

## 7. REVISED CRITERIA PROPOSAL

In order to facilitate amendments and final formulation of the revised criteria for the product group under study, the below chapter presents the legal text of the EC decision revising the existing EU Ecolabel criteria for the product group of “soaps, shampoos and hair conditioners”. The stakeholders are asked to revise this section with particular attention and to submit us with their written comments, if possible, prior to or during the 2nd AHWG meeting.



EUROPEAN COMMISSION

Brussels, XXX  
[...] (2013) XXX draft

### COMMISSION DECISION

of XXX

**revising the ecological criteria for the award of the EU Ecolabel for (selected) Rinse-off  
cosmetic products**

(Text with EEA relevance)

## COMMISSION DECISION

of **XXX**

### **revising the ecological criteria for the award of the EU Ecolabel for (selected) Rinse-off cosmetic products**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel<sup>1</sup>, and in particular Article 8(2) thereof,

After consulting the European Union Eco-labelling Board,

Whereas:

- (1) Under Regulation (EC) No 66/2010, the EU Ecolabel may be awarded to those products with a reduced environmental impact during their entire life cycle.
- (2) Regulation (EC) No 66/2010 provides that specific EU Ecolabel criteria are to be established according to product groups.
- (3) Since the consumption of rinse-off products contributes to environmental impacts, in particular regarding the toxicity to the aquatic environment, but also related to the consumption of raw materials for chemical compounds and packaging production, and due to very large consumption volume of these products in the EU, it is appropriate to revise and keep the EU Ecolabel criteria for this product group.
- (4) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 16 of Regulation (EC) No 66/2010.

HAS ADOPTED THIS DECISION:

#### *Article 1*

The product group “Rinse-off cosmetic products” shall comprise soaps, shampoos, hair conditioners and pre-shaving preparations, i.e. “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) and any rinse-off substance and preparation intended to be placed in contact with the epidermis with a view to protect it and to lubricate the hair before shaving (pre-shaving formulations)”.

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<sup>1</sup> OJ L 27, 30.1.2010, p. 1-19

Further, depending on the final decision on the scope extension, the following statement can be added:

"Shampoos for animals are eligible for EU Ecolabel"

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*

For the purpose of this Decision, the following definitions shall apply: ... [To be completed, if needed...]

#### *Article 3*

In order to be awarded the EU Ecolabel under Regulation (EC) No 66/2010, a product shall fall within the product group "Rinse-off cosmetic products" as defined in Article 1 of this Decision and shall comply with the criteria as well as the related assessment and verification requirements set out in the Annex to this Decision.

#### *Article 4*

The criteria for the product group "Rinse-off cosmetic products", as well as the related assessment and verification requirements, shall be valid for **three** years from the date of adoption of this Decision [insert date - the date of adoption of this Decision].

#### *Article 5*

For administrative purposes, the code number assigned to the product group "Rinse-off cosmetic products" shall be **"x"**.

#### *Article 6*

Decision 2007/506/EC is repealed.

#### *Article 7*

1. By derogation from Article 6, applications for the EU Ecolabel for products falling within the product group 'soaps, shampoos and hair conditioners' submitted before the date of adoption of this Decision shall be evaluated in accordance with the conditions laid down in Decision 2007/506/EC.

2. Applications for the EU Ecolabel for products falling within the product group 'Rinse-off cosmetic products' submitted from the date of adoption of this Decision but by **xxxxx** at the latest may be based either on the criteria set out in Decision 2007/506/EC or on the criteria set out in this Decision.

Those applications shall be evaluated in accordance with the criteria on which they are based.

3. Where the Ecolabel is awarded on the basis of an application evaluated in accordance with the criteria set out in Decision 2007/506/EC, that Ecolabel may be used for 12 months from the date of adoption of this Decision.

*Article 8*

This Decision is addressed to the Member States.

Done at Brussels,

*For the Commission  
Janez POTOČNIK  
Member of the Commission*

DRAFT

## ANNEX

### FRAMEWORK

#### **The aims of the criteria**

The criteria aim, in particular, at promoting products that have reduced impact on aquatic ecosystems, contain limited amount of substances of concern and contribute to the minimisation of waste production by reducing the amount of packaging. Additionally, the criteria enhance the consumers' environmental awareness.

