Révision de l'écolabel européen pour les lubrifiants

(Bilan de l'avancée des travaux du groupe de travail ad hoc)

Le texte ci-dessous résume les points abordés lors des 2 réunions du groupe de travail ad-hoc pour la révision de l'éco-label européen pour les lubrifiants (les réunions se sont tenues en mars et novembre 2009).

1. Révision des articles

Article 1 - Catégories de produits « lubrifiants »

- Lors de la première réunion du groupe de travail ad-hoc, les modifications suivantes ont été suggérées :
  1. Dans la catégorie 1 (contenant les fluides hydrauliques): inclusion des huiles à engrenages industrielles, des huiles pour transmission de tracteur et des huiles pour tube d'étambot.
  2. Dans la catégorie 2 (contenant les graisses): inclusion des graisses pour tube d'étambot.
  3. Dans la catégorie 3 (contenant les huiles de chaînes de tronçonneuse, les agents de décoffrage du béton, et les autres lubrifiants à usage perdu): inclusion des « mooring oils ».
  4. Dans la catégorie 4 (contenant les huiles pour moteurs-2-temps): distinction entre huiles pour moteurs-2-temps terrestres et marines.

Texte actuel	Modifications proposées suite à la première réunion
Article 1. The product group 'lubricants' shall comprise hydraulic oils, greases, chainsaw oils, two stroke oils, concrete release agents and other total loss lubricants, for use by consumers and professional users.	**Article 1.** The product group 'lubricants' shall comprise of 4 categories for use by consumers and professional users. Category 1 contains hydraulic fluids, industrial gear oils, tractor transmission oils and stern tube oils, Category 2 contains greases, stern tube greases, Category 3 contains chainsaw oils, concrete release agents, mooring oils and other total loss lubricants, Category 4 contains two-stroke oils.

- Lors de la seconde réunion du groupe de travail ad-hoc:
  1. Dans la catégorie 1: il est proposé (1) d'élargir les huiles à engrenages aux huiles à engrenages industrielles et marines; (2) de retirer les huiles pour tube d'étambot pour les placer dans la catégorie 3 (car ce sont des huiles qui se retrouvent dans l'environnement de manière beaucoup plus fréquente que les huiles hydrauliques).
  2. Dans la catégorie 3 : il est proposé de modifier l'appellation « mooring oils » par «wire rope lubricants » pour désigner les lubrifiants de câbles.

Article 2 - Définitions

- Lors de la première réunion du groupe de travail ad-hoc, les propositions suivantes ont été faites:
  1. Pour être en ligne avec le règlement REACH (Reg 1907/2006), un lubrifiant doit pouvoir être défini avec des termes tels que « préparation » et « substances » plutôt qu'en utilisant des concepts comme « ingrédients » ou « composants ».
  2. Le terme nanosubstance (ou nanoproduit) doit être défini afin de pouvoir exclure ce type de substance des produits écolabellisés. En effet, le principe sur lequel repose l'écolabel est « pas de donnée, pas d'écolabel ». Or les données et les connaissances scientifiques sur ces substances sont actuellement insuffisantes. Dans l'UE, de nombreux travaux sont menés afin de déterminer de quelle manière les risques des nanosubstances peuvent être évalués car les méthodologies actuelles d'évaluation des risques ne sont pas toujours nécessairement adaptées. Une définition donnée par la fédération des syndicats hollandais dans le projet européen NANOCAP a été proposée par IVAM.

Texte actuel	Modifications proposées suite à la première réunion
Article 2. 1. For the purpose of this Decision, the following definitions shall apply: (a) 'lubricant' means a preparation consisting of base fluids and additives; (b) 'base fluid' means a lubricating fluid whose flow, ageing, lubricity and anti-wear properties, as well as its properties, regarding contaminant suspension, have not been improved by the inclusion of additives; (c) 'thickener' means a substance in the base fluid used to thicken or modify the rheology of a lubricating fluid or grease; (d) 'main component' means any substance accounting for more than 5 % by weight of the lubricant; (e) 'additive' means a substance whose primary functions are the improvement of the flow, ageing, lubricity, anti-wear properties or of contaminant suspension; (f) 'grease' means a solid to semi-solid preparation which consists of a thickening agent in a liquid lubricant.	**Article 2.** 1. For the purpose of this Decision, the following definitions shall apply: (a) 'lubricant' means a preparation consisting of base fluids and additives; (b) 'base fluid' means a lubricating fluid whose flow, ageing, lubricity and anti-wear properties, as well as its properties, regarding contaminant suspension, have not been improved by the inclusion of additives; (c) "substance" as defined in Regulation 1907/2006 d) "preparation" as defined in Regulation 1907/2006 (f) "thickener" means a substance in the base fluid used to thicken or modify the rheology of a lubricating fluid or grease; (g)"main component" means any substance accounting for more than 5 % by weight of the lubricant; (h)"additive" means a substance whose primary functions are the improvement of the flow, ageing, lubricity, anti-wear properties or of contaminant suspension; (i)"grease" means a solid to semi-solid preparation which consists of a thickening agent in a liquid lubricant. (j) Engineered or Manufactered Nanoparticles are solid and water insoluble particles intentionally added *with the aim to improve specific lubricant properties with at least two (one?) dimensions between 1 and 100 nm.*

