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**Accompanying document to the
COMMUNICATION FROM THE COMMISSION ON THE REVIEWS OF ANNEXES
I, IV AND V TO REGULATION (EC) NO 1907/2006 OF THE EUROPEAN
PARLIAMENT AND OF THE COUNCIL CONCERNING THE REGISTRATION,
EVALUATION, AUTHORISATION AND RESTRICTION OF CHEMICALS
(REACH)**

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TABLE OF CONTENTS

1.	Introduction	5
1.1.	Background	5
1.2.	Relationship between Annex IV and Annex V	6
2.	Review of Annex IV	7
2.1.	Procedure.....	7
2.2.	Agreed criteria.....	8
2.3.	Nanotechnology	8
2.4.	Analysis of proposals	9
2.4.1.	Overview	9
2.4.2.	Methodology	10
2.5.	Evaluations of substances already in Annex IV.....	11
2.6.	Results	12
2.6.1.	Existing entries.....	12
2.6.2.	Proposed new entries.....	12
2.7.	Conclusion.....	13
3.	Review of Annex V	16
3.1.	Introduction.....	16
3.2.	Criteria for inclusion in Annex V and interpretation	17
3.2.1.	Registration is deemed inappropriate or unnecessary	17
3.2.2.	Exemption does not prejudice the objectives of REACH.....	18
3.2.2.1.	High level of protection of human health and the environment.....	18
3.2.2.2.	Promotion of alternative methods for assessment of hazards	19
3.2.2.3.	Free movement of substances on the internal market	19
3.2.2.4.	Enhancing competitiveness	19
3.2.2.5.	Enhancing innovation.....	19
3.3.	Process: Advisory Group, stakeholders and CAs	20
3.4.	Analysis of individual exemption categories in Annex V, taking into account the above-mentioned criteria.....	20
3.4.1.	Annex V, point 1	20

3.4.1.1. Background	20
3.4.1.2. Analysis.....	20
3.4.1.3. Commission proposal.....	21
3.4.2. Annex V, point 2	21
3.4.2.1. Background	21
3.4.2.2. Analysis.....	22
3.4.2.3. Commission proposal.....	22
3.4.3. Annex V, point 3	22
3.4.3.1. Background	22
3.4.3.2. Analysis.....	22
3.4.3.3. Commission proposal.....	23
3.4.4. Annex V, point 4	23
3.4.4.1. Background	23
3.4.4.2. Analysis.....	23
3.4.4.3. Commission proposal.....	24
3.4.5. Annex V, point 5	24
3.4.5.1. Background	24
3.4.5.2. Analysis.....	24
3.4.5.3. Commission proposal.....	25
3.4.6. Annex V, point 6	26
3.4.6.1. Background	26
3.4.6.2. Analysis.....	26
3.4.6.3. Commission proposal.....	27
3.4.7. Annex V, point 7	27
3.4.7.1. Background	27
3.4.7.2. Analysis.....	28
3.4.7.3. Existing entries.....	28
3.4.7.4. Proposed new entries.....	30
3.4.7.5. Commission proposal.....	34
3.4.8. Annex V, point 8	35
3.4.8.1. Background	35

3.4.8.2. Analysis.....	35
3.4.8.3. Commission proposal.....	36
3.4.9. Annex V, point 9	37
3.4.9.1. Background	37
3.4.9.2. Analysis.....	37
3.4.9.3. Commission proposal.....	38
Appendix I: Agreed criteria for inclusion of substances in Annex IV to Regulation No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).....	39
Appendix II: Submissions for addition to Annex IV	47
Appendix III: Commission proposals to amend Annexes IV and V	59

1. INTRODUCTION

1.1. Background

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 (REACH) is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. As part of the registration procedure, the registrant is required to document that substances can be used safely, with regard to human health and the environment.

Annex IV to REACH lists substances that are exempted from the REACH provisions on registration, evaluation and downstream users “*as sufficient information is known about these substances that they are considered to cause minimum risk because of their intrinsic properties*” (Article 2(7)(a)). Such substances are exempted irrespective of the tonnage they are manufactured or imported at (at present or in the future) or of their current or future uses.

The original Annex IV to REACH essentially reproduced the list of substances exempted from the obligation to submit information under the Existing Substances Regulation (Regulation (EEC) No 793/93). This list has not been revised since the Regulation was adopted and was incorporated in the REACH proposal where it remained unchanged, with the exception of the addition of one substance (cellulose pulp) to Annex IV during the co-decision procedure for adoption of the REACH Regulation.

The original entries in Annex V were mainly taken from the reporting rules for the EINECS inventory. They reflect the experience gained from operation of Directive 67/548/EEC on classification, packing and labelling of dangerous substances and are collected in the Manual of Decisions (MoD) to this Directive. During the co-decision negotiations on REACH a number of changes were made to the Commission proposal: several additional categories of substances were added to Annex V, together with a number of “basic elemental substances for which hazards and risks are already well known.” Details of these are given in Section 3 of this document.

Article 138(4) of the REACH Regulation gave the Commission a mandate to carry out a review of Annexes I, IV, and V by 1 June 2008, with a view to proposing amendments to them, if appropriate, in accordance with the regulatory procedure with scrutiny.

Recital 36 requires the review of Annexes IV and V to take into account the application of Article 2(7)(a) and (b) and Annex XI to substances derived from mineralogical processes.

This review was carried out by the Commission in cooperation with the REACH Competent Authorities expert group (REACH CA) and its Subgroup for the review of the annexes (CASG(Annexes)). As a result of this review, the Commission submitted a proposal for a Commission Regulation amending Annexes IV and V¹ to the REACH Committee, which gave a positive opinion on 5 June 2008. Subsequently, the proposal was submitted for scrutiny by the European Parliament and the Council. Neither the European Parliament nor

¹ Commission Regulation amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes IV and V.

the Council opposed the draft measure and the Commission Regulation was finally adopted on 8 October 2008 and published on 9 October 2008 (Commission Regulation (EC) No 987/2008, OJ L 268, 9.10.2008, p. 14). An overview of the reasons for the additions and deletions is given in a Communication on the reviews of Annexes I, IV and V to REACH². This Commission Staff Working Document is intended to give further details on the review of Annexes IV and V, the approaches taken and the considerations that led to the proposed additions and deletions. In addition, the Commission has drafted a recommendation for guidance on interpretation of Annex V. This guidance is intended to give further explanations to help companies concerned to identify whether their substances are covered by the exemptions in Annexes IV and V or whether they are subject to the provisions on registration, evaluation and downstream users. The Commission has transmitted this recommendation to the ECHA for finalisation and inclusion in the technical guidance document on registration³.

Concerning Annex I, the Commission has concluded that no amendment is necessary at present, as all issues have been and/or can be dealt with satisfactorily in the technical guidance document on information requirements and chemical safety assessment (TGD IR/CSA)⁴. The reasons for this conclusion are described exhaustively in the Communication on the reviews of Annexes I, IV and V of REACH and will therefore not be further explained in this document.

1.2. Relationship between Annex IV and Annex V

The Commission was required to review both Annexes IV and V. There are obvious similarities between the aims of the two Annexes in that they both grant exemptions from the provisions of REACH on registration, evaluation and downstream users. It is important, however, to be aware of the differences between them:

- Annex IV lists substances that are exempt from the provisions on registration, evaluation and downstream users because sufficient information is known about these substances that they are considered to cause minimum risk because of their intrinsic properties;
- Annex V provides criteria for groups of substances that are exempt from the provisions on registration, evaluation and downstream users because registration is deemed inappropriate or unnecessary for these substances and their exemption does not prejudice the objectives of REACH.

In addition, three substances (argon, nitrogen and limestone) were exempted by both Annex IV and Annex V, as adopted in 2006.

² Communication from the Commission on the reviews of Annexes I, IV and V to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

³ http://guidance.echa.europa.eu/docs/guidance_document/registration_en.htm?time=12323804417

⁴ http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_en.htm?time=1232380544

2. REVIEW OF ANNEX IV

2.1. Development of process

The concepts of “sufficient information” and “minimum risk” are not specified in REACH. Consequently, before the Commission could carry out the review of Annex IV these core concepts had to be defined. These concepts were described in the form of criteria, including the minimum dataset required and a format for proposals to add or remove substances. This makes it possible to consider, in a transparent and consistent way, whether further substances should be added to the Annex and whether substances currently in the Annex should remain there.

The Commission, together with an advisory group of Member States (MS) and other stakeholders⁵ developed the criteria, based on a proposal by a contractor engaged by the Commission for the purposes of the review⁶, and discussed them at the meetings of CASG(Annexes) on 3 September and 1 October 2007. These criteria were endorsed by the REACH Competent Authorities on 19 October 2007. The document “Criteria for inclusion of substances in Annex IV of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)” (the “Criteria Document”) was published on the Commission website and is reprinted in Appendix I.

Agreement was reached that proposals for inclusion in or deletion from Annex IV could be made to the Member States Competent Authorities (MSCA) and a number of industrial associations (IA) (CEFIC, CONCAWE REACH Alliance) by 30 November 2007. The MSCAs and IAs would then analyse the proposals by 10 January 2008 and submit them, and their analysis, to the contractor and the Commission. The original proposal was that submissions which did not meet the information requirements or criteria could be rejected by the MSCA or IA. However, during discussion of the process it became clear that no MSCA or IA intended to reject proposals due to liability concerns. It was consequently decided that all proposals would be forwarded to the Commission and the contractor, with the checklist filled in by the MSCA and IA plus a recommendation whether or not the dossier complied with the agreed criteria. The contractor had until 28 February 2008 to analyse the proposals and make recommendations to the Commission on the proposed additions and deletions.

Due to limited resources and the short timescales involved in the review, MS and stakeholders were asked to coordinate their efforts, particularly on assessing proposals concerning the same substance.

⁵ The Commission set up a subgroup of the REACH Competent Authorities, the Competent Authorities Subgroup on the Annexes – CASG(Annexes) –, consisting of certain MS (AT, BE, DE, DK, EE, ES, FI, FR, GR, IE, IT, LI, NL, PL, SE and UK) and stakeholders (NO, WWF, ETUC, CEFIC, CONCAWE and REACH Alliance) with a remit to discuss the reviews of Annexes I, IV, V, XI and XIII.

⁶ The draft proposal was prepared by DHI, Protection Through Knowledge (PTK) Ltd and Milieu Ltd.

2.2. Agreed criteria

During the discussions on the review, agreement was reached that:

- “Minimum risk because of intrinsic properties” means that negligible risk can be assumed on the basis of the intrinsic properties of the substance⁷;
- “sufficient information” means the information which is considered to be necessary to confirm the “minimum risk because of intrinsic properties” posed by a substance.

Under Article 2(7)(a), in this exercise minimum risk is based on intrinsic properties. Therefore use and exposure information cannot play a role in the analysis. Using only information on intrinsic properties of the substance, however, may lead to a more uncertain determination of the magnitude of any risk. Due to this inherent uncertainty and the need to include only substances which pose a minimum risk, strict hazard-based criteria were required. In addition, a certain dataset would also be necessary to fulfil the “sufficient information” criterion.

Agreement was reached that minimum risk because of intrinsic properties can be concluded only if all the criteria for physicochemical properties, toxicological properties and ecotoxicological properties are met.

One of the key issues related to development of criteria was that some of the substances that could potentially be proposed for addition to Annex IV would not have a comprehensive dataset, as they had been on the market for a long time without any identifiable concerns on their health or environmental effects. To allow these substances to be considered, agreement was reached that submitters would need to be able to show that there is clear scientific evidence that prolonged daily and continuous human and environmental exposure to the substance does not lead to more than minimum risk. It should also be justified that the information required in Annexes VII to X would add no useful data to the information already available. This principle was included in information requirement 8 in Section 3 of the Criteria Document to be used by submitters in their proposals for inclusion of substances in Annex IV.

2.3. Nanotechnology

At meetings of CASG(Annexes), several Member States argued that nanomaterials should not be exempted from registration under REACH and should therefore not be included in Annex IV.

⁷ Note that the principle of “minimum risk because of intrinsic properties” is clearly different from the approach applied in registration under REACH. The proposed criteria for minimum risk should apply to all tonnage levels and need to be independent of the specific uses of the substance and the resulting exposure of humans and the environment, as all future uses cannot possibly be predicted. Consequently, the rules in Annex XI, Section 3 should not apply, as they are based on an exposure assessment of a known use of the substance. Likewise, the tonnage of substances is not considered, as the future levels of manufacture and import of a substance cannot be predicted. The information requirements and associated criteria are therefore the same regardless of the tonnage currently manufactured in, or imported into, the EU.

The debate on how to ensure that nanomaterials are not exempted in Annex IV revolved around the possibility to include a general footnote indicating that nanoforms of the substances are not exempted. However, the Commission considered that this was not possible, as Annex IV exempts substances, in all their forms and uses, from the provisions on registration, evaluation and downstream users. Insertion of a footnote that will exclude some forms of the substances listed in the Annex would change the nature and scope of the Annex. Any such decision could only be taken by the co-legislators by co-decision. The Commission also concluded that in their view, should a nanoform of a substance not comply with the agreed criteria, the substance should not be an entry in Annex IV.

For analysing substances with nanoforms, the following approach was taken:

- Firstly there needed to be sufficient information about the properties of that substance at the nanoscale, on the basis of which it can be compared against the criteria. Substances could not be included in Annex IV if the information basis was deemed insufficient.

