

EMERGENCY ORDINANCE
on the classification, labelling and packaging of dangerous chemical substances and preparations

(GEO 200/2000)

THE GOVERNMENT OF ROMANIA,

Pursuant to the Constitution of Romania, and in particular Article 114(4) thereof,

HAS ADOPTED THIS EMERGENCY ORDINANCE:

CHAPTER I

General Provisions

Article 1

This Emergency Ordinance establishes the legal framework for the classification, labelling and packaging of chemical substances and preparations dangerous for persons and the environment.

Article 2

The basic principles for this Emergency Ordinance are as follows:

- a) the principle of ensuring an adequate protection level for persons and the environment;
- b) the principle of the free movement of goods;
- c) the principle of the technical progress.

Article 3

This Emergency Ordinance shall apply to chemical substances and preparations placed on the market and classified as dangerous.

Article 4

The following chemical substances and preparations in the finished product form and destined to the final user are exempt from the provisions of this Emergency Ordinance:

- a) medicinal and veterinary products;
- b) cosmetics;
- c) mixtures of substances turned into waste;
- d) foodstuffs;
- e) animal feedingstuffs;
- f) pesticides;
- g) radioactive substances;

- h) ammunition and explosives placed on the market with a view to obtaining a practical effect by explosion or a pyrotechnic effects;
- i) dangerous chemical substances which require special authorisation and approval procedures through legal regulations in force and for which the requirements are equivalent to those laid down in this Emergency Ordinance.

Article 5

The provisions of this Emergency Ordinance shall not apply for:

- a) the transportation of dangerous substances by rail, road, air and water;
- b) substances in transit, subject to customs supervision, provided they do not undergo any treatment or transformation.

CHAPTER II

Definitions

Article 6

For the purpose of this Emergency Ordinance:

- a) *substance* means chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the products and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;
- b) *preparation* means mixtures or solutions composed of two or more substances;
- c) *polymer* means a substance consisting of molecules characterised by the sequence of one or more types of monomer units and comprising a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant and consists of less than a simple weight majority of molecules of the same molecular weight. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. In the context of this definition a "monomer unit" means the reacted form of a monomer in a polymer;
- d) *placing on the market* means making available these substances to third parties, including importation into the Romanian territory which is deemed to be placing on the market for the purposes of this Emergency Ordinance;
- e) *EINECS* means the European Inventory of Existing Commercial Chemical Substances. This inventory contains the definitive list of all chemical substances deemed to be on the Community market on 18 September 1981.

Article 7

The following substances and preparations are dangerous within the meaning of this Emergency Ordinance:

- a) explosive substances and preparations: solid, liquid, pasty or gelatinous substances and preparations which may also react exothermically without atmospheric oxygen thereby quickly evolving gases, and which, under defined test conditions, detonate, quickly deflagrate or upon heating explode when partially confined;
- b) oxidising substances and preparations: substances and preparations which give rise to a highly exothermic reaction in contact with other substances, particularly flammable substances;
- c) extremely flammable substances and preparations: liquid substances and preparations having an extremely low flash-point and a low boiling-point and gaseous substances and preparations which are flammable in contact with air at ambient temperature and pressure;
- d) highly flammable substances and preparations:
 - substances and preparations which may become hot and finally catch fire in contact with air at ambient temperature without any application of energy, or
 - solid substances and preparations which may readily catch fire after brief contact with a source of ignition and which continue to burn or to be consumed after removal of the source of ignition, or
 - liquid substances and preparations having a very low flash-point, or
 - substances and preparations which, in contact with water or damp air, evolve extremely flammable gases in dangerous quantities;
- e) flammable substances and preparations: liquid substances and preparations having a low flash-point;
- f) very toxic substances and preparations: substances and preparations which in very low quantities cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin;
- g) toxic substances and preparations: substances and preparations which in low quantities cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin;
- h) harmful substances and preparations: substances and preparations which may cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin;
- i) corrosive substances and preparations: substances and preparations which may, on contact with living tissues, destroy them;
- j) irritant substances and preparations: non-corrosive substances and preparations which, through immediate, prolonged or repeated contact with the skin or mucous membrane, may cause inflammation;
- k) sensitising substances and preparations: substances and preparations which, if they are inhaled or if they penetrate the skin, are capable of eliciting a reaction of hypersensitisation such that on further exposure to the substance or preparation, characteristic adverse effects are produced;

