Draft Guidance for Annex V

Disclaimer:

"Please note that this document is a draft guidance document which the European Chemicals Agency (ECHA) is further elaborating in cooperation with Member States and relevant stakeholders in accordance with ECHA's Consultation Procedure on Guidance.[1] *It does not constitute or represent a formal view of ECHA and may still be subject to amendments.*

The final text will be inserted into the Guidance on Registration after the Consultation Procedure on Guidance has been completed.

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Article 2(7)(b) of the Regulation (EC) No 1907/2006 (REACH) sets out criteria for exempting substances covered by Annex V of this Regulation from the registration, downstream user and evaluation requirements. These criteria are formulated in a very general way. This guidance is intended to give more explanations and background information for applying the different exemptions and give clarifications when an exemption could be applied and when not. It should be noted that the companies benefiting from an exemption must provide the authorities (on request) with appropriate information to show that their substances qualify for the exemption.

The guidance below follows the same ordering as the entries in Annex V of the REACH regulation.

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.

Most substances present a certain level of instability upon exposure to environmental factors such as air, moisture, microbial organisms and the irradiation from sunlight. Any reaction products thus formed do not have to be registered as it

[1] The "Consultation Procedure on Guidance" can be found on the ECHA website at: http://echa.europa.eu/doc/ECHADocuments/ConsultationProcedureOnGuidance.pdf

would be impractical; they are generated incidentally and without the awareness of the manufacturer or importer of the original substance.

For example, the reaction products from the incidental hydrolysis of substances (e.g. esters, amides, acryl halides, anhydrides, halogenated organosilanes, etc.) in contact with the moisture from the environment are exempted from registration as they fall within this criterion. Another example is diethyl ether which may form peroxides after exposure to air or light. The peroxides thus formed do not have to be registered by the manufacturer or importer of diethyl ether, or by any downstream user or distributor of the substance on its own, in a preparation or in an article.

Finally, the decomposition products from paint, where the decomposition is caused by the activity of mould and the products from the bleaching of coloured textiles, which occurs due to the exposure to sunlight, could also be seen as examples falling under this entry.

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

Substances may present a certain level of inherent instability. The reaction products resulting from the inherent decomposition of substances do not need to be registered as it would be impractical; they are generated incidentally and without the awareness of the manufacturer or importer of the original substance.

An example of substances that could be covered by this entry are peroxides that are formed from ethers (e.g. diethyl ether, tetrahydrofuran), not only when these are exposed to light and air (see point 1 above), but also upon storage. These peroxides do not need to be registered. Note however, that the potential risks associated with the presence of peroxides in ethers must be taken into account in the assessment of the ethers. Other examples include partially polymerised drying oils (e.g. linseed oil) and decomposition of ammonium carbonate to form ammonia and carbon dioxide (especially if stored above 30°C).

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.

This entry covers substances which are generated during the end use of other substances, preparations or articles.

The end use of a substance on its own, in a preparation or in articles can result in a certain chemical reaction. However, provided that the reaction products obtained can neither be regarded as having been generated by any kind of manufacturing process nor being intentionally isolated after the “end use reaction” or having been

placed on the market, then these reaction products are exempted from the registration provisions.

End use means the use of a substance as such, in a preparation or in articles, before the substance enters into the service life of an article, is consumed in a process by reaction, or is emitted to waste streams or the environment.[2] Please note that the term "end use" is not limited to the use of a substance by professional or private consumers but includes any intended downstream use of a substance in the supply chain, provided it is not part of a manufacturing[3] process of a substance.

Examples of substances covered by this entry are the products resulting from the end use of adhesives and paints, combustion products of petrol during the use of cars, and the reaction products of bleaching agents during washing of textiles.

Two specific examples are:

1. Sodium perborate is used in the detergent industry as a bleaching agent. During the washing process sodium perborate decomposes into hydrogen peroxide and sodium metaborate. These two substances are reaction products obtained during the end use of sodium perborate and are therefore exempted from the registration obligation whereas sodium perborate requires registration.

2. Tetraacetylethylenediamine is a bleach activator used in laundry products. In the washing process (end use) it is perhydrolyzed to diacetylethylenediamine (DAED) and peracetate, the latter ultimately forming acetate. While tetraacetylethylenediamine requires registration, DAED, peracetate and acetate are reaction products obtained during end use and are therefore exempted from the registration obligation.

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

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[2] Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system, page 8.

[3] According to Article 3(8) "Manufacturing: means production or extraction of substances in the natural state". This means that all intended generations or isolations of substances should be regarded as manufacture. See also Guidance on Registration, page 17.

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.

In some cases the mode of action of a substance performing a specific function involves a chemical reaction. The aim is not to manufacture the substance which is thus formed, but for example to prevent an unwanted reaction such as oxidation, corrosion which otherwise would take place or to promote reactions such as aggregation, adhesion which are wanted. Therefore provided that this reaction is not a deliberate manufacturing process of the substance(s) resulting from this chemical reaction, they do not need to be registered as the risks of the substances generated will be assessed through the assessment of the precursors of the reaction.

It is important to note:

- The exemption only applies to the substances generated when the substances listed in Annex V(4)(a) and (b) function as intended, but it does not apply to the substances listed in Annex V(4)(a) and (b) themselves. In other words, the registration obligations apply to the manufacture or import of the groups of substances listed in Annex V(4)(a) and (b) and where a chemical safety report is required, it should cover the intended uses and the risks of the substance(s) generated during the use. For example, a neutralisation reaction for the purpose of manufacturing a substance is not covered by this rule.

- The substances resulting from a chemical reaction that occurs when a substance belonging to one of the groups listed in Annex V(4)(a) or (b) functions as intended are exempted but the substances thus formed are subject to registration whenever the chemical reaction is part of the manufacturing process of the resulting substance which is either further processed or placed on the market on its own, in preparations or in articles.

Subparagraph (a)

In section (a) of this entry, a comprehensive list of groups of precursors for substances exempted in accordance with this paragraph is provided. This list of precursors, given in alphabetic order for easy retrieval, includes:

i. Adhesion promoters

An adhesion promoter is a substance which is applied to a substrate to improve the adhesion of a product to the substrate. The adhesion is created by the formation of strong bonds (including both covalent and non-covalent

bonds) between the adhesion promoter and the surfaces of the products to be bound. In addition, some adhesion promoters in a first step chemically react to generate the adhesion properties (e.g. silanes hydrolyse into silanols in contact with moisture) and the substance thus obtained acts as adhesion promoter in a second step.

The substances thus formed during the use of an adhesion promoter are exempted from the registration provisions.

While the adhesion promoter itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the adhesion promoter functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

ii. Agglomerating agents

An agglomerating agent is a substance that binds solid particles together to form an agglomerate. The agglomeration process can involve chemical reactions between the agglomeration agent and the solid particles to be agglomerated.

While the agglomerating agent itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the agglomerating agent functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

iii. Antifoamer or defoamer

An antifoamer or defoamer is an additive which is used to prevent or reduce foam formation. They work by reducing the surface tension of the liquid to the extent that the foam bubbles collapse and thereby destroy the foam which is already formed.

While the antifoamer or defoamer itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the antifoamer functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

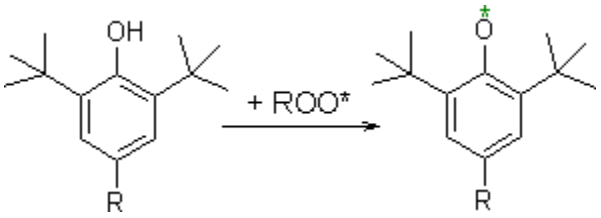
iv. Antioxidants

An antioxidant is a substance capable of slowing down or preventing the unwanted modification of other molecules (substances) caused by oxidation. Antioxidants inhibit oxidation reactions by being oxidized themselves or by removing free radicals. As a result, antioxidants are often reducing agents.

