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Questions and agreed answers concerning the correct implementation of Regulation (EC) No 648/2004 on detergents

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1. INTRODUCTION

This document gathers questions and agreed answers concerning the interpretation of Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents¹.

The answers were discussed and agreed between the Commission services and the representatives from the Member States in the Working Group on Detergents. It attempts to provide guidance to both Member States and economic operators.

These answers represent the opinion of the Commission services but may not necessarily represent the opinion of the Commission. This guidance document does not constitute any formal commitment on behalf of the Commission. Only the European Court of Justice can give an authoritative interpretation of Community legislation.

This guidance document is regularly updated and published on the website of the European Commission at:

http://ec.europa.eu/enterprise/sectors//chemicals/documents/specific-chemicals/detergents/index_en.htm

2. ANNEX VI RELATED ISSUES

2.1 Should nonyl phenol (NP) or nonyl phenol ethoxylate (NPE) be put on Annex VI of the Detergents Regulation (EC) No 648/2004?

NP/NPE are not included in Annex VI of the Detergents Regulation because that Annex is intended only for surfactants that have failed the tests of biodegradability specified in the Detergents Regulation. The restrictions imposed on NP/NPE, previously imposed under Directive 76/769/EEC, have now been transferred **without change** to Annex XVII of the Regulation (EC) 1907/2006 (REACH Regulation); these restrictions on NP and NPE can be found now in the Annex to Commission Regulation No 552/2009 amending REACH Regulation, under the entry 46².

These restrictions, while applicable to detergent products, were not made on the grounds of biodegradability under the scope of the Detergents Regulation but rather under Directive 76/769/EEC because of the environmental toxicity of the substances, as was established by means of a risk assessment.

¹ OJ L 104, 8.4.2004, p. 1

² OJ L164, 26.06.2009, p.7 - Commission Regulation (EC) No 552/2009 can be found at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:164:0007:0031:EN:PDF>

3. BIODEGRADATION ISSUES

3.1 Under what conditions does the Regulation enable the placing on the market of surfactants readily biodegradable but failing to pass the ultimate biodegradability criteria if they are only used in closed system?

As part of the tiered-approach to testing, Member States and the Commission services agreed on a general approach to grant derogation enabling the placing on the market of above mentioned surfactants without the need for detailed toxicological testing providing they are used only in closed systems and if the manufacturer can demonstrate that there is no discharge into the environment, for example because the waste is incinerated.

3.2 Can methods other than those defined in Annexes II and III to define the primary and ultimate biodegradability features of surfactants be used?

NO other test methods than those defined in Annex II and III could be used to define the primary and ultimate biodegradability of surfactants used in detergents.

Indeed EU Member States agreed that the placing on the market of surfactants shall be subject to a high environmental standard, taking both into consideration their primary and ultimate biodegradability properties, through an exhaustive set of standardised test methods. If a Member State decides to allow new standards, such a measure might be regarded by some economic operators as a barrier to the free movement of goods.

3.3 Does the Regulation permit the use of the “read-across” approach for generating data on surfactant homologs for the granting of derogation (Art. 5)?

The principle of “read-across” of data from one substance to a similar substance is already recognized in international risk assessment activities, including the OECD HPV Chemicals Programme.

This approach allows establishing the properties of individual substances by “reading-across” from the properties of substances on either side in the same homologous series.

This means the Grouping of substances whose physicochemical, toxicological or ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity. Therefore these substances may be considered as a group, or “category” of substances. Application of the group concept requires that physicochemical properties, human health effects and environmental effects/fate may be predicted from data for a reference substance within the group by interpolation to other substances in the group (read-across approach). This avoids the need to test every substance for every endpoint.

The similarities may be based upon:

1. A common functional group,
2. The common precursors and/or the likelihood of common breakdown products via physical and biological processes, which result in structurally similar chemicals, or
3. A constant pattern in the changing of the potency of the properties across the category.

As many commercial surfactants consist of a mixture of several substances belonging to the same homologous series, it was accepted in the Detergents Working Group meetings that interpolation should be integrated into the guideline on the methodology for the tiered approach to testing for surfactants that are primarily but not ultimately biodegradable.

The rules pertaining to 'read-across' are given in the Commission Recommendation C/2005/5677 on tiered approach technical guidance document for the purpose of implementing Regulation (EC) No 648/2004:

https://ec.europa.eu/growth/sectors/chemicals/legislation_en

In brief, the rules allow interpolation and exclude extrapolation. It was agreed by the Detergents Working Group that the technical dossier addressed to the competent authority granting derogation should explicitly mention cases where interpolations have been taken into consideration for determining the ultimate biodegradability features of surfactants.

3.4 Do the biodegradability criteria of the Detergents Regulation apply independently of the intended function of the surfactant in the detergent formulation?

