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## **QUESTION AND AGREED ANSWERS**

### **CONCERNING THE IMPLEMENTATION OF DIRECTIVE 76/769/EEC ON THE RESTRICTIONS TO MARKETING AND USE OF DANGEROUS SUBSTANCES**

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## 1. INTRODUCTION

This document gathers some questions and agreed answers concerning the interpretation of Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations<sup>1</sup>, amended for the last time by Decision No 1348/2008/EC concerning restrictions on the marketing and use of 2-(2-methoxyethoxy)ethanol, 2-(2-butoxyethoxy)ethanol, methylenediphenyl diisocyanate, cyclohexane and ammonium nitrate<sup>2</sup>.

The answers were discussed and agreed between the Commission services and the representatives from the Member States in the Working group on restrictions to marketing and use of dangerous substances. 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. DIRECTIVE 2006/139/EC ON ARSENIC COMPOUNDS (ENTRY 20 OF ANNEX I, DIRECTIVE 76/769/EEC)

### 2.1. Status of imported CCA treated wood

Are imports of CCA treated wood from outside the European Union banned under Directive 76/769/EEC as amended by Directive 2006/139/EC?

Under Entry 20 of Annex 1 to Directive 76/769/EEC as amended by Directive 2006/139/EC<sup>3</sup>, CCA type C cannot be used to treat wood in the EU due to the fact that it has not been authorised under Directive 98/8/EC. A request for authorisation could, however, be made in the future in line with the requirements of Directive 98/8/EC.

Concerning wood newly treated with CCA type C and imported from third countries:

- point 4 a) authorises only the treatment of wood with CCA type C if this biocidal product is authorised under Directive 98/8/EC.

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<sup>1</sup> OJ L 262, 27.9.1976, p. 201

<sup>2</sup> OJ L 348, 24.12.2008, p. 108.

<sup>3</sup> OJ L 384, 29.12.2006, p. 94

- under Entry 4 b) it is stated that “Wood treated with CCA solutions according to point a) may ....”

This implies that all wood that is placed on the market in the EU must conform to the requirements of paragraph 4 a).

Therefore wood newly treated with CCA type C may only be placed on the EU market if this biocidal product used for treatment is authorised under Directive 98/8/EC.

Whilst the Directive does not impose general obligations on wood treatment installations outside the EU, this requirement is valid for any manufacturer, distributor, or importer placing wood on the EU market whether this wood is manufactured in the EU or manufactured outside the EU and imported. Obviously the requirement does not apply to wood treatment installations outside the EU producing wood for marketing outside the EU.

In summary as of 30 June 2007, it is prohibited to place on the market and to import wood newly treated with CCA type C, until such time as a biocidal product containing this active substance is authorised in line with all the requirements of Directive 98/8/EC.

## **2.2. Applications of wood treated with CCA Type C**

Under Entry 20, paragraph 4b) of Annex 1 to Directive 76/769/EEC there is a list of applications for which wood treated with CCA type C can be used. May treated wood be used for other applications, such as railway sleepers other than underground railway sleepers?

Paragraph 4b) of Entry 20 of Annex 1 to Directive 76/769/EEC concerning arsenic compounds provides for a list of applications for which wood treated with CCA may be used. This is not a list of examples of possible uses but a limitative list of authorised applications.

Consequently, wood treated with CCA cannot be used for other applications than the ones listed in paragraph 4 b). Wood treated with CCA can, therefore, not be used for railway sleepers installed above ground.

## **3. DIRECTIVE 2003/53/EC ON NONYLPHENOL (ENTRY 46 OF ANNEX I, DIRECTIVE 76/769/EEC)**

### **Traces in cosmetic products**

Directive 76/768/EEC relating to cosmetic products, as amended by Commission Directive 2005/80/EC<sup>4</sup>, introduces a ban on the marketing of cosmetic products containing nonylphenol (CAS: 25154-52-3) and 4-nonylphenol, branched (CAS: 84852-15-3) (entry 1168 of Annex II).

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<sup>4</sup> OJL 303, 22.11.2005, p. 32

Article 4 §2 of Directive 76/768/EEC allows the presence of traces in products provided that such presence is technically unavoidable in good manufacturing practice and that the product does not cause damage to human health.

Directive 76/769/EEC relating to the marketing and use of dangerous substances and preparations amended by Directive 2003/53/EC<sup>5</sup> bans the placing on the market of nonylphenol and nonylphenol ethoxylates as a substance or constituent of preparation in a number of applications including cosmetic products, when the concentration is higher than 0.1% by mass.