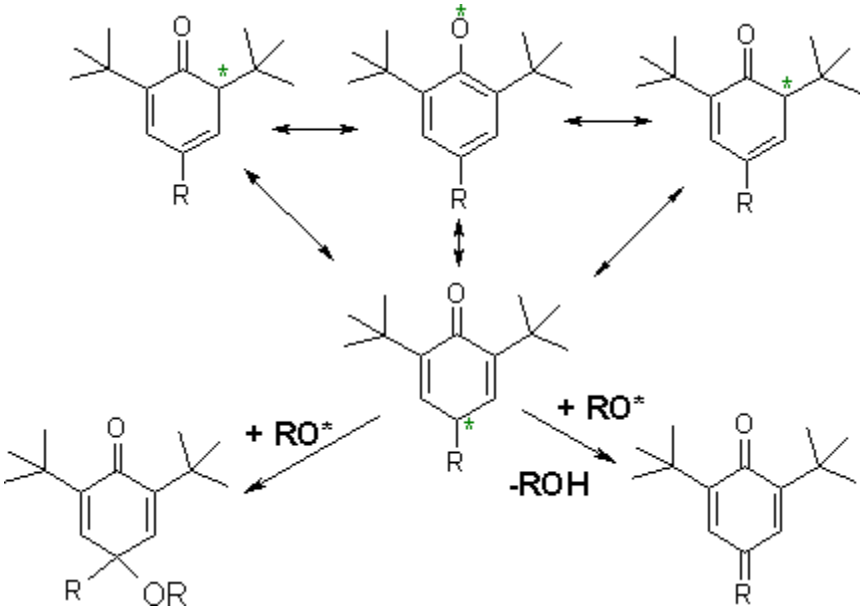
While the antioxidant itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the antioxidant functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market..

Example:

Phenols used as antioxidants (e.g. 2,6-bis(tert-butyl)-4-methyl-phenol (EC No: 204-881-4; CAS No: 128-37-0):



The phenoxy radicals generated are very stable due to their ability to build numerous mesomeric forms and are not subject to registration.



The end-products of the oxidation reaction are also not subject to registration.

Another example of this could be the production of the reaction product of the antioxidant tert-Butyl-hydroxyanisol, used to protect fatty acids from oxidation (with oxygen from air).

v. Binder

A binder is a substance used to bind different aggregates and other particles together and thereby adding strength to material. The reaction taking place can be either chemical or physical.

While the binder itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the binder functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

vi. Carrier

A carrier is used to facilitate the transport of another product especially in a technical process (e.g. the delivery of colour to paper in ink jet printing). Usually solid and inert substrates vis-à-vis active agents (e.g. in a catalyst) are considered carriers.

While the carrier itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the carrier functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

vii. Chelating agents

The function of chelating agents, also called ligands, chelants, chelators or sequestering agents is to form a complex ion.

While the chelating agent itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the chelating agents functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

It has to be clarified that complexes consisting of chelated ions must be registered if they are themselves manufactured, imported or placed on the market.

Examples:

The chelating agent dimethylglyoxime is used as a detecting agent in laboratory for detecting nickel via its ability to bind nickel ions into complex compounds. The manufacture and import of dimethylglyoxime is subject to registration. However, when this chelating agent is used to complex nickel ions in industrial processes, the resulting nickeldimethylglyoxime complex does not need to be registered, unless this complex is manufactured or

imported deliberately or placed on the market itself (e.g. by a formulator or importer).

Ethylenediaminetetraacetic acid (EDTA) is widely used to chelate metal ions in industrial processes. For example, in the textile industry, it prevents metals ions from modifying the colours for dyed products. It is also used in the production of chlorine-free paper where it chelates Mn^{2+} ions thus preventing the catalytic the decomposition of the bleaching agent, hydrogen peroxide.

While the general registration provisions apply to the manufacture or import of EDTA, the substances generated when EDTA functions as intended, are not subject to registration provided they are not themselves manufactured, imported or placed on the market.

viii. Coagulants and flocculants

A coagulant is a chemical substance used to contribute to the molecular aggregation of substances present in a solution into particles.

A flocculant is a chemical substance used to promote the aggregation of suspended particles present in a liquid into a macroscopic mass called floc.

Coagulation and flocculation are two techniques commonly combined and are used for instance to remove dissolved organic matter and particles in suspension from water.

While the coagulant or flocculant itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the coagulant or flocculant functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

Example:

Aluminium sulphate (EINECS no 233-135-0; CAS no 10043-01-3) is a coagulant used for the coagulation/flocculation process in the purification of water. When aluminium sulphate is added to the water to be treated, a complex series of reactions (including the hydrolysis of aluminium sulphate) takes place that are required for the purpose of coagulation and flocculation.

While the general registration provisions apply to the manufacture or import of aluminium sulphate, the substances derived from aluminium sulphate in the coagulation/flocculation process are not subject to registration. It should be noted that this entry does not specifically mention anti-coagulants, as used e.g. to stabilise blood by preventing it from clotting.

ix. Colorant

A colorant is used for inducing a change of colour in a product. Examples of colorants are for example dye or pigment.

While the colorant itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the colorant functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

x. Corrosion inhibitors

A corrosion inhibitor is a substance that, when added, even in small concentrations, stops or slows down corrosion of metals and alloys. One can distinguish between anodic and cathodic inhibitors depending on which reaction should be inhibited but both types of reaction products are exempted. Chemical corrosion inhibitors build a protective layer on the metal by a chemical reaction between the metal which has to be protected and the inhibitor.

While the corrosion inhibitor itself is subject to registration, if it meets the necessary requirement, any substance generated as a result of chemical reaction when the corrosion inhibitor functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

xi. De-emulsifiers

A de-emulsifier is a substance used to facilitate the separation of two immiscible liquid phases (or more) present as an emulsion. A general mechanism of action for the de-emulsification is based on the interaction between the de-emulsifier and the emulsifier present in the emulsion, and results in the destabilisation of this emulsion. The interaction between the de-emulsifier and the emulsifier may for instance consist of a chemical reaction between the two substances.

While the de-emulsifier itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the de-emulsifier functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

xii. Desiccant

A desiccant is a hygroscopic substance that functions as a drying agent, i.e. it withdraws moisture from other materials. It can retain water through capillarity or adsorption or by reacting chemically. Desiccants are used to dry solvents, gases and solids and lose their function as their water retention

increases. Silica gel and molecular sieves are examples of commonly used desiccants.

While the desiccant itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the desiccant functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

Example:

Calcium hydride (CaH_2) is commonly used as desiccant. The mode of action of this drying agent is based on the chemical reaction taking place between calcium hydride and water, which results in the formation of calcium hydroxide ($Ca(OH)_2$).

While the registration provisions apply to the manufacture or import of calcium hydride, the calcium hydroxide formed as a result of its use as desiccant is exempted from registration as such.

xiii. Dewatering agent

Dewatering agent is a very general term for substances added during chemical treatment to improve the efficiency of water removal, e.g. clarifiers, flocculants, surfactants, etc.

While the dewatering agent itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the dewatering agent functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

xiv. Dispersant

A dispersant is a substance that can promote the formation of a dispersion or stabilize the dispersion. The term dispersion is applied to a system of several phases in which one is continuous and at least one other is finely distributed. If two or more phases that are insoluble or only slightly soluble are finely distributed in one another, the term disperse system or, more simply, dispersion is used.

A dispersant generally does not change the solubility of the substance to be dispersed, but is often used to disperse sparingly soluble solids in water and keep them finely dispersed. Dispersants can be used to prevent a solution from turning into a colloidal dispersion.

[Strictly speaking one would consider this a suspending agent as a solid is finely dispersed in a liquid (emulsion)]

Dispersants are generally polyelectrolytes that are readily soluble in water, e.g. alkali-metal polycarbonates, polysulfonates, or polyphosphates, usually sodium salts. Ligninsulfonates and condensation products of aromatic sulfonic acid with formaldehyde are also widely used.

Dispersants are used in the following fields, e.g.: production of polymer dispersions, adhesive dispersions, dispersion of dyes (textile industry), pigment dispersion (industrial paints, printing inks), cosmetic, pharmaceutical and photographic industry, detergents, cleaning and polishing products.

