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. (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:

Article 1

Annex IV to Regulation (EC) No 1907/2006 is replaced by Annex I to this Regulation.

Article 2

Annex V to Regulation (EC) No 1907/2006 is replaced by Annex II to this Regulation.

Article 3

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

Done at Brussels, 8 October 2008.

For the Commission

Stavros DIMAS

Member of the Commission

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

ANNEX I

ANNEX IEXEMPTIONS FROM THE OBLIGATION TO REGISTER IN ACCORDANCE WITH ARTICLE 2(7)(a)Einecs NoName/GroupCAS No200-061-5D-glucitol C6H14O650-70-4200-066-2Ascorbic acid C6H8O650-81-7200-075-1Glucose C6H12O650-99-7200-233-3Fructose C6H12O657-48-7200-294-2L-lysine C6H14N2O256-87-1200-334-9Sucrose, pure C12H22O1157-50-1200-405-4α-tocopheryl acetate C31H52O358-95-7200-416-4Galactose C6H12O659-23-4200-432-1DL-methionine C5H11NO2S59-51-8200-559-2Lactose C12H22O1163-42-3200-711-8D-mannitol C6H14O669-65-8201-771-8L-sorbose C6H12O687-79-6204-664-4Glycerol stearate, pure C21H42O4123-94-4204-696-9Carbon dioxide CO2124-38-9205-278-9Calcium pantothenate, D-form C9H17NO5.1/2Ca137-08-6205-756-7DL-phenylalanine C9H11NO2150-30-1208-407-7Sodium gluconate C6H12O7.Na527-07-1215-665-4Sorbitan oleate C24H44O61338-43-8231-098-5Krypton Kr7439-90-9231-110-9Neon Ne7440-01-9231-147-0Argon Ar7440-37-1231-168-5Helium He7440-59-7231-172-7Xenon Xe7440-63-3231-783-9Nitrogen N27727-37-9231-791-2Water, distilled, conductivity or of similar purity H2O7732-18-5232-307-2LecithinsThe complex combination of diglycerides of fatty acids linked to the choline ester of phosphoric acid8002-43-5232-436-4Syrups, hydrolyzed starchA complex combination obtained by the hydrolysis of cornstarch by the action of acids or enzymes. It consists primarily of d-glucose, maltose and maltodextrins8029-43-4232-442-7Tallow, hydrogenated8030-12-4232-675-4Dextrin9004-53-9232-679-6StarchHigh-polymeric carbohydrate material usually derived from cereal grains such as corn, wheat and sorghum, and from roots and tubers such as potatoes and tapioca. Includes starch which has been pregelatinised by heating in the presence of water9005-25-8232-940-4Maltodextrin9050-36-6238-976-7Sodium D-gluconate C6H12O7.xNa14906-97-9248-027-9D-glucitol monostearate C24H48O726836-47-5262-988-1Fatty acids, coco, Me esters61788-59-8265-995-8Cellulose pulp65996-61-4266-948-4Glycerides, C16-18 and C18-unsaturated.This substance is identified by SDA Substance Name: C16-C18 and C18 unsaturated trialkyl glyceride and SDA Reporting Number: 11-001-0067701-30-8268-616-4Syrups, corn, dehydrated68131-37-3269-658-6Glycerides, tallow mono-, di- and tri-, hydrogenated68308-54-3270-312-1Glycerides, C16-18 and C18-unsaturated, mono- and di-This substance is identified by SDA Substance Name: C16-C18 and C18 unsaturated alkyl and C16-C18 and C18 unsaturated dialkyl glyceride and SDA Reporting Number: 11-002-0068424-61-3288-123-8Glycerides, C10-1885665-33-4

ANNEX II

ANNEX V

EXEMPTIONS FROM THE OBLIGATION TO REGISTER IN ACCORDANCE WITH ARTICLE 2(7)(b)

1. Substances which result from a chemical reaction that occurs incidental to exposure of another substance or article to environmental factors such as air, moisture, microbial organisms or sunlight.

2. Substances which result from a chemical reaction that occurs incidental to storage of another substance, preparation or article.