### CRITERIA

Criteria are set for each of the following aspects:

1. Toxicity to aquatic organisms: Critical Dilution Volume (CDV)
2. Biodegradability
3. Excluded or limited substances and mixtures
4. Packaging requirements
5. Sustainable sourcing of palm oil
6. Fitness for use
7. User information – Information appearing on the packaging

#### **(1) Assessment and verification**

##### a) Requirements

The specific assessment and verification requirements are indicated within each criterion.

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

Where appropriate, test methods other than those indicated for each criterion may be used if their equivalence is accepted by the competent body assessing the application.

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

Where appropriate, competent bodies may require supporting documentation and may carry out independent verifications.

Appendix I makes reference to the detergent ingredient database (DID list) which contains the most widely used ingoing substances used in detergent and cosmetics formulations. It shall be used for deriving the data for the calculations of the Critical Dilution Volume (CDV) and for the assessment of the biodegradability of the ingoing substances. For substances not present on the DID list, guidance is given on how to calculate or extrapolate the relevant data. The latest version of the DID list is available from the EU Ecolabel website or via the websites of the individual competent bodies.

b) Measurement thresholds

Unless indicated otherwise in the criteria, the compliance with the ecological criteria is required for substances intentionally added, as well as for by-products and impurities from raw materials, the concentration of which equals or exceeds 0.010 % by weight of final formulation.

For preservatives and colorants compliance with the criteria is required regardless of their concentration.

Substances in the product meeting the threshold limit as listed above are hereby referred to as “Ingoing substances”.

**(2) Functional unit and reference flow**

The functional unit refers to washing actions using the product. The reference flow is defined as the weight of the quantity of product containing 1 gram of ‘Active Content (AC)’. AC is defined as the sum of organic ingoing substances in the product (expressed in grams). It must be calculated on the basis of the complete formulation of the product.

Water and rubbing/abrasive agents in hand cleaning agents are not included in the calculation of AC.

**Requirements related to assessment and verification**

The following information shall be provided:

The full formulation indicating trade name, chemical name, CAS no. and INCI designations, DID no.\*, the ingoing quantity including and excluding water, the function and the form of all organic and inorganic ingoing substances and ingredients (regardless of concentration) in the product must be submitted to the competent body.

Safety data sheets for each ingoing substance shall be submitted to the competent body in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council<sup>2</sup>.

\* DID no. is the number of the ingoing substance on the DID list (“Detergent Ingredient Database” list), and is used in determining compliance with Criteria 1 and 2.

Part A and Part B of the DID list can be found on the EU Ecolabel website:

[http://ec.europa.eu/environment/ecolabel/documents/did\\_list/didlist\\_part\\_a\\_en.pdf](http://ec.europa.eu/environment/ecolabel/documents/did_list/didlist_part_a_en.pdf)

[http://ec.europa.eu/environment/ecolabel/documents/did\\_list/didlist\\_part\\_b\\_en.pdf](http://ec.europa.eu/environment/ecolabel/documents/did_list/didlist_part_b_en.pdf)

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<sup>2</sup> OJ L 396, 30.12.2006

## EU ECOLABEL CRITERIA

### Criterion 1 - Toxicity to aquatic organisms: Critical Dilution Volume (CDV)

The critical dilution volume toxicity (CDV) is calculated for each ingoing organic substance and for the whole product using the following equations:

$$\text{CDV(ingoing organic substance i)} = \text{weight (i)} \times \text{DF(i)} \times 1\,000/\text{TF chronic (i)}$$

$$\text{CDV} = \Sigma \text{CDV(ingoing organic substance i)}$$

Where:

weight (i) - is the weight of the **ingoing organic substance** (in grams) per functional unit.

DF (i) - is the degradation factor

TF chronic (i) - is the toxicity factor of the **ingoing organic substance** (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 **ingoing organic substance** 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 and attaching the associated documentation. The CDV is summed for each ingredient, making the CDV for the product.

The total CDV of the product shall not exceed the following limits:

Product	CDV (l/g AC)
Shampoo, shower products and liquid soaps	18 000
Solid soaps	3 000
Conditioners	(Discussion point)

To discuss after finalising the discussion on the scope extension:

Shaving foams, shaving gels, shaving creams: xxx l/g AC (Discussion point)

Shaving soaps: xxx l/g AC (Discussion point)

Shampoos for animals; and limits for: xxx l/g AC (Discussion point)

*Assessment and verification: the applicant shall provide the calculation of the CDV of the product. A spreadsheet for calculation of the CDV value is available on the EU Ecolabel website.*

## Criterion 2 - Biodegradability

### a) *Biodegradability of surfactants*

All surfactants must be biodegradable under aerobic conditions.

