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

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7. SCOPE OF THE LEGISLATION

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 detergents[1], amended for the last time by Regulation (EC) No 907/2006 of 20 June 2006 amending Regulation (EC) No 648/2004 on detergents, in order to adapt Annexes III and VII thereto.

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 will be regularly updated and published on the website of the European Commission.

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 will not be 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 under Directive 76/769/EEC were not made on the grounds of biodegradability but rather because of the environmental toxicity of the substances, as was established by means of a risk assessment.

The initial Commission proposal for the Detergents Regulation had an additional annex for listing substances such as NP/NPE that are banned or restricted under other legislation. This was included for the convenience of listing in one place all the substances restricted for detergent use. However, that additional annex was dropped from the proposal during the co-decision procedure because it merely duplicates information available elsewhere, and it was thought that any delay in updating such an annex might give rise to confusion as to whether the restrictions was actually in force or not.

[1] OJ L 104, 8.4.2004, p. 1

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 s ystem?

As part of the tiered-approach to testing, Member States and the Commission services agreed on a general approach to grant derogations enabling the placing on the market of above mentioned surfactants without the need for detailed toxicological tes ting 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?

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 decide to allow new standards, such a measu re 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 a 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 eco-toxicological 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 phy sicochemical 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 Detergent 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 (Commission Decision proposal on the adoption of tiered approach technical guidance document for the purpose of implementing Regulation (EC) No 648/2004).

In contrast, extrapolation is excluded from the "read-across" process.

It was agreed by the Detergent Working Group that the technical dossier addressed to the competent authority granting for a 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 physico-chemical properties of the substance. The function of the substance in the detergent formulation is not mentioned in the definition of surfactant, nor anywhere else in the Regulation. Therefore, 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. Therefore, 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.

4. DEFINITIONS

4.1 What does "Placing on the market" mean?

It appears that the definition of placing on the market in Article 2(9) could give rise to some uncertainties, both for surfactant manufacturers and for detergent formulators, concerning the phrase "making available to third parties". A useful criterion to apply in these doubtful cases would be to ask whether any change of ownership has taken place, and whether the product can therefore be easily returned to the manufacturer.

Thus, a load of detergent is not placed on the market at the moment that it leaves the factory gate on the lorry of a delivery company, but at the moment of delivery when the purchaser signs to acknowledge receipt. Similarly, a surfactant manufacturer who sends a batch of surfactant to a contractor for further processing, and who subsequently receives the processed product back again without a change in ownership taking place, would not be considered to have placed the

surfactant on the market

4.2 According to Article 9(3), the manufacturer placing on the market the preparations 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 1st paragraph of 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 cent re are able to 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 N° 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 Assoc iation 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" to surfactants cover?

The Detergent Regulation deliberately uses the same definition of substances and preparation as that given in the directives on Dangerous Substances (67/548/EEC ; DSD) and Dangerous Preparations, (1999/45/EC ; DPD). These directives 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.

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 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 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 retailers 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 How big must the reduction in surface tension be before a substance or preparation is regarded as a surfactant within the meaning of the Regulation ?

Article 2(6) provides a comprehensive set of surface active criteria to define "surfactant". One of the criteria is "capable of reducing the surface tension of water", but no numeric value is given for deciding whether the surface tension has been reduced within the meaning of the Regulation . For the purposes of the Regulation, the latter condition is fulfilled if the substance or preparation is capable of reducing the surface tension to below the internationally trade tariff value for surfactants of 45 mN/m.

5. LABELLING

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 a nother 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 Detergent 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) and that the risk and safety phrases specified by the DPD are already given for all 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 Must detergents for specific use with medical products carry CE marking?

CE marking for medical products is intended for medical devices covered by Directives 93/42/EC concerning medical devices, 90/385/EEC concerning Active Implantable Medical Devices, and 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 medical devices directive. The medical products directives are available at: http://europa.eu.int/comm/enterprise/medical_devices/index.htm

Instead, cleaning agents, insofar as they contain surfactants, fall within the scope of the detergents legislation and must comply with rules concerning the biodegradability of surfactants. Furthermore, disinfectants, or cleaning agents containing disinfectants, are subject to the biocides directive, 98/8/EC, which is available at:
http://europa.eu.int/comm/environment/biocides/index.htm

See also point 7.4 concerning contact lens care solutions

5.5 Is the provision of "equivalent information" on detergent ingredients in Safety Data Sheets (SDS) in compliance with Annex VIIA ?

