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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, XX.Y.2008
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Draft

COMMISSION REGULATION (EC) No .../..

of

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

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(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/EC¹, 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.

¹ OJ L 396, 30.12.2006, p. 1. Regulation as amended by Regulation (EC) No 1354/2007 (OJ L 304, 22.11.2007, p. 1).

- (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 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 Directive 67/548/EEC 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 that of its publication in the *Official Journal of the European Union*.

Done at Brussels,

For the Commission

Stavros DIMAS
Member of the Commission

Günter Verheugen
Member of the Commission

ANNEX I

"ANNEX IV

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

EINECS No	Name/Group	CAS No
200-061-5	D-glucitol C ₆ H ₁₄ O ₆	50-70-4
200-066-2	Ascorbic acid C ₆ H ₈ O ₆	50-81-7
200-075-1	Glucose C ₆ H ₁₂ O ₆	50-99-7
200-233-3	Fructose C ₆ H ₁₂ O ₆	57-48-7
200-294-2	L-lysine C ₆ H ₁₄ N ₂ O ₂	56-87-1
200-334-9	Sucrose, pure C ₁₂ H ₂₂ O ₁₁	57-50-1
200-405-4	α -tocopheryl acetate C ₃₁ H ₅₂ O ₃	58-95-7
200-416-4	Galactose C ₆ H ₁₂ O ₆	59-23-4
200-432-1	DL-methionine C ₅ H ₁₁ NO ₂ S	59-51-8
200-559-2	Lactose C ₁₂ H ₂₂ O ₁₁	63-42-3
200-711-8	D-mannitol C ₆ H ₁₄ O ₆	69-65-8
201-771-8	L-sorbose C ₆ H ₁₂ O ₆	87-79-6

EINECS No	Name/Group	CAS No
204-664-4	Glycerol stearate, pure C ₂₁ H ₄₂ O ₄	123-94-4
204-696-9	Carbon dioxide CO ₂	124-38-9
205-278-9	Calcium pantothenate, D-form C ₉ H ₁₇ NO _{5.1/2} Ca	137-08-6
205-756-7	DL-phenylalanine C ₉ H ₁₁ NO ₂	150-30-1
208-407-7	Sodium gluconate C ₆ H ₁₂ O ₇ .Na	527-07-1
215-665-4	Sorbitan oleate C ₂₄ H ₄₄ O ₆	1338-43-8
231-098-5	Krypton Kr	7439-90-9
231-110-9	Neon Ne	7440-01-9
231-147-0	Argon Ar	7440-37-1
231-168-5	Helium He	7440-59-7
231-172-7	Xenon Xe	7440-63-3
231-783-9	Nitrogen N ₂	7727-37-9
231-791-2	Water, distilled, conductivity or of similar purity H ₂ O	7732-18-5
232-307-2	Lecithins The complex combination of diglycerides of fatty acids linked to the choline ester of phosphoric acid.	8002-43-5
232-436-4	Syrups, hydrolyzed starch A complex combination obtained by the hydrolysis of cornstarch by the action of acids or enzymes. It consists primarily of d-glucose, maltose and maltodextrins.	8029-43-4

EINECS No	Name/Group	CAS No
232-442-7	Tallow, hydrogenated	8030-12-4
232-675-4	Dextrin	9004-53-9
232-679-6	Starch High-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 water.	9005-25-8
232-940-4	Maltodextrin	9050-36-6
238-976-7	Sodium D-gluconate $C_6H_{12}O_7 \cdot xNa$	14906-97-9
248-027-9	D-glucitol monostearate $C_{24}H_{48}O_7$	26836-47-5
262-988-1	Fatty acids, coco, Me esters	61788-59-8
265-995-8	Cellulose Pulp	65996-61-4

EINECS No	Name/Group	CAS No
266-948-4	Glycerides, C ₁₆₋₁₈ and C ₁₈ -unsaturated. This substance is identified by SDA Substance Name: C _{16-C₁₈} and C ₁₈ unsaturated trialkyl glyceride and SDA Reporting Number: 11-001-00.	67701-30-8
268-616-4	Syrups, corn, dehydrated	68131-37-3
269-658-6	Glycerides, tallow mono-, di- and tri-, hydrogenated	68308-54-3
270-312-1	Glycerides, C ₁₆₋₁₈ and C ₁₈ -unsaturated. mono- and di- This substance is identified by SDA Substance Name: C _{16-C₁₈} and C ₁₈ unsaturated alkyl and C _{16-C₁₈} and C ₁₈ unsaturated dialkyl glyceride and SDA Reporting Number: 11-002-00.	68424-61-3
288-123-8	Glycerides, C ₁₀₋₁₈	85665-33-4"

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.
3. Substances which result from a chemical reaction occurring upon end use of other substances, preparations or articles and which are not themselves manufactured, imported or placed on the market.
4. Substances which are not themselves manufactured, imported or placed on the market and which result from a chemical reaction that occurs when:
 - (a) a stabiliser, colorant, flavouring agent, antioxidant, filler, solvent, carrier, surfactant, plasticiser, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation inhibitor, desiccant, binder, emulsifier, de-emulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutraliser, sequesterant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent functions as intended; or
 - (b) a substance solely intended to provide a specific physicochemical characteristic functions as intended.
5. By-products, unless they are imported or placed on the market themselves.
6. Hydrates of a substance or hydrated ions, formed by association of a substance with water, provided that the substance has been registered by the manufacturer or importer using this exemption.
7. The following substances which occur in nature, if they are not chemically modified:

Minerals, ores, ore concentrates, raw and processed natural gas, crude oil, coal.

8. Substances which occur in nature other than those listed under paragraph 7, if they are not chemically modified, unless they meet the criteria for classification as dangerous according to Directive 67/548/EEC or unless they are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII or unless they were identified in accordance with Article 59(1) at least two years previously as substances giving rise to an equivalent level of concern as set out in Article 57(f).

9. The following substances obtained from natural sources, if they are not chemically modified, unless they meet the criteria for classification as dangerous according to Directive 67/548/EEC with the exception of those only classified as flammable [R10], as a skin irritant [R38] or as an eye irritant [R36] or unless they are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII or unless they were identified in accordance with Article 59(1) at least two years previously as substances giving rise to an equivalent level of concern as set out in Article 57(f):

Vegetable fats, vegetable oils, vegetable waxes; animal fats, animal oils, animal waxes; fatty acids from C₆ to C₂₄ and their potassium, sodium, calcium and magnesium salts; glycerol.

10. The following substances if they are not chemically modified:

Liquefied petroleum gas, natural gas condensate, process gases and components thereof, coke, cement clinker, magnesia.

11. The following substances unless they meet the criteria for classification as dangerous according to Directive 67/548/EEC and provided that they do not contain constituents meeting the criteria as dangerous in accordance with Directive 67/548/EEC present in concentrations above the lowest of the applicable concentration limits set out in Directive 1999/45/EC or concentration limits set out in Annex I to Directive 67/548/EEC, unless conclusive scientific experimental data show that these constituents are not available throughout the life-cycle of the substance and those data have been ascertained to be adequate and reliable:

Glass, ceramic frits.

12. Compost and biogas.

13. Hydrogen and oxygen. "