All non-ionic and cationic surfactants must also be biodegradable under anaerobic conditions.

### b) *Biodegradability of organic substances*

#### (i) *Aerobic biodegradability of non-surfactants (aNBDOnon-surf)*

The content of all organic ingoing substances in the product that are aerobically non-biodegradable (not readily biodegradable) or have not been tested for aerobic biodegradability shall not exceed the following limits:

Product	aNBDOnon-surf (mg/g AC)
Shampoo, shower products and liquid soaps	20
Solid soaps	10
Conditioners	45

To discuss after finalising the discussion on the scope extension:

Shaving foams, shaving gels, shaving creams: xxx mg/g AC (Discussion point)

Shaving soaps: xxx mg/g AC (Discussion point)

Shampoos for animals; and limits for: xxx mg/g AC (Discussion point)

Rubbing/abrasive agents in hand cleaning agents are not included in the calculation of the aNBDOnon-surf.

#### (ii) *Anaerobic biodegradability (anNBDO)*

The content of all ingoing organic substances in the product that are not biodegradable under anaerobic conditions shall not exceed the following limits:

Product	anNBDO (mg/g AC)
Shampoo, shower products and liquid soaps	20
Solid soaps	10
Conditioners	45

To discuss after finalising the discussion on the scope extension:

Shaving foams, shaving gels, shaving creams: xxx mg/g AC (Discussion point)

Shaving soaps: xxx mg/g AC (Discussion point)

Shampoos for animals: xxx mg/g AC (Discussion point)



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

**Assessment and verification:** *the applicant shall provide documentation for the degradability of surfactants as well as the calculation of  $aNBDO_{\text{non-surf}}$  and  $anNBDO$  for the product. A spreadsheet for use in calculating  $aNBDO_{\text{non-surf}}$  and  $anNBDO$  values is available on the EU Ecolabel website.*

*For both surfactants and  $aNBDO_{\text{non-surf}}$  and  $anNBDO$  values reference should be done to the DID List. For ingoing substances which are not included in the DID list, the relevant information from literature or other sources, or appropriate test results, showing that they are aerobically and anaerobically biodegradable shall be provided as described in Appendix I.*

*In the absence of documentation in accordance with the above requirements, a substance other than a surfactant may be exempted from the requirement for anaerobic degradability if one of the following three alternatives is fulfilled:*

- 1. Readily degradable and has low adsorption ( $A < 25\%$ ) or*
- 2. Readily degradable and has high desorption ( $D > 75\%$ ) or*
- 3. Readily degradable and non-bioaccumulating.*

*Testing for adsorption/desorption may be conducted in accordance with OECD guidelines 106.*

### **Criterion 3 - Excluded or limited substances and mixtures**

#### **a) Specified limited and/or excluded ingoing substances**

The following ingoing substances shall not be included in the product, neither as part of the formulation nor as part of any mixture 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
- Phthalates: Bis(2-methoxyethyl) phthalate, diisobutyl phthalate (DIBP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and bis (2-ethylhexyl)phthalate (DEHP).
- D4 (octamethylcyclotetrasiloxane)
- Butylated Hydroxi Toluene (BHT)
- The following preservatives: triclosan, parabens (Ethyl-, methyl-, propyl- and butyl-parabens), formaldehyde and formaldehyde releasers (bronopol, 5-bromo-5-nitro-1,3-dioxane, sodium hydroxyl methyl glycinate (SHMG), DMDM hydantoin, diazolidinyl urea and imidazolidinyl urea).
- The following fragrances: Cinnamal, Cinnamyl Alcohol, Citral, Coumarin, Eugenol, Farnesol, Geraniol, Hydroxycitronellal, Hydroxyisohexyl 3-cyclohexene carboxaldehyde (HICC), Isoeugenol, Limonene (oxidised), Linalool (oxidised), Chloroantranol and Atranol.

- 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:** the applicant shall provide a completed and signed declaration of compliance supported by declarations from manufacturers of substances, as appropriate, confirming that the listed substances have not been included in the product.

**b) Hazardous substances and mixtures**

According to the Article 6(6) of Regulation (EC) No 66/2010 on the EU Ecolabel, the product or any component of it shall not contain substances meeting criteria for classification with the hazard statements or risk phrases specified below in accordance with Regulation (EC) No 1272/2008 or Directive 67/548/EC nor shall it contain substances referred to in Article 57 of Regulation (EC) No 1907/2006. The risk phrases below generally refer to substances. However, if information on substances cannot be obtained, the classification rules for mixtures apply.

