COMMISSION DECISION

of 21 June 2007

establishing the ecological criteria for the award of the Community eco-label to soaps, shampoos and hair conditioners

(notified under document number C(2007) 3127)

(Text with EEA relevance)

(2007/506/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1980/2000 of the European Parliament and of the Council of 17 July 2000 on a revised Community eco-label award scheme [1], and in particular the second subparagraph of Article 6(1) thereof,

After consulting the European Union Eco-Labelling Board,

Whereas:

(1) Under Regulation (EC) No 1980/2000 the Community eco-label may be awarded to a product possessing characteristics which enable it to contribute significantly to improvements in relation to key environmental aspects.

(2) Regulation (EC) No 1980/2000 provides that specific eco-label criteria, drawn up on the basis of the criteria drafted by the European Union Eco-Labelling Board, are to be established according to product groups.

(3) The ecological criteria, as well as the related assessment and verification requirements, should be valid for a period of three years.

(4) The measures provided for in this Decision are in accordance with the opinion of the Committee instituted by Article 17 of Regulation (EC) No 1980/2000,

HAS ADOPTED THIS DECISION:

Article 1

The product group 'soaps, shampoos and hair-conditioners' shall comprise any rinse-off substance and preparation intended to be placed in contact with the epidermis and the hair system with a view exclusively or mainly to cleaning them. That product group shall also comprise any rinse-off substance and preparation intended to be placed in contact with the hair system with a view to improve the condition of the hair (hair conditioners).

The product group shall cover products for both private and professional use.

The product group shall not cover products that are specifically marketed for disinfecting or anti-bacterial use.

Article 2

1. In order to be awarded the Community eco-label for soaps, shampoos and hair-conditioners, under Regulation (EC) No 1980/2000, a product must fall within the product group 'soaps, shampoos, and hair-conditioners' and must comply with the ecological criteria set out in the Annex to this Decision.

2. This Regulation applies without prejudice to Council Directive 76/768/EEC of 27 July 1976 on the application of the laws of the Member States relating to cosmetic products [2].

Article 3

For administrative purposes the product group code number assigned to this product group shall be '30'.

Article 4

The ecological criteria for the product group 'soaps, shampoos and hair-conditioners' as well as the related assessment and verification requirements shall be valid until for three years from the date of notification of this Decision.

Article 5

This Decision is addressed to the Member States.

Done at Brussels, 21 June 2007.

For the Commission

Stavros DIMAS

Member of the Commission

[1] OJ L 237, 21.9.2000, p. 1.

[2] OJ L 262, 27.9.1976, p. 169. Directive as last amended by Commission Directive 2007/22/EC (OJ L 101, 18.4.2007, p. 11).

ANNEX

FRAMEWORK

The aims of the criteria

These criteria aim in particular at promoting:

— the reduction of water pollution both by limiting the quantity of potentially harmful ingredients and the total toxic load of the product,

— the minimisation of waste production by reducing the amount of packaging,

— the reduction or prevention of potential risks for the environment related to the use of hazardous substances.

Additionally, the criteria enhance the consumers' environmental awareness. The criteria are set at levels that promote the labelling of soaps and shampoos that have a lower environmental load than the market average.

Assessment and verification requirements

The specific assessment and verification requirements are indicated within each of the ecological criteria later in this Annex.

Where appropriate, test methods other than those indicated for each criterion may be used if the Competent Body assessing the application accepts their equivalence.

Where possible, the testing should be performed by laboratories that meet the general requirements of EN ISO 17025 or equivalent.

Where no tests are mentioned, or are mentioned as being for use in verification or monitoring, Competent Bodies should rely as appropriate on declarations and documentation provided by the applicant and/or independent verification.

Where appropriate, Competent Bodies may require supporting documentation and may carry out independent verification, including on-site visits to production sites.

Where the applicant is required to provide declarations, documentation, test reports, or other evidence to show compliance with the criteria, it is understood that these may originate from the applicant and/or his supplier(s) and/or their supplier(s), et cetera, as appropriate.

Where ingredients are referred to, this includes substances and preparations.

The text makes reference to the Detergent Ingredient Database (DID list), which contains many of the most widely used ingredients in soap and shampoo formulations. Part A of DID list shall be used for deriving the data for the calculations of CDV and for the assessment of the biodegradability of surfactants. Applicants may only present their own data if the list does not give a value, except for perfumes (including biological additives) and dyes.

For ingredients that are not included in the part A of DID list, the applicant shall, under his own responsibility, apply the procedure as described in part B of the DID list.