The objective of the Detergents Regulation as stated in Article 1(2) is to harmonize the rules concerning the biodegradability of surfactants in detergents. The definition of surfactant given in Article 2(6) is made exclusively in terms of the physicochemical properties of the substance. The function of the substance in the detergent formulation is not mentioned in the definition of surfactant. Therefore, as a general rule, the application of the Regulation does not depend on the intention of the manufacturer concerning the purpose or function of the surfactant in the detergent formulation; if a surfactant is not used for its surface active substances but added for another function, the manufacturer has still to ensure that it meets the biodegradability criteria as laid down in the Annexes II and III of the Detergents Regulation.

However, there is an exception to this rule which is regulated by Article 3(1) of the Regulation: surfactants that are also active substances within the meaning of Directive 98/8/EC (the Biocidal Products Directive, now repealed and replaced by Regulation (EU) No 528/2012) and that are used as disinfectants are exempt from the biodegradability criteria of the Detergents Regulation and are subject to the labelling provisions of Annex VII A.

4. DEFINITIONS

4.1 What does “placing on the market” mean?

In Article 2(9) of Regulation (EC) No 648/2004, 'placing on the market' is defined as *“the first making available on the Union market. Import into the Union customs territory shall be deemed to be placing on the market”*. The 'making available on the market' is defined in Article 2(9a) as *“any supply for distribution, consumption or use in the course of a commercial activity, whether in return for payment or free of charge.”*

When a manufacturer* or an importer supplies a product to a distributor or an end-user for the first time within the Union market, the operation is considered as "placing on the market". Any subsequent operation, for instance, from a distributor to a distributor or from a distributor to an end-user is considered as making available.

Placing a product on the market requires an agreement between two entities for the transfer of ownership. This transfer could be for payment or free of charge, and it can be based on any type of agreement (of written and verbal form). It does not require the physical handover of the product.

A product is placed on the market in the cases of transfer of ownership between two entities of the same organisation, provided that these are separate legal entities.

**It should be noted that the definition of a manufacturer under the Detergents Regulation is different from that under the REACH or CLP Regulation. For a better understanding of internal market legislation on industrial products (covering detergents) the reader is referred to the Commission's Blue Guide³.*

With regard to 'manufacturer' the following is stated in the Blue Guide:

- *The manufacturer is any natural or legal person who manufactures a product or has a product designed or manufactured, and places it on the market under his own name or trademark.*
- *The manufacturer is responsible for the conformity assessment of the product and is subject to a series of obligations including traceability requirements.*
- *When placing a product on the Union market, the responsibilities of a manufacturer are the same whether he is established outside the European Union or in a Member State.*
- *The manufacturer must cooperate with the competent national authorities in charge of market surveillance in case of a product presenting a risk or being non-compliant.*

4.2 According to Article 9(3), the manufacturer placing on the market the preparations/mixtures covered by this Regulation shall make available without delay and free of charge to any medical personnel, an ingredient data sheet. What does “without delay” mean?

The intention of Article 9(3) is to cover two separate medical needs:

A) Allergies

For allergies the needs are those of dermatologists who are investigating the cause of allergies in patients. This need is covered in the first paragraph of Article 9(3) and the term "without delay" means "as quickly as reasonably possible" e.g. on the same working day that the request is received.

B) Incidents of poisoning

For cases of poisoning, the need for information is more urgent than for cases of allergy. For this purpose, paragraph 2 of Article 9(3) foresees that doctors will follow standard medical practice and will contact their local poison centre. For this reason, paragraph 2 foresees that manufacturers can be required by Member States to provide the data to poison centres in advance, i.e. when the product is first placed on the market, so that the poison centres are able to

³ <http://ec.europa.eu/DocsRoom/documents/4942>

supply the information immediately to the doctor. This is simply a confirmation of the current practice in most Member States.

Some concerns were raised that this might lead to delays in information reaching a doctor treating a patient. In fact this would not be the case because the publicly available list of ingredients (required by Annex VII D of Regulation No 648/2004) could be supplied immediately which would provide sufficient information.

The current practice of supplying information to poison centres would also be continued so that doctors will have two sources of data in parallel. As many SMEs may have difficulty ensuring uninterrupted availability of the publicly available list of ingredients over a website, the International Association for Soaps, Detergents and Maintenance Products (AISE) has planned to offer an industry-wide service to manufacturers for this purpose.

It has been agreed between Industry, Member States (AISE guidelines) and the Commission that the manufacturer can request evidence of the professional status of a person requesting the datasheet intended for medical personnel.

4.3 What should the application of the definition of “preparation/mixture” to surfactants cover?

The Detergents Regulation deliberately uses the same definition of substances and preparation/mixture as that given in the directives on Dangerous Substances (Directive 67/548/EEC; DSD) and Dangerous Preparations (Directive 1999/45/EC; DPD), and in Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging (CLP). These Directives and that Regulation apply to detergents and surfactants in addition to the provisions of the Detergents Regulation. Thus any guidance given on questions relating to the meaning of these definitions within the Detergents Regulation should be consistent with their treatment under the DSD and DPD, and the CLP Regulation.