**List of hazard statements and risk phrases:**

<b>Hazard Statement<sup>1</sup></b>	<b>Risk Phrase<sup>2</sup></b>
H300 Fatal if swallowed	R28
H301 Toxic if swallowed	R25
H304 May be fatal if swallowed and enters airways	R65
H310 Fatal in contact with skin	R27
H311 Toxic in contact with skin	R24
H330 Fatal if inhaled	R23/26
H331 Toxic if inhaled	R23
H340 May cause genetic defects	R46
H341 Suspected of causing genetic defects	R68
H350 May cause cancer	R45
H350i May cause cancer by inhalation	R49
H351 Suspected of causing cancer	R40
H360F May damage fertility	R60
H360D May damage the unborn child	R61
H360FD May damage fertility. May damage the unborn child	R60/61/60-61
H360Fd May damage fertility. Suspected of damaging the unborn child	R60/63
H360Df May damage the unborn child. Suspected of damaging fertility	R61/62
H361f Suspected of damaging fertility	R62
H361d Suspected of damaging the unborn child	R63
H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.	R62-63
H362 May cause harm to breast fed children	R64
H370 Causes damage to organs	R39/23/24/25/26/27/28

H371 May cause damage to organs	R68/20/21/22
H372 Causes damage to organs through prolonged or repeated exposure	R48/25/24/23
H373 May cause damage to organs through prolonged or repeated exposure	R48/20/21/22
H400 Very toxic to aquatic life	R50
H410 Very toxic to aquatic life with long-lasting effects	R50-53
H411 Toxic to aquatic life with long-lasting effects	R51-53
H412 Harmful to aquatic life with long-lasting effects	R52-53
H413 May cause long-lasting harmful effects to aquatic life	R53
Sensitising substances	
H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled	R42
H317: May cause allergic skin reaction	R43

<sup>1</sup> Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

<sup>2</sup> Directive 67/548/EEC with adjustment to REACH according to Directive 2006/121/EC and Directive 1999/45/EC as amended

Note that this criterion also applies to known degradation products such as formaldehyde releasers.

Substances or mixtures which change their properties through processing e.g., become no longer bioavailable, or undergo chemical modification in a way that removes the previously identified hazard are exempted from the above requirement.

The final product must not be labelled according to the hazard statements above and moreover the final product formulation shall not contain any hazardous substances, or combinations thereof, that result in the formulation being greater than 0.85 of the limit required for classifying dangerous substances as defined within ANNEX II of Directive 1999/45/EC and as required by the Regulation (EC) No 1272/2008 (CLP Regulation).

### Derogations – for discussion<sup>3</sup>:

The following substances are specifically exempted from this requirement:

Fragrances	H412: Harmful to aquatic life with long-lasting effects	R52-53
	H413: May cause long-term adverse effects to aquatic life	R53
Preservatives*	H411: Toxic to aquatic life with long-lasting effects	R51-53

<sup>3</sup> For discussion: Derogation of Surfactants classified with R52-53 and H412: Harmful to aquatic life with long-lasting effects when readily biodegradable R52-53

	H412: Harmful to aquatic life with long-lasting effects H413: May cause long-term adverse effects to aquatic life	R52-53 R53
Antifungal, antimicrobial agent: Zinc pyrithione (ZPT)	H400 Very toxic to aquatic life	R50

\* Derogation is only for criterion 3)b. Preservatives should comply with criterion 3)e.

**Assessment and verification:** The applicant shall demonstrate compliance with this criterion by providing a declaration on the non-classification of each ingoing substance into any of the hazard classes associated to the hazard statements referred to in the above list in accordance with Regulation (EC) 1272/2008, as far as this can be determined, as a minimum, from the information meeting the requirements listed in Annex VII of Regulation (EC) 1907/2006. This declaration shall be supported by summarized information on the relevant characteristics associated to the hazard statements referred to in the above list, to the level of detail specified in section 10, 11 and 12 of Annex II of Regulation (EC) 1907/2006 (Requirements for the Compilation of Safety Data Sheets).

Information on intrinsic properties of substances may be generated by means other than tests, for instance through the use of alternative methods such as in vitro methods, by quantitative structure activity models or by the use of grouping or read-across in accordance with Annex XI of Regulation (EC) 1907/2006. The sharing of relevant data is strongly encouraged.

The information provided shall relate to the forms or physical states of the substance or mixtures as used in the final product.

