

## **ON THE DEVELOPMENT OF CHEMICAL LEGISLATION IN BULGARIA**

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**Abstract.** As in the other countries in transition a new chemical legislation is in the process of development in Bulgaria. This paper is a personal view and analysis of the chemical act adopted by the Bulgarian Parliament as a step for approximation of the national legislation with the European one. On the base of comparative analysis with the requirements and the spirit of the EU Directives related some critics are given and needed improvements shown. Changes proposed are mainly related to the next step developments of regulations to be developed, according to the basic principles of the chemical law in force. The main critics are in the area of responsible Competent Authority and its role in the process of practical implementation of the new legislation. The analysis are covering the requirements of the basic EU Directive for classification, packing and labelling of the dangerous chemical substances and preparations, but also attention is given to registration, inventories, notification and risk assessment of the chemicals. It is proposed an understanding that new normative acts should integrate the rights and responsibilities of all parties involved in the process of practical implementation of the new normative acts. It is stressed that the practical implementation will require high financial resources mainly from the companies of chemical industrial sector. The cost of this implementation should be taken into account, because the practice from other countries has shown that the problems sometimes could not be overcome by the companies. Training of the experts from the authorities and companies is also subject of discussion.

**Keywords:** chemical legislation, environment, Bulgaria.

### **GENERAL**

Bulgarian Parliament approved Bulgarian Law on Protection from the Harmful Impact of the Chemical Substances, Preparations and Products on 21 of January 2000 and after its promulgation in the State Gazette on 4 of February 2000 year, this Law shall enter into force on 5 of February 2002 year<sup>1</sup>.

This Law regulates the conditions and the order of manufacture, trade, import, export and use of chemical substances and preparations, the state control of these activities as well as the rights and duties of natural and legal persons who/ which manufacture and trade chemical substances and preparations. The purpose of this Law is to protect man and the environment from the harmful effects of dangerous chemical substances and preparations.

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<sup>1</sup> For correspondence.

This Law should help Bulgaria to adopt modernised chemical control legislation and to harmonise this legislation with the applicable legislation as part of the “acquis communautaire” of the future enlarged Internal Market. Indeed this approximation is essential to allow effective free circulation of goods whilst ensuring high health safety and environmental protection.

Law on Protection from the Harmful Impact of Chemical Substances, Preparations and Products has a wider scope compared to a simple transposition of “placing on the market” concept governed by Dangerous Substances Directive<sup>2</sup> (67/548/EEC up to 9th amendment), and Dangerous Preparations Directive (88/378/EEC as amended by 1999/45/EEC), and restrictions on marketing and use of certain dangerous substances and preparations mechanism governed by Directive 76/769/EEC.

Positive elements of this Law are:

1. Acceptance of this Law, which is a step for approximation of the national legislation with the European Union one.

2. The regulation of issues of:

- classification, packaging and labelling of dangerous chemical substances;
- notification of new chemical substances;
- registration of the manufacture of chemical substances and preparations;
- import, export and trade of chemical substances and preparations;
- measures for safe manufacture and use of chemical substances and preparations;
- state control of chemical substances;
- administrative puniness provisions.

To assess the covering the letter and the spirit of the “acquis”, in Table 1 are given item by item the correspondence of Bulgarian Law articles with EU directives.

**Table 1.** Comparison of the Bulgarian Law articles with EU directives

Title of the directive and regulation		Law on Protection from the Harmful Impact of the Chemical Substances and Preparations		
Correspondence of the Law with:	Provision	National Law provisions	Comments	
1	2	3	4	
Council Directive 67/ 548/ EEC <sup>2</sup>	relating to the classification, packaging and labelling of dangerous substances			