While the dispersant itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the dispersant functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

xv. Filler

A filler is usually added to materials, such as polymers, to lower the consumption of more expensive binders or to improve the properties of the material, e.g. better mechanic properties (rubber used for tyres), to improve viscosity of resins (epoxy resins), or to control cost and/or viscosity or increase its strength (polymers), or tenacity and volume (dry wall)

Common fillers are

- soot used in rubber tyres
- microspheres used in epoxy resins
- glass fibers used in polymers
- minerals, e.g. kaolin, limestone, gypsum used in paper

While the filler itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the filler functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

xvi. Fire retardants

A fire retardant is a substance used to protect a combustible material, for instance certain plastics or wood, against fire. The mechanism of action generally involves chemical reactions with the fire retardants under the conditions of a fire.

While the fire retardant itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the fire retardant functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

xvii. Flavouring agent

A flavouring agent can be understood as a substance that gives another substance flavour. The term flavour covers both the chemical sensations of taste and smell.

While the flavouring agent itself is subject to registration[4], if it meets the necessary requirements, any substance generated as a result of chemical reaction when the flavouring agent functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

Examples:

Denatonium benzoate, the bitterest chemical compound known to date, is a flavouring agent that imparts a bitter taste and is commonly used in rat poisons in order to prevent human consumption. It is also used in animal repellents, which are products designed to keep certain animals away from e.g. people, plants, or other animals.

Citral is a flavouring agent used in fragrances to impart a lemon oil smell to give a pleasant aroma to many toiletry or household cleaning products.

Cigarettes contain, besides tobacco leaves, flavouring agents that give cigarettes particular aromas.

xviii. Flow modifier

A flow modifier is a substance added to a material (mainly liquids but also soft solids or solids under conditions in which they flow rather than deform) in order to alter its flow characteristics. One example of the use of a flow modifier is in surface coatings in order to avoid surface defects such as craters, pinholes and orange peel when the coating is applied to a surface.

While the flow modifier itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the flow modifier functions as intended, is exempted from

[4] Note: Substances used as flavouring in foodstuffs within the scope of Directive 88/388/EEC are exempted from registration (Article 2(5)b ii of REACH).

registration, provided it is not itself manufactured, imported or placed on the market.

xix. Lubricants

A lubricant is a substance applied between two moving surfaces to reduce the friction and wear between them. A lubricant provides a protective thin film which allows two surfaces to be separated while performing certain functionality by reducing the friction between them, improving efficiency and reducing wear. They may also have the function of dissolving or transporting foreign particles and of distributing heat. An example of one of the largest applications for lubricants in form of motor oil is to protect the internal combustion engines in motor vehicles and powered equipment. Lubricants, such as 2-cycle oil, are also added to some fuels.

While the lubricant itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the lubricant functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

Example:

Zinc dithiophosphates (ZDDPs) are substances commonly used in the formulation of lubricating oils for engines. Their mode of action includes the formation of a boundary layer to the surface to be lubricated and is known to require the chemical reaction of the ZDDPs.

While the registration provisions apply to the manufacture or import of ZDDPs, the substances formed upon their use as lubricant and which contribute to the lubrication process are exempted from registration as such.

xx. pH Neutralisers

A pH neutraliser is a substance used to adjust the pH-value of a solution, generally an aqueous solution, to the intended level. pH neutralisers are for instance used to balance the pH of drinking water.

The neutralisation mechanism is based on acido-basic reaction between the pH neutraliser and the liquid to be treated. The reaction products from the pH neutraliser are exempted from the registration provisions. This does not apply to the deliberate formation of salts from acids or bases.

While the pH neutraliser is subject to registration, if it meets the necessary requirements, any substance generated as a result of the chemical reaction when the pH neutraliser functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

xxi. Plasticiser

A plasticiser is a substance that, when added increases flexibility, workability and elasticity of materials such as polymers or cement. They can chemically react or physically interact with polymers and thereby determine the physical properties of the polymer products.

Plasticizers are primarily used to lower the glass transition temperature of adhesives or sealants formulation in order to improve for example low temperature performance and workability of cement. Plasticizer exhibit flexibility and elongation and thus improve materials (where introduced) to thermal expansion differences due to seasonal and daily temperature variations.

While the plasticiser itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the plasticiser functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

Example:

DOC (Dioctyl adipate) is used as plasticiser in food packaging material as it has a good stability to temperature (heat and cold) characteristics.

xxii. Precipitation inhibitors

Precipitation is the process of separating a substance from a solution as a solid. Inhibitors are substances which inhibit or prevent the processes needed for this to take place. Therefore precipitation inhibitors inhibit or prevent the formation of a solid in a solution.

While the precipitation inhibitor itself is subject to registration, if it meets the necessary requirements,, any substance generated as a result of chemical reaction when the precipitation inhibitor functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

xxiii. Quality control agents

A quality control agent is a substance used to qualitatively or quantitatively determine a specified parameter in a product for keeping an established quality.

While the quality control agent itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the quality control agent functions as intended, is exempted

from registration, provided it is not itself manufactured, imported or placed on the market.

Examples:

Examples of quality control agents include solutions used for the Karl-Fisher titration techniques. In accordance with these techniques, a series of chemical reactions take place which involve water and the substances constituting the quality control preparations. While the substances in the preparation are subject to registration, the reaction products obtained as a result of the titration are exempted from registration.

xxiv. Solvent

A solvent is a substance, which is used to dissolve a solid, liquid or gaseous substance (solute), forming a solution.

While the solvent itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the solvent functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

xxv. Stabiliser

A stabiliser is a substance which, when added, prevents unwanted changes of other substances.

While the stabiliser itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the stabiliser functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

Example:

Examples of stabilisers are polymerisation inhibitors. For instance, *tert*-butyl catechol is added to styrene, a monomer susceptible to polymerise spontaneously in the presence of a radical source. The mechanism of action of *tert*-butyl catechol is based on its ability to chemically react with radicals and by this mean scavenging the initiation of the polymerisation.

While the registration provisions apply to the manufacture or import of *tert*-butyl catechol, the substances formed upon its reaction with radical initiators are exempted from registration as such.

xxvi. Surfactants

A surfactant is a surface active agent, i.e. a substance that, because of its design, seeks out the interface between two distinguished phases, thereby altering significantly the physical properties of those interfaces through the modification of some superficial or interfacial activity. The interfaces can independently be liquid, solid or gaseous immiscible liquids, a solid and a liquid.

While the surfactant itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the surfactant functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

Example:

The manufacture or import of a surfactant used for the waterproofing treatment of leather is subject to registration. However, when the surfactant chemically reacts with the surface of the leather the substances that are generated in this reaction are exempted from registration, provided they are not themselves manufactured, imported or placed on the market.

Subparagraph (b)

In this section, the group of substances exempted from the registration provisions is an extension of the list of substances provided in subparagraph (a). Whenever a substance is used with the aim of providing a specific physicochemical characteristic and where a chemical reaction takes place for the purpose of this application, the substances thus produced do not have to be registered, provided that these substances are not themselves manufactured or placed on the market. The substance produced and its risks shall be assessed through the life-cycle assessment of the precursors/reactants of the reaction.

Adhesives

An adhesive or glue is a material in a liquid or semi-liquid state that bonds items together. Adhesives fill the voids or pores of the surfaces and hold surfaces together by interlocking.

For example a two-component glue of substance A and substance B, when A and B are mixed, react to bind items together.

While the adhesive itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reactions when the adhesive functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

Emulsifier

An emulsifier is a substance which stabilizes an emulsion, frequently a surfactant.

For example detergents are a class of surfactants that physically interact with both oil and water, thus stabilizing the interface between oil or water droplets in suspension.

While the emulsifier itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reactions when the emulsifier functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

Lubricants

A **lubricant** (as already described in section 4a xix) is a substance that reacts with the surface of a metal to provide a physically attached 'oil' layer. Non-liquid lubricants include grease, powders (e.g. graphite, PTFE, molybdenum disulfide, tungsten disulfide), teflon tape used in plumbing, air cushion and others.