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

6. OLD STOCKS

6.1 How should old stock which does not comply with the new Regulation be treated?

Both industry and Member States emphasised their commitment to ensuring that stock on the shelves of retailers would be labelled in accordance with the Regulation by 8 th October 2005. Nevertheless, it is possible that some stocks of some specialized cleaning products may remain unsold in small retailers by this date. It was agreed that these small scale stocks would not need to be withdrawn. This flexibility would not however be extended to larger retailers such as supermarkets, or to distributors.

7. SCOPE OF LEGISLATION

7.1 Criteria for deciding if a product falls within the scope of the Regulation?

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 shampo o. 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 under Article 2(1) last bullet point, i.e. ' *other cleaning and washing preparations' 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 labellin g provisions of the Detergent Regulation.

However, that bullet point is not intended to include in its scope soaps and shampoo intended for personal care; those products are covered by the Cosmetics Directive 76/768/EEC.

7.2 Do products that have a cleaning/rinsing function based on organic solvents fall within the scope of the regulation?

Products with a cleaning function fall within the scope of the Detergents Regulation, as also explained under question 16 according to Article 2(1) Rinsing preparations which do not have a cleaning function within the meaning of Article 2(3) would be classified as auxiliary washing preparations under Article 2(1). These auxiliary preparations do fall within the scope of the 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 s till need to comply with the labelling provisions of the Detergent Regulation. Whether a particular product falls within the scope of Detergents Regulation depends on its purpose (cleaning function or not) and not on its composition (containing surfactants or not).

7.3 How should “soap” and “fragrances” be labelled?

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 detergent (intended for washing and cleaning processes), then the requirements on labelling and classification are those set out in Regulation (EC) N° 648/2004, Directive 99/45/EC or Directive 67/548/EEC.

On the other hand, if the soap is used as a cosmetic product (intended for cleaning the human body), then the provisions set out in Dir ective 76/768/EEC on cosmetics apply.

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 Dir ective 76/768/EEC and be labelled under the indication "parfum" or "aroma" (Art 6.g) of that directive. In particular, the 7th amendment (2003/15/EC) of Directive 76/768/EEC requires the labelling of 26 fragrances that may cause allergies.

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

7.4 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.

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 makes use of the ISO definition which refers to cleaning as the removal of “soil” i.e. to the “removal of an undesirable deposit on and/or within the substrate which changes some characteristics or appearance or feel of a clean surface”. 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.

7.5 Do hydrocarbon propellants in oven cleaning spray produ cts 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 VIIA as one of the constituents that must be labelled. Moreover, the propellant clearly has a dual role: it produce 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 c omply with the requirements of Annex VII of the Detergents Regulation.

7.6 Do "fuel additives" and "lube-oils" fall within the scope of the Detergent 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 ISO 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.

7.7 Do animal cleaning products fall within the scope of the Detergent Regulation?

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

The Commission and Member States agree that these types of products do not fall under the Detergents Regulation as the cleaning of the hair, fur or skin of live animals is not covered by the definition of washing in Article 2(2). Shampoo for humans falls under the Cosmetics Directive as regards human health effects, and environmental effects are covered by REACH. There is no sector specific EU legislation for the products used for the cleaning of pets.

(b) Products for cleaning the nipples of animals (e.g. cows or goats). As with case (a) above, these products fall outside the scope of Detergents Regulation. However, they fall within the scope of the Directive 98/8/EC on the placing 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 Directive is applicable, the biodegradability criteria of the Detergent Regulation are also satisfied as the biodegradability criteria are the same in both pieces of legislation.

7.8 Do products for the cleaning of food and vegetables fall within the scope of the Detergent 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 washing purposes (e.g. for removing the wax on fruit) so they meet the ISO definition of cleaning (Article 2(3)). Moreover, other legislation may apply in addition to the Detergents Regulation for this type of products, such as the Biocidal Products Directive requirements in case a biocidal effect is claimed.

7.9 Do cleaning products containing bacteria fall within the scope of the Detergent 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 product, though it contains surfactants, does not seem to have a cleaning action within the meaning of ISO definition (i.e. "the process by which soil is dislodged from the substrate and brought into a state of solution or dispersion").

7.10 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.