to be continued

Continuation of Table I

1	2	3	4
Art. 1	objectives and scope	Art. 1; paragraph (1), (2)	the scope of the law corresponds to the scope of the Directive including also the chemical preparations which are subject of the Directive 88/379/EEC mainly. But the Law has a wider scope, compared to the simple transportation of "placing on the market". The Law includes the production and the transport of chemical substances and preparations also
Art. 2	definitions	Art. 2; additional provisions § 1 paragraphs (1-16)	the law strictly follows the provisions of the Directive, giving precise definitions of the main terms in the field, but there are four paragraphs 13-16, which are connected with risk assessment most of all
Art. 3	testing and assessment of the properties of substances	Art. 11 and 13, Art. 20, p.p.3	the Law does not define the procedures for testing and assessment of risks to human health and the environment. It is stipulated that the provisions will be further developed in two by-laws, issued by the Council of Ministers
Art. 4	classification	Art. 5, paragraphs (1), (2); Art. 2; additional provisions § 1 paragraphs (7) and (8)	the Law lays down a classification, but it stipulates that the methods and rules will be laid down in a regulation issued by the Council of Ministers
Art. 5	duties of the Member States		the provision is not applicable before joining the EU
Art. 6	obligation to carry out investigation	Art.9, paragraph (1),p.p.1, Art. 10, Art. 20, p.p.3	obligation to carry out investigation of physical and chemical properties, when prepare technical dossier and risks to human health and the environment
Art. 7	full notification	Art. 8, 9, 10, 11, 12, 13	ministry of environment and water notifies the substances and preparations and realises public register of notified substances
Art. 8	reduced notification requirements for substances placed on the market in quantities of less than one tonne per annum per manufacturer		in the law is not specified full notification and reduced notification
Art. 9	substances already notified (10-year rule)	Art. 8, paragraph (2), p.p. 1	

to be continued

Continuation of Table 1

1	2	3	4
Art. 10	placing of notified substances on the market	Art. 6, art. 8	
Art. 11	substances manufactured outside the Community		the provision is not applicable before joining the EU
Art. 12	polymers	Art. 8, paragraph (2), p. 4	
Art. 13	exemptions	Art. 3, paragraph 1-7; Art. 8, paragraph 2	
Art. 14	follow-up information		it is stipulated that the provisions will be further developed in a by-law
Art. 15	re-notification of the same substance and avoidance of duplicating testing on the vertebrate animals		it is stipulated that the provisions will be further developed in a by-law
Art. 16	rights and duties of the authorities	Art. (5), (10), (12), (13), (14), (16), (18), (22), (27), (28), (29), (31), (33), (36), 3, § 5	it is stipulated that the provisions will be further developed in a by-law
Art. 17	involvement of the Commission in the notification procedure		the provision is not applicable to the present analysis
Art. 18	duties of the Commission		the provision is not applicable to the present analysis
Art. 19	confidentiality of data	Art. 28, paragraph(2)	the requirements on the confidentiality of information correspond to those in the Directive
Art. 20	exchange of the summary dossier		the provision is not applicable to the present analysis
Art. 21	lists of existing and new substances	§ 1, p.p. 5, 6	
Art. 22	packaging	Art. 6	
Art. 23	labelling	Art. 7	
Art. 24	implementation of labelling requirements	Art. 7, paragraph (1)	
Art. 25	exemptions from labelling and packaging requirements	Art. 7, paragraph (2)	

to be continued

Continuation of Table I

1	2	3	4
Art. 26	advertisement	Art. 4	the provisions of the draft correspond to the provisions of the Directive
Art. 27	safety data sheet	Art.7, paragraphs (4), (5), (6), (7), (9), Art. 20, p. p.1, 2	the provisions of the draft correspond to the provisions of the Directive
Art. 28	adaptation to technical progress	Art. 20, paragraph (13)	
Art. 29	procedure for adaptation to technical progress		the provision is not applicable before joining the EU
Art. 30	free movement clause	Chapter 6 relating to the import & export and trade	
Art. 31	safeguard clause		the provision is not applicable to the present analysis
Art. 32	reports		the provision is not applicable to the present analysis
Art. 33	final provision		the provision is not applicable to the present analysis
Art. 34	final provision		the provision is not applicable to the present analysis
Directive 88/379/EEC <sup>3</sup>	on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous preparations	§ 1, p. 2;	what was said about the correspondence with Directive 67/548 applies to this Directive
Directive 91/155/EEC <sup>4</sup>	defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations in implementation of Article 10 of Directive 88/379/EEC		the requirements of the Directive on the information to be included in the safety data sheet are implemented in the law. Further requirements on the safety data sheet shall be laid down