The most up to date version of the DID list available at the time of application should be used, and will be available from the Competent Body dealing with the application. The list can also be found at the following web address: http://ec.europa.eu/environment/ecolabel/product/pg_did_list_en.htm

For ingredients which are not listed in the DID-list, the applicant may use an approach to provide the necessary documentation of anaerobic biodegradability described in Appendix II.

For the purposes of these criteria 'surfactant' means any organic substance and/or preparation used in detergents, which has surface-active properties and which consists of one or more hydrophilic and one or more hydrophobic groups of such a nature and size that it is capable of reducing the surface tension of water, and of forming spreading or adsorption mono-layers at the water, air interface, and of forming emulsions and/or micro-emulsions and/or micelles, and of adsorption at water-solid interfaces.

The Competent Bodies are recommended to take into account the implementation of recognised environmental management schemes, such as EMAS or ISO 14001, when assessing applications and monitoring compliance with the criteria in this Annex.

(Note: It is not required to implement such management schemes in order to apply for the eco-label or to comply with the criteria of the eco-label.)

FUNCTIONAL UNIT

The Functional unit is 1 gram of 'Active Content (AC)'. AC is defined as the weight of organic ingredients in the product. It must be calculated on the basis of the complete formulation of the product. Rubbing/abrasive agents in hand cleaning agents are not included in the calculation of AC.

Assessment and verification:

The following information shall be provided:

— technical description of the contents of the product (complete formulation), including known pollutants. The description must include a specification of quantities, CAS-No. and INCI designations;

— a specification of the function of each individual ingredient in the product, stating the purpose for which the component is added;

— safety data sheet/Product data sheet with the names of the suppliers of all ingredients.

ECOLOGICAL CRITERIA

1. **Toxicity to aquatic organisms**

The critical dilution volume toxicity (CDV) is calculated for each ingredient (i) and for the whole product using the following equation:

CDV(ingredient i)= weight (i) × DF(i) × 1 000/TF chronic (i)

CDV = Σ CDV(ingredient i)

where weight (i) is the weight of the ingredient (in grams) per functional unit. DF (i) is the degradation factor and TF chronic (i) is the toxicity factor of the ingredient (in milligrams/litre).

The values of DF and TF chronic shall be as given in the Detergent Ingredient Database list-part A (DID list-part A). If the ingredient in question is not included in the DID list-part A, the applicant shall estimate the values following the approach described in the DID list-part B. The CDV(tox) is summed for each ingredient, making the CDV for the product.

The total CDV of the product must not exceed the following values:

Shampoo, shower products and liquid soaps: 20 000 l/g AC

Solid soaps: 3 500 l/g AC

Conditioner: 30 000 l/g AC

Assessment and verification:

The exact formulation of the product must be given. Furthermore the exact chemical description of ingredients (e.g. identification according to IUPAC, CAS-no, INCI-name, purity, type and percentage of impurities, additives; for mixtures e.g. surfactants: DID-number, composition and spectrum of homologue distribution, isomers and trade names).

Copies of the Material Safety Data Sheet of all ingredients must be given.

The calculation of CDV and the related score shall be provided in detail. For all ingredients included in the DID-list the appropriate ingredient number must be given. For ingredients not included in the DID-list, test results and test methods for eco-toxicity (long-term effects (NOEC data) on fish, Daphnia magna, and algae), biodegradation and bioaccumulation shall be submitted. The reference for the relevant tests shall be the appropriate Annexes of Council Directive 67/548/EEC [1].

[1] OJ 196, 16.8.1967, p. 1.

2. **Environmentally harmful products**

The product must not fulfil the requirements for classification for any of the following risk phrases according to Directive 67/548/EEC:

N, R50/53: $(W_{R50/53}/25\ \%) \geq 1$

N, R51/53: $((W_{R50/53}/2{,}5\ \%) + (W_{R51/53}/25\ \%)) \geq 1$

R52/53: $((W_{R50/53}/0{,}25\ \%) + (W_{R51/53}/2.5\ \%) + (W_{R52/53}/25\ \%)) \geq 1$

$W_{R50/53}$ = weight percent of ingredients that may be classified as R50/53.

$W_{R51/53}$ = weight percent of ingredients that may be classified as R51/53.

$W_{R52/53}$ = weight percent of ingredients that may be classified as R52/53.

Rubbing/abrasive agents in hand cleaning agents are not included.

Assessment and verification:

Test results for aquatic toxicity and biodegradation of relevant ingredients must be given, according to part 2, testing methods, of Directive 67/548/EEC. Toxicity results from the DID-list cannot be used since these are median values and are not in compliance with Directive 67/548/EEC.