- Lors de la seconde réunion du groupe de travail ad-hoc:
  1. Pour être en ligne avec le nouveau règlement européen relatif à la classification, l'étiquettage et l'emballage des subtstances et des mélanges chimiques (règlement CLP1), il est proposé de remplacer le terme « préparation » par « préparation/mélange ».
  2. Concernant la question des nanosubstances, le consultant IVAM recommande pour l'instant de ne pas inclure de critère. En effet : 1) A l'exception de certaines graisses, il est très peu probable que les fabricants ajoutent de manière délibérée ce type de substances dans leurs formulations (puisqu'ils cherchent en général à éviter la présence de toute particule solide) ; 2) Si un critère est établi concernant les nanosubstances, cela posera des problèmes d'ordre pratique puisqu'il existe un manque évident de données les concernant. Lors de la prochaine révision des critères de l'écolabel, il sera cependant nécessaire de revenir sur ce point.

Article 3

- L'article 3 définit à partir de quelle étape de la fabrication d'un lubrifiant les critères de l'écolabel s'appliquent, avec les seuils retenus. Pour les graisses, il explique aussi comment procéder concernant les systèmes épaississants réactifs.
- Lors de la première réunion du groupe de travail ad-hoc, les propositions suivantes ont été faites:
  1. Modifier la phrase «au moment de la livraison» par «au moment de l'application» afin d'éviter que les formulations écolabellisées ne soient modifiées juste avant l'application du produit.
  2. Ajouter le paragraphe suivant «All constituent substances that are intentionally added and/or are formed intentionally after any chemical reaction before application shall be unambiguously stated above 0.01% (w/w), giving their names and the mass concentrations in which they are used and where applicable, their CAS Registry and EU registry number. ».

Texte actuel	Modifications proposées suite à la première réunion
Article 3. In order to be awarded the Community eco-label for lubricants under Regulation (EC) No 1980/2000, a lubricant must fall within the product group 'lubricants' and must comply with the criteria set out in the Annex to this Decision. The criteria shall apply to the freshly manufactured product at the time of	**Article 3.** a. In order to be awarded the Community eco-label for lubricants under Regulation (EC) No 1980/2000, a lubricant must fall within the product group 'lubricants' and must comply with the criteria set out in the Annex to this Decision.

[1] « Classification, Labelling, Packaging », réglement (CE) n° 1271/2008 du Parlement européen et du Conseil du 16 décembre 2008). Avec ce nouveau règlement, applicable dans tous les Etats membres de la communauté depuis le 20 janvier 2009, la terminologie change : notamment, on ne parle plus de « préparation » mais de « mélange »

delivery. Where criteria are formulated in terms of constituent substances, those criteria shall apply to any substance which has been deliberately added and which constitutes more than 0,1 % of the product's content, as measured both before andafter any chemical reaction has taken place between the substances mixed to provide the lubricant preparation.	b. The criteria shall apply to the freshly manufactured product at the time of application. c. All constituent substances that are present above 0.01% (w/w) and which are intentionally added and/or are formed intentionally after any chemical reaction in the freshly manufacture product at the time of application shall be unambiguously stated giving their names and the mass concentrations in which they are present and where applicable, their CAS Registry and EU/REACH registry number. Where criteria are formulated, those criteria shall apply as follows: • to the product criteria 1, 6 and 7 • to each stated substance above 0.01% (w/w) criterion 2 • to each stated substance above 0.1% (w/w) criterion 3,4 and 5. In addition the total fraction of the stated substances where the formulated criteria 3 and 4 do not apply shall remain below 0.5% (w/w).