- l) carcinogenic substances and preparations: substances or preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce cancer or increase its incidence;
- m) mutagenic substances and preparations: substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce heritable genetic defects or increase their incidence;
- n) substances and preparations which are toxic for reproduction: substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may produce, or increase the incidence of, non-heritable adverse effects in the progeny and/or an impairment of male or female reproductive functions or capacity;
- o) substances and preparations which are dangerous for the environment: substances and preparations which, were they to enter the environment, would or could present an immediate or delayed danger for one or more components of the environment.

CHAPTER III

Classification of Dangerous Chemical Substances and Preparations

Article 8

Substances are classified on the basis of their intrinsic properties, according to the categories laid down in Article 7.

Article 9

The classification of dangerous preparations according to the degree and specific nature of the hazards involved shall be based on the definitions of categories of danger laid down in Article 7.

Article 10

The procedure for the classification of dangerous chemical substances and preparations is carried out according to the methodological norms for the application of this Emergency Ordinance, except for the case where provisions contrary to this are specified in other legal rules and regulations for certain dangerous preparations.

Article 11

The testing of the chemical substances and preparations, of their physical and chemical properties, of their toxicity and ecological toxicity respectively is made in accordance with the norms established for the application of this Emergency Ordinance.

Article 12

If some of the chemical substances included in *EINECS* have been classified according to test results obtained with other methods than those established in this Emergency Ordinance methodology, the decision for the test repetition shall be taken for each case individually.

Article 13

Laboratory tests shall be conducted in compliance with the principles of good laboratory practice, by approved and appointed laboratories, according to the legal rules and regulations in force.

CHAPTER IV

Packaging of Dangerous Chemical Substances and Preparations

Article 14

Dangerous substances cannot be placed on the market unless their packaging satisfies the following requirements:

- a) the packages shall be so designed and constructed so as to prevent any loss of content during handling, transportation and storing;
- b) the materials constituting the packaging and fastenings must not be susceptible to adverse attack by the contents, or liable to form dangerous compounds with the contents;
- c) the packaging and fastenings shall be solid and resistant to avoid any leakage and safely meet the normal stresses and strains of handling;
- d) the containers fitted with replaceable fastening devices shall be so designed that the packaging can be refastened repeatedly without losing the contents;
- e) any container of whatever capacity, containing substances made available or sold to the general public, shall be provided with a safety device for children protection and shall carry warnings of danger, according to certain categories of danger specified in the methodological norms and regulations implementing this Emergency Ordinance;
- f) the package shall be closed initially with a seal in such a way that when the packaging is opened for the first time the seal is irreparably damaged;

Article 15

The placing on the market of dangerous preparations shall be allowed only if the following requirements for the packages are satisfied:

- a) the provisions of Article 14(a) to (d), for the integrity, avoidance of losses and for the fastening systems;
- b) the recipients containing dangerous preparations made available or sold or to the general public shall not have:
 - either a shape and/or graphic presentation likely to attract or arouse the active curiosity of children or to mislead consumers, or
 - a presentation and/or a design used for foodstuffs or animal feedingstuffs or medicinal or cosmetic products so as not to be confused;
- c) the recipients containing certain categories of dangerous chemical substances offered or sold to the general public, which are specified in the norms and regulations implementing this Emergency Ordinance shall be fitted with:
 - child-resistant fastenings,
 - tactile warnings of danger.

CHAPTER V

Labelling of Dangerous Chemical Substances and Preparations

Article 16

The dangerous substances cannot be placed on the market unless the following information is clearly and indelibly marked on their packages:

- a) trade name or designation of the substance, as given in the methodological norms implementing this Emergency Ordinance. If the name of the substance is not clear, the name must be given using an internationally recognised designation;
- b) name, full address and telephone number of the person who is responsible for placing the dangerous chemical substance or preparation on the market, whether it be manufacturer, importer or distributor;
- c) danger symbols, and, if necessary, indications of danger involved in the use of the substance;
- d) standard phrases for the use of dangerous substances, concerning the risks arising from the danger involved in using the substances (R phrases);
- e) standard phrases showing advices relating to safety while using the dangerous preparation (S phrases);
- f) assignment of the EEC number from EINECS, when it is allocated.

