Commission Regulation (EC) No 987/2008 of 8 October 2008 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes IV and V (Text with EEA relevance)

COMMISSION REGULATION (EC) No 987/2008

of 8 October 2008

amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes IV and V

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1907/2006 of 18 December 2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC⁽¹⁾, and in particular Article 131 thereof,

Whereas:

- (1) Regulation (EC) No 1907/2006 establishes registration obligations of Community manufacturers or importers of substances on their own, in preparations or articles, as well as provisions concerning evaluation of substances and the obligations of downstream users. Article 2(7)(a) of that Regulation provides that substances included in Annex IV are exempted from Titles II, V and VI of the same regulation as sufficient information is known about these substances that they are considered to cause minimum risk because of their intrinsic properties. In addition, Article 2(7)(b) of the same Regulation provides that substances covered by Annex V are exempted from the same titles of the Regulation, as registration is deemed inappropriate or unnecessary for these substances and their exemption from these titles does not prejudice the objectives of the Regulation.
- (2) Article 138(4) of that Regulation requires the Commission to review Annexes IV and V by 1 June 2008 with a view to proposing amendments, if appropriate.
- (3) The review carried out by the Commission pursuant to Article 138(4) has revealed that three substances listed in Annex IV should be removed from that Annex, as insufficient information is known about these substances for them to be considered as causing minimum risk because of their intrinsic properties. This is the case with vitamin A, as that substance may present significant risks of reproductive toxicity. This is also the

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EC) No 987/2008, Introductory Text. (See end of Document for details)

- case with carbon and graphite, in particular due to the fact that the concerned Einecs and/or CAS numbers are used to identify forms of carbon or graphite at the nano-scale, which do not meet the criteria for inclusion in this Annex.
- (4) Furthermore, three noble gases (helium, neon and xenon) fulfil the criteria for inclusion into Annex IV and should therefore be moved there from Annex V. Another noble gas, krypton, which meets the criteria for inclusion in Annex IV, should be added to the Annex for reasons of consistency. Three other substances (fructose, galactose and lactose) should be added because they have been identified as meeting the criteria for inclusion in Annex IV. Limestone should be deleted from Annex IV as it is a mineral and is already exempted in Annex V. Finally, certain existing entries on oils, fats, waxes, fatty acids and their salts should be deleted, as not all of those substances meet the criteria for inclusion in Annex IV and it is more consistent to include them in a generic entry in Annex V, using a formulation to limit the exemption to substances with a lower hazard profile.
- (5) The review carried out by the Commission pursuant to Article 138(4) of the Regulation has revealed that certain amendments should also be made to Annex V. Magnesia should be added, as it has been identified as a substance meeting the criteria for inclusion in Annex V. What is more, it is appropriate to add certain types of glass and ceramic frits which do not meet the classification criteria set out in Council Directive 67/548/ EEC⁽²⁾ and which, in addition, do not have dangerous constituents above the relevant concentration limits, unless there is scientific data proving that these constituents are not available. Certain vegetable oils, fats and waxes and animal oils, fats and waxes, as well as glycerol, that are obtained from natural sources, which are not chemically modified and which do not have any hazardous properties beyond flammability and skin or eye irritancy, should be added to Annex V in order to provide a more consistent treatment of comparable substances and to limit the exemption to substances with lower hazard properties. The same applies to certain fatty acids, which are obtained from natural sources and which are not chemically modified and which do not have any hazardous properties beyond flammability and skin or eye irritancy. The addition of oils, fats, waxes and fatty acids in Annex V corresponds to the deletion of certain individual substances of these groups listed in Annex IV.
- (6) The amendments provided for in this Regulation, in particular compost and biogas, are without prejudice to Community legislation on waste.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

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- (1) OJ L 396, 30.12.2006, p. 1; as corrected by OJ L 136, 29.5.2007, p. 3.
- (2) OJ 196, 16.8.1967, p. 1.

Changes to legislation:

There are currently no known outstanding effects for the Commission Regulation (EC) No 987/2008, Introductory Text.