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Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
amending Council Directive 67/548/EEC adapting it to the “REACH Regulation”

ORIGINAL: EN

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. INTRODUCTION

Directive 67/548/EEC on the classification, packaging and labelling of dangerous substances, as amended and adapted to technical progress, sets out rules not only how to classify, package and label dangerous substances, but also how to notify new substances to the Competent Authorities in the relevant Member State before placing them on the market. An unofficial consolidated version of this Directive, its amendments and adaptations is available on the Europa website as of 1 March 2003, (internet address: http://www.europa.eu.int/comm/environment/dansub/home_en.htm#ConsolidatedVersion).

The Commission presented in February 2001 a White Paper¹ on the strategy for a future chemicals policy. In this White Paper the Commission identified the objectives that must be met in order to achieve sustainable development in the chemicals industry within the framework of the single market. It also set out the key elements of the strategy, in particular the creation of a single regulatory system for all substances (entitled REACH for the Registration, Evaluation and Authorisation of Chemicals) and giving industry the responsibility for generating data on the inherent properties of substances and for assessing the risks related to their use.

In parallel to the present proposal the Commission now puts forward a proposal² for a Regulation which lays down the general principles of the chemicals policy and establishes the legal requirements and procedures comprising the REACH system. It creates a European Chemicals Agency and defines its tasks and responsibilities.

The new REACH Regulation will introduce the same registration requirements for new chemicals as for the existing substances which means that the rules for notification of new chemicals in Directive 67/548/EEC have to be repealed. However, for reasons explained below, the REACH proposal does not at present include rules for classification, labelling and packaging of dangerous substances, the relevant parts of Directive 67/548/EEC will continue to apply. Directive 1999/45/EC on the classification, packaging and labelling of dangerous preparations will also continue to apply for the classification, packaging and labelling of dangerous preparations. Other parts of Community legislation, i.e. certain Directives on worker protection and the so called Seveso II Directive on major-accident hazards of certain industrial activities, which are based on the rules for the classification and labelling in Directive 67/548/EEC, will also continue to apply.

Directive 67/548/EEC contains several annexes related to information requirements and testing methods to be used. The content of these annexes will be taken over by the annexes to the REACH legislation and thus they have to be repealed from the Directive. Moreover, a substantial number of references to testing methods and information requirements has to be amended as a consequence of the introduction of the REACH legislation.

As a result of the Rio declaration on Environment and Sustainable Development 1991 a globally harmonised system on the classification and labelling of chemicals (GHS) has been developed and was adopted in July 2003 by the UN Economic and Social Council.

¹ COM(2001)88 final, 27 February 2001

² insert reference following adoption by COM

The European Commission, the majority of the Member States as well as many of the new Member States have actively taken part in the work to elaborate GHS. The Johannesburg World Summit on the Sustainable Development in 2002 agreed, in its plan of implementation, “to encourage countries to implement the new globally harmonized system for the classification and labelling of chemicals as soon as possible with the view to have it fully operational by 2008.” In line with this agreement, it is the intention of the Commission to propose the inclusion of the internationally agreed GHS into Community law as soon as possible. However, as the GHS has very recently been formally adopted, and because the Commission wishes to examine in more detail the implications of its adoption in terms of its impact on stakeholders and downstream legislation, it has not been considered appropriate to put forward a proposal to implement GHS into Community law at the same time as the proposal for REACH. Accordingly, the Commission will come forward with the necessary proposals for having it adopted at the same time as the final adoption of the REACH legislation.

2. CONTENT OF THE DIRECTIVE

Article 1

This article amends the articles in Directive 67/548/EEC as needed due to the introduction of the REACH legislation. It includes the deletion of the paragraphs related to the notification of new chemicals, and superfluous definitions as well as the annexes, which will be transferred to or taken over by the new legislation. The article also amends the relevant references from the deleted annexes to the annexes of the REACH Regulation.

Article 2

This article repeals Commission Directive 93/67/EEC of 20 July 1993 laying down the principles for assessment of risks to man and the environment of substances notified in accordance with Council Directive 67/548/EEC³ as such principles will be included in the REACH Regulation.

Article 13 of Directive 67/548/EEC exempts certain groups of substances from the notification requirements. This article is repealed through article 1 of this directive and as Directive 2000/21/EC is an adaptation of Article 13 of Directive 67/548/EEC it has also to be repealed.

Article 3

This standard article requires the Member States to bring into force the relevant legislation from the date of the application of the REACH Regulation. This points to the need for Member States to apply the two different pieces of legislation from same day in order to prevent any gaps and legal uncertainty.

Article 4

This article refers to the entry into force of the Directive.

³ OJ L 227, 8.9.1993, p. 9-18.