In relation to biodegradability of surfactants, testing on preparations rather than on the constituent substances is **ONLY** permitted in recognition of the fact that many commercial surfactants are derived from petrochemical refinery fractions which therefore consist of a homologous series i.e. a range of substances with closely related chemical structures and differing only in molecular weight, and which are not easily separated on a commercial scale.

However, the Commission services and Member States fully agree that this flexibility should not be exploited by mixing together an easily biodegradable surfactant with a poorly biodegradable one, i.e. one which, on its own, would not pass the test, to produce a preparation/mixture that does pass the test.

4.4 Is the meaning of “detain” in Article (18) including the possibility of seizure?

“Detain” is intended to include the possibility to seize any detergents that do not comply with the Regulation. Article 3(1) states that detergents and surfactants for detergents when placed on the market shall conform with the Regulation. Article 18 places the responsibility for enforcement of the Regulation on the Member States. Enforcement should be through measures that are effective, dissuasive and proportionate. In order to prevent the placing on the market of a non-conforming product, seizure would appear to be an appropriate measure. It is certainly effective, and is also

dissuasive.

A manufacturer might try to argue that seizure is not proportionate and that he would suffer financial loss because he is deprived of the possibility of exporting the non-conforming product from the EU. However, Article 18 allows Member States to impose fines on manufacturers selling non-conforming products. Such fines could be several times the value of the consignment in order to be dissuasive. The financial loss resulting from seizure therefore cannot be considered disproportionate. Seizure is therefore a measure that conforms with the conditions of Article 18.

4.5 Responsibility of “retailers” for the conformity of detergents to the provisions of the Regulation

Generally speaking retailers are not to be held responsible for the conformity of the detergents they sell. The idea behind the extended definition of manufacturer in Article 1(10) is that any economic operator who has no control over the composition or packaging of the detergent should not have to bear any responsibility under the Regulation.

However, if the retailer imports a detergent for sale in his shop, then he is deemed to be an importer under the Regulation and he does bear full responsibility for the conformity of the product.

Similarly, if a retailer has a detergent made and/or packaged for him by a third company for sale under the retailer’s own label, then the retailer is deemed to be a manufacturer, and again it is the retailer that bears full responsibility for the conformity of the product.

The only exemption from responsibility for retailers who re-label detergents concerns those retailers who provide a translation of the labelling of imported detergents into the national language of the country of sale. In such cases the responsibility of the retailer is limited to providing a correct translation.

4.6 Which value for the surface tension of water is used in the definition of a surfactant?

Article 2(6) defines the term “surfactant” using a number of criteria, one of which is: “capable of reducing the surface tension of water”. However, many detergent ingredients are capable of reducing surface tension by small amounts, leading to uncertainty concerning the scope of the definition. It was therefore decided that the reduction in surface tension should be quantified, and the international trade tariff value for surfactants of 45 mN/m was chosen.

Reduction of surface tension is only one part of the definition of surfactants, however, and there must also be an ability to form adsorption monolayers. Consequently, substances which are capable of reducing surface tension below 45 mN/m, but which do not form adsorption monolayers (for example alcohols or acetic acid) are not to be regarded as surfactants with the meaning of the Detergents Regulation.

5. LABELLING AND INFORMATION REQUIREMENTS

5.1. Should the act of translating the label be considered as a change to the label?

The Regulation defines any person changing the labelling of a detergent or surfactant as a manufacturer. Manufacturers have extensive responsibilities under Article 9 of the Regulation.

The European Court of First Instance has previously recognized, in another context, that a distinction must be made between the information content of the label and the language used to present that information (case C-33/97). According to this ruling, an accurate translation does not change the information content and such a translation is therefore not considered to be a change to the labelling. Within the meaning of the Detergents Regulation, a person who affixes an accurate translation to a package would therefore not be considered to be a manufacturer. An inaccurate translation which changes the information content of the label would however constitute a change to the labelling, and the person who does this assumes the responsibilities of a manufacturer.

5.2 Can INCI names be translated into national languages?

INCI nomenclature is an agreed standard within the EU and no translation of these substance names is needed. The labelling of detergents must also conform to the provision of the Dangerous Preparations Directive 1999/45/EC (DPD) or the CLP Regulation (EC) No 1272/2008 and the risk and safety phrases specified by the DPD or the hazard and precautionary statements specified by CLP are already given for all of the 20 languages of the Member States so that accurate translations are available.

5.3 Could “blind trials” be exempted from label requirements?

These blind trials involve the comparative testing of detergents by a limited number of consumers for the purposes of market research (e.g. is product X better than product Y?). According to the Regulation, such trials involve placing detergents on the market because they are made available to third parties, and the detergents should therefore be labelled. However, an essential feature of such trials is that the products are tested “blind” i.e. without information which may influence the judgement of the tester. Labelling in accordance with the Regulation would render blind testing impossible.