Current guidelines for testing of substances are being reviewed by the OECD with regard to their applicability to nanomaterials. It is likely that some existing test guidelines are applicable to nanomaterials, while others may be partly applicable and may need to be improved. For some endpoints, new guidelines may need to be developed. The most up-to-date test guidelines should be applied. However, the absence of specific test guidelines for nanomaterials as such was not considered a justified reason to exclude nanomaterials *per se* from Annex IV.

Information from tests other than standard OECD guidelines was also considered acceptable if it was justified why the test was more appropriate for evaluation of the properties of the nanoform.

There were no additional information requirements for nanomaterials in the Annex IV criteria.

- Secondly, in order for a substance at the nanoscale, or for a substance with a nanoscale form, to be included in Annex IV, it needed to pose minimum risk because of its intrinsic properties (in the case of a substance with a nanoscale form, minimum risk requirement had to be met by all its forms, including the nanoscale form), i.e. the criteria for inclusion had to be met.

Existing Annex IV entries were evaluated to see whether they might also refer to nanoforms. Submissions for deletion of a substance from the existing Annex IV due to its nanoform had to include a dossier supporting a conclusion that the nanoform of the substance does not meet the criteria for inclusion in Annex IV.

2.4. Analysis of proposals

2.4.1. Overview

The review by the contractor comprised:

- i. a completeness check of the submissions against the information and documentation requirements; and

- ii. an evaluation of the documentation for compliance with the criteria laid down in the Criteria Document.

To pass the completeness check, a complete dossier must have been submitted. A complete dossier includes according to documentation requirement 1 under Section 4 of the Criteria Document:

- An overall conclusion;
- A conclusion (descriptive and numerical) per endpoint;
- The information specified in Section 3 on “Information requirements” and a completed format in accordance with the instructions in Appendix 2 to the Criteria Document (including completed Tables 1-4, robust study summaries and descriptions of and justifications for adaptations in accordance with column 2 in Annexes VII to X of REACH or with Annex XI to REACH) or clear scientific evidence (in the form of quantitative data or observations) related to commonly used substances.

To pass the evaluation, in accordance with the Criteria Document, minimum risk because of intrinsic properties could be concluded only if all the criteria for physicochemical properties, toxicological properties and ecotoxicological properties in Sections 2.1 to 2.3 of the Criteria Document were met.

2.4.2. Methodology

The methodology applied for the review was a step-by-step process consisting of:

- i. Examination of whether a complete dossier had been submitted or not. Submissions without a complete dossier, e.g. submissions that were characterised as “position papers”, were rejected and not evaluated.
- ii. Submissions with a complete dossier were reviewed to identify if there were data gaps in the dossier. Such data gaps could be, e.g., missing robust study summaries, or missing justification for applying the adaptations in accordance with column 2 in Annexes VII to X of REACH or with Annex XI to REACH. If the substance was a commonly used substance then there needed to be clear scientific evidence (in the form of quantitative data or observations) for all individual endpoints for substances.
- iii. For complete submissions containing all the data required, the next step was to examine if the ecotoxicological criteria were met. If one criterion was not met, the submission was regarded as failing the criteria and the data on other criteria were not considered further (Criteria Document, Section 5.1).
- iv. The submissions fulfilling the ecotoxicological criteria were further evaluated to examine if the toxicological and physicochemical criteria were met.

With regard to the second step, Section 3 of the Criteria Document, setting out the information requirements, prescribes that:

- Robust study summaries shall be provided for a minimum of one key study per endpoint for physicochemical, toxicological and ecotoxicological properties (see information requirement 4 in Section 3 of the Criteria Document).

- The standard information corresponding to the endpoints set out in Annexes VII-X is required with the clarifications specified in information requirement 2 in Section 3 of the Criteria Document, including the possibility to apply the specific rules for adaptation provided in column 2 of the Annexes (this would require that a description and justification is provided in the submission, as stated in Appendix 2 to the Criteria Document).
- The general rules for adaptation of the standard testing regime, as described in Annex XI, Sections 1 and 2, may be applied, provided that their use is fully justified (this would require that a description and justification is provided in the submission, as stated in Appendix 2 to the Criteria Document).

2.5. Evaluations of substances already in Annex IV

The existing entries in Annex IV were also reviewed to see if they meet the criteria developed.

To this end, the following approach was applied:

- The contractor collected data in accordance with the information requirements for inclusion in Annex IV from easily accessible sources, i.e. ECOTOX, GESAMP, IUCLID and HSDB. The format developed for submissions was used as far as possible.
- The contractor grouped substances in Annex IV, where possible, so that read-across principles could be used for all substances belonging to the same group.
- The contractor checked whether the entries fulfil the data requirements and the criteria above. Bearing in mind the historical evidence on substances in Annex IV, the burden of proof was directed at identifying evidence of human health or environmental effects according to the above-mentioned criteria⁸.
- When the contractor found indications in the information assessed, leading to the conclusion that a substance did not fulfil the criteria, the relevant industrial association was given an opportunity to dispute the findings by sending information showing that the substance in question does fulfil the criteria for inclusion in Annex IV.

To present the results of the evaluation of existing Annex IV entries to CASG(Annexes), the contractor chose the “traffic light approach”, with

- 14 substances passing the criteria (highlighted in green);
- 39 substances failing at least one criterion, but with no evidence of human or environmental effects (highlighted in yellow); and

⁸ As opposed to proposals for additions to Annex IV, where the burden of proof is directed at demonstrating compliance with the criteria and information requirements described in Section 2.2 of this document.

- 15 substances failing the criteria and with evidence of human or environmental effects (highlighted in red).

2.6. Results

2.6.1. Existing entries

The analysis of the existing entries concluded that the following substances fail the criteria with evidence of human or environmental effects:

- Lauric acid, pure $C_{12}H_{24}O_2$;
- Potassium oleate $C_{18}H_{34}O_2K$;
- Graphite C;
- Carbon;
- Vitamin A;
- Fatty acids, tallow, Me esters;
- Fatty acids, C_{12-18} ;
- Fatty acids, C_{8-18} and C_{18} unsaturated;
- Fatty acids, C_{14-18} and C_{16-18} unsaturated;
- Fatty acids, C_{16-18} and C_{18} unsaturated;
- Fatty acids, C_{14-18} and C_{16-18} unsaturated, Me esters;
- Fatty acids, C_{6-12} ;
- Fatty acids, C_{14-22} and C_{16-22} unsaturated;
- Fatty acids, C_{12-14} ;
- Fatty acids, C_{12-18} and C_{18} unsaturated.

2.6.2. Proposed new entries

Following the initial screening, a total of 292 submissions for addition to Annex IV (see Appendix II to this document) and two submissions for deletion from Annex IV were forwarded to the contractor. The information was analysed and all the new proposals for inclusion were rejected (the analysis of the proposals is available as document CASG(Annexes)/04/08). However, when the Commission services considered the contractor's assessment, as part of their responsibility for carrying out a review of Annex IV, they were of the opinion that the three sugars fructose, galactose and lactose should be added

to Annex IV, as the Commission could accept that they posed minimum risk because of their intrinsic properties.

The two proposals for deletion (carbon and graphite) were accepted by the contractor, primarily because of the presence of nanoforms of these substances (see Section 2.3 of this document) but also because the contractor identified issues with these substances during its review of existing entries.

2.7. Conclusion

The Commission therefore proposed the following additions to and deletions from Annex IV (see also Appendix III to this document):

(1) Noble gases

- Addition of the following substances from Annex V:
 - Helium He;
 - Neon Ne;
 - Xenon Xe.
- Addition of one other noble gas:
 - Krypton Kr.

The Commission services were of the opinion that the noble gases fulfil the criteria for inclusion in Annex IV. Moreover, the initial Annex already included one noble gas (argon) and Annex V included three more (helium, neon and xenon). For consistency reasons, it therefore seemed appropriate to re-group all noble gases in Annex IV and to delete the corresponding entries in Annex V.

(2) Sugars

- Addition of the following sugars that the Commission has accepted are of minimum risk:
 - Fructose;
 - Galactose;
 - Lactose.

The Commission services consider that these three substances fulfil the criteria for inclusion in Annex IV.

(3) Carbon and graphite

- Deletion of the following substances based on the analysis by the contractor:
 - Graphite;

- Carbon.

In the past the CAS numbers of these substances have been used to identify nanoforms of carbon or graphite. Insufficient information is available on these nanoforms to conclude that they pose minimum risk because of their intrinsic properties. As Annex IV draws no distinction between different forms of the same substance, carbon and graphite should be deleted and registration should be required for these substances. With regard to deletion of both carbon and graphite from Annex IV, Member States agreed on the need to ensure that nanoforms of carbon and graphite were not exempted in Annex IV. At the same time, a majority of the Member States urged the Commission to continue to seek a solution that would require registration of only the nanoforms of carbon and graphite, but not of the bulk forms.

The Commission considered that deletion of these substances from Annex IV would be the only possibility in the given legal framework to ensure, in practice, that nanoforms of carbon and graphite will be subject to registration in view of the following:

- A simple footnote in Annex IV or V was not considered appropriate, as Annex IV and V both exempt substances as such and the REACH definition of substance does not differentiate between different forms of the same substance. Such a conceptual change would probably require an amendment to the Articles of REACH by co-decision, in particular with respect to Annex IV which refers to specific EINECS or CAS numbers.
- The idea of inclusion of carbon and graphite (with the exception of their nanoforms) in Annex V would not be feasible either, because it is currently impossible clearly to define the nanoforms which should not be exempted.

The Commission committed itself to review, in cooperation with the REACH CA Subgroup on Nanomaterials (CASG(Nano)), the possibility of including carbon and graphite in Annex IV or Annex V, while ensuring that nanoforms are not exempted from registration. It completed this review by the end of 2008 and is now considering to prepare a proposal for amendment to Annex V on this issue by 31 March 2009.

(4) Vitamin A

- Deletion of the following substance based on the analysis by the contractor:
 - Vitamin A.

Deletion was proposed because vitamin A can exhibit significant risks on the basis of its intrinsic properties (e.g. reproductive toxicity).

(5) Limestone

Deletion of limestone was proposed, as this mineral is already covered by exemption 7 in Annex V. This deletion was made to avoid duplication with the exemption in Annex V.

(6) Oils, fats, waxes, fatty acids and their salts

- Deletion of all the current entries for vegetable oils, as the Commission proposed a generic entry in Annex V to cover all vegetable oils⁹:
 - Sunflower oil;
 - Soybean oil;
 - Safflower oil;
 - Linseed oil;
 - Corn oil;
 - Castor oil;
 - Rape oil.

- Deletion of all the current entries for fatty acids, as the Commission proposed a generic entry in Annex V¹⁰ to cover a number of these substances:
 - Palmitic acid, pure $C_{16}H_{32}O_2$;
 - Stearic acid, pure $C_{18}H_{36}O_2$;
 - Oleic acid, pure $C_{18}H_{34}O_2$;
 - Lauric acid, pure $C_{12}H_{24}O_2$;
 - Potassium oleate $C_{18}H_{34}O_2K$;
 - Sodium stearate, pure $C_{18}H_{36}O_2.Na$;
 - Calcium distearate, pure $C_{18}H_{36}O_{2.1/2}Ca$;
 - Fatty acids, tallow, Me esters;
 - Fatty acids, castor oil;
 - Fatty acids, tallow;

⁹ The following substances extracted 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 [...].

¹⁰ The following substances extracted 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): [...] fatty acids from C_6 to C_{24} and their potassium, sodium, calcium and magnesium salts; [...].

- Fatty acids, C₁₂₋₁₈;
- Fatty acids, C₁₆₋₁₈;
- Fatty acids, C₈₋₁₈ and C₁₈ unsaturated;
- Fatty acids, C₁₄₋₁₈ and C₁₆₋₁₈ unsaturated;
- Fatty acids, C₁₆₋₁₈ and C₁₈ unsaturated;
- Fatty acids, C₁₄₋₁₈ and C₁₆₋₁₈ unsaturated, Me esters;
- Fatty acids, C₆₋₁₂;
- Fatty acids, C₁₄₋₂₂ and C₁₆₋₂₂ unsaturated;
- Fatty acids, soya;
- Fatty acids, C₁₄₋₂₂;
- Fatty acids, linseed oil;
- Fatty acids, C₁₂₋₁₄;
- Fatty acids, C₁₂₋₁₈ and C₁₈ unsaturated;
- Fatty acids, rape oil, erucic acid low.

Following the analysis of oils, fats, waxes, fatty acids and their salts, the Commission services concluded that at least some of those substances do not fulfil the criteria for minimum risk because of their intrinsic properties. At the same time, other comparable substances belonging to one of these groups which may pose relatively low risk are not included in the current Annex IV. To provide greater consistency, it was therefore proposed to delete all current entries for these substances from Annex IV (see Appendix III to this document) and to replace them by a generic entry in Annex V, limiting the exemption to low-hazard substances on the basis of classification criteria.

The Commission proposal amending Annex IV, including the changes made, is set out in Appendix III. On 5 June 2008, the REACH Committee gave a positive opinion on the Commission proposal amending Annex IV. Following the scrutiny by the European Parliament and the Council the Commission Regulation amending REACH as regards Annexes IV and V was adopted on 8 October 2008 and published on 9 October 2008 (Commission Regulation (EC) No 987/2008, OJ L 268, 9.10.2008, p. 14).