If the lowest toxicity is ≤10 mg/l, then test results for potential bioaccumulation (Bio-concentration factor (BCF) or logKow) must also be given. If no results are available the ingredient will be regarded as R 50/53. The following exceptions apply:

Fragrances and dyes: R 51/53.

Biological additives, i.e. plant extracts and other ingredients isolated from plants or animals and with little or no chemical alteration: R 51/53.

Any ingredient (substance or preparation) whose concentration exceeds 0,010 % by weight of the final product shall be considered regardless of if it is used in the formulation as a single substance or as a constituent of preparation. This also applies to each ingredient of any preparation used in the formulation that exceeds 0,010 % by weight of the final product.

3. **Aerobic biodegradability**

(a) *Aerobic biodegradability of surfactants*

Each surfactant used in the product shall be readily biodegradable.

Assessment and verification:

The exact formulation of the product as well as a description of the function of each ingredient shall be provided to the competent body.

The DID list-part A indicates whether a specific surfactant is aerobically biodegradable or not (the surfactants with an entry of 'R' in the column on aerobic biodegradability are readily biodegradable). For surfactants which are not included in the DID list-part A, the relevant information from literature or other sources, or appropriate test results, showing that they are aerobically biodegradable shall be provided. The tests for ready biodegradability shall be as referred to in Regulation (EC) No 648/2004 of the European Parliament and of the Council [1].

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

Surfactants shall be considered as readily biodegradable if the level of biodegradability (mineralisation) measured according to one of the five following tests is at least 60 % within 28 days: CO_2 headspace test (OECD 310), Carbon dioxide (CO_2) Evolution Modified Sturm test (OECD 301B; Council Directive 67/548/EEC Annex V.C.4-C), Closed Bottle test (OECD 301D; Council Directive 67/548/EEC Annex V.C.4-E), Manometric Respirometry (OECD 301F; Council Directive 67/548/EEC Annex V.C.4-D), or MITI (I) test (OECD 301C; Council Directive 67/548/EEC Annex V.C.4-D), or their equivalent ISO tests. Depending on the physical characteristics of the surfactant, one of the following tests might be used to confirm ready biodegradability, if the level of biodegradability is at least 70 % within 28 days: Dissolved Organic Carbon DOC Die-Away (OECD 301A; Council Directive 67/548/EEC Annex V.C.4-A) or Modified OECD Screening DOC Die-Away (OECD 301E, Council Directive 67/548/EEC Annex V.C.4-B), or their equivalent ISO tests. The applicability of test methods based on measurement of dissolved organic carbon needs to be appropriately justified as set out in Regulation (EC) No 648/2004.

All ingredients (substances or preparations) that exceed 0,010 % by weight of the final product shall be considered. This includes also each ingredient of any preparation used in the formulation that exceeds 0,010 % by weight of the final product.

(b) *Aerobic biodegradability of non-surfactants ($aNBDO_{non\text{-}surf}$)*

The content of ingredients that are not readily biodegradable (or have not been tested for aerobic biodegradability) must not exceed the following levels:

Shampoo, shower products and liquid soaps: 30 mg/g AC

Solid soaps: 15 mg/g AC

Conditioner: 50 mg/g AC

Rubbing/abrasive agents in hand cleaning agents are not included.

All ingredients (substances or preparations) exceeding 0,010 % by weight of the final product shall be considered. This includes also each ingredient of any preparation used in the formulation exceeding 0,010 % by weight of the final product.

Assessment and verification:

Identical to requirement 3(a).

4. **Anaerobic Biodegradability ($annbdo_{tox}$)**

The content of ingredients that are not anaerobically degradable (or have not been tested for anaerobic biodegradability) and have a lowest acute toxicity LC_{50} or EC_{50} < 100 mg/l (similar to the classification limit for R52 in Directive 67/548/EEC must not exceed the following levels:

Shampoo, shower products and liquid soaps: 25 mg/g AC

Solid soaps: 15 mg/g AC

Conditioner: 50 mg/g AC

Rubbing/abrasive agents in hand cleaning agents are not included.

Assessment and verification:

The DID list-part A indicates whether a specific ingredient is anaerobically biodegradable or not (the surfactants with an entry of 'Y' in the column on anaerobic biodegradability are biodegradable under anaerobic conditions). For ingredients which are not included in the DID list-part A or which are included with an entry '0' the relevant information from literature or other sources, or appropriate test results, showing that they are anaerobically biodegradable shall be provided. The reference test for anaerobic biodegradability shall be OECD 311, ISO 11734, ECETOC No 28 (June 1988) or an equivalent test method, with the requirement of a minimum of 60 % ultimate biodegradability under anaerobic conditions. Test methods simulating the conditions in a relevant anaerobic environment may also be used to document that 60 % ultimate biodegradability has been attained under anaerobic conditions (see Appendix II).