Article 17

Dangerous preparations cannot be placed on the market unless the following information is clearly and indelibly marked on the label of their packages:

- a) trade name or the end-use of the preparation;
- b) name, full address and telephone number of the person who is responsible for placing the dangerous preparations on the market, whether it be the manufacturer, importer or distributor;
- c) chemical name of the components classified as dangerous;
- d) danger symbols, and if necessary, indications about the dangers involved in the use of the preparation;
- e) standard phrases for the use of dangerous preparations, concerning the risks arising from the use of dangerous preparation (R phrases);
- g) one or more standard phrases showing advices relating to safety while using the dangerous preparation (S phrases);
- h) the nominal quantity (the nominal mass or nominal volume) of the contents in the case of dangerous preparations made available or sold to the general public.

Article 18

The provisions of Articles 16 and 17 shall apply in accordance with the methodological norms and regulations implementing this Emergency Ordinance.

Article 19

The label shall be written in Romanian, except for the provisions of Article 17(c) when the internationally accepted language can be used for components.

CHAPTER VI

Advertisement and Safety Data Sheets

Article 20

Any advertisement shall be allowed for the chemical substances, which belong to one or more of the categories of danger, provided that the respective category/categories is/are mentioned.

Article 21

To enable professional and industrial users to take all the necessary measures as regards the protection of the environment and health and safety at workplace, each manufacturer, importer or distributor shall communicate the safety data sheet to the recipient, at the first delivery of the dangerous substances and preparations or even before delivery. The sheet must contain all the actual available information necessary to ensure the protection of man and the environment.

Article 22

The safety data sheet shall be submitted to the recipient. Subsequently, the manufacturer, importer or distributor shall forward to the recipient of the safety data sheet any new information on the substance, which has become known to him.

CHAPTER VII

Duties and Responsibilities

Article 23

- (1) The National Agency for Dangerous Chemical Substances and Preparations as a legal entity of public interest, subordinated to the Ministry of Industry and Trade shall be established with the following main duties and responsibilities:
 - a) requesting and receiving information on the properties, including chemical composition, of the dangerous chemical substances and preparations to be used in order to meet any medical requirements, in prophylactic and curative purposes, especially in emergencies;
 - b) co-ordinating together with line ministries the training and further training of the staff certified to control and supervise chemical substances and training the competent bodies;
 - c) co-ordinating and supplying information about the dangerous chemical substances and preparations;
 - d) authorising specialised inspectors to check upon the observance of the provisions of the regulations in the field of dangerous chemical substances and preparations;

- e) supplying specific and detailed information to all Government agencies and bodies with duties in the field of dangerous chemical substances and preparations (customs authorities, labour protection inspectorates, public health authorities, environment protection agencies, etc.);
 - f) ascertaining and sanctioning any breach of the regulations in the field of dangerous chemical substances and preparations and establishing remedies and deadlines for fulfilling them.
- (2) The organising and functioning of the National Agency for Dangerous Chemical Substances and Preparations shall be established by Government Decision. The financing of the National Agency for Dangerous Chemical Substances and Preparations shall be ensured from extra budgetary funds.

Article 24

The manufacturers and importers have the following duties and responsibilities:

- a) testing the properties of the chemical substances and preparations in order to establish the classes of danger they belong to in accordance with the provisions of this Emergency Ordinance;
- b) classifying, labelling and packaging the dangerous chemical substances and preparations according to the provisions of this Emergency Ordinance;
- c) issuing technical safety data sheets for the dangerous chemical substances and preparations which shall be further submitted to the recipient free of charge, at the moment of delivery at the latest;
- d) providing the National Agency for Dangerous Chemical Substances and Preparations with all the data about the properties of the substances and preparations which could endanger the health of persons or the environment;

CHAPTER VIII

Misdemeanours and Sanctions

Article 25

The following deeds of the legal or natural persons authorised to place on the market dangerous chemical substances and preparations shall constitute misdemeanours unless committed under circumstances that might allow their classification as felonies, pursuant to the Criminal Code:

- a) misrepresentation of data, or their presentation as incomplete or distorted, about dangerous chemical substances and preparations which can severely damage the health of persons or the environment;
- b) failure to submit safety data sheets or presentation of incomplete or distorted data;
- c) misclassification, mispackaging and mislabelling dangerous chemical substances and preparations;

- d) infringement of the provisions of this Emergency Ordinance in any manner other than that stipulated in points (a), (b) and (c) above.