3. REVIEW OF ANNEX V

3.1. Introduction

Article 2(7)(b) sets out that for substances covered by Annex V, *registration is deemed inappropriate or unnecessary and their exemption does not prejudice the objectives of REACH.*

The review of Annex V therefore involves checking all existing entries and proposed new entries against two criteria, both of which have to be met:

- registration of the substances included in Annex V should be deemed inappropriate or unnecessary; **and**
- any such exemption from registration does not prejudice the objectives of REACH.

Note that the co-legislators did not require the Commission's review to consider only additions to Annex V, but the contents of Annex V as a whole instead. The Commission could therefore propose both deleting existing entries in Annex V and adding new ones. The explanation of the Commission's thinking set out below takes this into account.

3.2. Criteria for inclusion in Annex V and interpretation

During the co-decision negotiations, Finland produced a Council Working Document (150/05) that reviewed the contents of Annexes IV and V. The paper proposed a number of reasons for exempting substances from registration in Annex V, based on the existing entries at that time (pre-Common Position):

- registration of listed substances would be impractical; they are produced incidentally and without producers' awareness;
- risks of the substances will be assessed through the assessment of other registered substances;
- natural substances that do not meet the classification criteria;
- registration is not the right instrument to cover these substances;
- safety of substances is covered by other legislation.

In the later stages of the negotiations recital 36 was added which states that "*it is necessary to consider the application of Article 2(7)(a) and (b) and Annex XI to substances derived from mineralogical processes and the review of Annexes IV and V should fully take this into account.*" This therefore needed to be fully taken into account in the review. Moreover, the Council and Parliament added the following substances to Annex V, point 7: ore concentrates, cement clinker, liquefied petroleum gas, natural gas condensate, process gases and components thereof and coke. Other substances such as lime were considered but not added. Annex V, point 9 was added to include basic elemental substances for which hazards and risks are already well known. These included hydrogen, oxygen, nitrogen and the noble gases argon, helium, neon and xenon.

3.2.1. Registration is deemed inappropriate or unnecessary

The terms "inappropriate" and "unnecessary" are not further defined by law for the purposes of REACH. Their interpretation is therefore subject to a certain degree of ambiguity. However, the initial entries in the Annex (including those that were part of the Commission proposal and those considered and added or not during the legislative process) provide an indication of the general intent of the legislator.

Building on Council Working Document 150/05, it is proposed that reasons why *registration is deemed inappropriate or unnecessary* would be that:

- registration of the listed substance(s) could be impractical, as they are produced incidentally and without producers' awareness;
- risks of the listed substances will be assessed through the assessment of other registered substances;
- registration is not the right instrument to cover naturally occurring substances and certain substances derived from mineralogical processes, as they are soon further transformed/modified/processed and registered in that transformed/modified/processed form. The risks from naturally occurring substances will consequently be assessed through the assessment of other registered substances;
- registration of some basic elemental substances where there is substantial experience and scientific evidence that the risks to health and the environment result from their physicochemical properties only and are well known.

3.2.2. *Exemption does not prejudice the objectives of REACH*

Article 1(1) states that the objectives of Regulation 1907/2006 (REACH) are: *to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation.*

It should be noted that measures are rarely neutral or equally beneficial for all objectives. Therefore, it may be necessary to weigh some of these objectives against others. As a result, the interpretation is taken that exemptions, via Annex V, of substances or groups of substances from the registration, evaluation and downstream user requirements under REACH, for all their possible uses (currently or in the future), irrespective of the tonnage manufactured or imported, must not undermine these objectives as a whole.

3.2.2.1. High level of protection of human health and the environment

REACH seeks to ensure a high level of protection of human health and the environment by subjecting substances to registration, evaluation, authorisation and restrictions. Substances that are subject to registration and are manufactured or imported at and above 10 tonnes per year are required to have a chemical safety assessment that demonstrates that the substance is not classified for any endpoint or is safe for all its identified uses. This safe use should apply to the entire lifecycle of the substance, including disposal.

To ensure that substances exempted from registration in Annex V still meet the requirement for a high level of protection of human health and the environment, the hazards and risks posed by substances to be included in Annex V should, as far as possible, be well known (based on a sufficient standard of information), properly controlled by other legislation (worker protection legislation, IPPC, etc.) or covered in another chemical safety assessment¹¹.

¹¹ It may be of concern if a substance is exempted from registration and its uses are not demonstrated to be safe by another chemical safety report (CSR) but the substance is used throughout the supply chain without suitable information on risk management. One example of this could be a mineral that is not

One important point to note is that exempting substances from the obligation to register could result in lack of data that might affect safe use and proper risk management of the exempted substances along the supply chain as there will be no chemical safety report (CSR) on them (i.e. no development of exposure scenarios and no information on uses) and the information in the safety data sheets (SDS) provided with these substances will be of lower quality. This lack of data will also affect application of the other provisions of REACH, for example on authorisation and restrictions.

3.2.2.2. Promotion of alternative methods for assessment of hazards of substances

Inclusion of a substance or group of substances in Annex V will not negatively affect the promotion of alternative methods for hazard assessment.

3.2.2.3. Free movement of substances on the internal market

Inclusion of a substance or group of substances in Annex V will not negatively affect the free movement of substances on the internal market.

3.2.2.4. Enhancing competitiveness

Inclusion of a substance or group of substances in Annex V will not negatively affect the competitiveness of the EU chemicals industry as a whole. This is due to the fact that, within the EU, importers will have to fulfil the same obligations as EU manufacturers.

Seen from the perspective of individual sectors of industry, inclusion of individual substances in Annex V could give their manufacturers and importers an advantage over other sectors whose substances are not exempted. Therefore, the review had to consider treating similar substances in the same way, in particular if they are obtained through similar processes. However, to ensure that the objectives of REACH as a whole are not undermined, it might be necessary to treat similar substances differently, especially considering their hazard and risk profile, the practicability of covering the entire sector and where substances are manufactured through different processes.

3.2.2.5. Enhancing innovation

One of the main reasons for the introduction of REACH was to put an end to the pre-REACH discrimination between “existing” (EINECS) substances on the EU market before September 1981 and “new” substances (not in EINECS). The analysis carried out at that time demonstrated that the fact that new substances were subject to strict notification requirements, whereas existing substances were not, was hindering innovation¹² by allowing sometimes more hazardous existing substances to stay on the market without further information requirements or obligations. Therefore, any inclusion of substances in Annex V should, as far as possible, not undermine this objective.

¹²

chemically modified and meets the criteria for classification as dangerous, which enters the supply chain with only physical modification.
COM(2001) 88: White Paper “Strategy for a Future Chemicals Policy”.

3.3. Process: Advisory Group, stakeholders and CAs

The Commission conducted the review of Annex V in house, with DG Environment taking the lead. Member States and stakeholders were involved via a REACH Competent Authorities Subgroup set up for this purpose (REACH CASG(Annexes)). Regular progress reports on the reviews of the Annexes were also made to meetings of the REACH CA.

The process for review of Annex V entailed the following stages:

- A draft review was developed by the Commission, and the ECB prepared an initial draft guidance on current entries in Annex V (based on its experience with application of the EINECS reporting rules and application of Directive 67/548/EEC).
- The draft review was then discussed by the REACH CASG(Annexes) and sent for comments to the REACH CAs. On 5 June 2008, the REACH Committee gave a positive opinion on the Commission proposal amending Annex V to REACH. Following the scrutiny by the European Parliament and the Council the Commission Regulation amending REACH as regards Annexes IV and V was adopted on 8 October 2008 and published on 9 October 2008 (Commission Regulation (EC) No 987/2008, OJ L 268, 9.10.2008, p. 14).
- The Commission, with the involvement of Member States and other stakeholders, developed a recommendation for draft guidance on interpretation of Annex V as amended and transmitted it to the European Chemicals Agency for finalisation and insertion in the technical guidance document on registration ("Guidance on registration").

3.4. Analysis of and conclusions on individual exemption categories in Annex V, taking into account the above-mentioned criteria

This section gives an initial analysis of the categories in Annex V to REACH and of the amendments made. This analysis has been further elaborated in the recommendation for guidance on interpretation of Annex V, which has been developed by the Commission services and handed over to the European Chemicals Agency (ECHA). It should therefore not be considered as final on all points at this stage.

3.4.1. Annex V, point 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.

3.4.1.1. Background

This criterion reproduces one of the criteria for substances that did not need to be reported under EINECS.

3.4.1.2. Analysis

The substances exempted under this point would meet the criteria for inclusion in Annex V set out in Section 3.2 of this document, as their registration would be impractical; they are

produced incidentally and without producers' awareness. In addition, they do not prejudice the objectives of REACH, as information on these substances should be part of the registration dossier of the substance(s) that react(s) and, consequently, a high level of protection of human health and the environment is maintained. It is also a general criterion and, therefore, should not reduce competitiveness and innovation.

However, the Commission proposed that further interpretation of this exemption is given in the Guidance on registration, to make it clear that the exemption has to be for a substance that is generated from a chemical reaction that occurs incidentally, e.g. generation is not intended, and is due to exposure to environmental factors which might occur under normal conditions of use. Examples could include:

- decomposition of polyvinyl chloride by solar irradiation: the decomposition products result from an undesired reaction caused by exposure to sunlight;
- decomposition products from paints caused by the activity of mould.

The Commission also proposed to exempt compost and biogas from registration. Although it has been suggested that this point already covers these substances, the Commission considers that production of compost and biogas is not incidental and therefore they are not covered. Compost is a substance for which no corresponding substance exists that is not a recovered substance. Therefore, compost cannot benefit from the exemption for recovered substances in Article 2(7)(d) of REACH on the basis that a registration for a corresponding virgin material has been received before. Moreover, compost is not listed in EINECS and does not fulfil any other criterion of Article 3(20). Therefore, it does not qualify as a phase-in substance. An exemption is therefore required to ensure that this method of "recycling" remains competitive and is not assessed as reducing the high level of protection of human health and the environment sought by REACH. Further explanation to allow adequate identification of compost is also necessary.

3.4.1.3. Commission proposal

- Maintain point 1, as in the original REACH text.
- Add a new point 12 to Annex V to make it clear that compost and biogas are exempted from registration with the necessary further explanation (see also Section 3.4.7.4 of this document).
- Develop and introduce guidance on this point and the new point 12 in the REACH "Guidance on registration".

3.4.2. Annex V, point 2

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

3.4.2.1. Background

This criterion reproduces one of the criteria for substances that did not need to be reported under EINECS.

3.4.2.2. Analysis

The substances exempted under this point would meet the criteria for inclusion in Annex V set out in Section 3.2 of this document, as registration of the listed substances would be impractical; they are produced incidentally and without producers' awareness. In addition, they do not prejudice the objectives of REACH, as information on the resulting substances should be part of the chemical safety report of the substance(s) that react(s) and, consequently, a high level of protection of human health and the environment is maintained. It is also a general criterion and, therefore, should not reduce competitiveness and innovation.

An example is given in the Manual of Decisions to Directive 67/548/EEC in the form of partially polymerised drying oils or other degradation products formed incidental to storage. The Commission proposed further interpretation of this exemption in the "Guidance on registration".

3.4.2.3. Commission proposal

- Maintain point 2, as in the original REACH text.
- Develop and introduce guidance on this point in the REACH "Guidance on registration".

3.4.3. Annex V, point 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.

3.4.3.1. Background

This criterion reproduces one of the criteria for substances that did not need to be reported under EINECS. Examples given in the EINECS reporting rules of substances, preparations or articles which can react during end use include adhesives, paints, miscellaneous cleansers or housekeeping products, fuels, fuel additives, water softeners, photographic films, batteries and matches. It also notes that substances that are components of these products should be reported.

3.4.3.2. Analysis

The substances exempted under this point would meet the criteria for inclusion in Annex V set out in Section 3.2 of this document, as registration of the listed substances would be impractical. In addition, they do not prejudice the objectives of REACH, as information on the resulting substances should be part of the chemical safety report of the substance(s) that react(s) and, consequently, a high level of protection of human health and the environment is maintained. It is also a general criterion and, therefore, should not reduce competitiveness and innovation.

Examples of substances that would be covered by this entry include the products produced from use of adhesives and paints, combustion products of petrol during use of cars and the reaction products of bleaching agents during washing of textiles. This entry also covers substances present as ionic mixtures resulting from mixing salts, acids and bases. However, the toxicological and ecotoxicological properties of salts are determined by the properties of

their acidic and alkaline constituents. To this extent, registration would be inappropriate for substances produced in a solution through mixing acids, bases or salts, provided all the acids, bases and salts introduced into the mixture have already been registered by an actor up the supply chain and none of the substances produced is isolated from the mixture.

The Commission proposed that further interpretation of this exemption is given in the “Guidance on registration” to clarify this point.

3.4.3.3. Commission proposal

- Maintain point 3, as in the original REACH text.
- Develop and introduce guidance on this point in the REACH “Guidance on registration”.

3.4.4. Annex V, point 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.*

3.4.4.1. Background

This criterion reproduces one of the criteria for substances that did not need to be reported under EINECS. No further guidance is given in the Manual of Decisions to Directive 67/548/EEC.

3.4.4.2. Analysis

The substances exempted under this point would meet the criteria for inclusion in Annex V set out in Section 3.2 of this document, as registration of the listed substances would be impractical; they are produced incidentally and possibly without producers’ awareness. In addition, they do not prejudice the objectives of REACH, as information on the resulting substances should be part of the chemical safety report of the substance(s) that react(s) and, consequently, a high level of protection of human health and the environment is maintained. It is also a general criterion and, therefore, should not reduce competitiveness and innovation.