While the lubricant itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reactions when the lubricant functions as intended is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

Viscosity modifiers

A viscosity modifier is a substance that is widely used to control the flow of liquids in industrial processes. For example, in oil drilling polyanionic cellulose is added to water-based drilling fluids as thickeners to modify fluid flow. In the lubrication industry, viscosity modifiers are added to lubricant oils to vary the fluid flow as a function of temperature. In the latter case, the modifiers are typically polymeric molecules that are heat sensitive, in that the contract or relax depending on temperature.

While the viscosity modifier itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reactions when the modifier functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

Solvent

A solvent is a substance, which is used to dissolve a solid, liquid or gaseous substance (solute), forming a solution.

While the solvent itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the solvent functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market.

For example, if water is added to a salt (e.g. $CuSO_4$), ionic pairs in equilibrium are formed in solution as a result. Further examples concerning ionic mixtures where water is used as solvent and functioned as intended are given in the appendix at the end of this guidance document.

Note: Water is listed in Annex IV of Regulation (EC) No 1907/2006 and therefore exempted from registration.

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

A *'by-product'* means a production residue that is not deliberately obtained in a manufacturing process and which is not considered *'waste'*.

Article 5 of Directive 2008/98/EC ("Waste Framework Directive") defines by-products as: *"A substance or object, resulting from a production process, the primary aim of which is not the production of that item, […] if the following conditions are met:*

(a) further use of the substance or object is certain;

(b) the substance or object can be used directly without any further processing other than normal industrial practice;

(c) the substance or object is produced as an integral part of a production process; and

(d) further use is lawful, i.e. the substance or object fulfils all relevant product, environmental and health protection requirements for the specific use and will not lead to overall adverse environmental or human health impacts."

Note: A list of by-products are currently under the development of the Waste Framework Directive.

(Note: *'Waste'* in accordance with Directive 2008/98/EC means any substance or object which the holder discards or intends or is required to discard).

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.

Hydrates of a substance are characterised by the fact that water molecules are linked, in particular by hydrogen bonds, to other molecules or ions of the substance.

A substance that does not contain any water is referred to as anhydrous. Solid hydrates contain water of crystallization in a stoichiometric ratio, an example of which would be $NiSO_4 \cdot 7H_2O$. The chemical formula expresses the fact that one molecule of $NiSO_4$ can crystallise with seven molecules of water.

For the purposes of this Annex, hydrates and water free forms (anhydrous) of compounds shall be regarded as the same substance despite the fact that hydrated and anhydrous forms of the substance can have different chemical names and different CAS numbers.

Examples				
Name	**Formula**	**CAS number**	**EC number**	**Rule**
Copper sulphate Copper sulphate pentahydrate	$CuSO_4$ $CuSO_4 \cdot 5H_2O$	7758-98-7 7758-99-8	231-847-6	This substance is covered by its anhydrous form (EC number: 231-847-6)

It is important to note:

- The manufacturer or importer relying on this exemption registers the substance as the anhydrous form. It is recommended to make reference to the hydrated form(s) in the registration dossier.

- Companies undertaking the hydration of an anhydrous substance or changing the hydration state of an **already hydrated** substance (i.e. changes the number of water molecules associated with the substance), are considered as downstream users provided that the anhydrous form of the substance has already been registered by the manufacturer or importer up the supply chain. These hydration or drying processes should be covered in any applicable exposure scenario in the registration by the manufacturer or importer.

- A registrant who wants to make use of the exemption under this entry needs to add up the quantities of the anhydrous form and the different hydrated forms in his technical dossier (but excluding the water which is attached to the parent molecule).

Entries 7 and 8 cover naturally occurring substances, if they are not chemically modified. Therefore the definitions 'substances which occur in nature' and 'not chemically modified substance' are here first explained and concern both of the exemptions.

This group of substances is characterised via the definitions given in Article 3(39) and 3(40):

According to Article 3(39), *'substances which occur in nature'* means *'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'*.

It should be noted as background explanation that prior to REACH naturally occurring substances shared a single EINECS entry which is wider than the current interpretation under REACH:

EINECS No: 310-127-6, CAS No: 999999-99-4

Naturally occurring substances

Living or dead material occurring in nature as such which is chemically unprocessed, or which is extracted from air by any means or physically processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation or by heating solely to remove water.

The REACH definition can be split into several parts in order to obtain a clear understanding:

- **Naturally occurring substances as such**: means, substances obtained, for example, from plants, micro-organisms, animals, or certain inorganic matter such as minerals, ores and ore concentrates, crude oil, coal, natural gas. It should be noted that whole living or dead organisms (e.g. yeast, freeze-dried bacteria) or parts thereof (e.g. body parts, branches, leaves, flowers etc.) are not considered as substances, preparations or articles in the sense of REACH and are therefore outside of the scope of REACH. The latter would also be the case if these have undergone digestion or decomposition resulting in waste as defined in Directive 2008/98/EC, even if, under certain circumstances, these might be seen as non-waste recovered materials[5].

- **Naturally occurring substances unprocessed**: no treatment at all of the substance takes place.

[5] This explanation is without prejudice to discussions and decisions to be taken under Community waste legislation on the status, nature, characteristics and potential definition of such materials, and may need to be updated in the future.

- **Processed only by manual, mechanical or gravitational means**: parts of the substance as such may for instance be removed by hand or by machine (e.g. by centrifugation). If minerals are processed *only* by mechanical methods, e.g. by grinding, sieving, centrifugation, flotation, etc., they are still considered to be the same naturally occurring minerals as originally mined.[6]

- **By dissolution in water**: the only solvent which can be used is water. The dissolution by any other solvent or mixture of solvents or mixture of water with other solvents disqualifies the substance as naturally occurring.

- **By flotation**: physical separation process taking place in water/liquid without chemical reaction.

- **By extraction with water**: separation process which is based on the different distribution of a certain constituent or constituents from a material by using water only.

- **By steam distillation**: distillation of naturally occurring substances with water vapour as carrier for the separation of certain constituent(s) without chemical reaction.

- **Heating solely to remove water**: purification or concentration of a substance by removing water by heat while no chemical reaction occurs.

- **Extracted from air by any means**: substances which occur naturally in air, extracted by applying any methods and solvents as far as no chemical reaction occurs.

According to Article 3(40), a *'**not chemically modified** substance'* means '*a substance whose chemical structure remains unchanged, even if it has undergone a chemical process or treatment, or a physical mineralogical transformation, for instance to remove impurities'*.

- The exemption under point 7 and 8 requires that the substances are *substances which occur in nature, if they are not chemically modified*. This requirement implies that in order to decide if the exemption applies to a particular substance, first the criteria of being a substance that occurs in nature according to the Article 3(39) definition have to be met. If they are

[6] (ECHA, 2007) Guidance for identification and naming of substances under REACH, page 38.

met, it is further assessed whether there has been chemical modification according to the definition Article 3(40). Hence in this context the condition 'not chemical modified' shall mean "not further chemically modfied".

Therefore, as soon as a naturally occurring substance has been processed in accordance with a process other than the ones listed in Article 3(39), the exemptions under points 7 and 8 of Annex V do not apply. This is the case regardless of whether the substance meets the definition of "not chemically modified substance", since the applied process disqualifies it from being a substance which occurs in nature.

In addition, if a naturally occurring substance, that is processed only in accordance with any of the processes listed in Article 3(39), subsequently undergoes a chemical modification of one or more of the constituents originally present in the naturally occurring substance, hence resulting in a change of chemical structure, the exemptions under points 7 and 8 of Annex V do not apply either.

Note that the exemptions in points 7 and 8 do not apply to synthetic versions of the substances described in the relevant sections as such substances do not meet the definition of substances which occur in nature.

The following examples illustrate circumstances under which a substance does or does not meet the requirement of s*ubstances which occur in nature, if they are not chemically modified.*

Example 1:

A substance is obtained in accordance with a steam distillation process of the leaves from *Mentha arvensis*. The chemical analysis of the *Mentha arvensis* extract thus manufactured indicates that this substance consists of several stereo-isomers including the constituent (-)-menthol (i.e. (1R,2S,5R)-5-methyl-2-(propan-2-yl)cyclohexanol). All the constituents in the substance were originally present in the leaves. This substance fulfils the requirements for *substances which occur in nature, if they are not chemically modified*.