Member states and the Commission agreed that no action should be taken against blind testing, provided it is done on a limited scale and for a short period only. The manufacture should therefore keep records to show that these conditions are respected.

5.4 How long shall the Ingredient Data Sheet of a withdrawn detergent be made available for the consumer?

The Detergents regulation does not specify for how long the Ingredient data sheet has to be made available after a product is withdrawn from sale. However the objective of Article 11(2) is that

information should be available to the consumer. It is then logical that the consumer could ask for this information as long as the product remains in the supply chain.

REACH provisions require that Safety Data Sheets are maintained for a period of 10 years. Although the SDS does not have the same purpose as the Ingredient Data Sheet (See question 5.6), consistency with REACH has not been opposed by the detergent Industry. Therefore, it is recommended to keep Ingredient Data Sheets available for 10 years after the detergent is withdrawn from the market place.

5.5 Is the provision of “equivalent information” on detergent ingredients in Safety Data Sheets (SDS) in compliance with Annex VII A?

The criteria in Annex VIIA of the Detergents Regulation for listing detergent ingredients differ in three important respects from the corresponding criteria for Section 3 of the SDS as given in Annex II of REACH (previously Section 2 of the Annex to the Safety Data Sheet Directive 91/155/EC):

- Annex VII A does not distinguish between hazardous and non-hazardous ingredients, whereas the SDS requires only hazardous substances to be listed.
- The concentration thresholds for listing ingredients are higher in the SDS than in Annex VII A.
- The SDS requires listing of individual hazardous substances, whereas Annex VII A requires listing of classes of substances.

Therefore, a single ingredient list cannot be expected to successfully meet the requirements of both pieces of legislation. However, both lists (list of hazardous substances according to the DSD, and list of detergents ingredients according to the Detergents Regulation) can be displayed under Section 3 of the SDS, providing that these are clearly distinguished from each other by means of suitable (sub) headings indicating to which piece of legislation they apply.

5.6 When do the new labelling provisions for consumer automatic dishwasher detergents (“CADD”), as adopted by Reg. 259/2012, apply?

The labelling rules introduced by Regulation No 259/2012 in Annex VII B for consumer automatic dishwasher detergents are applicable with effect from 19 April 2012.

However, during the legislative process having led to this amendment, no transition period for their implementation was foreseen, although this is traditionally foreseen in others pieces of legislation dealing with labelling requirements for chemicals. This was due to an oversight during the legislative procedure.

Hence, the Commission services invite the Member States to take this unintended omission into account during their market surveillance activities.

5.7 Is there a requirement for the ingredient information to be located on a particular location on the manufacturer's website?

Manufacturers of detergents are required to make available on a website the ingredient data sheet (Annex VII D of the Detergents Regulation). While the location on the website is not stipulated

the information should be easily accessible and intuitive to the general public/consumers. Access to the website shall not be subject to any restriction e.g. requirement to enter a specific code or to register as a user. If a URL link is given on the packaging label, the path to the ingredient data sheet should be intuitive and easy to follow for any consumer with basic internet knowledge, starting with a "click" on the URL given on the packaging. Ideally (when technically possible, depending from the company's website structure), this URL link should give direct access to the product's ingredient data sheet.

With regard to the language used on the website, it is recommended that the ingredient information is made available in all languages of the Member States where the product is placed on the market.

6. SCOPE OF LEGISLATION

6.1 Criteria for deciding whether a product falls within the scope of the Regulation

Whether a particular product falls within the scope of the Detergents Regulation depends on its purpose (cleaning function or not) and not on its composition (containing surfactants or not).

There are a number of products on the market for which it is not immediately clear whether they fall within the scope of the Detergents Regulation or not. An example is furniture polish. A useful criterion to apply in such cases is whether the product has a cleaning action. A polish which contains a surfactant may simply apply a wax layer to a surface, or it may have a combined cleaning plus wax application action, similar to a car shampoo. In the first case the polish would not fall under the Regulation, but in the second case it would.

Furthermore, it should be noted that from the wording of Article 2(1) last bullet point, i.e. '*other cleaning and washing mixtures*' intended for any other washing and cleaning processes it follows that detergents do not necessarily need to contain surfactants to fall within the scope of the Regulation. For example, an alcohol-based cleaning product without surfactants would still need to comply with all the labelling provisions of the Detergents Regulation (unless it would fall under one of the cases discussed under 6.2 *Do any cleaning products fall outside the scope of the Regulation?*).

6.2 Do any cleaning products fall outside the scope of the Regulation?

The definition of detergent in Article 2(1) mentions five distinct product types which cover all known uses of detergents. However, following the wording of this article, three of those product types definitions (namely 'auxiliary washing mixture', 'cleaning mixture' and 'other cleaning and washing mixtures') refer exclusively to **mixtures**, and hence do not include detergents that are substances.

