who places a substance or a preparation on the market and appropriate warning symbols and inscriptions, in accordance with provisions referred to in Article 26 and information on the procedure to be followed in relation to empty containers if required by separate provisions. Labelling should be in Polish, in accordance with the requirements laid down in separate provisions. Packaging of dangerous substances and dangerous preparations may not include any symbols or inscriptions indicating that such a substance or a preparation is not dangerous. When new substances and preparations containing at least 1% of the substance are placed on the market, if they cannot be labelled in accordance with the Act due to the lack of appropriate data, labelling shall include the following warnings:

1) for substances "Warning: the substance has not been fully tested",

2) for preparations "Warning: the product contains a substance which has not been fully tested".

Whoever, in violation of the decision of the Inspector for Chemical Substances and Preparations, places on the market a preparation entailing an unacceptable hazard for human health and/or the

environment or does not comply with the conditions of its placing on the market laid down in a decision - shall be subject to a fine, restricted freedom or imprisonment for up to 2 years.

Whoever places on the market a dangerous substance or a dangerous preparation:

1) without labelling or inappropriately labelled,

2) without required safety data sheet

- shall be subject to a fine.

Whoever provides an incomplete or unreliable safety data sheet - shall be subject to a fine.

Whoever advertises a dangerous substance without indicating the category of danger relating to this substance.

The same penalty shall apply for anyone who advertises a dangerous preparation without providing information on a type or types of hazards specified on the labelling of the packaging of such a preparation if the advertisement enables the purchase of the preparation without prior notice of the labelling on its packaging.

Whoever places a new substance on the market either on its own or as a component of a preparation without prior notification required by the Act is obliged to pay to the State budget the equivalent of 100% of the revenue from the sales of the substance or preparation in question.