Example 2:

The substance isolated in example 1 is further processed by crystallisation in water and ethanol to isolate (-)-menthol. Although the process did not result in the chemical modification of the substance within the meaning of Article 3(40), the isolated substance is not a substance which occurs in nature any longer and therefore does not fulfil the requirements for *substances which occur in nature, if they are not chemically modified*.

Example 3:

The substance isolated in example 1 is heated solely to remove water. Upon heating, a fraction of the (-)-menthol constituent decomposes. Although the isolated substance fulfils the definition of a substance which occurs in nature, it has been chemically modified and therefore does not fulfil the requirements for *substances which occur in nature, if they are not chemically modified*.

Example 4:

A multi-step synthesis is used for the manufacturing of (-)-menthol. Although this substance consists of the same constituent as the one found in the leaves of *Mentha arvensis*, it is not a substance which occurs in nature and does therefore not fulfil the requirements for *substances which occur in nature, if they are not chemically modified*.

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.

This exemption includes only the above listed groups of 'substances which occur in nature' as defined in Article 3(39), if they are not chemically modified as defined in Article 3(40), independently from whether or not they are classified as dangerous according to Directive 67/548/EEC.

The specific substances covered by the exemption are:

i. Minerals

A mineral is defined as a combination of inorganic constituents as found in the earth's crust, with a characteristic set of chemical compositions, crystalline forms (from highly crystalline to amorphous) and physical properties. In general minerals are inorganic and most of them are crystalline. Whenever minerals are manufactured in accordance with any method other than the ones mentioned in the definition of ‘substances which occur in nature’ these substances are not exempted from the obligation to register.

Minerals which occur in nature are covered by the exemption if they are not chemically modified. This applies to naturally occurring minerals, which have undergone a chemical process or treatment, or a physical mineralogical transformation, for instance to remove impurities, provided that none of the constituents of the final isolated substance has been chemically modified’

An example of minerals is asbestos. Asbestos is the common name of a number of naturally occurring, hydrated silicate minerals like

Crocidolite CAS No 12001-28-4

Amosite	CAS No 12172-73-5
Anthophyllite	CAS No 77536-67-5
Actinolite	CAS No 77536-66-4
Tremolite	CAS No 77536-68-6
Chrysotile	CAS No 12001-29-5 and 132207-32-0

Asbestos is exempted from registration provisions, because these minerals occur in nature and are not further chemically modified. However, they are not exempted from other obligations of REACH. Furthermore, asbestos fibres are listed in Annex XVII of REACH and their manufacturing, placing on the market and use is restricted.

Note: Chrysotile is not entirely restricted as it is exempted from the Annex XVII entry for the placing on the market and use of diaphragms containing chrysotile (point (f)) for existing electrolysis installations until they reach the end of their service life, or until suitable asbestos-free substitutes become available, whichever is the sooner.

Other examples of minerals include (but are not limited to):

dolomite (CAS number 16389-88-1) $CaCO_3$. $MgCO_3$, a rock-forming mineral;

limestone (CAS number 1317-65-3), which consists principally of calcium carbonate and may also contain magnesium carbonate;

barite (CAS number 13462-86-7), which principally consists of barium sulfate;

fluorapatite (CAS number 1306-05-4), the most common phosphate rock mineral.

Note: The exemption does not apply to synthetic substances having the same structures as the natural occurring minerals.

ii. Ores

Ores is a general expression for mineral aggregates or rocks from which metals or metal components can be extracted as well as for mineral aggregates whose mining have an economical benefit.

The ores themselves can be regarded as substances which occur in nature and which therefore are exempted from the obligation to register. It should be noted however, that when ores are processed or treated with methods not mentioned in the definition of ‘substances which occur in nature’, or with methods which modify the chemical structure of the final substance, the final ‘product’ of the treatment can

normally not be regarded as a substance which occurs in nature and hence will need to be registered.

Example: The iron ore type 'banded ironstone formation (BFI)' which is composed predominantly of magnetite ($Fe^{2+}Fe_2^{3+}O_4$) and quartz is processed mechanically in the first steps by means of coarse crushing and screening, followed by rough crushing and fine grinding to comminute the ore to the point where the crystallised magnetite and quartz are fine enough that the quartz is left behind when the resultant powder is passed under a magnetic separator. Up to this stage all substances, including the original ore, created through the whole process are regarded as substances which occur in nature.

To convert magnetite to metallic iron it must be smelted or sent through a direct reduction process. Magnetite (or any other iron ore) must be powdered and mixed with coke. During the process in the blast furnace the following reduction or oxidation-reactions take place:

Air blast and coke: $2C + O_2 \rightarrow 2CO$

Carbon monoxide (CO) is the principal reduction agent

Stage One: $3Fe_2O_3 + CO \rightarrow 2Fe_3O_4 + CO_2$

Stage Two: $Fe_3O_4 + CO \rightarrow 3FeO + CO_2$

Stage Three: $FeO + CO \rightarrow Fe + CO_2$

During this manufacturing process different treatments take place which disqualify the final iron as a substance occurring in nature:

- Heating was not solely applied for removing water
- The iron oxide is subject to a reduction / oxidation reaction which is a chemical reaction leading to a new / different substance from the starting material

As a consequence, iron is regarded as a substance for which the registration obligations need to be fulfilled.

iii. Ore concentrates

Ore concentrates are extracted from the original ore mostly by mechanical measures or flotation resulting in mineral-rich fraction which is used for further processing of e.g. metals. Such processes include, but may not be limited to, sorting; magnetic separation; electrostatic separation; preferential crushing, grinding and milling; sieving and screening; hydrocycloning; filtration and flotation.

Therefore ore concentrates are generally regarded as substances which occur in nature provided the manufacturing processes are only mechanical and/or by flotation (e.g. grinding, sieving, centrifugation, etc.).

iv. Raw and processed natural gas

Natural gas is a gaseous fossil fuel which consists predominantly of saturated hydrocarbons. Natural gas can have different compositions depending on the source and can be divided into following groups:

- natural gas from pure natural gas deposits is composed of methane and small amounts of ethane; it is saturated with water vapour and contains liquid and free water.

- natural gas from coal deposits is composed of methane, small amounts of ethane and variable amounts of nitrogen and carbon dioxide; it is saturated with water vapour and contains liquid and free water.

- natural gas from crude oil deposits generally contains in addition larger amounts of ethane, propane, isobutane, hexane, heptane, carbon dioxide, hydrosulfides, helium, nitrogen and arsenic compounds.

- natural gas from condensate and distillate deposits which contains besides methane and ethane also higher amounts of hydrocarbons with more than 7 C-atoms.

The raw natural gas itself, without further processing, can be regarded as a substance which occurs in nature. However, raw natural gas has to be processed to make it suitable for the use by residential, commercial and industrial consumers. The processed natural gas is almost pure methane and is very much different from the raw natural gas.

The European Inventory of Existing commercial Chemical Substances (EINECS) lists one entry for natural gas which gives the following description:

EINECS number: 232-343-9, CAS number: 8006-14-2

Natural gas

Raw natural gas, as found in nature, or gaseous combination of hydrocarbons having carbon numbers predominantly in the range of C1 through C4 separated from raw natural gas by the removal of natural gas condensate, natural gas liquid, and gas condensate/natural gas.

Natural gas isolated through any further processing of the raw natural gas, other than the steps listed in the definition of a substance occurring in the nature, can in fact not be regarded as a substance which occurs in nature.

Note: It has to be emphasised that only methane which is processed from raw natural gas can be regarded as natural gas. Methane processed from other sources than fossil, e.g. biogas, is not regarded as natural gas.

v. Crude oil

Crude oil is a lipophilic mixture of hydrocarbons which is incorporated into the earth's crust. Crude oil can consist of more than 17,000 constituents and is one of the most complex mixtures of organic compounds. The formation of crude oil is based on sapropel of flat inshore waters emanated from carbohydrates, proteins and fats from small animals and small plants under the influence of bacteria, enzymes, pressure, mineral catalyst etc. The crude oil production is based on mechanical measures which qualifies crude oil as a substance which occurs in nature.