Although the two texts pursue the same objective and impose the same restriction, they diverge concerning the tolerance of trace contamination.

#### **4. DIRECTIVE 2005/59/EC<sup>6</sup> ON TOLUENE (ENTRY 48 OF ANNEX I, DIRECTIVE 76/769/EEC)**

##### **Toluene in Adhesive Tapes**

For adhesive tapes, does the concentration limit for toluene of 0.1% in adhesives apply to the whole mass of the tape or just to the mass of the adhesive layer on the tape?

Entry 48 of Annex I to Directive 76/769/EEC prohibits the placing on the market for sale to the general public of toluene as a substance or as a constituent of preparations in adhesives and spray paints at concentrations equal to or greater than 0.1%.

Adhesive tapes consist of a layer of adhesive coated on a flexible substrate. As the restriction concerns the concentration of toluene in adhesives, the concentration of toluene must be calculated with reference to the amount of adhesive on the tape, and not with reference to the total mass of the adhesive and substrate.

#### **5. DIRECTIVE 2005/69/EC ON PAH IN EXTENDER OILS AND TYRES (ENTRY 50 OF ANNEX I, DIRECTIVE 76/769/EEC)**

##### **Interpretation of the term “major operational change”**

Questions have arisen concerning the requirement to control the calibration of the PAH/PCA ratio after each “major operational change” under Directive 2005/69/EC<sup>7</sup>.

As stated in Recital 8 of the Directive, there are at present no harmonized test methods for measuring PAHs in the extender oils, or for measuring PAHs in tyres that contain such oils. Until suitable harmonized methods are available, the only named method that is permitted for measuring the PAH content of extender oils is the IP346 analysis method. This method is permitted providing that certain additional

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<sup>5</sup> OJ L178, 17.7.2003, p.24

<sup>6</sup> OJ L309, 25.11.2005, p.13

<sup>7</sup> OJ L323, 9.12.2005, p.51

conditions are met. These additional conditions are necessary because the IP346 method does not measure the PAH content directly.

In fact IP346 measures the total content of polycyclic aromatic compounds (PCA) rather than the PAH content. The PCAs are a group of substances to which PAHs belong, but in which PAHs are present in only very small amounts. The legal limit for PAHs in extender oils, which is 1 part per million (ppm) of BaP and 10ppm total PAH content, is considered to be met if the total PCA content is <3%. In other words, the PCA content of 3% is taken as a proxy measurement for a PAH content of 10ppm. The proxy measurements will be valid only if the ratio between the PAH and PCA content in the extender oil is known and does not change over time. The additional conditions therefore require an initial calibration of the technique (measurement of the PAH/PCA ratio) and recalibration at intervals of six months, or after “major operational change”, in order to ensure that the measurements remain valid over time.

The term “major operational change” should therefore be taken to mean any change in materials or processes that could invalidate the results of the proxy measurement. The principle cause of invalid results would be a change in the PAH/PCA ratio in the extender oil. However, it should be remembered that not only is IP346 a proxy method for measuring PAH, but that the quantity that it does measure, namely PCA content, is measured in a rather indirect way, namely by a change in the refractive index of a solution, and that PCAs are not the only substances that affect the refractive index of a solution. The potential for obtaining invalid results is therefore quite high and the method should therefore be used with considerable caution. It would therefore be advisable to recalibrate in case of doubt.

The provision to control the calibration of the PAH/PCA ratio every six months is to safeguard the validity of the IP346 results against unintentional or unknown changes. This would apply for the case where the manufacturing process and materials used remain the same, and where there is no reason to expect a change in the PAH/PCA ratio. However, it is possible to imagine, for example, that a tyre manufacturer receives a reformulated extender oil from his supplier without being made aware of the change that has been made, and the results from the IP346 could be invalidated as a consequence. A six month recalibration interval was considered sufficient to cover such occurrences.

Conclusion: The provision to control the calibration of the PAH/PCA ratio after each “major operational change” is to safeguard the validity of the IP346 results. A major operational change is therefore a deliberate change to materials or processes that might be expected to significantly influence the PAH/PCA ratio, or otherwise affect the validity of the measurement. Examples of such a change would be where the source of supply for the extender oil is changed, or where the method of using the oil is changed.

Judgment of whether a particular change is sufficiently important to trigger the need for recalibration will necessarily be made case-by-case and will require expert opinion.