Article 26

- (1) The deeds provided for in Article 25(a) shall be sanctioned with a fine amounting between ROL 10 000 000 and ROL 30 000 000 and with the withdrawal of the authorisation to carry on commercial activities.
- (2) The deeds provided for in Article. 25(b) and (c) shall be sanctioned with a fine between ROL 30 000 000 and ROL 55 000 000.
- (3) The deeds provided for in Article 25(d) shall be sanctioned with a fine amounting between ROL 25 000 000 and ROL 60 000 000.

Article 27

- (1) The repetition of any of the misdemeanours stipulated in Article 25 or the failure to fulfil the remedies established by the National Agency for Dangerous Chemical Substances and Preparations shall be sanctioned with the double of the maximum fine provided for by law.
- (2) The amount of the fines shall be annually updated by Government Decision.

Article 28

The application of the sanctions for the misdemeanours provided for in Article 25 shall be carried out by the National Agency for Dangerous Chemical Substances and Preparations.

Article 29

- (1) The fine shall be paid within 30 days from the date of ascertaining the non-observance of the duties stipulated in this Emergency Ordinance.
- (2) The delay in paying the fines shall entail penalties in accordance with the legal provisions in force.
- (3) Complaints against the minutes ascertaining the misdemeanour and against sanctions shall be filed within 30 days from the day of the notification thereof.
- (4) The competent court shall settle all complaints.

Article 30

The repeated breach or the non-observance of the provisions of this Emergency Ordinance shall entail the temporary or final interdiction to carry on any activity, according to the provisions of the Law for the Protection of the Environment No 137/1995, republished.

Article 31

Fines shall constitute returns to the state budget.

Article 32

Any deed of a natural or legal person related to the activities provided for in this Emergency Ordinance, which has the characteristics of an offence shall be sanctioned in accordance with the provisions of the Criminal Code.

Article 33

The competent staff of the National Agency for Dangerous Chemical Substances and Preparations shall ascertain the non-observance of duties and the commitment of misdemeanours, and shall impose fines.

Article 34

Where this Emergency Ordinance does not decide accordingly, the provisions ruling the general regime of contraventions shall apply to the misdemeanours provided for in Article 25.

CHAPTER IX

Final and Transitional Provisions

Article 35

The Ministry of Industry and Trade shall issue the instruments on the organisation and operation of the National Agency for Dangerous Chemical Substances and Preparations and the norms implementing this Emergency Ordinance, which shall be further submitted to the Government for approval.

Article 36

The Ministry of Industry and Trade together with the Ministry of Health, the Ministry of Waters, Forests and Environment Protection and the Ministry of Labour and Social Protection shall establish norms on:

- a) restrictions for the marketing and use of some dangerous chemical substances and preparations;
- b) the notification of new chemical substances and the evaluation of their risk for man and environment.

Article 37

This Emergency Ordinance shall be implemented after 12 months from its publication in the Romanian Official Journal, Part I.

Article 38

Point 18 of Annex 2: "Technical norms on the cultivation of plants containing toxic substances, the manufacturing, treatment, storing, packaging, transportation and handling of toxic products and substances" to the Decree No 466/1979 of the State Council on the regime of toxic products and substances, published in the Official Bulletin, Part I, No 2 of 3 January 1980 is repealed as soon as this Emergency Ordinance enters into force.

PRIME MINISTER,
MUGUR CONSTANTIN ISĂRESCU

Endorsed by:
Minister of Industry and Trade,
Radu Berceanu

Minister of Waters, Forests and Environment
Protection,
Romică Tomescu

Minister of Health,
State Minister,
Hajdu Gabor

For the Minister of Civil Service,
State Secretary,
Marian Pârjol

Office for Consumer Protection,
State Secretary,
Eliade Corneliu Mihăilescu

Minister of Finance,
Decebal Traian Remeş

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