However, the Commission proposed that further interpretation of this exemption is given in the “Guidance on registration”, to clarify that substances which result from the chemical reaction during production are not covered by this criterion. It is also essential to clarify that this exemption applies to the reaction products only when these substances function as

intended, but does not apply to the substances listed in paragraphs (a) and (b) themselves, and that where a chemical safety report is required that it covers such a use. Examples include:

➤ Dewatering agents

Calcium hydride (CaH_2) is a dewatering agent. The dewatering mechanism is based on the chemical reaction between calcium hydride and water, which results in formation of calcium hydroxide (Ca(OH)_2). The registration provisions apply to the manufacture or import of calcium hydride, but the calcium hydroxide formed as a result of its use as a dewatering agent is exempted from registration as such (but should be included in the CSR for calcium hydride).

3.4.4.3. Commission proposal

- Maintain point 4, as in the original REACH text.
- Develop and introduce guidance on this point in the REACH “Guidance on registration”.

3.4.5. Annex V, point 5

By-products, unless they are imported or placed on the market themselves.

3.4.5.1. Background

This criterion reproduces one of the criteria for substances that did not need to be reported under EINECS. By-products were exempted from reporting under EINECS, but EINECS made it clear that substances such as reaction residues, sludges, fly ashes, dusts and slags can be reported if they are placed on the market. In addition, a separate point exempted impurities from being reported.

3.4.5.2. Analysis

The substances exempted under this point would meet the criteria for inclusion in Annex V set out in Section 3.2 of this document, as the risks posed by the listed substances will be assessed through the assessment of other registered substances. To this extent, they do not prejudice the objectives of REACH, as information on the by-products will be part of the chemical safety report of the substance(s) from which the by-product results and, consequently, a high level of protection of human health and the environment is maintained. It is also a general criterion and, therefore, should not reduce competitiveness and innovation.

One MS suggested changing the exemption from by-products to impurities as, according to this MS, this was the intention of the criterion in the EINECS reporting rules. Regarding impurities, in the course of a chemical reaction a substance is produced, normally consisting quantitatively of main constituents, impurities and additives. EINECS exempted impurities from separate reporting. Under REACH, information on impurities is part of the registration of the main constituent. This is in line with REACH Annex VI, Section 2.3.2. Therefore, no exemption for impurities is needed in Annex V.

The Commission recently published a Communication on by-products¹³. The Communication defines “by-product” as “a production residue that is not a waste” and “production residue” as “a material that is not deliberately produced in a production process”. A production residue may be considered a by-product if it possesses characteristics that make it ready for further use in the economy; in addition, its further use must be possible without any further processing and the by-product must be created as part of a continuing production process. The Communication also provides several examples of materials that can be classified as waste or by-products and explains the rationale used. These examples include slags and dusts from iron and steel production, by-products from the food and drink industry used for animal feed, by-products from combustion processes and off-cuts from sawmills or excess material from a primary production process.

Some of these materials may be “production residues” which are not placed on the market. Under the current interpretation of the existing waste legislation, these materials are likely to be waste and therefore exempted from REACH. It is debatable whether these materials should be considered waste or not in future. It is also understood that discussions on this point are still in progress in the framework of waste legislation. Therefore, it is not considered appropriate to take any decisions on this issue within the framework of REACH. Nevertheless, if at any point in time these substances will be considered as non-waste, they will become subject to the REACH registration obligations unless they are covered by an exemption. It is considered that the outcome of the debate on by-products should not influence the registration obligations under REACH. Therefore, the Commission proposed to maintain this entry in order to make sure that such materials will not be covered by registration obligations, whatever the outcome of the debate on the waste legislation.

If “production residues” are placed on the market as by-products, then they should continue to be subject to the provisions of REACH on registration, evaluation and downstream users, similarly to the rules on EINECS reporting and as provided for in the original text of Annex V. For example, slags were reported to EINECS and should be registered whenever they are considered to be by-products and when they are placed on the market. Note that by-products cannot benefit from Article 2(7)(d) if they have not been waste at any stage and have therefore not undergone a recovery process.

The Commission proposed that further interpretation of this exemption is given in the “Guidance on registration”.

3.4.5.3. Commission proposal

- | |
|--|
| <ul style="list-style-type: none">➤ Maintain point 5, as in the original REACH text.➤ Develop and introduce guidance on this point in the REACH “Guidance on registration”. |
|--|

¹³ COM(2007) 59 final, 21.2.2007: Communication from the Commission to the Council and the European Parliament on the Interpretative Communication on Waste and By-products.

3.4.6. Annex V, point 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.

3.4.6.1. Background

This criterion reproduces one of the criteria for substances that did not need to be reported under EINECS. It clarified that the anhydrous form can be reported and will, by implication, represent all hydrated forms. By contrast, products of discrete chemical reactions in which water is a reactant, e.g. a metal hydroxide formed by the reaction between a metal oxide and water shall be reported.

3.4.6.2. Analysis

The substances exempted under this point would meet the criteria for inclusion in Annex V set out in Section 3.2 of this document, as the risks posed by one form of a substance will be assessed through the assessment of another form of the substance that has been registered. In addition, they do not prejudice the objectives of REACH, as information on the resulting substances should be part of the chemical safety report of the anhydrous form of the substance and, consequently, a high level of protection of human health and the environment is maintained. It is also a general criterion and, therefore, should not reduce competitiveness and innovation.

However, the Commission proposed that further interpretation of this exemption is given in the “Guidance on registration”.

Hydrates and water-free (anhydrous) forms of substances must be regarded as the same substance.

The Manual of Decisions to Directive 67/548/EEC notes that if the anhydrous form of the substance has been notified, all the hydrated forms of the substance are covered by the notification. This is consistent with the interpretation that registration should cover all the forms that are manufactured (cf. also the guidance document for identification and naming of substances under REACH). The “Guidance on registration” gives the following example: for hydrates or hydrated ions, copper (II) sulphate pentahydrate formed by association of copper (II) sulphate with water will not require registration by the manufacturer, provided the copper (II) sulphate was registered (or exempted from registration).

Another question that has been asked is if downstream users who make a hydrate of the registered substance other than the original hydrate supplied to them would also be exempted from registration. The interpretation of the Commission services is that hydrated forms of a substance are covered by a registration up the supply chain. Nevertheless, downstream users need to make sure that the relevant uses (including generation of the hydrated form) are covered in exposure scenarios, if applicable.

In addition, the Commission services have been asked to confirm the exemption of hydrates of substances that are themselves exempt from registration. The Commission services consider that this is the case.

This should be made clear in the “Guidance on registration”.

3.4.6.3. Commission proposal

- Maintain point 6, as in the original REACH text.
- Develop and introduce guidance on this point in the REACH “Guidance on registration”.

3.4.7. Annex V, point 7

The following substances which occur in nature, if they are not chemically modified:

Minerals, ores, ore concentrates, cement clinker, natural gas, liquefied petroleum gas, natural gas condensate, process gases and components thereof, crude oil, coal, coke.

3.4.7.1. Background

The original criterion in the Commission proposal for REACH reproduced one of the criteria for substances that did not need to be reported under EINECS, as follows:

Substances occurring in nature as such, unprocessed or processed only by manual, mechanical or gravitational means; by dissolution in water, by flotation, or by heating solely to remove water, or which are extracted from air by any means, will be listed in EINECS under the collective name ‘naturally occurring substances’ and should not be reported individually. However, substances as such or as part of mixtures which are produced by chemical modification of naturally occurring products or are separated from them by physical processing can be reported.

The criteria in the Commission proposal were separated into two parts during the discussions leading to the Common Position (see also Section 3.4.7.2 below). The original Commission proposal covered:

8. *Minerals, ores, or substances occurring in nature if they are not chemically modified during their manufacturing, unless they meet the criteria for classification as dangerous according to Directive 67/548/EEC;*
9. *Natural gas, crude oil, coal.*

The text was amended to group together minerals, ores, natural gas, crude oil and coal in a single point, with the addition of ore concentrates, cement clinker, liquefied petroleum gas, natural gas condensate and process gases.

In addition, the conditions for the exemption were modified for both elements: the limitation to non-classified substances was dropped (consequently, these substances do not need to be registered even if they meet the classification criteria) and crude oil, natural gas and coal are now exempted only if they are not chemically modified.

The remaining text relating to other substances occurring in nature was transferred to a separate point (see Section 3.4.8 of this document). The conditions for exemption of these (non-chemically modified and non-dangerous) substances remained unchanged.

3.4.7.2. Analysis

The substances initially exempted under this point would meet the criteria for inclusion in Annex V set out in Section 3.2, as they are:

- naturally occurring substances that are further transformed/modified/processed and registered in that transformed/modified/processed form; or
- chemically modified naturally occurring substances that are further transformed/modified/processed and registered in that transformed/modified/processed form.

These exemptions do not prejudice the objectives of REACH, as the risks posed by these naturally occurring substances or chemically modified substances will be managed in the supply chain, as the further transformed/modified/processed substances will need to be registered.

Some substances not occurring in nature and for which significant hazards are known were also intensively discussed during the legislative process. Moreover, recital 36 indicates that the legislators wished to give special consideration to substances derived from mineralogical processes. Clearly, this left the Commission with a rather difficult task of assessing the intention of the legislators with respect to those substances. Generally, the line proposed to the Commission was not to remove substances which the legislators introduced as a key part of the compromise achieved between Parliament and the Council. However, for new entries this review proposed only substances which are clearly in line with the criteria for health and environmental protection.

3.4.7.3. Existing entries

The heading of Annex V, point 7 exempted natural substances that are on the list but are not chemically modified. Therefore, this exemption did **not** apply to:

- naturally occurring substances whose chemical structure has been modified;
- non-chemically modified substances derived from nature and processed by means other than manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or heating solely to remove water, or which is extracted from air by any means.

The individual substances listed in point 7 were:

- *Minerals, ores and ore concentrates*. These are not listed in Annex I to Directive 67/548/EEC as they are generic entries, although individual substances that are minerals, ores and ore concentrates may be. They fulfil the definition of substances that occur in nature. A number of mineral ores and concentrates are listed in EINECS as they were separated by means other than mechanical methods and marketed.
- *Cement clinker*. This is not listed in Annex I to Directive 67/548/EEC and is not in EINECS. Cement clinker is limestone, clay, bauxite, iron ore and quartz ground to a fine powder that is heated under oxidising conditions to around 1400-1450°C, at which temperature partial melting (sintering) takes place, producing hard spherical nodules of around 5-20 mm in diameter. That way, chemical bonds in the raw material

cease to exist and new bonds are irregularly formed through material melting. The melted material is rapidly cooled (quenched) to preserve its reactive mineral constituents. Cement (EC number 266-043-4) is listed in EINECS. There are also restrictions in Annex XVII of REACH related to its possible content of chromates. In SDSs from industry, cement clinker is noted for causing effects as irritating to respiratory system and skin (R37/38), serious damage to eyes (R41) and skin sensitisation (R43). This substance does not comply with the definition of substances which occur in nature.

- *Natural gas* (EC number 232-343-9), *coal* (not listed in EINECS) and *crude oil* (not listed in EINECS). These are not listed in Annex I to Directive 67/548/EEC and comply with the definition of substances which occur in nature.
- *Liquefied petroleum gas* (EC number 270-704-2) is classified in accordance with Annex I to Directive 67/548/EEC as carcinogen, Cat 1, mutagen, Cat 2 and flammable. This substance does not comply with the definition of substances which occur in nature.
- *Natural gas condensates* (EC number 272-896-3) are classified in accordance with Annex I to Directive 67/548/EEC as carcinogens, Cat 2 and are corrosive and in Annex XVII of REACH. This substance does not comply with the definition of substances which occur in nature.
- *Coke* (EC number 272-896-3). This substance is not listed in Annex I to Directive 67/548/EEC. It does not comply with the definition of substances which occur in nature. Coke is manufactured through a chemical transformation of coal or petroleum.
- *Process gases*. These are not naturally occurring substances, but the result of industrial processes.

Several of the above-mentioned substances (cement clinker, coke, process gases, liquefied petroleum gas and natural gas condensates) do not comply with the definition of substances occurring in nature. Nevertheless, it was suggested that they are maintained in Annex V, as it was considered that the legislators intended to exempt all these substances.

Therefore, it would be appropriate to split Annex V, point 7 into two separate entries, one covering substances which occur in nature and the other for naturally occurring substances and certain substances derived from mineralogical processes which are soon further transformed/modified/processed and registered in that transformed/modified/processed form, as follows:

(a) 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.

(b) The following substances if they are not chemically modified:

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

The Commission proposed that further interpretation of these exemptions is given in the “Guidance on registration”. It could also be useful to give further guidance on the terms used in the exemptions such as:

- **Mineral:** A mineral is a naturally occurring substance formed through geological processes that has a characteristic chemical composition, a highly ordered atomic structure and specific physical properties.
- **Ore:** A general expression for mineral aggregates or rocks from which metals or metal components can be extracted as well as all mineral aggregates whose mining have an economic benefit.