## 6. DIRECTIVE 2005/84/EC ON PHTHALATES IN TOYS AND CHILDCARE ARTICLES (ENTRIES 51 AND 51A OF ANNEX I, DIRECTIVE 76/769/EEC)

### 6.1. Traces of phthalates in toys and childcare articles

The Annex to Directive 2005/84/EC<sup>8</sup> states that DEHP, DBP and BBP (or DINP, DIDP and DNOP) "shall not be used as substances or as constituents of preparations, at concentrations of greater than 0.1% by mass of the plasticised material".

The question has been asked whether that means that the 0.1% limit applies to each phthalate listed individually, or whether it applies to the 3 or 6 phthalates combined. How should this limit of 0.1% be applied when a product contains traces of more than one these substances?

The threshold of 0.1% is the standard threshold used in the Limitations Directive (Directive 76/769/EEC). The value of 0.1% has been chosen because it represents a measurable quantity. It is being used to take into account impurities, not to allow the use of certain substances, e.g. phthalates in toys and childcare articles. One should be aware that in order to plasticise a toy or childcare article concentrations of phthalates of more than 10 per cent are needed.

Different restrictions are applied to each of the two groups of phthalates. The limit value of 0.1% should therefore be applied for each group of phthalates combined, i.e. the concentration of DEHP, DBP and BBP combined should not be higher than 0.1% and the concentration of DINP, DIDP and DNOP combined should also not be higher than 0.1%.

Conclusion: A toy or childcare article would not comply with the Directive if it contained either more than 0.1% of DEHP, DBP and BBP combined or more than 0.1% of DINP, DIDP and DNOP combined. However, it would be considered compliant if it contained only 0.09% of DEHP, DBP and BBP combined and 0.09% of DINP, DIDP and DNOP combined.

### 6.2. Phthalates in articles used for the hygiene of children

Are the articles destined to be used for the hygiene of children such as bathtubs, articles for the bath, bathtub mats, hairbrushes, bath thermometers, or nail cutters covered under Directive 2005/84/EC?

The Directive specifies that "Childcare article" means "any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children."

As these articles are intended to facilitate the hygiene of children they should be considered as "childcare articles" as defined by the Directive 2005/84/EC.

In conclusion, articles which are used for the hygienic care of children such as bathtubs, articles for the bath, bathtub mats, hairbrushes, bath thermometers, or nail cutters are therefore covered by the Directive 2005/84/EC on the restriction to the

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<sup>8</sup> OJ L 344, 27.12.2005, p. 40

marketing and use of phthalates and should conform to the prescriptions of the Directive.

## 7. DIRECTIVE 2006/122/EC ON PFOS (ENTRY 52 OF ANNEX I, DIRECTIVE 76/769/EEC)

### 7.1. PFOS definition and limits of concentration

How the term “Perfluorooctane sulfonates” is to be interpreted in Directive 2006/122/EC<sup>9</sup> and how are the limits of concentration to be calculated?

The term Perfluorooctane sulfonates (PFOS), means any substance containing the PFOS moiety ( $C_8F_{17}SO_2$ ) with the potential to degrade to the anionic form  $C_8F_{17}SO_3^-$  in the environment. These substances include the acid form of PFOS, the metal salts and the halides of PFOS and also the amides. Polymers including the PFOS moiety are also within the scope of Directive 2006/122/EC.

The limit values in the Directive mean the concentration of extractable PFOS measured with CEN methods and expressed as the corresponding amount of PFOS acid.

Official controls for the enforcement of the limits mentioned in the Directive will make use of CEN standards (currently under development). The limits in the Directive will therefore, eventually mean the PFOS content as measured by the CEN methods. The analytical methods under consideration by CEN are Liquid Chromatography/Mass Spectroscopy (LC/MS) for anionic PFOS species, and Gas Chromatography/ Mass Spectroscopy (GC/MS) for non-ionic PFOS species. As both methods require liquid samples, for semi-finished products and articles, solvent extraction of PFOS will be required and a CEN method for this will be developed. The extracted PFOS species are expected to be mainly anionic, but non-ionic species may also be present in the liquid samples.

In practice, samples may well contain several PFOS species and they must all be taken into account for calculating the total PFOS concentration. However, the molecular weights of the various PFOS species in a sample can cover a wide range of values. Aggregation of the amounts of the different species is therefore best achieved by first calculating the corresponding amounts of a reference species, i.e. PFOS acid  $C_8F_{17}SO_3H$ .