to be continued

Continuation of Table 1

1	2	3	4
Directive 91/442/EEC	on dangerous preparations the packaging of which must be fitted with child-resistant fastenings		such requirement is not established on the draft
Directive 76/769/EEC	on the approximation of laws, regulations and administrative provisions of the marketing and use of certain dangerous substances and preparations	Chapter 7	a permission regime corresponding to the one laid down in the Directive is established. It shall be further developed in a by-law
Directive 93/67/EEC <sup>5</sup>	laying down the principles for assessment of risks to man and the environment of substances notified in accordance with Council Directive 67/548/EEC	Art.10, paragraph (2); Art. 11, Art. 29, Art. 30	the basic principles of the risk assessment are stipulated in the law. It shall be further developed in a by-law, issued by the Council of Ministers
Commission Regulation No 1488/94 <sup>6</sup>	laying down the principles for the assessment of risk to man and the environment of existing substances in accordance with Council Regulation 793/93/EEC	Art.10, paragraph (2); Art. 11, Art. 29, Art. 30	the basic principles of the risk assessment are stipulated in the law. It shall be further developed in a by-law, issued by the Council of Ministers

On a base of the comparative analysis with the requirements and the letter and spirit of the EU Directives the following general conclusions can be emphasised:

The Bulgarian Law on Protection from the Harmful Impact of Chemical Substances and Preparations has a wider scope compared to the simple transposition of "placing on the market" and it should be taken into account:

- some of the Provisions may cause barriers to trade (Art. 7, Art. 9, Art. 11);
- Law has to comply with wide range of secondary legislation (Directives, Regulations, etc.) with distinguished objectives and in the cases using the same term in different meanings and it may cause misinterpretation and improper operation of the Community Law.

Provisions of the Law pertinent to placing on the market of the dangerous substances and preparations in principle follow the Community "asquis", never-

theless some provisions need to be rectified in order to avoid requirements incompatible with the Community “acquis” and resulting in adverse effects on chemical industry and trade (Chapter 5). The implementing legislation needs to be linked-up to EU Directives and the relevant annexes to EU Directives, as well as to relevant Community mechanisms (the Law lacks such link-up and references) .

Is it clear the need to introduce a mechanism to ensure the active involvement of all stakeholders such as industry both in the preparatory phase as well as in the implementation of the legislation. It was, therefore, recommended that the Competent Authority would be assisted by an Advisory Board or a Chemical Safety Commission comprising representatives of the authorities, as well as different stakeholders such as industry. The relevant provisions should be further developed in a by-law.

Chapter 5 provides for measures for safe manufacture and use of chemical substances and preparations. Requirements of this chapter present a mixture of provisions related to transposition of EU legislation on safety at work, EU legislation on risk assessment of existing and new chemical substances (while new substances are subject of Chapter 3), good manufacturing practice, EU legislation on the control of major-accident hazards involving dangerous substances (subject of Chapter 4) and EU legislation of waste. The relevant provisions should be further developed in a by-law to clarify competencies of the relevant authorities in these areas in order to avoid overlap in competencies and parallel efforts of the authorities leading to waste of resources both on the side of authorities and industry. Practical implementation of this Chapter 5 will require high financial resources mainly from the companies of chemical industrial sector. The cost of this implementation should be taken into account, because the practice from other countries has shown that the problems sometimes could not be overcome by the companies.

Responsible competent authority for notification and its role in the process of practical implementation of the new legislation is not clear from the Law. Training of the experts from authorities and companies is also a subject of discussion.

## CONCLUSIONS

The approved Bulgarian Law on Chemical Substances, Preparations and Products is a certain contribution to the approximation process, but it still needs a number of improvements on the way to comply with the spirit and practice of EU legislation.

## REFERENCES

1. Bulgarian Law on Protection from the Harmful Impact of Chemical Substances and Preparations( in force from 5 February 2002 year).

2. Directive 67/548/EEC on the Approximation of Laws, Regulations and Administrative Provisions Relating to Classification, Packing and Labelling of Dangerous Substances (8th amendment).
3. Directive 88/379/EEC on the Approximation of Laws, Regulations and Administrative Provisions Relating to Classification, Packing and Labelling of Dangerous Preparations (3th amendment).
4. Directive 88/379/EEC on the Approximation of Laws, Regulations and Administrative Provisions of the Marketing and Use of Certain Dangerous Substances and Preparations (17th amendment).
5. Directive 93/67/EEC Laying down Principles for the Assessment of Risks to the Man and the Environment, Notified in Accordance with Council Directive 67/548/EEC.
6. Commission Regulation 1488/94 Laying down Principles for the Assessment of Risks to the Man and the Environment of Existing Substances in Accordance with Council Regulation 793/93/EEC.

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