For substances listed in Annexes IV and V of REACH, exempted from registration obligations under Article 2(7)(a) and (b) of Regulation 1907/2006 REACH, a declaration to this effect will suffice to comply with the requirements set out above.

The applicant shall also demonstrate compliance with this criterion by providing the calculations as required based on the R-phrases/H-statements that apply to the formulation and as indicated using the rules provided by the CLP Regulation.

**c) Substances listed in accordance with article 59(1) of Regulation (EC) No 1907/2006**

No derogation from the exclusion in Article 6(6) of the Regulation (EC) No66/2010 shall be given concerning substances identified as substances of very high concern and included in the list foreseen in Article 59 of Regulation (EC) No 1907/2006, present in the product in concentrations higher than 0.010 % (weight by weight).

**Assessment and verification:** The list of substances identified as substances of very high concern and included in the candidate list in accordance with Article 59 of Regulation (EC) No 1907/2006 can be found here:

[http://echa.europa.eu/chem\\_data/authorisation\\_process/candidate\\_list\\_table\\_en.asp](http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp)

Reference to the list shall be made on the date of application. The applicant shall provide the exact formulation of the product to the competent body. The applicant shall also provide a declaration of compliance with this criterion, together with related documentation, such as declarations of compliance signed by the material suppliers and copies of relevant Safety Data Sheets for substances or mixtures.

**d) Fragrances**

(i) Products intended for infants, babies and children under the age of three year should be fragrance-free. Infant, baby and/or children products refers to products that are marketed as designed and intended for infants, babies and/or children or have any of these words on the label/packaging.

(ii) Any ingoing substance added to the product as a fragrance shall be manufactured and handled following the code of practice of the International Fragrance Association (IFRA). The code can be found on IFRA website: <http://www.ifraorg.org>. The recommendations of the IFRA Standards concerning prohibition, restricted use and specified purity criteria for materials shall be followed by the manufacturer.

**For discussion** if the list of fragrances excluded already in 3a) should be extended to the following:

**(iii) Fragrances reported as established contact allergens in humans, as indicated in Table 13-1 of the Opinion on fragrance allergens in cosmetic products of the Scientific Committee on Consumer Safety (2011)<sup>4</sup>, shall not be present in quantities  $\geq 0,010\%$  ( $\geq 100$  ppm) per substance in the final product.**

**Assessment and verification:** *the applicant shall provide a declaration of compliance.*

**e) Preservatives**

(i) The product may only include preservatives 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.

(ii) Preservatives must not release substances that are classified in accordance with the requirements of Criterion 3b or/and are endocrine disrupters<sup>5</sup>.

(iii) It is prohibited to claim or suggest on the packaging or by any other communication that the product has an antimicrobial or disinfecting effect.

(iv) The product may contain preservatives provided that they are not bioaccumulating. A biocide is not considered bioaccumulating if  $BCF < 100$  or  $\log Pow < 3,0$ . If both BCF and  $\log Pow$  values are available, the highest measured BCF value shall be used.

**Assessment and verification:** *the applicant shall provide copies of the material safety data sheets of any preservative added, together with information on their BCF and/or  $\log Pow$  values and information on their exact concentration in the product. The manufacturer or*

<sup>4</sup> The Scientific Committee on Consumer Safety – Opinion on fragrance allergens in cosmetic products, December 2011, available online at:

[http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/docs/sccs\\_o\\_073.pdf](http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_073.pdf)

<sup>5</sup> [http://ec.europa.eu/environment/endocrine/strategy/substances\\_en.htm#priority\\_list](http://ec.europa.eu/environment/endocrine/strategy/substances_en.htm#priority_list)

supplier of the preservatives shall provide information on the dosage necessary to preserve the product.

**f) Colorants**

Colorants allowed in the product must not be bioaccumulating. A colorant is considered not bioaccumulating if  $BCF < 100$  or  $\log Pow < 3.0$ . If both – BCF and  $\log Pow$  – values are available, the highest measured BCF value shall be used. In the case of colouring agents approved for use in foodstuffs it is not necessary to submit documentation of bioaccumulation potential.

**Assessment and verification:** the applicant shall provide copies of the material safety data sheets of any colorants added, or documentation to ensure that the colouring agent is approved for use in foodstuff.