### 7.2. Definition of “new” products

Recital 5 to Directive 2006/122/EC provides that: *"This Directive should only restrict new products and should not apply to products already in use or on the second hand market"*.

However, the Directive itself, in adding Entry 52 to Annex 1 of Directive 76/769/EEC, makes no reference to the restrictions applying only to "new" products. It simply provides that PFOS "may not be placed on the market or used" (whether as

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<sup>9</sup> OJ L 372, 27.12.2006, p. 32



a substance, constituent of a preparation, or in semi-finished products/articles) except in the case of those derogations listed in paragraph 3.

Can you explain what Recital 5 means when it says the restrictions should not apply to "new" products? What is meant by "new" products?

Could you also explain what is meant by the fact that the restrictions should not apply to products "already in use". When will a product be taken to be "already in use"? When it is in the supply chain? When it is in the hand of an end-user? After it has actually been used?

Answer: Under Directive 76/769/EEC, there is no definition of placing on the market, neither a definition of products nor articles. Recital 5 in Directive 2006/122/EC gives an indication of the intention of the legislator to restrict the placing on the market of "*new products*" only and not of "*products already in use or on the second hand market*".

The Annex of Directive 2006/122/EC refers to the term "articles" instead of "products".

One can conclude from this, that under Directive 2006/122/EEC articles containing PFOS which are already in use or which are placed on the second hand market before 27 June 2008 are not covered by the restriction. Furthermore an article remains "new" until it leaves the supply chain. Once an article has left the supply chain, it is "in use". An article is on the second hand market if it is offered for sale after it has been "in use".

### **7.3. Semi-finished products**

The question is how Directive 2006/122/EC should be read. Should it be read that PFOS may not be placed on the market:

(1) in "*semi-finished products*" or "*semi-finished articles*",

or on the other hand

(2) in "*semi-finished products*" or "*articles*"?

The way the Directive is drafted, with no comma before the words "or articles", could suggest that the term "semi-finished" applies both to the words "products" and "articles". Indeed, this seems to be how some entities are interpreting it. But some Member States interpret the phrase according to option 2 above.

Answer: It is proposed to interpret and apply this restriction as indicated in the second paragraph: PFOS may not be placed on the market in "semi-finished products" or "articles".

### **7.4. Structurally and micro-structurally distinct parts**

Could you advise the definition of this term found in Annex 2 "the mass of structurally or micro-structurally distinct part"?

Answer: Directive 2006/122/EC (PFOS) places various limits on the concentration of PFOS in substances, preparations, articles, semi-finished products, textiles and coated materials in order to protect the environment. For example:

“(2) May not be placed on the market in semi-finished products or articles, or parts thereof, if the concentration of PFOS is equal to or higher than 0,1 % by mass calculated with reference to the mass of **structurally or microstructurally distinct parts** that contain PFOS or, for textiles or other coated materials, if the amount of PFOS is equal to or higher than  $1 \bullet \text{g/m}^2$  of the coated material.”

One of the principal uses of PFOS in articles, semi-finished products, textiles and coated materials is in surface coatings. Risk reduction measures must therefore target the release of PFOS to the environment from surface coating, either during use or at the end of the service life. This is to be achieved by limiting the concentration of PFOS in such layers, which may be invisible to the naked eye, and can be seen only with the aid of a microscope. It follows that the limit on the concentration of PFOS in coated articles should not be calculated in relation to the entire article, but rather to that part of the article that contains the PFOS.

The terms “*structurally or microstructurally distinct part*” were introduced as a generic way of referring to the part of the article that contains PFOS, and which is intended to avoid uncertainties that might arise by referring simply to, for example, “*articles or parts thereof*”.

#### PFOS in small parts

For example, a car is an article, but an electronic item in a car – e.g. the radio - can arguably be considered to be either an article in its own right, or to be a part of the car. Furthermore, an integrated circuit used in a car radio is a part of an article when installed in the radio, but the same integrated circuit was an article in its own right when first placed on the market. Clearly, none of these distinctions is of any relevance to the release of PFOS into the environment. What is important is the concentration of PFOS in the integrated circuit. The integrated circuit can be extracted from the radio, so it is a **structurally distinct part**. The PFOS concentration should therefore be calculated with reference to the mass of the smallest structurally distinct part i.e. to the mass of the integrated circuit, not to the mass of the radio, nor to the mass of the car.