If several toxicity results are available the lowest validated value shall be used. The toxicity values on the DID-list are median values that cannot be used for this purpose.

All ingredients (substances or preparations) exceeding 0,010 % by weight of the final product shall be considered. This includes also each ingredient of any preparation used in the formulation exceeding 0,010 % by weight of the final product.

5. **Fragrances**

Any ingredient added to the product as a fragrance must have been manufactured, handled and applied in accordance with the code of practice of the International Fragrance Association.

Assessment and verification:

A declaration of compliance with this criterion shall be provided to the competent body by the fragrance manufacturer.

6. **Dyes or colouring agents**

Organic dyes or colouring agents must not be potentially bio-accumulating. In the case of colouring agents approved for use in foodstuffs it is not necessary to submit documentation of bioaccumulation potential. In this context, a colouring agent or dye is considered to be potentially bio-accumulating if the experimentally determined BCF is > 100. If no BCF (Bio-concentration Factor) test result is available, bioaccumulation may be demonstrated by the log Pow (log octanol/water partition coefficient). If logPow is > 3,0 the colouring agent or dye is considered as potentially bio-accumulating.

Assessment and verification:

The manufacturer must submit a test report or a published test result together with a reference to the publication. If the dye or colouring agent has been approved for use in foodstuffs a declaration from the manufacturer stating this fact must be submitted.

7. **Biocides**

(a) The product may only include biocides in order to preserve the product, and in the appropriate dosage for this purpose alone. This does not refer to surfactants which may also have biocidal properties.

Assessment and verification:

Copies of the material safety data sheets of any preservatives added shall be provided, together with information on their exact concentration in the product. The manufacturer or supplier of the preservatives shall provide information on the dosage necessary to preserve the product.

(b) Biocides, either as part of the formulation or as part of any preparation included in the formulation, that are used to preserve the product and that fulfil the criteria for classification with R50-53 or R51-53 risk phrases, in accordance with Directive 67/548/EEC or Directive 1999/45/EC of the European Parliament and of the Council [1], are only permitted if they are not potentially bio-accumulating. In this context, a biocide is considered to be potentially bio-accumulating if the bio-concentration factor (BCF) is > 100 or, if no BCF-results are available, the log Pow (log octanol/water partition coefficient) is > 3,0.

Assessment and verification:

Test results for aquatic toxicity must be supplied. If the lowest toxicity is ≤ 10 mg/l a test result for ready biodegradability must be given. If the biocide is not readily biodegradable test results for bioaccumulation potential must be given. Test procedures are as specified in Directive 67/548/EEC.

(c) Preservatives must not release substances that are classified in accordance with the criterion 8a.

Assessment and verification:

A completed and signed declaration from the biocide manufacturer.

[1] OJ L 200, 30.7.1999, p. 1.

8. **Environmentally hazardous ingredients**

The requirements concern all ingredients (substances or preparations) exceeding 0,010 % by weight of the final product. This includes also each ingredient of any preparation used in the formulation exceeding 0,010 % by weight of the final product.

(a) *Classified ingredients*

No constituent substance must be classified as carcinogenic (Carc), mutagenic (Mut) or toxic to reproduction (Rep) including rules for self-classification class III.

Assessment and verification:

copies of the material safety data sheets shall be provided for all ingredients (whether substances or preparations). A signed declaration prepared by the manufacturer of ingredients and showing compliance with this criterion shall be provided by the applicant.

(b) *Specified excluded ingredients*

The following ingredients shall not be included in the product, either as part of the formulation or as part of any preparation included in the formulation:

— Alkyl phenol ethoxylates (APEOs) and other alkyl phenol derivatives

— NTA (nitrilo-tri-acetate)

— Boric acid, borates and perborates

— Nitromusks and polycyclic musks

Assessment and verification:

A completed and signed declaration from the manufacturer must be submitted.

(c) *Specified limited ingredients*

Ethylenediaminetetraacetate (EDTA) and its salts and non-readily biodegradable phosphonates may only be added to solid soaps and only to a maximum content of 0,6 mg/g AC.

Assessment and verification:

A completed and signed declaration from the manufacturer must be submitted.