However, when processing and separating crude oil, the constituents or mixtures of constituents arising from these processes can normally no longer be regarded as substances which occur in nature, for example:

EINECS number: 272-871-7, CAS number: 68918-99-0

Gases (petroleum), crude oil fractionation off

A complex combination of hydrocarbons produced by the fractionation of crude oil. It consists of saturated aliphatic hydrocarbons having carbon numbers predominantly in the range of C1 through C5.

For example: Diesel, in general a fuel used in diesel engines, is a specific fractional distillates of petroleum fuel oil, derived from petroleum. Diesel is obtained by chemical modification of petroleum and therefore not exempt from registration.

The EINECS lists diesel fuels which give the following descriptions:

EINECS number: 269-822-7, CAS number: 68334-30-5

Fuels, diesel

A complex combination of hydrocarbons produced by the distillation of crude oil. It consists of hydrocarbons having carbon numbers predominantly in the range of C9 through C20 and boiling in the range of approximately 163°C to 357°C (325°F to 675°F).

EINECS Number: 270-676-1, CAS number: 68476-34-6

Fuels, diesel, no. -2

A distillate oil having a minimum viscosity of 32.6 SUS at 37.7°C (100°F) to a maximum of 40.1 SUS at 37.7°C (100°F).

vi. Coal

Coal is a solid fossil fuel formed by carbonisation of plants. There are two types of coal; brown coal and black coal which differ in their carbon content. Brown coal contains 60 – 80 % carbon and black coal contains 80 – 98 % carbon. Coal is usually processed only by mechanical means which qualifies coal as a substance which occurs in nature.

Charcoal obtained by thermal decomposition of wood is not regarded as a substance which occurs in nature and therefore it is not covered by this exemption.

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).

This exemption includes 'substances occuring in nature' if they are not chemically modified, and which are not listed in paragraph 7, unless they meet the criteria for classification as dangerous according to Directive 67/548/EEC.

To determine if your substance fulfils the requirements for this exemption, the following points should be considered:

- The substances *must* meet the definition of a 'substance which occurs in nature' as defined in Article 3(39)[7].

- The substance must *not* be chemically modified as defined in Article 3(40). In this context ‘not chemically modified’ shall mean “not further chemically

[7] See point 7/8 above for guidance on this definition.

modified". Chemical modification includes but is not limited to hydrogenation, neutralization, oxidation, esterification, and amidation.

- The substances must *not* meet the criteria for classification as dangerous according to Directive 67/548/EEC. A naturally occurring substance is not covered by this exemption if it is either on Annex I of Directive 67/548/EEC or the manufacturer or importer of the substance has determined that it meets the criteria set out in Annex VI of Directive 67/548/EEC. In addition, a naturally occurring substances meeting the criteria for PBTs and or vPvBs in Annex XIII is also not exempted. A substance giving rise to an equivalent level of concern according to Article 57(f) and included on the candidate list (according to Article 59(1)) at least two years previously, is no longer subject to an exemption under this point and should be registered.

In all cases, the burden of proof rests with the manufacturer/importer that wishes to use this exemption for his substance. An absence of information on the properties of a substance *cannot* be equated to the absence of hazardous properties. Many substances that might fall into the 'substances which occur in nature' category have insufficient information available on them to be able to conclude that they are not dangerous. To exempt such substances would undermine the aims of REACH to gather information on substances in order to determine their potential hazards.

Examples of substances that are *not* covered by this exemption include but are not limited to, e.g. fermentation products. In these examples, the substances have undergone chemical modification, i.e. solvent extraction (bonemeal), fermentation products (enzymes), or are dangerous and thus not exempt from registration.

Examples of substances that are covered by this exemption include but are not limited to sea salt, mineral sand, clays, wool, with the provision that fulfils the conditions of Articles 3(39) and 3(40) and not meeting the classification criteria to be dangerous according to Directive 67/548/EEC.

If the classification of a substance is changed from not meeting the criteria to meeting the criteria for classification due to new information and the substance therefore meets the criteria for classification as dangerous according to Directive 67/548/EEC, the exemption from registration provisions no longer applies and thus the substance needs to be registered.

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.

This exemption comprises 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 a combination thereof. A substance meeting the criteria for PBTs and vPvBs in Annex XIII is also not exempted. A substance giving rise to an equivalent level of concern according to Article 57(f) and included on the candidate list (according to Article 59(1) at least two years previously, is no longer subject to an exemption under this point and should be registered.

In all cases, the burden of proof rests with the manufacturer/importer that wishes to use this exemption for his substance. An absence of information on the properties of a substance *cannot* be equated to the absence of hazardous properties. Many substances that might fall into the 'substances which occur in nature' category have insufficient information available on them to be able to conclude that they are not dangerous. To exempt such substances would undermine the aims of REACH to gather information on substances in order to determine their potential hazards.

In this exemption ‘obtained from natural sources' means that the original source must be a natural material (plants or animals) and 'not chemically modified' means that the substances covered by this exemption, once obtained from a natural source, are not further chemically modified; in other words the chemical structure of each substance listed remains unchanged.

This exemption is not limited to ‘naturally occurring substances’ in the sense of the definition of Article 3(39). This means that the specified substances falling under this exemption can also be obtained through other processes than those described in Article 3(39).

In particular ‘fatty acids from C6 to C24, and their potassium, sodium, calcium and magnesium salts’ are listed in Annex V.9. They have to be obtained from natural sources to be covered by this exemption, and also they must not be further chemically modified. This means that the chemical structure of the ‘fatty acids from C6 to C24, and their potassium, sodium, calcium and magnesium salts’ substance

cannot be changed. Therefore, as an example, hydrogenation of the listed substances is excluded as this would be considered a further chemical modification.

Note: The exemption does not apply to synthetic materials.

In general, fats and oils derived from natural sources such as plants or animals are mainly composed of triglycerides (up 97% triglyceride (i.e., triesters of glycerol with fatty acids); up to 3 % diglycerides and up to 1 % monoglycerides). The triglycerides of naturally occurring fats and oils contain saturated and unsaturated fatty acids.

Note: 'Hydrogenated fats and hydrogenated oils' are not considered as natural sources but manufactured substances, which have undergone a chemical modification of the original fats and oils and are therefore not covered by this entry.

Groups of substances covered by this exemption are:

(i) Vegetable fats and vegetable oils

Vegetable fats and oils are substances that are obtained from the seeds of oilseed plants, although some other parts of the plants may also yield oils. Most vegetable oils and fats, mainly composed of triglycerides, contain fatty acids, which consist predominantly of palmitic, oleic, and linoleic acids.

For example, cocoa butter, contains a high proportion of C_{16}– C_{18} fatty acids and C18 unsaturated fatty acids, whereas coconut oil contains a high proportion of C_6– C_{16} fatty acids and C18 unsaturated fatty acids.

(ii) Vegetable waxes

Vegetable waxes are composed of non-glycerolic esters of long chain fatty acids esterified with long chain fatty alcohols, triterpenic alcohols and sterols. An example for a vegetable wax is carnauba wax derived from the leaves of the carnauba palm.

Note: This exemption exclusively applies to vegetable fats, vegetable oils and vegetable waxes but does not cover essential oils. Essential oils are hydrophobic liquids of complex composition, derived from plants, containing volatile organic compounds, such as alcohols, aldehydes, ketones, phenols, esters, ethers and terpenes, in varying proportions.

(iii) Animal fats and animal oils

Animal fats and animal oils can be obtained from the tissue fats of a variety of animals.

For example, fats such as tallow and lard, mainly composed of triglycerides, contain predominantly C_{16} and C_{18} fatty acids, whereas milk fat (butterfat) contains a high proportion of C_6– C_{12} fatty acids.

Animal oils contain a higher proportion of polyunsaturated fatty acids with a chain length of C_{16} – C_{24}, rich in omega-3 fatty acids (e.g. fish oils and whale oil) than other animal fats.

(iv) Animal waxes

Animal waxes are composed of nonglycerolic esters of long chain fatty acids esterified with long chain fatty alcohols, triterpenic alcohols and sterols. Examples are beeswax and lanolin from sheep wool.