**Criterion 4 - Packaging requirements**

**a) Packaging Impact Ratio (PIR)**

The Packaging Impact Ratio (PIR) must be less than 0,2 g (for discussion) of packaging per gram of product for all products except of shaving preparations packed in metal aerosol containers, for which PIR must be less than 0,xx g (for discussion) of packaging per gram of product. PIR shall be calculated as follows:

$$PIR = \frac{\text{Sum } (W_i + (\text{Wirefill} \times F) + N_i + (\text{Nirefill} \times F))}{(D + (\text{Drefill} \times F))}$$

Where:

- W<sub>i</sub>* – weight of packaging (Primary + proportion of secondary per Stock Keeping Unit (SKU))
- Wirefill* – weight of refill packaging (Primary + proportion of secondary per SKU)
- N<sub>i</sub>* – weight of Non renewable + non-recycled packaging (Primary + proportion of secondary per SKU)
- Nirefill* – weight of non-renewable and non-recycled refill packaging (Primary + proportion of secondary per SKU)
- D* – weight of product contained by the "parent" pack
- Drefill* – weight of product delivered by the refill
- F* – number of refills required to meet the total refillable quantity, calculated as follows:

$$F = V \times R / V_{\text{refill}}$$

Where;

- V* – volume capacity of the parent pack
- V<sub>refill</sub>* – volume capacity of the refill pack
- R* – the refillable quantity. This is the number of times that the parent pack can be refilled. Where *F* is not a whole number it should be rounded up to the next whole number

**For discussion:**

A new criterion has to be set for determining the refillable quantity R. In the current criteria R was set to 20 for plastics and 10 for corrugated board unless the applicant can document a higher number. Comparing this factor with other Ecolabels, it appears to be too high. It is proposed that manufacturer should provide the number of foreseen refills. It could be proposed that R=5 for plastics and R=2 for cardboard is set as default values.

**Assessment and verification:** *the applicant shall provide the calculation of the PIR of the product. A spreadsheet for this calculation is available on the EU Ecolabel website. The applicant shall provide a completed and signed declaration for the content of recycled or material from renewable origin in the packaging and a description of the refill system offered, if applicable (kinds of refills, volume). For approval of refill packaging, the applicant and/or retailer shall document that the refills will be/are available for purchase on the market.*

**b) Single use products – For discussion (if accepted, to consider if it should be in the section of the product group scope):**

Products that are intended for very limited number of washing actions, approximately 4 or less and, in case they are in liquid form, are sold without the option of refilling shall not be awarded the EU Ecolabel. Therefore, a minimum product net weight of 50 ml for liquid soaps, hair conditioners and shampoos and a minimum product net weight of 10 g for solid soaps are required.

**Assessment and verification:** *The applicant shall provide completed and signed declaration of compliance.*

**c) Requirements on substances used in packaging**

**(i) Substances listed in accordance with article 59(1) of Regulation (EC) No 1907/2006**

Packaging shall not contain any substances identified as substances of very high concern and included in the list foreseen in Article 59 of Regulation (EC) No 1907/2006, present in mixtures in a product in concentrations higher than 0.010 % (weight by weight).

**Assessment and verification:** *The list of substances identified as substances of very high concern and included in the candidate list in accordance with Article 59 of Regulation (EC) No 1907/2006 can be found here:*

[http://echa.europa.eu/chem\\_data/authorisation\\_process/candidate\\_list\\_table\\_en.asp](http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp).

*Reference to the list shall be made on the date of application. The applicant shall provide the exact formulation of the product to the competent body. The applicant shall also provide a declaration of compliance with this criterion, together with related documentation, such as declarations of compliance signed by the material suppliers and copies of relevant Safety Data Sheets for substances or mixtures.*

***(ii) Phthalates used in plastic packaging***

Only phthalates that at the time of application have been risk assessed and have not been classified according to criterion 3(b) (and combinations hereof) may be used in the plastic packaging.

***Assessment and verification:*** *the applicant shall provide completed and signed declaration of compliance.*

***(iii) Classified substances used in packaging***

The packaging material shall not contain substances or preparations exceeding 0,01 % by weight of the final product packaging that are classified as carcinogenic (Carc), mutagenic (Mut) or toxic to reproduction (Rep) including rules for self-classification class III.

***Assessment and verification:***

*The applicant shall provide completed and signed declaration of compliance. Copies of the safety data sheets shall be provided for all ingredients used in the packaging material (whether substances or preparations) together with a signed declaration prepared by the manufacturer of packaging material showing compliance with this criterion.*

***d) Sustainable sourcing of paper and cardboard packaging and paper bleaching process***  
– ***For discussion, whether this criterion should be kept***

Chlorine shall not be used in bleaching processes.