#### PFOS in coatings other than textiles

The above considerations also apply to PFOS in coatings as to PFOS in small parts. However, the coatings are not structurally distinct in the sense that they cannot be easily separated from the substrate. Nevertheless, they are, **microstructurally distinct** in the sense that they can be identified when a cross-section of the coated surface is viewed through a microscope.

#### PFOS in textiles

Coatings on textiles usually concern mainly the surface fibres. Each of the surface fibres could be considered either to be a **structurally distinct part**, or the coating on each fibre could be considered to be a **microstructurally distinct part**, as described above. However, analysis for control purposes using either of those two approaches would be difficult to achieve in practice. The analysis is therefore simplified by calculating the concentration per square meter using sampling, extraction and analysis methods developed by CEN.

**8. DIRECTIVE 98/48/EC ON AEROSOL GENERATORS FOR ENTERTAINMENT AND DECORATIVE PURPOSES (ENTRY 41 OF ANNEX I, DIRECTIVE 76/769/EEC)**

Directive 98/48/EC<sup>10</sup> (Entry 41 of Annex I to Directive 76/769/EEC) prohibits the use of flammable, highly flammable or extremely flammable substances in “aerosol generators placed on the market for the general public for entertainment and decorative purposes”.

A question was raised whether aerosol generators containing coloured hairsprays and glitter for the body and sold to the general public are restricted under this Directive.

Directive 98/48/EC establishes a non-exhaustive list of examples of products that are covered by the restriction. These examples are all products to be used for decoration of venues of festivities/parties and for use during parties. None of these examples are cosmetic products.

Cosmetic products are covered under Directive 76/768/EEC<sup>11</sup>. Coloured hair sprays and body glitter enter in the definition of cosmetic products as they are intended “to be placed in contact with an external part of the human body” with a view to “changing its appearance”. They have a similar use as the more classical cosmetic products and such as normal hair sprays and should not be considered as having an entertainment purpose.

For these reason it is considered that Directive 94/48/CE does not cover aerosols dispensers containing cosmetic products which are also covered by Directive 76/768/EEC.

Moreover on 1st June 2009 Directive 76/769/EEC will be replaced by Title VIII and Annex XVII of REACH<sup>12</sup>. Article 67 de REACH excludes cosmetics products from the scope of the restrictions when the restriction is targeting a risk for human health. This restriction on aerosol dispensers is entirely linked with human health.

Conclusion: The restriction in Entry 41 of Annex I to Directive 76/769/EEC, prohibiting the use of flammable, highly flammable or extremely flammable substances in “aerosol generators placed on the market for the general public for entertainment and decorative purposes” does not cover aerosol dispensers which contain cosmetic products.

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<sup>10</sup> OJ L 331, 21.12.1994, p.7

<sup>11</sup> OJ L 262, 27.9.1976, p.169

<sup>12</sup> JO L 396, 30.12.2006, p.1

**9. DIRECTIVES 94/27/EC<sup>13</sup> AND 2004/96/EC<sup>14</sup> ON NICKEL AND ITS COMPOUNDS (ENTRY 28 OF ANNEX I, DIRECTIVE 76/769/EEC)**

The question was raised whether mobile telephones are covered by the restriction set in Directive 76/769/EEC, Annex I, entry 28 on nickel.

In accordance with entry 28 of Annex I to Directive 76/769/EEC nickel may not be used “in products intended to come into direct and prolonged contact with the skin, if the rate of nickel release from the parts of these products coming into direct and prolonged contact with the skin is greater than 0.5 µg/cm<sup>2</sup>/week”.

The aim of this restriction to protect consumers against nickel allergy which may be caused by prolonged contact of the skin with nickel-releasing articles that come into direct and prolonged contact with the skin such as jewellery, buttons, tighteners, zips and rivets in items of clothing.

It has emerged that some mobile telephones contain nickel in surface material and that consumers are at risk of developing eczema through skin contact with the mobile telephone.

As mobile telephones are clearly intended to come into direct contact with the skin, and as they are used on a daily basis often for prolonged periods of time, it is considered that mobile telephones fulfil the condition of “direct and prolonged contact with the skin”. Therefore mobile telephones are covered by the restriction and should comply with the conditions set by Directive 76/769/EC in entry 28 of Annex I.

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<sup>13</sup> OJ L 188, 22.7.1994, p. 1.

<sup>14</sup> OJ L 301, 29.8.2004, p. 51.