- Lors de la seconde réunion du groupe de travail ad-hoc:
  1. Il a finalement été décidé d'abandonner la phrase « au moment de l'application » puisque l'idée est déjà reprise dans l'expression «produits de fabrication récente».
  2. Plusieurs participants ont proposé de retirer la partie de phrase « above 0.01% » car en pratique il est extrêmement rare pour un fomulateur d'ajouter des substances représentant moins de 0.01% du produit final. Selon eux, l'expression « intentionnally added » suffit. Le consultant IVAM suggère cependant de conserver cette partie de phrase afin de garder une certaine uniformité dans le document. Les impuretés présentes au-delà de 0.01% ne devront pas être déclarées.

2. Révision des critères

Critère 1 – Phrases de risques indiquant un danger pour l'environnement et la santé humaine

- Lors de la première réunion du groupe de travail ad-hoc, il a été proposé de supprimer le paragraphe « Il convient de déclarer tous les composants principaux du produit avec précision, en donnant leur nom et, le cas échéant, leur numéro Einecs ou Eilincs et les concentrations auxquelles ils sont utilisés » qui devenait redondant avec le nouvel article 3 (voir plus haut).

Texte actuel	Modifications proposées suite à la première réunion
Criterion 1. The product shall not have been assigned any R-phrase at the time of applying for the eco label, indicating environmental and human health hazards according to Directive 1999/45/EC. The following R-phrases are considered relevant for this product group: **R 20, R 21, R 22, R 23, R 24, R 25, R 26, R 27, R 28, R 33, R 34, R 35, R 36, R 37, R 38, R 39, R 40, R 41, R 42, R 43, R 45, R 46, R 48, R 49, R 50, R 51, R 52, R 53, R 59, R 60, R 61, R 62, R 63, R 64, R 65, R 66, R 67, R 68, and combinations thereof**. *Assessment and verification of criterion 1* Conformity with criterion 1 shall be stated in writing and signed by the applicant company. All main components included in the product shall be unambiguously stated, giving their names and where applicable, their Einecs or Elincs number and the concentrations in which they are used. The producer of the product shall provide the competent body with: — a product safety data sheet (meeting the requirements of	**Criterion 1.** The product shall not have been assigned any R-phrase at the time of applying for the eco label, indicating environmental and human health hazards according to Directive 1999/45/EC. The following R-phrases are considered relevant for this product group: **R 20, R 21, R 22, R 23, R 24, R 25, R 26, R 27, R 28, R 33, R 34, R 35, R 36, R 37, R 38, R 39, R 40, R 41, R 42, R 43, R 45, R 46, R 48, R 49, R 50, R 51, R 52, R 53, R 59, R 60, R 61, R 62, R 63, R 64, R 65, R 66, R 67, R 68, and combinations thereof**. *Assessment and verification of criterion 1* Conformity with criterion 1 shall be stated in writing and signed by the applicant company. The producer of the product shall provide the competent body with: — a product safety data sheet (meeting the requirements of Commission Directive 91/155/EEC — safety data sheets of applicant suppliers (meeting the requirements of Directive 91/155/EEC and Council Directive

Commission Directive 91/155/EEC — safety data sheets of applicant suppliers (meeting the requirements of Directive 91/155/EEC and Council Directive 67/548/EEC for each main component. Sufficient data shall be available to allow for the evaluation of the environmental hazards (indicated by the R-phrases: R 50, R 50/53, R 51/53, R 52, R 52/53, R 53), of the product in accordance with Directives 91/155/EEC and 1999/45/EC. The evaluation of a product for hazards to the environment shall be performed by the conventional method as indicated in Annex III to Directive 1999/45/EC. However, as defined by part C of Annex III to that Directive, the results of testing the preparation (either the product preparation or the additive package) as such can be used to modify the classification concerning the aquatic toxicity that would have been obtained using the conventional method.	67/548/EEC for each main component, additive or additive package. Sufficient data shall be available to allow for the evaluation of the environmental hazards (indicated by the R-phrases: R 50, R 50/53, R 51/53, R 52, R 52/53, R 53), of the product in accordance with Directives 91/155/EEC and 1999/45/EC. The evaluation of a product for hazards to the environment shall be performed by the conventional method as indicated in Annex III to Directive 1999/45/EC. However, as defined by part C of Annex III to that Directive, the results of testing the preparation (either the product preparation or the additive package) as such can be used to modify the classification concerning the aquatic toxicity that would have been obtained using the conventional method.

- Lors de la seconde réunion du groupe de travail ad-hoc, aucun commentaire n'a été fait concernant ce critère.