Note: This exemption does not apply to synthetic materials such as silicone wax that exhibit similar properties or any synthetic waxes manufactured from by distillation from natural petroleum or completely synthetic waxes.

(v) Fatty acids from C6 to C24 and their potassium, sodium, calcium and magnesium salts

Fatty acids do not typically occur in nature. They are present in chemically bonded form as triglycerides in natural sources, hence oils, fats and waxes as a combinations of various fatty acids with varying proportions depending on the origin of the fats, oils or waxes. These fatty acids are predominantly even-numbered, unbranched, aliphatic monocarboxylic acids with chain lengths ranging from C_6 to C_{24} which are either saturated or unsaturated. Unsaturated fatty acids differ in number and position of double bonds and in configuration (i.e. cis- or trans-isomers).

Fatty acids from C6 to C24 and their potassium, sodium, calcium and magnesium salts covered by this exemption must be obtained from natural sources.

Separation of the single fatty acids by distillation of the crude fatty acids originated from e.g. fats or oils are also covered by this exemption provided that no chemical modification of the individual fatty acids occurs, hence their individual structures remain unchanged.

The exemption includes

(a) groups of fatty acids which are even numbered, unbranched saturated and/or unsaturated fatty acid having a range from C6 to C24 and their potassium, sodium, calcium and magnesium salts

(b) single fatty acids which are even numbered, unbranched, saturated and/or unsaturated fatty acid ranging from C6 to C24 and their potassium, sodium, calcium and magnesium salts

Examples:

(a) fatty acids, olive oils; fatty acids, palm oil; fatty acids, sunflower oil; etc. and fatty acids, C8-16; fatty acids, C10-14; fatty acids, C8-18 and C18-unsatd.; calcium salts; fatty acids, tallow, sodium salts.

(b) Hexanoic acid, Octanoic acid, Decanoic acid, and so on, up to Tetracosanoic acid. It also includes hydroxyl-fatty acids obtained from natural sources, e.g. 12-hydroxy-9-cis-octadecanoic acid obtained from castor oil.

Note: This exemption does not cover other fatty acids than those described above (i.e. odd numbered fatty acid such as heptanoic acid, nonanoic acid, etc.).

(vi) Glycerol

Glycerol, which is also commonly called glycerine or propane-1,2,3-triol, forms the backbone of triglycerides bound to a number of fatty acids.

Note: This exemption refers to glycerol which is obtained from natural sources as described above. Glycerol manufactured synthetically needs to be registered.

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.

This exemption comprises a number of substances that are exempted unless they are chemically modified[8]:

i. Liquefied petroleum gas (LPG)

In general, liquefied petroleum gas comprises the hydrocarbons propane, propene, butane, butene, isobutane and combinations thereof. These combinations of gases can be liquefied by cooling, compression, or a combination of both processes. Liquefied petroleum gas is extracted from crude oil and natural gas streams. It can also be obtained by processing of crude oil in refineries and in some instances as a by-product from chemical plants. The composition of LPG depends on the

[8] the notion of 'not chemically modified substance' term is explained under point 7 and 8 of this guidance

manufacturing process applied. For example, commercially supplied butane and propane combinations would fall under this category.

The EINECS is listing LPG under the following entry:

EINECS number: 270-704-2, CAS number: 68476-85-7

Petroleum gases, liquefied

A complex combination of hydrocarbons produced by the distillation of crude oil. It consists of hydrocarbons having carbon numbers predominantly in the range of C3 through C7 and boiling in the range of approximately -40°C to 80°C (-40°F to 176°F).

ii. Natural gas condensate

Natural gas condensate is a low-density combination of hydrocarbon liquids that are present as gaseous components in the raw natural gas. It condenses out of the raw natural gas if the temperature is reduced below the hydrocarbon dew point temperature of the raw natural gas. Natural gas condensate is regarded as a by-product of the processing of the natural gas. Depending on the processes used to isolate it, natural gas condensate may be regarded as a substance which occurs in nature and falling under entry iv of Annex V.(7).

EINECS number 272-896-3, CAS number 68919-39-1

Natural gas condensates

A complex combination of hydrocarbons separated and/or condensed from natural gas during transportation and collected at the wellhead and/or from the production, gathering, transmission, and distribution pipelines in deeps, scrubbers, etc. It consists predominantly of hydrocarbons having carbon numbers predominantly in the range of C2 through C8.

iii. Process gases and components thereof

Process gases are not naturally occurring substances. The expression ‘process gas’ can be regarded as an umbrella term for all kinds of gases produced during certain technical processes. Any risks from the process gas should be covered in the Chemical Safety Assessment of the substances involved in the process itself. An example of a ‘process gas’ is blast furnace gas. This gas is produced during the combustion of coke in blast furnaces in the iron and steel industry. It is recovered and used as a fuel partly within the plant and partly in other steel industry processes or in power stations equipped to burn it.

iv. Cement clinker

Cement clinker is a component of cement. Cement is regarded as a preparation composed of cement clinker, gypsum and other constituents depending on the cement type. Cement clinker is manufactured from the raw materials limestone, clay, bauxite, iron ore and quartz, grounded to a fine powder which is heated under oxidising conditions up to around 1400°-1450° C, at which temperature partial melting (sintering) takes place, resulting in drab granules. This process warrants that chemical bonds in the raw material cease to exist and new bonds are irregularly formed through material melting, producing the granules containing mainly tricalcium silicate, dicalcium silicate, dicalcium aluminate ferrite, tricalcium aluminate and calcium oxide. The melted material is rapidly cooled (quenched) to preserve its reactive mineral constituents.

Cement clinker does not have an EINECS number but it is very close in composition to "Cement, portland, chemicals" and/or "Cement, alumina, chemicals". Both of these substances have entries in EINECS (included below for reference):

1. EINECS number 266-043-4, CAS number 65997-15-1

Cement, portland, chemicals

Portland cement is a mixture of chemical substances produced by burning or sintering at high temperatures (greater than 1200°C (2192°F)) raw materials which are predominantly calcium carbonate, aluminium oxide, silica, and iron oxide. The chemical substances which are manufactured are confined in a crystalline mass. This category includes all of the chemical substances specified below when they are intentionally manufactured in the production of Portland cement. The primary members of the category are Ca_2SiO_4 and Ca_3SiO_5. Other compounds listed below may also be included in combination with these primary substances

$CaAl_2O_4$ $Ca_2Al_2SiO_7$

$CaAl_4O_7$ $Ca_4Al_6SO_{16}$

$CaAl_{12}O_{19}$ $Ca_{12}Al_{14}Cl_2O_{32}$

$Ca_3Al_2O_6$ $Ca_{12}Al_{14}F_2O_{32}$

$Ca_{12}Al_{14}O_{33}$ $Ca_4Al_2Fe_2O_{10}$

CaO $Ca_6Al_4Fe_2O_{15}$

$Ca_2Fe_2O_5$

2. EINECS number: 266-045-5, CAS number: 65997-16-2

Cement, alumina, chemicals

High-Alumina cement is a mixture of chemical substances produced by burning or sintering at high temperature (greater than 1200°C (2192°F)) raw materials which are predominantly calcium carbonate, aluminium oxide, silica, and iron oxide. The chemical substances which are manufactured are confined in a crystalline mass.

This category includes all of the chemical substances specified below when they are intentionally manufactured in the production of high-alumina cement. The primary members of this category are $CaAl_2O_4$, $Ca_4Al_2Fe_2O_{10}$, $Ca_{12}Al_{14}O_{33}$, and Ca_2SiO_4. Other compounds listed below may also be included in the combination with these primary substances.

$CaAl_4O_7$ $Ca_2Al_2SiO_7$

$CaAl_{12}O_{19}$ $Ca_4Al_6SO_{16}$

$Ca_3Al_2O_6$ $Ca_{12}Al_{14}Cl_2O_{32}$

CaO $Ca_{12}Al_{14}F_2O_{32}$

Ca_3SiO_5 $Ca_6Al_4Fe_2O_{15}$

$Ca_2Fe_2O_5$

v. Magnesia

Magnesia, (MgO, magnesium oxide) rarely occurs as a natural mineral (also known as periclase). It is mostly manufactured from natural magnesite ($MgCO_3$), seawater and natural and synthetic brines.