Materials made of wood fibres used for packaging should be demonstrated to be produced from forest managed according to the principles of Sustainable Forestry Management (SFM).

***Assessment and verification:*** *Manufacturers should provide a declaration of compliance with the criterion and provide documentation to prove that forests are managed according to Sustainable Forest Management principles. For verification, certificates of chain of custody for the wood fibers certified as FSC, PEFC or any other sustainable forest management official standard will be accepted as proof of compliance*

***e) Aerosol propellants – For discussion***

Aerosols containing hydrocarbon propellants shall not be used.

***Assessment and verification:*** *the applicant shall provide completed and signed declaration of compliance.*

***f) 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:** *the applicant shall submit a completed and signed declaration of compliance and a sample of primary packaging.*

**g) Disassembly of packaging**

All materials in the packaging should be separable by hand (paper, cardboard, plastic, metal, glass) for sorting or should be suitable for recycling. Packaging elements such as caps or labels also have to be considered to ensure that these elements do not pose difficulties in recycling processes.

**Assessment and verification:** *the applicant or packaging producer shall submit a declaration of compliance.*

**Criterion 5 – Sustainable sourcing of palm oil – For discussion:**

Vegetable ingredients made of palm oil should be made of oil coming from sustainable managed source according to the principle of sustainability for economic, social and environmental aspects.

**Assessment and verification:** *the applicant shall provide supply-chain-evidence that the ingredients originate from a certified and well managed source and that products are not mixed with products from uncertified sources at any point in the supply chain.*

*Certification RSPO would be accepted as evidence, as well as other official certifications if considered sure enough and in conformance with ISO Guide 65/66.*

**Criterion 6 – 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 II for testing of product efficiency.

Claims placed on the product label and/or packaging shall also be tested.

**Assessment and verification:** *the applicant shall provide a report from a laboratory test or consumer test documenting satisfactory efficiency of the product and substantiating the claims placed the product label and/or packaging.*

**Criterion 7 - User information - Information appearing on the packaging**

**(a) Information on the packaging / product information sheet**

The following recommendations must appear on the packaging, and/or on product information sheet or equivalent.

For discussion, e.g.: “To minimize the environmental impacts of this product apply proper dosage of the product and rationally consume water, in particular hot water”.

**(b) Information appearing on the EU Ecolabel**

The logo should be visible and legible. The use of the EU Ecolabel logo is protected in primary EU law. The EU Ecolabel registration/licence number must appear on the product, it must be legible and clearly visible.

The optional label with text box shall contain the following text:

- Reduced impact on aquatic ecosystems,
- Fulfils strict biodegradability requirements,
- Limits packaging waste.

For discussion:

- Fulfils strict environmental requirements on the use of substances, or
- Minimized use of substances harmful to the environment

The guidelines for the use of the optional label with text box can be found in the "Guidelines for use of the Ecolabel logo" on the website:

[http://ec.europa.eu/environment/ecolabel/documents/logo\\_guidelines.pdf](http://ec.europa.eu/environment/ecolabel/documents/logo_guidelines.pdf)

**Assessment and verification (a-b):** *the applicant shall provide a sample of the product label and/or product sheet, together with a declaration of compliance with this criterion.*

## Appendix I

### Detergents Ingredients Database (DID) list

The DID list (part A) is a list containing information of the aquatic toxicity and biodegradability of ingoing substances typically used in detergent formulations. The list includes information on the toxicity and biodegradability of a range of substances used in washing and cleaning products. The list is not comprehensive, but guidance is given in part B of the DID list concerning the determination of the relevant calculation parameters for substances not present on the DID list (e.g. the Toxicity Factor (TF) and degradation factor (DF), which are used for calculation of the critical dilution volume). The list is a generic source of information and substances present on the DID list are not automatically approved for use in EU Ecolabelled products. The DID list (part A and B) can be found on the EU Ecolabel website.

For substances with no data regarding aquatic toxicity and degradability, structure analogies with similar substances may be used to assess the TF and DF. Such structure analogies shall be approved by the competent body granting the EU Ecolabel license. Alternatively, a worst case approach shall be applied, using the parameters below:

Worst case approach:

Ingoing substance	Acute toxicity			Chronic toxicity			Degradation		
	LC50/EC50	SF <sub>(acute)</sub>	TF <sub>(acute)</sub>	NOEC*	SF <sub>(chronic)</sub> *	TF <sub>(chronic)</sub>	DF	Aerobic	Anaerobic
"Name"	1 mg/l	10,000	0.0001			0.0001	1	P	N

\* If no acceptable chronic toxicity data are found, these columns are empty. In that case TF(chronic) is defined as equal to TF(acute)

### Documentation of ready biodegradability

The following test methods for ready biodegradability shall be used:

- (1) Until 1 December 2010 and during transition period from 1 December 2010 to 1 December 2015:

The test methods for ready biodegradability provided for in Council Directive 67/548/EEC, in particular the methods detailed in Annex V.C4 to that Directive, or their equivalent OECD 301 A-F test methods, or their equivalent ISO tests.