3.4.7.4. Proposed new entries

In the course of the review process, Member States and stakeholders proposed a number of substances for inclusion in this point: glass, ethane, methane, propane, butane, biogas, natural gas liquids, crude tall oil, naturally derived materials like fats and oils, fatty acids and glycerides, sugars, lime, ceramic frits, calcined petroleum coke and metallurgical coke, magnesia, magnetite/hematite iron ore pellets, oil shale and crude shale oil.

Some of the substances were proposed for inclusion in Annex IV, but it was considered that compliance with the agreed criteria for minimum risk because of their intrinsic properties could not be demonstrated (either due to lack of data or because there were indications that the substance does not fulfil the criteria). Concerns have been expressed that some of these substances originally included in Annex IV clearly do not comply with the criterion of minimum risk because of their intrinsic properties (see Section 2 of this document on the review of Annex IV).

The Commission considered all the substances proposed against the criteria in Section 3.2. As outlined in Section 3.2.2.1, the Commission proposed to limit additions to Annex V to substances that are clearly in line with the criteria on protection of human health and the environment. Therefore, the Commission recommended inclusion of only the following substances:

- Certain types of glass;
- Certain ceramic frits;
- Certain vegetable oils, fats and waxes;
- Certain animal oils, fats and waxes;
- Certain fatty acids;
- Glycerol;
- Magnesia;
- Compost and biogas.

Glass and ceramic frits

According to the scientific literature, glass is the state of a substance rather than a substance as such. For legislative purposes, it can best be defined through its starting materials and production process, like many other UVCB substances. EINECS identifies glass as follows:

- Glass, nonoxide, chemicals (EC: 295-731-7), Glass, oxide, calcium magnesium potassium sodium phosphosilicate (EC: 305-415-3), Glass, oxide, calcium magnesium sodium phosphosilicate (EC: 305-416-9) and Glass, oxide, chemicals (EC: 266-046-0)¹⁴.

On the other hand, it appears that EINECS notification was not systematically applied to glass in the past, partly due to lack of clarity relating to its status under chemicals legislation. Therefore, EINECS numbers do not seem fit to identify all relevant types of glass.

Similarly to glass, EINECS identifies frits under the following name:

- Frits, chemicals (EC: 266-047-6).

Glass in various forms and ceramic frits were proposed for addition to both Annexes IV and V. However, the consultant assessing the compliance of applications for inclusion in Annex IV with the agreed criteria concluded that insufficient information had been submitted to demonstrate compliance with the criterion of minimum risk due to intrinsic properties. Therefore, the Commission concluded that inclusion in Annex IV was not warranted. Nevertheless, glass is one of the substances resulting from mineralogical processes posing relatively low risks unless they contain hazardous substances. Nevertheless, it was clearly the Commission's intention to exempt only glasses and ceramic frits which have no significant hazard properties.

This limitation was proposed to be done in two ways: Firstly, glass or ceramic frits should be exempted only if they do not meet the classification criteria. Secondly, in addition, they should also be excluded from the exemption if dangerous *constituents* are present above the relevant concentration limits, unless these constituents are not available throughout the lifecycle of the substance.

Therefore, the Commission proposed wording the entry for glass and ceramic frits as follows:

“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 lifecycle of the substance and those data have been ascertained to be adequate and reliable:

Glass, ceramic frits.”

¹⁴ Note that the description following the heading in the EINECS listing of these substances is part of the substance entry and, in most cases, is most decisive for substance identification.

This wording was chosen to follow the wording in the upcoming legislation on classification, labelling and packaging of substances and mixtures.

It is the responsibility of manufacturers or importers to assess and document the conclusive scientific data to demonstrate that their substance(s) fulfil(s) these criteria.

Vegetable fats, vegetable oils and vegetable waxes; Animal fats, animal oils and animal waxes

This group of substances covers a wide variety of different types of substances, with a wide range of entries in EINECS.

The original Annex IV contained various entries referring to oils, fats and waxes, e.g. sunflower oil, whereas similar oils, fats and waxes, e.g. palm oil or olive oil, were not exempted. The oils, fats and waxes in the original Annex IV were generally evaluated by the consultant as posing relatively low risks based on their intrinsic properties. The Commission therefore considered that they should remain exempted from registration, the downstream user obligations and evaluation.

Moreover, a number of oils, fats and waxes were proposed for addition to Annex IV. However, their addition to Annex IV was deemed inappropriate as it could not be demonstrated that they are of minimum risk based on their intrinsic properties (cf. the consultant's report). At the same time, the distinction between different origins of fats, oils and waxes was considered to be problematic, as it was not based on the hazard properties of the substances and could lead to distortion of competition.

Even though they may not meet the criteria concerning minimum risk because of their intrinsic properties, both the original and proposed entries have a relatively low hazard profile. Therefore, the Commission considered that most existing Annex IV entries and fats/oils/waxes proposed meet the criteria set out in Section 3.2 of this document and therefore fit better in Annex V than in Annex IV.

The Commission proposed to limit the exemption to fats, oils and waxes which are obtained from natural sources and which are not chemically modified and, at the same time, have no hazardous properties beyond flammability or skin or eye irritancy. Fats, oils and waxes which are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative, in accordance with the criteria set out in Annex XIII to REACH, and which have been 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) of REACH, should also not be exempted. The transition period of two years is intended to allow manufacturers and importers to prepare a registration dossier if a substance is accordingly identified.

These conditions have been included to ensure that the exemption does not cover further transformation products on the one hand and more dangerous substances on the other hand, for which the generation of more information and improved risk management are considered necessary.

The Commission therefore proposed a generic entry in Annex V for vegetable fats, vegetable oils and vegetable waxes and also for animal fats, animal oils and animal waxes along the lines set out above. This exemption does not cover essential oils. Essential oils are hydrophobic liquids of complex composition, derived from plants and containing volatile

organic compounds, such as alcohols, aldehydes, ketones, phenols, esters, ethers and terpenes, in varying proportions.

Fatty acids

A number of fatty acids were proposed for addition to Annex IV. However, their addition to Annex IV was deemed inappropriate as it could not be demonstrated that they are of minimum risk based on their intrinsic properties (cf. the consultant's report on the evaluation of proposals for inclusion in Annex IV). In addition, there are a number of fatty acids in the groups originally listed in Annex IV where risks due to particular intrinsic properties cannot be excluded (potential aquatic toxicity, bioaccumulation and persistence predicted from QSAR).

However, due to the similarity of those substances and high number of substances in this category, it was considered very difficult to give a robust scientific justification why certain substances should remain in Annex IV and other substances should be deleted. Moreover, similarly to the foregoing considerations for fats, oils and waxes, it was considered that most fatty acids meet the criteria set out in Section 3.2 of this document and fit better in Annex V than in Annex IV.

Nevertheless, the Commission proposed to limit the exemption to fatty acids which are obtained from natural sources and which are not chemically modified and to fatty acids which have no hazardous properties beyond flammability and skin or eye irritancy. In other words, any fatty acids where there is available information that they meet the criteria for classification, e.g. for aquatic toxicity, bioaccumulation or persistence, therefore need to be registered. Fatty acids which are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative, in accordance with the criteria set out in Annex XIII to REACH, and which have been 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) of REACH should also not be exempted. The transition period of two years is intended to allow manufacturers and importers to prepare a registration dossier if a substance is accordingly identified.

These limitations are imposed in order to ensure that the exemption does not cover further transformation products on the one hand and more dangerous substances on the other hand, for which the generation of more information and improved risk management are considered necessary.

The Commission therefore proposed a generic entry in Annex V for fatty acids along the lines set out above.

Glycerol

When fatty acids are obtained from fats and oils by ester hydrolysis, glycerol is also formed in the process. The Commission therefore proposed that glycerol should be exempted together with fats, oils, waxes and fatty acids.

Magnesia

Magnesia is a mineral composed of magnesium oxide (EC 215-171-9). It is used as an antacid and mild laxative and has many other non-medical uses. Currently there is no information

available indicating that magnesita meets the criteria for classification. However, inhalation of magnesium oxide is reported as causing metal fume fever.

Magnesita is the result of mineralogical processes.

As magnesita has a relatively low hazard profile compared with other similar substances, the proposal was to include it in Annex V.

The Commission proposed further interpretation of this exemption in the “Guidance on registration”.

Biogas

It was decided to add biogas under the same entry as compost, to avoid interpretation of biogas as an example of “process gases” which would make the scope of the exemption too wide.

As regards the other substances proposed, the Commission took the view that insufficient information and discussion were available at the time of the review and that it would be inappropriate to make exhaustive lists of such borderline cases.

3.4.7.5. Commission proposal

➤ Point 7 should be split into two entries:

Point 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.

New point 10: The following substances if they are not chemically modified:

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

➤ New point 11: Glass and ceramic frits, 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 lifecycle of the substance and those data have been ascertained to be adequate and reliable.

➤ New point 9: 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; 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).

- Develop and introduce guidance on these points in the REACH “Guidance on registration”.

3.4.8. Annex V, point 8

Substances occurring 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.

3.4.8.1. Background

This original criterion in the Commission proposal for REACH reproduces one of the criteria for substances that did not need to be reported under EINECS (see first part in Section 3.4.7 above).

3.4.8.2. Analysis

The substances exempted under this point meet the criteria for inclusion in Annex V set out in Section 3.2 of this document, as they are naturally occurring substances that are usually further transformed/modified/processed and registered in that transformed/modified/processed form. The risks from naturally occurring substances will consequently be assessed through the assessment of other registered substances. In addition, they do not prejudice the objectives of REACH, as the chemically modified substances will be registered. In addition, only naturally occurring substances that do not meet the criteria for classification as dangerous are exempted. This will ensure that a high level of protection of human health and the environment is maintained. The hazard profile as such of the substance should give rise to only negligible risks.

Member States and stakeholders have proposed addition of a number of substances to this point: amino acids found in proteins, proteins (including caseins, caseinates and whey proteins), liquid milk, fatty acids obtained from natural oils unless dangerous, kieselgur (diatomaceous earth), vegetable oils and fats derived from oilseed crops, nuts and fruit obtained not only by mechanical means but also by industrial solvent extraction processes, compost, palm oil, palm kernel oil, coconut oil and their oleochemical derivatives and protein meals derived from oilseed crops, nuts and fruit not only by mechanical means but also by industrial solvent extraction processes.

Some of the substances were proposed for inclusion in Annex IV but were rejected or were recommended for deletion from Annex IV.

The Commission considered all the substances proposed against the criteria in Section 3.2 of this document. The following substances are already covered by other headings in Annex V:

- Compost (point 12, cf. Section 3.4.7.4 of this document);
- Certain vegetable oils, fats and waxes (see Section 3.4.7.4);
- Certain animal fats and waxes (see Section 3.4.7.4);

- Certain fatty acids (see Section 3.4.7.4).

A proposal was made to remove “classified as dangerous” from this point and exempt low-hazard substances. Another suggestion was to delete this point entirely, as it is too wide and uncertain. However, neither of these options was considered appropriate. This is because the existing entry was considered to be a good balance between taking into account practicality constraints for registration and the interest in gaining more information and ensuring better management of the risks of substances where such risks may occur due to their hazard properties. A general exemption for natural substances, including for dangerous substances, was not deemed appropriate because the wide range of substances covered by this category and the broad variety of uses justify the need for more information and safe management of risks, at least for dangerous substances.

Another proposal was to reduce the exemption, by excluding substances which are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII to REACH and which 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) of REACH. The Commission concluded that this will be appropriate in the context of this exemption, as explained above, and decided to add a transition period of two years for substances identified as giving an equivalent level of concern to CMRs, PBTs and vPvBs, which is intended to allow manufacturers and importers to prepare a registration dossier if a substance is accordingly identified.

It has also been suggested that this point should cover not only the naturally occurring substance itself but also the synthetic versions of a substance occurring in nature (e.g. gypsum occurring naturally and as a by-product of an industrial process). The original entry does not do this as only substances which meet the definition of “substance which occurs in nature” are exempted (Article 3(39)), i.e. *a naturally occurring substance as such, unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which is extracted from air by any means*. If a substance occurring in nature is produced synthetically it is not covered by this definition and is therefore not covered by this exemption.

Extending the exemption for naturally occurring substances to their synthetic equivalents was, however, deemed impractical. Firstly, it would undermine the objectives of REACH by potentially exempting a very large number of substances, because a very large number of synthetic substances also occur in nature. Secondly, in practice it will be very difficult to verify in each case whether a particular synthetic substance also occurs in nature. This will create legal uncertainty whether a substance needs to be registered or not.

The Commission proposed that further interpretation of this exemption is given in the “Guidance on registration”.

3.4.8.3. Commission proposal

- Amend point 8 as follows in order to take account of PBTs, vPvBs and substances of equivalent concern:
“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).”

- Develop and introduce guidance on this point in the REACH “Guidance on registration”.

3.4.9. Annex V, point 9

Basic elemental substances for which hazards and risks are already well known:

hydrogen, oxygen, noble gases (argon, helium, neon, xenon), nitrogen.

3.4.9.1. Background

This criterion does not reproduce any of the criteria for substances that did not need to be reported under EINECS. It was suggested by Finland in Ad Hoc Working Party Document 150/05, although limited to hydrogen and oxygen. This point was finally introduced, with the addition of noble gases and nitrogen, as part of the changes made by the Common Position and maintained in the final Regulation.