This means that any single substance cleaning product falling under one of those three product types that is neither a soap nor a surfactant should not be considered to be a detergent within the scope of the Detergents Regulation. This means, for example, that alcohols for cleaning glass,

acids for removing lime scale, bases or bleach for cleaning drains could fall outside the scope of the regulation, provided they consist of a single substance. However, as soon as a product claims to have a "surface cleaning" function, it should fall under the scope of the Detergents Regulation. It would be then up to the Member States' competent authorities to verify whether the product is a substance or a mixture.

For consistency reasons, the criteria for deciding whether a product is a substance or a mixture must be the same as used in REACH and CLP. According to the "Guidance for identification and naming of substances under REACH and CLP" published by ECHA⁴, a substance is "a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition." In the same document, a mixture is defined as a "mixture or solution composed of two or more substances", which is the same definition contained in Article 2(8) of the CLP Regulation. Additionally, a mono-constituent substance is defined as "a substance, defined by its quantitative composition, in which one main constituent is present to at least 80% (w/w)." Finally, it is also stated that "the difference between mixture and multi-constituent substance is that a mixture is obtained by blending of two or more substances without chemical reaction. A multi-constituent substance is the result of a chemical reaction."

Single substance cleaning products to which any other ingredients, such as colorants or perfumes, have been added are mixtures, however, and hence certainly fall within the scope of the Regulation.

6.3 Do products that have a rinsing function (including those based on organic solvents) fall within the scope of the Detergents Regulation?

Rinsing preparations/mixtures which do not have a cleaning function within the meaning of Article 2(3) would be classified as auxiliary washing preparations/mixtures under Article 2(1) 'Other cleaning and washing mixtures'. These auxiliary preparations/mixtures do fall within the scope of the Regulation. Consequently, rinsing additives for dishwashers are considered to fall within the scope of the Detergents Regulation.

Moreover, Article 13(2) explicitly mentions "solvent-based" detergents i.e. organic solvent-based detergents. Therefore, any products having a cleaning function and based on organic solvents would still need to comply with the labelling provisions of the Detergents Regulation.

6.4 How should "soap" and "fragrances" be labelled?

(a) Soap

Different pieces of European legislation apply to the labelling of soap depending on the usage of this ingredient. As a surfactant, soap may be used in a wide range of applications. If the surfactant is used as a component of a detergent (intended for washing and cleaning processes), then the requirements on labelling and classification are those set out in Regulation (EC) No

⁴ http://echa.europa.eu/documents/10162/13643/substance_id_en.pdf, 'Guidance for identification and naming of substances under REACH and CLP', ECHA, March 2012, pp. 7, 8, 19 and 21.

648/2004, Directive 1999/45/EC, Directive 67/548/EEC and Regulation (EC) No 1272/2008.

(b) Fragrances

If the fragrance is added to a detergent preparation/mixture, then it must be labelled as required by Regulation (EC) No 648/2004 and Directive 1999/45/EC or Regulation (EC) No 1272/2008.

In particular, according to Annex VII of the Detergents Regulation, the 26 allergenic fragrances as listed by the 7th amendment (2003/15/EC) of Directive 76/768/EEC shall be mentioned on the label if they have been added to detergents sold to the general public at concentrations exceeding 0.01% by weight. This list of allergenic fragrances, to be found in Annex III, Part 1 of Regulation (EC) No 1223/2009 can be adapted to technical progress.

6.5 Do hydrocarbon propellants in oven cleaning spray products have to be listed as ingredients of the detergent?

The propellants in oven cleaning sprays are gases such as butane/propane i.e. they are aliphatic hydrocarbons. As such they are specifically mentioned in Annex VII A as one of the constituents that must be labelled. Moreover, the propellant clearly has a dual role: it produces a foam as well as acting as a propellant. The bubbles of propellant in the foam constitute an integral part of the preparation. The propellant is therefore an ingredient that must comply with the requirements of Annex VII of the Detergents Regulation.

6.6 Do “fuel additives” and “lube-oils” fall within the scope of the Detergents Regulation?

(a) Lube-oils

These products are exclusively used to prevent deposition within the engine (e.g. to keep particles in suspension in engine oil), thereby to keep combustion and wear residues from settling in the engine oil circuits. Member States and the Commission agreed that these products do not fall within the definition of cleaning (as mentioned in Article 2(3) of the Detergents Regulation), therefore they fall outside the scope of the Detergents Regulation.

(b) Fuel additives

Two types of after-market fuel additives have been considered. One is intended to keep engine parts such as fuel injectors clean by reducing engine deposits. The other is intended to increase the cetane rating of diesel fuel. Additives are already present in about 75% of the fuels sold to the public in the EU, but additives are also sold separately for the consumer to add to the fuel. Both types of additives are completely combusted before leaving the engine. Neither type is considered to fall under the Detergents Regulation as neither has a cleaning action within the meaning of the Regulation. This is clearly the case with additives that increase the cetane rating of diesel fuel as they are intended only to improve fuel combustion and no cleaning action is claimed by the manufacturer.