9. **Packaging**

(a) The Weight/Content Relationship (WCR) must be less than 0,30 g of packaging per gram of product, and is calculated as follows.

$$WCR = \sum((W_i + N_i)/(D_i \times r))$$

Where;

W_i = the weight (in grams) of packaging-component i (this applies to both primary or secondary packaging), including any labels.

N_i = the weight (in grams) of the packaging component that comes from virgin material rather than recycled sources (this applies to both primary or secondary packaging). If the packaging component does not contain recycled material then $N_i = W_i$.

D_i = the weight in grams of product that the packaging-component contains.

r = the Return number, i.e. the number of times the packaging-component i is used for the same purpose through a system of return or refill (by default r = 1 if no reuse occurs).

If the packaging is reused r is set to 20 for plastics and 10 for corrugated board unless the applicant can document a higher number.

Assessment and verification:

Presentation of the calculation of WCR.

(b) *Labelling of packaging*

To allow for identification of different parts of the packaging for recycling, plastic parts in the primary packaging must be marked in accordance with DIN 6120, Part 2 or the equivalent. Caps and pumps are exempted from this requirement.

Assessment and verification:

Completed and signed declaration.

Sample of primary packaging.

(c) *Dosage*

The packaging must be designed to make correct dosage easy, e.g. by ensuring that the opening at the top is not too wide.

Assessment and verification:

Description of the dosage device.

(d) The packaging must contain neither additives based on Cadmium or Mercury or compounds with these elements, nor additives that do not fulfil criterion 8.

Assessment and verification:

Declaration from the packaging producer.

10. **Fitness for use**

The product's fitness for use must be demonstrated either through laboratory test(s) or a consumer test.

The test must be in conformity with the guidelines in Appendix I for testing of product efficiency.

Assessment and verification:

Report from a laboratory test or consumer test documenting satisfactory efficiency.

11. **Information appearing on the eco-label**

According to Annex III of Regulation (EC) No 1980/2000, Box 2 of the eco-label shall contain the following text:

'* Minimal impact on aquatic ecosystems

* fulfils strict biodegradability requirements

* limits packaging waste'

Assessment and verification:

The applicant shall provide a sample of the product packaging showing the label, together with a declaration of compliance with this criterion.

Appendix I

Guidelines for performance test

The product's efficiency of performance can be demonstrated either through a laboratory test or a consumer test. If a laboratory test is employed the producer's own test shall be acceptable. The applicant must, however, demonstrate that the test gives a measure of the product's performance.

If a consumer test is employed the following guidelines must be followed:

A consumer test must include as minimum of 10 people. The consumers must be asked about the product's efficiency compared to a market-leading product. The questions to the consumers must cover at least the following aspects:

1. How well does the product perform in comparison with the market-leading product?

2. How easy is it to apply the desired dosage of the product in comparison with the market-leading product?

3. How easy is it to apply the product to the hair and/or skin in comparison with the market-leading product?

At least 80 % of the consumers must be at least as satisfied with the product as with the market-leading product.

Appendix II

Documentation of anaerobic biodegradability

The following approach may be used to provide the necessary documentation on anaerobic biodegradability for any ingredients that are not listed in the DID list.

Apply reasonable extrapolation. Use test results obtained with one raw material to extrapolate the ultimate anaerobic biodegradability of structurally related surfactants. If anaerobic biodegradability has been confirmed for a surfactant (or a group of homologues) according to the DID list, it can be assumed that a similar type of surfactant is also anaerobically biodegradable (for example, C12-15 A 1-3 EO sulphate (DID No 8) is anaerobically biodegradable, and a similar anaerobic biodegradability may also be assumed for C12-15 A 6 EO sulphate). If anaerobic biodegradability has been confirmed for a surfactant by use of an appropriate test method, it can be assumed that a similar type of surfactant is also anaerobically biodegradable (for example, literature data confirming the anaerobic biodegradability of surfactants belonging to the group alkyl ester ammonium salts may be used as documentation for a similar anaerobic biodegradability of other quaternary ammonium salts containing ester-linkages in the alkyl chain(s)).

Perform screening test for anaerobic biodegradability. If new testing is necessary, perform a screening test by use of OECD 311, ISO 11734, ECETOC No 28 (June 1988) or an equivalent method.

Perform low-dosage biodegradability test. If new testing is necessary, and in the case of experimental problems in the screening test (for example, inhibition due to toxicity of test substance), repeat testing by using a low dosage of surfactant and monitor degradation by 14C measurements or chemical analyses. Testing at low dosages may be performed by use of OECD 308 (24 April 2002) or an equivalent method provided that strict anaerobic conditions are applied. The testing and the interpretation of the test results should be conducted by an independent expert.