The 10 days window principle shall not apply for surfactants. The pass levels shall be 70% for the tests referred to in Annex V.C4-A and C4-B to Directive 67/548/EEC (and their equivalent OECD 301 A and E tests and ISO equivalents), and shall be 60% for tests C4-C, D, E and F (and their equivalent OECD 301 B, C, D and F tests and ISO equivalents).

- (2) After 1 December 2015 and during transition period from 1 December 2010 to 1 December 2015:

The test methods provided for in Regulation (EC) No 1272/2008 of 16 December 2008<sup>6</sup>.

<sup>6</sup> OJ L 353/1, 31.12.2008

## Documentation of anaerobic biodegradability

The reference test for anaerobic degradability shall be EN ISO 11734, ECETOC No. 28 (June 1988), OECD 311 or an equivalent test method, with the requirement of 60% ultimate degradability under anaerobic conditions. Test methods simulating the conditions in a relevant anaerobic environment may also be used to document that 60% ultimate degradability has been attained under anaerobic conditions.

### *Extrapolation for substances not listed in the DID-list*

Where the ingoing substances are not listed in the DID-list the following approach may be used to provide the necessary documentation of anaerobic biodegradability:

- (1) Apply reasonable extrapolation. Use test results obtained with one raw material to extrapolate the ultimate anaerobic degradability of structurally related surfactants. Where 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 (e.g., 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). Where 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 (e.g., 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)).
- (2) Perform screening test for anaerobic degradability. If new testing is necessary, perform a screening test by use of EN ISO 11734, ECETOC No. 28 (June 1988), OECD 311 or an equivalent method.
- (3) Perform low-dosage degradability test. If new testing is necessary, and in the case of experimental problems in the screening test (e.g. inhibition due to toxicity of test substance), repeat testing by using a low dosage of surfactant and monitor degradation by <sup>14</sup>C measurements or chemical analyses. Testing at low dosages may be performed by use of OECD 308 (August 2000) or an equivalent method.

## Appendix II

### 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. The requirements regarding the laboratory test are given below:

- The analysis laboratory must meet the general requirements pursuant to standard EN ISO 17025 or be an officially GLP-approved analysis laboratory.
- The applicant's analysis laboratory/measurement may be approved to conduct analyses and measurements if:
  - the authorities monitor the sampling and analysis process, or
  - the manufacturer has a quality system incorporating testing and analyses and which is certified in accordance with ISO 9001, or
  - the manufacturer can show that there is conformity between a first-time test conducted as a parallel test between an impartial test institution and the manufacturer's own laboratory and that the manufacturer takes samples in accordance with a prescribed sampling plan.
- The manufacturer's test laboratory can be approved to conduct testing to document effectiveness if the following additional requirements are met:
  - It must be possible for ecolabelling organisations to monitor the performance of testing
  - The ecolabelling organisation must have access to all data on the product
  - The samples must be made anonymous for the test laboratory
  - Performance of the effectiveness test must be described in the quality control system.

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

A consumer test must include as minimum of 30 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. Is the packaging designed in such a way that the desired dosage is easily provided to the user (e.g. the opening is not too wide) in comparison with the market-leading product and the user expectation?
3. How easy is it to apply the product to the hair and/or skin in comparison with the market-leading product?
4. How easy is it to rinse-off the product in comparison with the market-leading product?
5. If the product does not cause to consumers any sensitising effects in use and/or after use.

At least 80 % of the consumers must be at least as satisfied with the product as with the market-leading product. All raw data from the test must be specified. Additionally, the test procedure must be described in detail

For discussion:

### **Claims substantiation**

In order to test the claims placed on the product label and/or packaging the approach described in the “Practical guidance on methodology for cosmetic claim substantiation”<sup>7</sup> developed and published by Cosmetics Europe should be followed.

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<sup>7</sup> Practical guidance on methodology for cosmetic claim substantiation, Cosmetics Europe, May 2008.