In contrast, additives that keep engines clean are often claimed by the manufacturer to have a cleaning action. However, such additives do not clean in the strict sense of the Detergents Regulation. Deposits are both created and removed by thermal processes in engines and the rates of the two processes reach an equilibrium associated with specific driving behaviour and fuel quality. Fuel additives act to reduce the rate of deposition thereby changing the equilibrium

between the deposition and removal processes, leading to a reduced amount of deposit in the engine. The additives do not affect the removal of deposits, which is a purely thermal process. Therefore, considering that fuel additives do not have a cleaning effect within the meaning of the Regulation, Member States and the Commission agreed that these products do not fall within the scope of the Detergents Regulation.

6.7 Do animal washing products fall within the scope of the Detergents Regulation?

(a) Products for washing of pets (e.g. shampoo for dogs, horses etc.)

There is no sector specific EU legislation for the products used for the washing of pets unless such products have additional uses beyond washing, such as insect-repelling shampoos, which may fall within the scope of the Biocidal Products Regulation 528/2012.

Shampoos for humans fall under the Cosmetics Regulation as regards human health effects, while environmental effects of the ingredients are covered by REACH. Information requirements under REACH cover the (ready) biodegradability of substances. Additionally, pet shampoos need to fulfil all legal requirements pursuant to the General Product Safety Directive, which stipulates requirements related to other safety aspects of consumer products.

As such, pet shampoos should not be covered by the Detergents Regulation.

(b) Products for washing the nipples of animals (e.g. cows or goats).

These products fall outside the scope of Detergents Regulation. However, they may fall within the scope of the Regulation (EU) No 528/2012 concerning the making available on the market of biocidal products (as indicated by Commission Regulation (EC) No 1662/2006 amending Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin). It should be noted that if the Biocidal Product Regulation is applicable, the biodegradability criteria of the Detergents Regulation are also satisfied as the biodegradability criteria are the same in both pieces of legislation.

6.8 Do products for the cleaning of food and vegetables fall within the scope of the Detergents Regulation?

The Commission and Member States agree that products for cleaning of fruits and vegetables fall within the scope of the Detergents Regulation as they are used for cleaning purposes (e.g. for removing the wax on fruit) so they meet the definition of cleaning (Article 2(3)). Moreover, depending from the characteristics of the specific products, other European legislation may apply in addition to the Detergents Regulation (e.g. Biocidal Product Regulation).

6.9 Do cleaning products containing bacteria fall within the scope of the Detergents Regulation?

The Commission and Members States examined a request for clarification as to whether a product with a claimed cleaning effect depending on the action of bacteria falls within the scope of the Detergents Regulation. The label of the product claims that its cleaning action is a result of applying bacteria to feed on the excrement of dust mites. It was agreed that such a product,

though it contains surfactants, does not seem to have a cleaning action as defined in Article 2.3 of Regulation No 648/2004 as last amended by Regulation No 259/2012 (i.e. “the process by which undesirable deposit is dislodged from the substrate or from within and substrate brought into a state of solution or dispersion”), and consequently **does not fall within** the scope of the Detergents Regulation. However, there are other products on the market (like certain drain cleaners) which work through a combined action of surfactants, enzymes and bacteria. As the cleaning process of these products is not based solely on the action of bacteria, they do fall within the scope of the Detergents Regulation.

6.10 Do water softeners fall within the scope of the Detergents Regulation (and does the phosphate restriction in Annex VI A) apply to them?

After June 30, 2013 a consumer machine laundry detergent which is used in the main cycle of the washing process cannot contain more than 0.5 grams of phosphorus per recommended dosage. Some products, which contain phosphorus, are used as water softeners. These products may be used with laundry during the main washing cycle or without laundry to clean the washing machine itself.

If such products are used without laundry they are hard surface cleaners, and thus not considered as a consumer laundry detergent; and therefore not subject to the phosphorus restrictions of Annex VI A.

But if the water softener is used with laundry during the main washing cycle, while indeed softening water, it is also added as auxiliary washing detergent, as it optimises the cleaning of the laundry by preventing deposits. Thus, in this case it is subject to the phosphorus restriction in Annex VI A.

If the water softener doesn't contain any recommendation to be used with laundry, it may be considered outside the scope of the legislation. However, if there is a claim on the product that it may potentially be used in both circumstances - with or without laundry - then the phosphorus restriction applies, as the 'with laundry' use will prevail on the 'without laundry' use.

6.11 The status of manufacturer's claims concerning the cleaning action of a product

The question of whether a product falls within the scope of the Detergents Regulation is not determined by the manufacturer's claims regarding the cleaning action of the product.

Instead, the decision should depend on whether the product has a cleaning action within the meaning of the Regulation. The Detergents Regulation therefore differs from, for example, the Biocides Directive in which it is sufficient to claim a biocidal action (more precisely to state an intended use for the product) to automatically fall within the scope of that Directive.