3.4.9.2. Analysis

The substances exempted under this point would meet the criteria for inclusion in Annex V set out in Section 3.2 of this document, as they are basic elemental substances for which there is substantial experience and scientific evidence that the risks to health and the environment result from their physicochemical properties only and are well known. During the co-decision procedure Finland argued that registration of hydrogen and oxygen, although they are known to be dangerous and pose risks, would provide no added value as their hazards and risks are well known. Both substances have a harmonised classification under Directive 67/548/EEC, as follows:

- Hydrogen F+; R12;
- Oxygen O; R8.

The noble gases argon, helium, neon, xenon and nitrogen, are not classified in Annex I to Directive 67/548/EEC. The noble gas krypton has not been included for no apparent reason, except that the majority of krypton isotopes are radioactive (and therefore outside the scope of the REACH Regulation, as stipulated by Article 2(1)(a)).

In addition, the list contained individual substances that might be better placed in Annex IV (e.g. argon and nitrogen already feature there) as they clearly fulfil the criteria for inclusion in Annex IV.

Member States and stakeholders raised a number of issues related to this point. The following substances were proposed for inclusion: cement clinker, natural gas, liquefied petroleum gas, natural gas condensate, process gases and components thereof, ore concentrates, crude oil, coke, graphite and carbon, liquid manure, biogas and compost, krypton and sulphur, calcium oxide, calcium hydroxide, magnesium oxide, magnesium hydroxide, silicon, ethanol, monomers of natural and post-reacted natural polymers, vegetable and animal fats, oils,

waxes, their components and substances made thereof, fatty acids C4-C24, glycerine, inorganic silicates, vitamins and provitamins, saccharides and saccharide syrups, polyols (sugar alcohols) and polyol syrups, amino acids where they are present as monomers in polymeric proteins, monomers of protein or carbohydrate polymers from staple foods, insofar as they are a component of protein, carbohydrate or glycoprotein polymeric substances and ceramic frits.

The Commission assessed these suggestions and concluded that a number of them are already covered by earlier points.

The Commission proposed that further interpretation of this exemption is given in the “Guidance on registration”.

3.4.9.3. Commission proposal

- The duplicated substances (i.e. argon and nitrogen) should be deleted from Annex V, point 9 and the three other noble gases explicitly mentioned (i.e. helium, neon and xenon) should be proposed for inclusion in Annex IV.
- Hydrogen and oxygen should be maintained in Annex V as point 13.
- Develop and introduce guidance on this point in the REACH “Guidance on registration”.

The final Commission proposal for a revised Annex V including the new entries, (which has been later adopted as Annex II to Commission Regulation (EC) No 987/2008 of 8 October 2008), is set out in Appendix III to this document.

Appendix I: Agreed criteria for inclusion of substances in Annex IV of Regulation No. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

1. Introduction

The concepts of 'sufficient information' and 'minimum risk' are not laid down in REACH, so for the Commission to carry out the review of Annex IV it required these core concepts to be defined. These concepts were described in the form of criteria, including a minimum data-set required, and a format for proposing to add or remove substances. This enables the consideration of whether additional substances should be added to the Annex and whether substances currently in the Annex should remain, in a transparent and consistent way.

The Commission, together with an advisory group of Member States (MS) and other stakeholders¹⁵ developed the criteria in this Appendix, based on a proposal by a contractor engaged by the Commission for the purposes of the review¹⁶, and discussed them at the CASG(Annexes) meetings of 3 September and 1 October 2007. The criteria were endorsed by the REACH Competent Authorities on 19 October 2007 and the document "Criteria for inclusion of substance in Annex IV of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)" (hereinafter the 'Criteria Document') was published on the Commission website. The below criteria are drawn from this document.

2. Criteria for determining minimum risk because of intrinsic properties

As following Article 2.7(a) minimum risk in this exercise is based on intrinsic properties; use and exposure information will not be included. Using only information on intrinsic properties of the substance leads to a more uncertain determination of the magnitude of risk. Due to this inherent uncertainty and the need to include only substances which pose a minimum risk, strict hazard-based criteria needed to be developed. Such criteria are proposed below. Minimum risk because of intrinsic properties can only be concluded if all criteria for physicochemical properties, toxicological properties and ecotoxicological properties mentioned in sections 2.1 to 2.3 are met.

2.1 Physicochemical properties

All the following criteria must be met:

- (1) The data specified in section 3 on Information requirements must be provided.
- (2) The substance does not meet the criteria for classification as dangerous in accordance with Directive 67/548/EEC.

¹⁵ The Commission set up a subgroup of the REACH Competent Authorities, the Competent Authorities Subgroup on the Annexes – CASG(Annexes) –, consisting of certain MS (AT, BE, DE, DK, EE, ES, FI, FR, GR, IE, IT, LI, NL, PL, SE and UK) and stakeholders (NO, WWF, ETUC, CEFIC, CONCAWE and REACH Alliance) with a remit to discuss the reviews of Annexes I, IV, V, XI and XIII.

¹⁶ The draft proposal was prepared by DHI, Protection Through Knowledge (PTK) Ltd and Milieu Ltd.

- (3) The substance does not meet any of the criteria laid out in Appendix IA of this document for the following endpoints (a. to n.):
- a. Explosive, in Divisions 1.1, 1.2, 1.3, 1.4 and 1.5;
 - b. Flammable gas, Category 1 or Category 2;
 - c. Flammable liquid, Category 1, Category 2, Category 3 or Category 4;
 - d. Flammable solid, Category 1 or Category 2;
 - e. Oxidising gas, Category 1;
 - f. Oxidising liquid, Category 1, Category 2 or Category 3;
 - g. Oxidising solid, Category 1, Category 2 or Category 3;
 - h. Corrosive to metals, Category 1;
 - i. Self-reactive substance, Types A to F;
 - j. Pyrophoric liquid, Category 1;
 - k. Pyrophoric solid, Category 1;
 - l. Self-heating substance, Category 1 or Category 2;
 - m. Substance which in contact with water emits flammable gas, Category 1, Category 2 or category 3;
 - n. Organic peroxide, of Type A to F.

2.2 Toxicological properties

All the following criteria must be met:

- (1) The data specified in section 3 on information requirements must be provided.
- (2) The substance does not meet the criteria for classification as dangerous in accordance with Directive 67/548/EEC.
- (3) The substance does not meet the criteria for a substance of very high concern (SVHC) in accordance with Article 57 of REACH.
- (4) The intrinsic properties of the substance are well below the criteria for classification as dangerous in accordance with Directive 67/548/EEC (using all available data for all relevant toxicological endpoints). This is demonstrated by an absence of ‘*significant toxicological effects*’ in the relevant toxicological studies.
- (5) Absence of “significant toxicological effects” means:

- a. Acute oral toxicity: no evident toxicity¹⁷ at dose levels ≤ 2000 mg/kg. Additionally the LD₀ must be ≥ 5000 mg/kg where the substance has been tested at this level;
- b. Acute dermal toxicity: no evident toxicity² at dose levels ≤ 2000 mg/kg. Additionally the LD₀ must be ≥ 5000 mg/kg where the substance has been tested at this level;
- c. Acute inhalational toxicity: no evident toxicity² at an exposure level of ≤ 20 mg/litre/4h for gases or vapours and ≤ 5 mg/litre/4h for aerosols or particulates. Additionally the LD₀ must be ≥ 50 mg/litre/4h for gases or vapours and ≥ 12.5 mg/litre/4h for aerosols or particulates where the substance has been tested at this level;
- d. Skin irritation: the substance does not meet the criteria for (a) assignment of the Risk Phrase R66 in Annex VI of Directive 67/548/EEC or (b) mild skin irritation according to the criteria laid down in Annex 1B of this document;
- e. Eye irritation: the substance does not meet the criteria for “mildly irritating to eyes” according to the criteria laid down in Annex 1B of this document;
- f. Sensitisation: no evidence of sensitisation potential from structural alerts, in animal tests (no evidence of a positive response in any animal tested) and no human evidence of sensitisation potential (no human cases of sensitisation reported);
- g. Repeated dose toxicity by the oral route: no evident toxicity¹⁸ at ≤ 500 mg/kg/day (NOAEL) in the case of a 90-day study¹⁹. Results from longer-term (e.g. 2-year) studies should be evaluated by the applicant on a case-by-case basis using this criterion as a guide. For the purpose of reviewing current Annex IV entries, if only results from short-term studies (e.g. 28 day) are available, then these data should be evaluated on a case-by-case basis using this criterion as a guide;
- h. Repeated dose toxicity by the dermal route: no evident toxicity³ at ≤ 1000 mg/kg/day (NOAEL) in the case of a 90-day study⁴. Results from longer-term studies should be evaluated by the applicant on a case-by-case basis using this criterion as a guide. For the purpose of reviewing current Annex IV entries, if only results from short-term studies (e.g. 28 day) are available, then these data should be evaluated on a case-by-case basis using this criterion as a guide;
- i. Repeated dose toxicity by the inhalation route: no evident toxicity³ at ≤ 2.5 mg/litre/6h/day (NOAEL) in the case of a 90-day study.⁴ Results from longer-term

¹⁷ Comprising: an absence of clinical signs of toxicity during the post-dosing observation period, no treatment-related body weight changes, no macroscopic findings at autopsy and no microscopic findings in cases where histopathological investigations have been undertaken.

¹⁸ Comprising: an absence of clinical signs of toxicity during the period of the study including e.g. behavioural changes, no treatment-related body weight or food consumption changes, no macroscopic findings at autopsy, no treatment-related effects on organ weights, clinical chemical or haematological parameters or urinalysis, no treatment-related microscopic findings.

¹⁹ The data set for application for an exemption from registration will normally include a 90-day study

studies should be evaluated by the applicant on a case-by-case basis using this criterion as a guide. For the purpose of reviewing current Annex IV entries, if only results from short-term studies (e.g. 28 day) are available, then these data should be evaluated on a case-by-case basis using this criterion as a guide;

- j. Carcinogenicity: no evidence of carcinogenic potential based on available data and application of relevant (Q)SAR models or other structural alerts;
 - k. Mutagenicity: no evidence of mutagenic potential in vitro or in vivo nor from the application of relevant (Q)SAR models or other structural alerts;
 - l. Reproductive toxicity: no evidence of reproductive toxicity at ≤ 1000 mg/kg/day by the oral route, at ≤ 2000 mg/kg/day by the dermal route or at ≤ 20 mg/litre/6h/day for gases or vapours or ≤ 5 mg/litre/6h/day for aerosols or particulates (limit tests) by the inhalation route²⁰, nor from the application of relevant (Q)SAR models or other structural alerts;
 - m. Harm to breastfed babies: the substance should not interfere or be suspected to be able to interfere with lactation, nor should it be a substance which may be present in breast milk or be suspected to be able to pass over to breast milk;
 - n. Narcotic effects: the substance should not cause any signs of CNS depression even after prolonged or repeated exposure;
 - o. Danger of cumulative effects: the substance should not have been shown to accumulate in the human body or be suspected to have properties leading to such accumulation.
- (6) The substance must not meet any of the screening criteria for PBT or vPvB set out in the TGD for the CSA/CSR²¹ nor must it be on the PBT working group list.
- (7) The substance shall not be identified or suspected to have endocrine activity from in vivo or in vitro tests, nor from the application of relevant (Q)SAR models or other structural alerts, which may raise any concern for endocrine-disrupting properties (DG Environment, ENV.D4./ETU/2005/0028r; http://ec.europa.eu/environment/endocrine/documents/final_report_2007.pdf)
- (8) The substance shall not be listed in Annex II or Annex III of the Cosmetic Directive 76/768/EEC.

²⁰ There is currently limited scientific basis for the indicated figures for the dermal and inhalation routes.

²¹ The TGD for the CSA/CSR is not yet finalised and, thus, the best available draft TGD will be used.

2.3 Ecotoxicological properties

All the following criteria must be met:

- (1) The data specified in section 3 on Information requirements must be provided.
- (2) The substance does not meet the criteria for classification as dangerous in accordance with Directive 67/548/EEC.
- (3) The substance does not meet the criteria for a substance of very high concern in accordance with Article 57 of REACH.
- (4) The intrinsic properties of the substance are well below the criteria for classification as dangerous in accordance with Directive 67/548/EEC (using all available data), i.e.:
 - a. The substance shall have a very low potential to bioaccumulate in aquatic species, e.g. fish, i.e. experimentally determined bioconcentration factor is <10 . For organic substances an alternative criteria of $\log Pow < 2.0$ can be applied.
 - b. The substance shall be readily biodegradable (excluding inorganic substances)
 - c. The aquatic toxicity shall fulfil both of the following criteria:
 - (i) Acute, short-term EC/LC50 > 1000 mg/L, or $>$ water solubility, or no significant adverse effects recorded at 100 mg/l in acute, short-term aquatic toxicity tests *and* validated QSAR data showing acute effects (EC/LC50) > 1000 mg/l.
 - (ii) Chronic long-term NOEC > 10 mg/L
- (5) The substance must not have adverse effects on terrestrial organisms, meaning that no adverse effects are reported in any of the tests required under Annex IX of the REACH Regulation at the maximum test concentrations prescribed by the respective OECD guidelines.
- (6) The substance must not meet any of the screening criteria for PBT or vPvB set out in the TGD for the CSA/CSR²² nor must it be on the PBT working group list.
- (7) The substance shall not be identified or suspected to have endocrine activity from in vivo or in vitro tests, nor from the application of relevant (Q)SAR models or other structural alerts, which may raise any concern for endocrine-disrupting properties (DG Environment, ENV.D4./ETU/2005/0028r; http://ec.europa.eu/environment/endocrine/documents/final_report_2007.pdf)
- (8) The substance shall not present a risk to the ozone layer, i.e. the substance shall not be included in Annex I to EC 2037/2000.