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Council Directive 67/548/EEC in order to adapt it to Regulation (EC) n. [..] of the European Parliament and of the Council concerning the registration, evaluation, authorisation and restriction of chemicals

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission⁴,

Having regard to the opinion of the European Economic and Social Committee⁵,

Having regard to the opinion of the Committee of the Regions⁶,

Acting in accordance with the procedure laid down in Article 251 of the Treaty⁷,

Whereas:

- (1) In view of the adoption of Regulation (EC) n.[..] of the European Parliament and of the Council, of...., concerning the registration, evaluation, authorisation and restrictions of chemicals...]⁵, Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances⁸, should be adapted and its rules on the notification and risk assessment of chemicals should be deleted.

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 67/548/EEC is amended as follows:

- (1) In Article 1, paragraph 1, points (a), (b) and (c) are deleted;
- (2) In Article 2, paragraph 1, points (c), (d), (f) and (g) are deleted;

⁴ OJ C [...], [...], p. [...].

⁵ OJ C [...], [...], p. [...].

⁶ OJ C [...], [...], p. [...].

⁷ OJ C [...], [...], p. [...].

⁵ OJ L...

⁸ OJ 196, 16.8.1967, p. 1 (Directive as last amended by Council Regulation (EC)n.807/2003 Dire(OJ L 225, 21.8.2001, p. 1).

(3) Article 3 is replaced by the following:

“Article 3

Testing and assessment of the properties of substances

Tests on substances carried out within the framework of this Directive shall be conducted according to the requirements of Article 12 of Regulation (EC) n.[...] of the European Parliament and of the Council *.

* OJ L...”

(4) Article 5 is amended as follows:

(a) In paragraph 1, the first subparagraph is replaced by the following:

"Member States shall take all the necessary measures to ensure that substances cannot be placed on the market on their own or in preparations unless they have been packaged and labelled in accordance with Articles 22 to 25 and with the criteria in Annex VI, and, for registered substances, in accordance with the information obtained through the application of Articles 11 and 12 of Regulation (EC)n[..], save in the case of preparations where provisions exist in other Directives."

(b) In paragraph (2) the words “in the second indent of paragraph 1” are replaced by the words “in the first subparagraph of paragraph 1”.

(5) Articles 7 to 20 are deleted.

(6) In Article 23 paragraph 2, the following point (g) is added:

“(g) the registration number, when available.”

(7) Article 27 is deleted.

(8) Article 30 is replaced by the following:

“Article 30

Free movement clause

Member States may not prohibit, restrict or impede the placing on the market of substances which comply with the requirements of this Directive, on grounds relating to classification, packaging or labelling within the meaning of this Directive.”(9)Article 32 is deleted.

(10) Annex V is deleted.

(11) Annex VI is amended as follows:(a)In points 1.6, 1.6.2, 1.7.2, 1.7.3, 2.1, 2.2.1, 2.2.2, 2.2.2.1, 2.2.3, 2.2.4, 2.2.5, 3.1.1, 3.1.5.1, 3.1.5.2, 3.2.1, 3.2.2, 3.2.3, 3.2.5, 3.2.6.1, 3.2.6.2, 3.2.7.2, 3.2.8, 4.2.3.3, 5.1, 5.1.3, 9.1.1.1, 9.1.1.2, 9.3, 9.5 of Annex VI, the words “Annex V”, are replaced by “Annex X of the Regulation(EC)n.[...]”.

- (b) In section 1.6 (a), the words “Annex VII” are replaced by “Annexes IV, V and VI of Regulation(EC)n.[...]” and the words “Annex VIII” are replaced by “Annexes VII and VIII of Regulation(EC)n.[...]”.
 - (c) In section 5.1, the words “Annex VII” are replaced by “Annexes V and VI of Regulation(EC)n.[...]” and the words “Level 1 (Annex VIII)” are replaced by “Annex VII or VIII of Regulation(EC)n.[...]”.
 - (d) In section 5.2.1.2, the words “Level 1 (Annex VIII)” are replaced by “Annex VII of Regulation(EC)n.[...]”.
 - (e) All other references to Annexes VIIA, VIIB, VIIC, VIID and VIII shall be construed as references to the corresponding Annexes IV, V, VI, VII, VIII and IX Regulation(EC)n.[...].
- (12) Annexes VIIA, VIIB, VIIC, VIID and VIII are deleted.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive as from the 60th day from the entry into force of the REACH Regulation. They shall forthwith inform the Commission thereof.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the main provisions of national law, which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the twentieth day following its publication in the *Official Journal of the European Union*.

This Directive is addressed to the Member States.

Done at Brussels, [...]

For the European Parliament
The President
[...]

For the Council
The President
[...]

⁹ OJ L 227, 8.9.1993, p. 9.

¹⁰ OJ L 103, 28.4.2000, p. 70.