It is necessary to make a further distinction regarding claims about cleaning action because the definition of “cleaning” in the Regulation does not always fully coincide with the normal usage of the word “cleaning”. It is therefore possible, without misleading the consumer, for a manufacturer to claim a cleaning action for a product that does not have a cleaning action within the meaning of the Regulation.

An example of such a “normal usage” meaning of cleaning is that of a fuel additive as mentioned in 7.6(b) which prevent deposits forming in engines, and which therefore has a cleaning action in the sense of keeping a surface clean.

There is no infringement of the Regulation if the manufacturer makes a cleaning claim that is not consistent with the definition of cleaning in the Detergents Regulation. However, if the cleaning claim is not consistent with either the definition of cleaning in the Detergents Regulation, nor with the wider “normal usage” meaning of cleaning, then the marketing of such a product might be contested under consumer protection legislation.

6.12 Do 'soap nuts' fall within the scope of the Detergents Regulation?

Soap nuts are not considered to be either a substance or a mixture according to the definitions of the Detergents Regulation, and consequently soap nuts fall outside the scope of the Detergents Regulation.

However, as consumer products, soap nuts are covered by the rules of the General Product Safety Directive (Directive 2001/95/EC) and the Market Surveillance Regulation (Regulation (EC) No 765/2008).

6.13. Do 'foam sponges' fall within the scope of the Detergents Regulation?

It has been questioned if 'foam sponges which aim to clean and polish shoes' fall within the scope of the Detergents Regulation or not.

Foam sponges that are pre-charged with detergent when placed on the market, and that are intended for cleaning and polishing (for example shoes or cars), are considered to be a form of packaging for a carrier for that detergent. The foam sponge itself is therefore not considered to be one of the ingredients of the detergent formulation, but the detergent in the sponge does fall within the scope of the Regulation. Thus, detergent pre-charged foam sponges are considered to fall within the scope of the Detergents Regulation.

However, foam sponges intended for cleaning that are not pre-charged with detergent when placed on the market are considered to be articles and do not fall within the scope of the Regulation.

6.14. Scope of Annex VIa (limitations on the content of phosphates and of other phosphorus compounds)

Consumer laundry detergents

- Are **consumer laundry heavy duty detergents** subject to the phosphorus restriction defined in Annex VIa?

Yes, as of 30 June 2013 consumer laundry heavy duty detergents are subject to a limit of 0.5 g of phosphorus per dosage as specified in Annex VII part B.

- Are **consumer laundry delicate fabrics detergents** subject to the phosphorus restriction defined in Annex VIa?

Yes, as of 30 June 2013 consumer laundry delicate fabrics are subject to a limit of 0.5 g of phosphorus per dosage as specified in Annex VII part B.

- Are **consumer hand-wash only laundry detergents** subject to the phosphorus restriction defined in Annex VIa?

Yes, as of 30 June 2013 consumer hand-wash only laundry detergents are subject to a limit of 0.5 g of phosphorus per recommended dosage as for hard water.

- Are **consumer in-wash water softeners** subject to the phosphorus restriction defined in Annex VIa?

Yes, consumer in-wash water softeners are 'other cleaning and washing mixtures' and thus fall under the definition of 'detergent' and 'consumer laundry detergent'. As of 30 June 2013 they are subject to a limit of 0.5 g of phosphorus per recommended dosage.

- Are **consumer fabric conditioners** subject to the phosphorus restriction defined in Annex VIa?

Yes, consumer fabric conditioners are 'laundry fabric-softeners' and thus fall under the definition of 'detergent' and 'consumer laundry detergent'. As of 30 June 2013 they are subject to a limit of 0.5g of phosphorus per recommended dosage.

- Are **consumer laundry bleaches** subject to the phosphorus restriction defined in Annex VIa?

Yes, consumer bleaches are 'auxiliary washing mixtures' and thus fall under the definition of 'detergent' and 'consumer laundry detergent'. As of 30 June 2013 they are subject to a limit of 0.5 g of phosphorus per recommended dosage.

- Are **consumer washing machine cleaners** subject to the phosphorus restriction defined in Annex VIa?

No, although consumer laundry machine cleaners fall under the definition of 'detergent' they are not 'consumer laundry detergents' as they are not intended to clean or treat laundry.

Consumer automatic dishwasher detergents

- Are **consumer automatic dishwasher detergents** subject to the phosphorus restriction defined in Annex VIa?

Yes, as of 1 January 2017 all consumer automatic dishwasher detergents are subject to a limit of 0.3 g of phosphorus per recommended dosage.

- Are **consumer hand dishwash detergents** subject to the phosphorus restriction defined in Annex VIa?

No, consumer hand dishwash detergents are not meant to be used in automatic dishwashers and

thus are not 'consumer automatic dishwasher detergents'.

- Are **consumer rinse aids** subject to the phosphorus restrictions defined in Annex VIa?