²² The TGD for the CSA/CSR is not yet finalised and, thus, the best available draft TGD will be used.

3. Information requirements

The information required in a submission requesting the addition of a substance to Annex IV shall be sufficient for an evaluation of the fulfillment of the criteria for determining minimum risk because of intrinsic properties. The information shall consist of:

- (1) The information needed for identification of the substance (as defined in REACH Annex VI, section 2).
- (2) The standard information corresponding to the endpoints set out in Annex VII, Annex VIII, Annex IX and Annex X, subject to the following clarifications:
 - The specific rules for adaptation provided in column 2 of the Annexes apply, in relation to exceptions from the standard information requirements listed above *except* when these are based on exposure or risk considerations ;
 - Information is required on all the physicochemical properties of the substance according to the requirements in Annexes VII and IX with the clarification that information is not required for the endpoints 7.2 Melting/freezing point, 7.4 Relative density, 7.6 Surface tension, 7.15 Stability in organic solvents and identity of relevant degradation products, and 7.16 Dissociation constant;
 - Toxicological information is required sufficient to demonstrate that the criteria set out in section 2 of this document have been met and referring to requirements in Annexes VII-X, as appropriate (information according to Annex X is only required when such studies are available);
 - Ecotoxicological information sufficient to demonstrate that the criteria set out in section 2 of this document have been met and referring to requirements in Annexes VII-X, as appropriate, with the clarification that a minimum of one long-term toxicity study as described in endpoint 9.1 (Annex IX) for the most sensitive organism (crustacean or fish) is always required (information according to Annex X is only required when such studies are available).
- (3) All available test data and non-test data on the substance and its known metabolites. This includes the information in literature and databases and, when applicable, information obtained from (Q)SARs, grouping of substances or read-across approach, in vivo and in vitro testing, and epidemiological studies, cf. Annex XI section 1. If such information is used, in accordance with Annex XI, this must be fully justified and documented. In this context, available information from risk and hazard assessments performed under international, national and Community programmes or legislation as well as voluntary initiatives may be used to provide reliable information on intrinsic properties.
- (4) Robust study summaries, in accordance with the IUCLID 5 manual and the OECD HPV Chemicals Programme Manual shall be provided for a minimum of one key study per endpoint for physicochemical, toxicological and ecotoxicological properties. If the key study for any toxicological or ecotoxicological endpoint is not the study giving rise to the highest concern, the use of the particular key study must be fully justified and robust study summaries shall be provided for the study or studies

showing a higher effect than the key study. Full study reports need not be submitted but the applicant should be in legitimate possession of, or have permission to refer to, the full study report and be able to submit it to the European Commission or the contractor upon request. Evidence of such rights must be available on request (e.g. ownership, letter of access).

- (5) When the results submitted are not in accordance with publicly available sources (i.e. ESIS, IUCLID,...), the applicant must present scientific judgement which justifies that the key studies in the submission are superior to the publicly available studies showing different results; as a minimum the applicant is requested to review the information in the IUCLID database.
- (6) The information submitted shall be sufficient to enable a conclusion to be reached on the intrinsic hazard of the substance, for each relevant endpoint. The information shall be presented clearly and succinctly.
- (7) If the general rules for adaptation of the standard testing regime as described in Annex XI, sections 1 and 2, have been applied, their use must be fully justified. As previously indicated the rules described in Annex XI section 3 do not apply as they are based on an exposure assessment and, thus, a known use of the substance; consequently exposure resulting from unknown future uses cannot be addressed.
- (8) Commonly known substances, where there is clear scientific evidence that prolonged daily and continuous human and environmental exposure does not lead to more than minimum risk may be evaluated case-by-case as the information required in Annexes VII to X would not add useful data to the already available information. This approach could be warranted for substances such as sugar which can be considered to constitute a minimum risk even though a full dataset may not be available. Waiving of standard information requirements for such substances may refer to Annex XI, particularly sections 1.1 (Use of existing data) and 1.2 (Weight of evidence). Minimum risk can, however, not be concluded based alone on a Community risk assessment not resulting in risk management measures being recommended.
- (9) If grouping of substances and the read-across approach are applied, in accordance with Annex XI section 1.5, this must be fully justified and documented. This means that unambiguous identification of the substances included in the grouping and information on the endpoints where the approach is applied must be clearly provided.
- (10) Information need not be provided if testing is not technically possible due to the intrinsic physicochemical properties of a substance, cf. Annex XI section 2. If waiving of the requirement for information is applied for this reason in accordance with Annex XI, it must be fully justified and documented.

4. Documentation requirements

The following documentation requirements must be met:

- (1) Submissions to be considered for the inclusion of an additional substance in Annex IV shall consist of a dossier including:

- An overall conclusion from the applicant on whether the substance meets the criteria laid down in this document, with justification;
 - A conclusion (descriptive and numerical) per endpoint based on consideration of the information required; and
 - The information specified in section 3 on ‘Information requirements’ and a completed format in accordance with the instructions in Appendix 2.
- (2) The information in the dossier must be clearly presented in accordance with these instructions, the information requirements and in English only. Any submission with an incomplete or unclear dossier will be rejected without further consideration.
 - (3) If there is publicly available information on the substance or known metabolites of the substance, not addressed in the submission, which leads to any doubt on the potential risk of the substance, then the submission will be rejected without further consideration.
 - (4) If robust study summaries or other relevant information, e.g. (Q)SAR results with clear justification, are not presented in a clear manner for all key studies, then the submission will be rejected without further consideration.
 - (5) Submissions to be considered for deletion of a substance in the existing Annex IV shall include a dossier containing a conclusion that the substance does meet the criteria laid down in this document. Documentation and justification shall be provided by completion of the relevant sections of the format (Appendix 2).

Appendix II: Submissions for addition to Annex IV²³

Substance
Glycerol
Sodium alginate
Carrageenan, PES (processed eucheuma seaweed)
Glass
Fructose
Invert sugar
Calcium carbonate (sugar factory lime)
Tannin
Isomaltulose
Palatinose syrup
D-lactobionic acid (4-O-beta-D galactopyranosyl-D-gluconic acid)
Sodium lactobionate
Calcium lactobionate
Potassium lactobionate
Palatinose syrup
D-gluconic acid
Sodium gluconate
Potassium gluconate
Calcium gluconate (glycogenic acid)
Trehalulose (1-O- α -D-glucofuranosyl-D-fructose)
Isomalt (mixture of 6-O- α -D-glucofuranosyl-D-sorbitol (1,6-GPS) and 1-O- α -D-glucofuranosyl-D-mannitol (1,1-GPM) which are simultaneously obtained by the hydrogenation of 6-O- α -D-glucofuranosyl-D-fructose)

²³ The substances are listed under the names and in the order they have been submitted. The list also includes multiple submissions received for the same substance that have been evaluated on their own merits against the agreed criteria.

Substance
D-lactobionic acid
Sodium lactobionate
Calcium lactobionate
Potassium lactobionate
D-maltobionic acid 4-O-alpha-D-glucopyranosyl-gluconic acid
Titanium antimony chromium III oxide rutile (C.I. pigment brown 24)
Calcium magnesium orthophosphate
Ammonium dihydrogenorthophosphate (monoammonium phosphate)
Sodium dihydrogenorthophosphate (monosodium phosphate)
Methyl-cis-9-octadecenoate (fatty acids, rape oil, Me esters)
Lanolin
Lanolin alcohol
Methyl palmitate
Fatty acids, C16-18, C18 unsaturated methyl esters
Fatty acids C16-18, methyl esters
Methyl ester, palm based
Methyl ester, palm kernel based
Methyl myristate
D-gluconic acid
Sodium gluconate
Potassium gluconate
Calcium gluconate
D-maltobionic acid 4-O-alpha-D-glucopyranosyl-gluconic acid
Trehalulose (1-O- α -D-glucopyranosyl-D-fructose)

Substance
Isomaltulose (6-O- α -D-glucopyranosyl-D-fructose)
Microcrystalline cellulose, cellulose gel
Gelatine
Gelatine hydrolysate
Collagen
Erythritol
Collagen hydrolysate
Collagen ossein
Collagen (ox)
Bone, defatted
Bone meal
Animal fat
Pork fat
2-hydroxypropane-1,2,3-tricarboxylic acid (citric acid)
Tripotassium 2-hydroxypropane-1,2,3 tricarboxylate monohydrate (tripotassium citrate)
Trisodium 2-hydroxypropane-1,2,3, tricarboxylate dihydrate (trisodium citrate dihydrate)
Polyglycitol syrup
LPG, propane and butane
Pectin
Glass
Microcrystalline cellulose, cellulose gel
Pentane 1,2,3,4,5-pentol/1,2,3,4,5-pentahydroxypentane (xylitol)
Lactitol, 4-O-beta-D-galactopyranosyl-D-glucitol
Fatty acids, C16-18 and C18-unsaturated methyl esters
High-alumina, low-silica fibres

Substance
4-O-alpha-D-glucopyranosyl-D-glucitol (maltitol)
Maltitol syrup
Sorbitol syrup
Pentane 1,2,3,4,5-pentol/1,2,3,4,5-pentahydroxypentane (xylitol)
Tannin
Pentane 1,2,3,4,5-pentol/1,2,3,4,5-pentahydroxypentane (xylitol)
Gluconic acid
Glucono-delta-lactone
Sodium gluconate
Calcium gluconate
Potassium gluconate
Glycerol tristearate
Stearic acid, monoester with glycerol
Glycerides, C14-C18 mono- and di-
Glycerides, C16-18 mono- and di-
Glycerides, C16-18 mono-
D-fructose (fruit sugar, levulose)
Caramel
Invert sugar
Isomaltose
Xanthan gum
D-fructose
Hydrogenated glucose syrup
Caramel
Xanthan gum

Substance
Invert sugar
Isomaltose
Calcium carbonate
Beta-cyclodextrin, cycloheptaamylose
D-erythro-hex-2-enoic acid gamma-lactone (erythorbic acid)
Sodium salt of 2,3 didehydro-D-erythro-hexono-lactone (erythorbic acid sodium salt, sodium erythorbate)
Fructose
Methyl-cis-9-octadecenoate (fatty acid rape oil- Me ester (RME))
Calcium sulphate
Corn steep liquor (CSL)
Olive oil
Peanut oil
Sesame oil
Palm oil
Coconut oil
Palm kernel oil
Shea butter
Illipe fat
Sal oil
Lard
Lard oil
(2R,3R)-2,3-dihydroxybutanedioic acid (tartaric acid)
Monopotassium (+)-(2R,3R)-2,3-dihydroxybutanedionate (monopotassium tartrate)
Monopotassium monosodium (+)-(2R,3R)-2,3-dihydroxybutanedionate (potassium sodium tartrate tetrahydrate)

Substance
Disodium (+)-(2R,3R)-2,3-dihydroxybutanedionate (sodium tartrate dihydrate)
Dipotassium (+)-(2R,3R)-2,3-dihydroxybutanedionate (dipotassium tartrate)
Calcium hydrogenorthophosphate
Calcium phosphate
Calcium bis(dihydrogenorthophosphate)
Magnesium hydrogenorthophosphate
9-hexadecenoic acid
Isooctadecanoic acid
Fatty acids, coco
Fatty acids, vegetable oil
Fatty acids, dehydrated castor oil
Fatty acids, tall oil
Fatty acids, tallow, hydrogenated
Fatty acids, castor oil, hydrogenated
Fatty acids, C14-18
Fatty acids, C14-18 and C16-22-unsaturated
Fatty acids, palm kernel oil
Octadecadienoic acid
Fatty acids, C16-22 and C18-22-unsaturated
Fatty acids, coco, hydrogenated
Fatty acids, fish oil, hydrogenated
Fatty acids, C16-18 and C18 unsaturated
Fatty acids, palm kernel oil, potassium salts
Fatty acids, palm oil, hydrogenated
Fatty acids, sunflower oil

Substance
Fatty acids, C8-16
Fatty acids, rape oil
Fatty acids, C8-18
Fatty acids, C10-14
Fatty acids, C18-22
Fatty acids, olive oil
9-octadecenoic acid (Z)-, potassium salt
Octadecanoic acid, sodium salt
9-octadecenoic acid, 12-hydroxy-, monopotassium salt, [R-(Z)]-
Dodecanoic acid, potassium salt
Fatty acids, coco, sodium salts
Fatty acids, palm kernel oil, sodium salts
Dodecanoic acid, magnesium salt
Tetradecanoic acid, magnesium salt
Dodecanoic acid, calcium salt
Octadecanoic acid, magnesium salt
Octadecanoic acid, potassium salt
Fatty acids, tallow, calcium salts
Fatty acids, tallow, hydrogenated, calcium salts
Fatty acids, palm oil, potassium salts
Fatty acids, C14-18 and C16-18-unsaturated, sodium salts
Fatty acids, C8-18 and C18-unsaturated, magnesium salts
Fatty acids, tallow, sodium salts
Tetradecanoic acid, potassium salt
9-octadecenoic acid (Z)-, sodium salt