There are several forms of magnesia covered by this exemption. These include dead-burned magnesia, caustic-calcinated (light-burned magnesia), hard-burned magnesia and fused magnesia.

The EINECS is listing Magnesium oxide under the following entry:

EINECS number 215-171-9, CAS number 1309-48-4

Magnesium oxide

vi. Coke

Coke is a black, combustible residue of the coking processes, predominantly consisting of carbon. All types of coke are exempted regardless of the starting materials from which they are obtained. Coking is a general term for high temperature treatment of substances such as coal or the residues from the petroleum refinery processes. The conditions of the processes depend on the starting materials used (e.g. coking of coal involves heating up to 1100ºC in the absence of oxygen).

Examples of different types of coke on EINECS are listed as follows:

EINECS number 310-221-7, CAS number 140203-12-9

coke (coal tar), high-temperature pitch

The carbon containing residue from the carbonization coking of pitch from high temperature (>700°C or >1272°F) coal tar. Consists primarily of carbon. Also contains small amounts of sulfur and ash.

EINECS number 266-010-4, CAS number 65996-77-2

Coke (coal)

The cellular carbonaceous mass resulting from the high temperature (greater than 700°C (1292°F)) destructive distillation of coal. Composed primarily of carbon. May contain varying amounts of sulfur and ash.

EINECS number 265-080-3, CAS number 64741-79-3

Coke (petroleum)

A solid material resulting from high temperature treatment of petroleum fractions. It consists of carbonaceous material and contains some hydrocarbons having a high carbon-to-hydrogen ratio.

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 limit set out in Annex I to Directive 67/548/EEC, unless conclusive scientific experimental data show that these constituents are not available throughout the life-cycle of the substance and those data have been ascertained to be adequate and reliable:

Glass, ceramic frits.

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, similar to many other UVCB substances. EINECS has several entries for glasses 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)[9];

A frit is a ground glass or glaze used in pottery; some materials have to be fritted before they can be used because they are soluble or toxic.

EINECS lists frits under the following entry:

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

The glass and frits substances are very similar in composition and manufacturing process.

Only those types of glass and ceramic frits are exempted which do not have any significant hazard properties:

- Firstly, glass or ceramic frits are only to be exempted if they (as substances as such) do not meet the criteria for classification as dangerous according to Directive 67/548/EEC. There are two possibilities to assess this criterion: look at the glass itself or look at the starting materials.

- Secondly, they are not exempted if the substance contains constituents meeting the criteria as dangerous in accordance with Directive 67/548/EEC that are present in concentrations above the lowest of the applicable concentration limits set out in Directive 1999/45/EC or concentration limit set out in Annex I to Directive 67/548/EEC, unless conclusive scientific experimental data show that these constituents are not available throughout the life-cycle of the substance and those data have been ascertained to be adequate and reliable. In this case, industry has to look at the constituents after the production of the glass (constituents could be different than the starting materials) to see if they are classified and present above the relevant concentration limit. If this is the

[9] Please note that the description following the heading in the EINECS listing of these substances is part of the substance entry and in most cases it is most decisive for substance identification.

case then they are not exempted unless the constituent is not available throughout the life-cycle of the substance[10].

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

Man Made Vitreous Fibres (mmvf) included in Annex I to Directive 67/548/EEC are not covered by this exemption as they meet the criteria in Annex VI of that Directive. In addition, mmvf, which are not listed in Annex I to Directive 67/548/EEC, but that meet the criteria for classification as dangerous according to Annex VI of Directive 67/548/EEC are also not to be exempted.

12. Compost and biogas

This exemption covers compost when it is potentially subject to registration, i.e. when it is no longer a waste, and is understood as being applicable to substances consisting of solid particulate material that has been sanitised and stabilised through the action of micro-organisms and that result from the composting of any biowaste capable of undergoing aerobic decomposition in its entirety.

This explanation is without prejudice to discussions and decisions to be taken under Community waste legislation on the status, nature, characteristics and potential definition of compost, and may need to be updated in the future.

Biogas is gas produced by the biological breakdown of organic matter in the absence of oxygen and consists of mainly methane.

13. Hydrogen and oxygen

This exemption covers two substances, hydrogen (EC Number 215-605-7) and oxygen (EC Number 231-956-9).

[10] ECHA will provide guidance related to this point to take into account similar issues related with other parts of the REACH Regulation.

Ionic mixtures

In order to provide a specific physicochemical characteristic, water is added to mixtures of ionic substances (salts, acids and bases). The ionic pairs in equilibrium in the aqueous solution are then the result of the water functioning as intended and would consequently not be considered to be themselves manufactured, imported or placed on the market.

In order for this exemption to be applicable, the following conditions must be fulfilled:

1. All starting substances (salts, acids and bases) of the aqueous solution must be registered;

2. None of the salts in the aqueous solution is isolated from the solution; and

3. The salts remain in their ionic form in the solution.

These three conditions equally apply to imported solutions. In particular, this requires that all starting substances of the imported solution must be known and registered in the EU; otherwise the exemption does not apply.

The latter two conditions must also be fulfilled by any customer down the supply chain. If a customer removes any salt from the solution his/her role as downstream user is ending here and he/she becomes a manufacturer which must register the isolated substances.

For solutions of salts in water no registration is required of ionic pairs as long as the combinations of ions co-exist with their different equilibria in the solution and no salts are isolated. In this context, it might be useful to clarify that

(1) whenever ionic pairs exist only as a part of the chemical equilibrium in the aqueous solution, they are not themselves considered to be manufactured, imported or placed on the market and thus do not require registration.

(2) whenever a salt is isolated from the solution, it is manufactured and needs to be registered.

(3) deliberate neutralisation of acids or bases to form the corresponding salts, including neutralisation during formulation, is usually a manufacturing process and is not covered by this exemption.

It should be noted that although the registration of substances ionised in water as described above is deemed inappropriate and is therefore exempted, the potential risks associated with the substances ionised in water must be taken into account in the chemical safety assessment of the starting materials (i.e. salts, acids or bases introduced in the aqueous solution), where applicable.

In some cases, there are water solutions that are manufactured by mixing many different kinds of substances (e.g. salts, acids, bases) in water. One example of this can be a detergent used as all-purpose cleaner. A formulation of such a product can contain the following substances (First list):

- Sodium lauryl ether sulphate
- (Linear) alkylbenzene sulphonic acid
- Oleic acid
- Nitrilotriacetic acid (NTA)
- Phosphoric acid
- Citric acid
- Sodium hydroxide
- Potassium hydroxide
- Non-ionic surfactant, preservative, dyes, fragrance: do not participate to acid/base equilibria

In this case, some salts, acids and basis are mixed in different proportions in order to achieve a product with a certain surfactant properties. As a consequence of the dissolution of the different substances, the different cations and anions find an equilibrium state forming pairs of ions. In the example shown above, it is theoretically possible to identify 12 anions and 2 cations. In this case, more than 40 substances may theoretically coexist in solution. Some of them may be the same as the precursor substances. A non-exhaustive list of potential substances in solution (based on acid-base reactions/equilibria achieved via the protolytic reactions with water) that could be formed in addition of the above-mentioned ingredients (and identified only if water is removed) is shown below (Second list):

- Sodium alkylbenzene sulphonate
- Potassium alkylbenzene sulphonate
- Trisodium citrate

- Disodium citrate
- Monosodium citrate
- Tripotassium citrate
- Dipotassium citrate
- Monopotassium citrate
- Monosodium, monopotassium citrate
- Sodium oleate
- Potassium oleate
- Sodium phosphates
- Potassium phosphates
- Potassium lauryl ether sulphate
- Potassium salt of NTA

Adding one more base (e.g. ammonia) to the formulation would lead to an even greater number of potential ion pairs in solution.

As long as the salts in solution remain stable in their ionic form in the solution and are not isolated from it, it is only necessary to register the precursors (first list) but not the potential substances that may be formed in a solution (second list).