Yes, consumer rinse aids are 'other cleaning and washing mixtures' and thus fall under the definition of 'detergent' and 'consumer automatic dishwasher detergent'. As of 1 January 2017 they are subject to a limit of 0.3 g of phosphorus per recommended dosage.

7. USE OF THE SAFEGUARD CLAUSE

7.1 When should the safeguard clause (Article 15) of the Detergents Regulation be used?

The safeguard clause (Article 15) may only be used by Member States for those detergents which **fully comply** with the Regulation, and which nevertheless pose a risk to the safety of humans or of animals or a risk to the environment.

Furthermore, the safeguard clause may only be used **on a case-by-case basis for a specific product**, not for a class of product, and any decision taken by the Commission will be similarly limited.

The safeguard clause therefore cannot be used to introduce risk management measures of a general nature.

As the safeguard clause can be used only for a specific product, the product in question should be unambiguously identified in the notification to the Commission (product name(s), manufacturer, importer, unique ISO/IEC 15416 bar code number, chemical composition). Variations in labelling and packaging due to parallel or grey imports should be mentioned.

From a procedural point of view, it is important to stress that the Member State intending to use the safeguard clause must immediately inform the Commission **and** the other Member States, documenting the reasons for this decision.

If the detergent is **not compliant** with the Regulation, national sanctions adopted under Article 18 should be used instead of the safeguard clause. Detergents that are not compliant with the Biocidal Products Regulation as mentioned in Article 3, or with the Directives and regulation on classification, labelling and packaging as mentioned in Article 11, are also not compliant with the Detergents Regulation.

8. INTERFACE BETWEEN THE DETERGENTS REGULATION AND THE MEDICAL DEVICES DIRECTIVE

8.1 Must detergents for specific use with medical products carry CE marking?

CE marking for medical products is intended for medical devices covered by Directive 93/42/EC concerning medical devices, Directive 90/385/EEC concerning Active Implantable Medical Devices, and Directive 98/79/EC concerning In Vitro Diagnostics. For these directives, ISO 9001 accreditation is useful in the context of the manufacturer's declaration of conformity.

CE marking of detergents as medical devices must be such that it is clearly pertinent only to the properties assessed according to the medical devices directives. The medical devices directives are available at:

http://ec.europa.eu/consumers/sectors/medical-devices/index_en.htm

Detergents which are medical devices have to fulfil the requirements of CE marking as well as the requirements of the Detergents Regulation.

8.2 Do contact lens care solutions fall under the Detergents Regulation?

Contact lens care solutions do not fall under the Detergents Regulation. Instead, they fall under the Medical Devices Directive where they must comply with the requirements for **Class IIb** medical devices.

http://ec.europa.eu/health/medical-devices/files/wg_minutes_member_lists/borderline_manual_ol_en.pdf - see page 49

According to **rule 15** of Annex IX of Directive 93/42/EEC, *all devices intended specifically to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses* are in **Class IIb**, and in MEDDEV 2.4/1 rev.9, comfort solutions are given as an example to rule 15.

http://ec.europa.eu/health/medical-devices/files/meddev/2_4_1_rev_9_classification_en.pdf

Although contact lens care solutions may contain surfactants, they do not have a cleaning function within the meaning of the Detergents Regulation. Article 2(3) of the Regulation defines cleaning as 'the process by which an undesirable deposit is dislodged from a substrate or from within a substrate and brought into a state of solution or dispersion'. In fact, deposits on contact lenses continue to build up despite daily treatment with the care solutions until the lenses can no longer be worn and have to be replaced. The main purpose of the surfactants in the care solutions is to rewet the surface of the lens, not to clean it.

9. INTERFACE BETWEEN THE DETERGENTS REGULATION AND THE COSMETICS REGULATION

9.1 Which soap, shampoo and fragrances do not fall under the Detergents Regulation?

Soaps and shampoo intended for personal care are out of the scope of the Detergent Regulation but are covered by the Cosmetic Products Regulation (EU) N°1223/2009, **and its provisions**.

http://ec.europa.eu/consumers/sectors/cosmetics/documents/revision/index_en.htm

With regard to “fragrances”, similar considerations apply. If the fragrance is sold as an ingredient for a cosmetic purpose, it must follow the requirements provided by Regulation (EU) No 1223/2009 and comply with the labelling provisions of that Regulation.

10. INTERFACE BETWEEN THE DETERGENTS REGULATION AND THE BIOCIDES REGULATION

Disinfectants, or cleaning agents containing disinfectants, are subject to the Biocides Regulation (EU) No 528/2012. However, as stated in Article 3(1) of the Detergents Regulation, surfactants that are also active substances within the meaning of Regulation (EU) No 528/2012 and that are used as disinfectants are exempt from the biodegradability criteria of the Detergents Regulation but are still subject to the labelling provisions of Annex VII A. In addition, they are covered by the biodegradability related provisions under the Biocides Regulation.