Substance
Calcium distearate
Hexadecanoic acid, potassium salt
Calcium(2+) 12-hydroxyoctadecanoate
Fatty acids, C14-18 and C16-18-unsaturated, potassium salts
Fatty acids, tallow, hydrogenated, potassium salts
Fatty acids, tallow, hydrogenated, sodium salts
Fatty acids, C16-18 and C18-unsaturated, sodium salts
Fatty acids, C16-18, sodium salts
Fatty acids, C16-22, calcium salts
Fatty acids, palm kernel oil, potassium salts
Fatty acids, C8-18 and C18-unsaturated, calcium salts
Fatty acids, C16-18, calcium salts
Fatty acids, castor oil, hydrogenated, calcium salts
Fatty acids, C16-18, magnesium salts
Fatty acids, C12-18, potassium salts
Fatty acids, rape oil, hydrogenated, calcium salts
Fatty acids, rape oil, hydrogenated, magnesium salts
Fatty acids, tallow, hydrogenated, magnesium salts
Fatty acids, palm oil, hydrogenated, sodium salts
Fatty acids, C16-22
Fatty acids, C10-16
Fatty acids, cotton-seed oil
Fatty acids, C12-20 and C12-20-unsaturated
Fatty acids, peanut oil
Fatty acids, palm oil

Substance
Fatty acids, vegetable oil, saturated
Fatty acids, vegetable oil, unsaturated
Fatty acids, C6-10
Fatty acids, C8-10
Fatty acids, C16-20
Fatty acids, coco heavy fractions
9,12-octadecadienoic acid
12-hydroxy-octadecanoic acid
Docosanoic acid
Erucic acid {(Z)-docos-13-enoic acid}
Octadecanoic acid, 9,10-dihydroxy
Ricinoleic acid
Capric acid (decanoic acid)
9,12,15-octadecatrienoic acid, (9Z,12Z,15Z)-
Eicosanoic acid (arachidic acid) C ₂₀ H ₄₀ O ₂
Myristic acid (tetradecanoic acid)
(Z)-tetradec-9-enoic acid
Fructose
Invert sugar
Sugar factory lime as a specific form of calcium carbonate
Ceramic frits
Milk proteins and milk protein hydrolyses
Lactose
Milk fat and milk fat components
Vinasse

Substance
Full lead crystal
Crystal glass
Fructose
Invert sugar
Sugar factory lime as a specific form of calcium carbonate
Epoxidised soybean oil
Fatty acids, coco, potassium salts
Fatty acids, coco, calcium salts
Fatty acids, tall oil, calcium salts
Glycerides, tall oil, mono-, di- and tri-
Octanoic acid, tri- (octanoic acid 1,2,3-propanetriyl)
Glycerol trilaurate
Castor oil, hydrogenated
Peanut oil; arachidic oil
Octadecanoic acid, ester with 1,2,3-propanetriol
Glycerides, coco mono-
Monosodium citrate
Monoglycerides, hydrogenated tallow
Monoglycerides, tallow
Castor oil, dehydrated
Decanoic acid, ester with 1,2,3-propanetriol octanoate
Glycerides, C12-18
Glycerides, C14-18
Glycerides, C8-18 and C18-unsaturated
Glycerides, C14-18 and C16-18-unsaturated

Substance
Glycerides, C16-18 and C18-unsaturated
Glycerides, C16-18
Glycerides, mixed coco, decanoyl and octanoyl
Glycerides, wheat-germ oil, mono-, di- and tri-
Glycerides, mixed decanoyl and octanoyl
Glycerides, C8-10
Glycerides, C10-18
Glycerides, C8-18 and C18-unsaturated, mono-, di- and tri-
Glycerides, C16-18 and C18-unsaturated, mono-, di- and tri-
Glycerides, vegetable oil, mono- and di-, hydrogenated
Glycerides, vegetable oil, mono- and di-
Glycerides, C16-18 and C18-unsaturated, mono-, di- and tri-
Toilet soap, shaving cream
Grapeseed oil
Cottonseed oil
Canola oil, low erucic rapeseed oil
High oleic sunflower oil
Hydrogenated rapeseed oil
Hydrogenated soybean oil
Hydrogenated sunflower oil
Hydrogenated palm oil
Hydrogenated palm stearin
Hydrogenated palm olein
Hydrogenated palm kernel oil
Hydrogenated palm kernel stearin

Substance
Hydrogenated palm kernel olein
Hydrogenated coconut oil
Hydrogenated shea olein
Hydrogenated shea stearin
Hydrogenated cottonseed oil
Interesterified shea butter
Palm stearin
Palm olein
Palm kernel stearin
Palm kernel olein
Shea starin
Shea olein
Olive oil
Sesame oil
Palm oil
Coconut oil
Palm kernel oil
Shea butter
Illipe fat
Sal oil
Fatty acids, tall oil
Castor oil, hydrogenated
Hydrogenated shea butter

Appendix III: Commission proposals to amend Annexes IV and V²⁴

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
<u>200-233-3</u>	<u>Fructose C₆H₁₂O₆</u>	<u>57-48-7</u>
200-294-2	L-lysine C ₆ H ₁₄ N ₂ O ₂	56-87-1
200-312-9	Palmitic acid, pure C₁₆H₃₂O₂	57-10-3
200-313-4	Stearic acid, pure C₁₈H₃₆O₂	57-11-4
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
<u>200-416-4</u>	<u>Galactose C₆H₁₂O₆</u>	<u>59-23-4</u>
200-432-1	DL-methionine C ₅ H ₁₁ NO ₂ S	59-51-8
<u>200-559-2</u>	<u>Lactose C₁₂H₂₂O₁₁</u>	<u>63-42-3</u>
200-711-8	D-mannitol C ₆ H ₁₄ O ₆	69-65-8
201-771-8	1-sorbose C ₆ H ₁₂ O ₆	87-79-6
204-007-1	Oleic acid, pure C₁₈H₃₄O₂	112-80-1

²⁴ Proposed additions in italics and underlined; proposed deletions in strikethrough.

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 $C_9H_{17}NO_{5.1/2}Ca$	137-08-6
205-582-1	Lauric acid, pure $C_{12}H_{24}O_2$	143-07-7
205-590-5	Potassium oleate $C_{18}H_{34}O_2K$	143-18-0
205-756-7	DL-phenylalanine $C_9H_{11}NO_2$	150-30-1
208-407-7	Sodium gluconate $C_6H_{12}O_7.Na$	527-07-1
212-490-5	Sodium stearate, pure $C_{18}H_{36}O_2.Na$	822-16-2
215-279-6	Limestone A noncombustible solid characteristic of sedimentary rock. It consists primarily of calcium carbonate	1317-65-3
215-665-4	Sorbitan oleate $C_{24}H_{44}O_6$	1338-43-8

EINECS No	Name/Group	CAS No
216-472-8	Calcium distearate, pure $C_{18}H_{36}O_{2,1/2}Ca$	1592-23-0
<u>231-098-5</u>	<u>Krypton Kr</u>	<u>7439-90-9</u>
<u>231-110-9</u>	<u>Neon Ne</u>	<u>7440-01-9</u>
231-147-0	Argon Ar	7440-37-1
<u>231-168-5</u>	<u>Helium He</u>	<u>7440-59-7</u>
<u>231-172-7</u>	<u>Xenon Xe</u>	<u>7440-63-3</u>
231-153-3	Carbon C	7440-44-0
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
<u>231-955-3</u>	<u>Graphite C</u>	<u>7782-42-5</u>
232-273-9	Sunflower oil Extractives and their physically modified derivatives. It consists primarily of the glycerides of the fatty acids linoleic, and oleic. (<i>Helianthus annuus</i>, <i>Compositae</i>).	8001-21-6

EINECS No	Name/Group	CAS No
232-274-4	Soybean oil Extractives and their physically modified derivatives. It consists primarily of the glycerides of the fatty acids linoleic, oleic, palmitic and stearic (<i>Soja hispida</i>, <i>Leguminosae</i>).	8001-22-7
232-276-5	Safflower oil Extractives and their physically modified derivatives. It consists primarily of the glycerides of the fatty acid linoleic (<i>Carthamus tinctorius</i>, <i>Compositae</i>).	8001-23-8
232-278-6	Linseed oil Extractives and their physically modified derivatives. It consists primarily of the glycerides of the fatty acids linoleic, linolenic and oleic (<i>Linum usitatissimum</i>, <i>Linaceae</i>).	8001-26-1
232-281-2	Corn oil Extractives and their physically modified derivatives. It consists primarily of the glycerides of the fatty acids linoleic, oleic, palmitic and stearic (<i>Zea mays</i>, <i>Gramineae</i>).	8001-30-7

EINECS No	Name/Group	CAS No
232-293-8	Castor Oil Extractives and their physically modified derivatives. It consists primarily of the glycerides of the fatty acid ricinoleic (<i>Ricinus communis</i>, <i>Euphorbiaceae</i>).	8001-79-4
232-299-0	Rape oil Extractives and their physically modified derivatives. It consists primarily of the glycerides of the fatty acids erucic, linoleic and oleic (<i>Brassica napus</i>, <i>Cruciferae</i>).	8002-13-9
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
234-328-2	Vitamin A	11103-57-4
238-976-7	Sodium D-gluconate C ₆ H ₁₂ O ₇ .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
262-989-7	Fatty acids, tallow, Me esters	61788-61-2
263-060-9	Fatty acids, castor oil	61789-44-4
263-129-3	Fatty acids, tallow	61790-37-2
265-995-8	Cellulose pulp	65996-61-4

EINECS No	Name/Group	CAS No
266-925-9	Fatty acids, C₁₂₋₁₈ This substance is identified by SDA Substance Name: C₁₂-C₁₈-alkyl carboxylic acid and SDA Reporting Number: 16-005-00.	67701-01-3
266-928-5	Fatty acids C₁₆₋₁₈ This substance is identified by SDA Substance Name: C₁₆-C₁₈-alkyl carboxylic acid and SDA Reporting Number: 19-005-00.	67701-03-5
266-929-0	Fatty acids, C₈₋₁₈ and C₁₈-unsaturated. This substance is identified by SDA Substance Name: C₈-C₁₈ and C₁₈ unsaturated alkyl carboxylic acid and SDA Reporting Number: 01-005-00.	67701-05-7
266-930-6	Fatty acids, C₁₄₋₁₈ and C₁₆₋₁₈-unsaturated. This substance is identified by SDA Substance Name: C₁₄-C₁₈ and C₁₆-C₁₈ unsaturated alkyl carboxylic acid and SDA Reporting Number: 04-005-00	67701-06-8
266-932-7	Fatty acids, C₁₆-C₁₈ and C₁₈-unsaturated. This substance is identified by SDA Substance Name: C₁₆-C₁₈ and C₁₈ unsaturated alkyl carboxylic acid and SDA Reporting Number: 11-005-00	67701-08-0

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: <i>C₁₆-C₁₈ and C₁₈ unsaturated trialkyl glyceride</i> and SDA Reporting Number: 11-001-00.	67701-30-8
267-007-0	Fatty acids, C₁₄₋₁₈ and C₁₆₋₁₈-unsaturated, Me esters This substance is identified by SDA Substance Name: <i>C₁₄-C₁₈ and C₁₆-C₁₈ unsaturated alkyl carboxylic acid methyl ester</i> and SDA Reporting Number: 04-010-00.	67762-26-9
267-013-3	Fatty acids, C₆₋₁₂ This substance is identified by SDA Substance Name: <i>C₆-C₁₂ alkyl carboxylic acid</i> and SDA Reporting Number: 13-005-00.	67762-36-1
268-099-5	Fatty acids, C₁₄₋₂₂ and C₁₆₋₂₂-unsaturated. This substance is identified by SDA Substance Name: <i>C₁₄-C₂₂ and C₁₆-C₂₂ unsaturated alkyl carboxylic acid</i> and SDA Reporting Number: 07-005-00	68002-85-7
268-616-4	Syrups, corn, dehydrated	68131-37-3
269-657-0	Fatty acids, soya	68308-53-2
269-658-6	Glycerides, tallow mono-, di- and tri-, hydrogenated	68308-54-3

EINECS No	Name/Group	CAS No
270-298-7	Fatty acids, C₁₄₋₂₂	68424-37-3
270-304-8	Fatty acids, linseed oil	68424-45-3
270-312-1	Glycerides, C ₁₆₋₁₈ and C ₁₈ -unsaturated, mono- and di- This substance is identified by SDA Substance Name: <i>C₁₆-C₁₈ and C₁₈ unsaturated alkyl and C₁₆-C₁₈ and C₁₈ unsaturated dialkyl glyceride</i> and SDA Reporting Number: 11-002-00.	68424-61-3
288-123-8	Glycerides, C ₁₀₋₁₈	85665-33-4
292-771-7	Fatty acids, C₁₂₋₁₄	90990-10-6
292-776-4	Fatty acids, C₁₂₋₁₈ and C₁₈ unsaturated.	90990-15-1
296-916-5	Fatty acids, rape oil, erucic acid low	93165-31-2

ANNEX V

EXEMPTIONS FROM THE OBLIGATION TO REGISTER

IN ACCORDANCE WITH ARTICLE 2(7)(b)²⁵

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.

²⁵ Proposed additions in italics and underlined; proposed deletions in strikethrough.

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 lifecycle of the substance and those data have been ascertained to be adequate and reliable:

Glass, ceramic frits.

12. Compost and biogas.

13. Basic elemental substances for which hazards and risks are already well known:
Hydrogen and oxygen, noble gases (argon, helium, neon, xenon), nitrogen.