Critère 2 – Exigences supplémentaires en matière de toxicité aquatique

- Lors de la première réunion du groupe de travail ad-hoc, trois changements principaux avaient été proposés pour le critère 2 (devenant critère 3):
  1. Inclure la possibilité d'utiliser des tests en eau de mer (ceci permettant notamment d'augmenter la compatibilité entre l'éco-label et la convention OSPAR).
  2. Inclure des rapports analytiques supplémentaires pour les substances UVCB[2] démontrant que les susbtances UVCB dans le lubrifiant ont une composition analytique équivalente (à au moins 95%) à celle des substances testées.
  3. Diminuer la concentration en masse cumulée des susbtances considérées comme très toxiques de 1% à 0.1% pour les lubrifiants appartenant à la catégorie 1.

Texte actuel	Modifications proposées suite à la première réunion
Criterion 2. The applicant shall demonstrate compliance by meeting the requirements of either criterion 2.1 or criterion 2.2. *Criterion .2. 1. Requirements for the preparation and main components* Data are required on the aquatic toxicity of: - the preparation, and - the main components. The critical concentration for the aquatic toxicity of each main component shall be at least 100 mg/l. The test shall be carried out on algae and daphnia (OECD 201 and 202). For hydraulic oils the critical concentration for the aquatic toxicity shall be at least 100 mg/l. For greases, chainsaw oils, concrete release agents and other total loss lubricants the critical concentration for the aquatic toxicity shall be at least 1 000 mg/l. Greases may be evaluated by providing data for the preparation and the main components only if the thickener shows ultimate biodegradation (see criterion 3) or inherent biodegradation according to: — a biodegradation > 70 % in the OECD 302 C test for inherent biodegradation or equivalent test methods, or — a biodegradation > 20 % but < 60 % after 28 days in the OECD 301 tests based on oxygen depletion or carbon dioxide	**Criterion 3.** The applicant shall demonstrate compliance by meeting the requirements of either criterion 3.1 or criterion 3.2. *Criterion .3. 1. Requirements for the preparation and main components* Data are required on the acute aquatic toxicity of: - the preparation, and - the main components. *Acute aquatic toxicity data for each main component shall be stated on each of the following two trophic levels, algae and crustacean*. The critical concentration for the acute aquatic toxicity for each main component shall be at least 100 mg/L. *Acute aquatic toxicity data for the freshly manufactured lubricant at the time of application shall be stated on each of the following three trophic levels, algae, crustacean and fish.* The critical concentration for the acute aquatic toxicity for a lubricant in Category 1 shall be at least 100 mg/l and for a lubricant in Category 2, 3 and 4 at least 1000 mg/l. Table 2 summarises the requirements for the different lubricant categories according to criterion 3.1. *Insert Table 2*

[2] UVCB : sous REACH, les substances sont réparties en 2 groupes aux fins de l'identification et de la nomenclature : les « susbtances bien définies » et les substances « UVCB ». Ces dernières sont des substances dont la composition est inconnue ou variable ou qui sont des produits de réactions complexes ou des matériels biologiques.

generation, or — biodegradation > 60 % in ISO 14593 (CO2 headspace test).

The test on the preparation shall be carried out on all three groups of species (OECD 201, 202, and 203).

Table 1 summarises the requirements for the different product subgroups according to criterion 2.1.

Table 1 (lubricant classes)

Assessment and verification of criterion 2.1

Reports shall be submitted to the competent body including the data on the aquatic toxicity of the preparation and all main components by making use of either existing material from registrations or new tests, allowing compliance to be demonstrated with the requirements set out in table 1.

The aquatic toxicity of the preparation shall be determined according to the OECD 201, 202 and 203 or equivalent methods.

The aquatic toxicity of each individual main component shall be determined according to the OECD 201 and 202 or equivalent methods.

Criterion 2.2. Requirements for each constituent substance

Aquatic toxicity data shall be provided for each constituent substance intentionally added in the product.

One or more substances exhibiting a certain degree of aquatic toxicity are allowed in the lubricant for a cumulative mass concentration as indicated in Table 2.

Aquatic toxicity requirements for the different product subgroups — Data requirements for each constituent substance.
Insert Table 2

Assessment and verification of criterion 2.2

Reports shall be submitted to the competent body including the data on the aquatic toxicity of each constituent substance by making use of either existing material from registrations or new tests, demonstrating compliance with the requirements set out in Table 2.

The aquatic toxicity of each constituent substance shall be determined according to the OECD 201 and 202 or equivalent methods.

Assessment and verification of both criteria 2.1 and 2.2

In the case of slightly soluble components (< 10 mg/l) the method of the water accommodated fraction (WAF) can be used in the aquatic toxicity determination. The established loading level, sometimes referred to as LL50 and related to the lethal loading, may be used directly in the classification criteria. The preparation of a water accommodated fraction shall follow the recommendations set out according to one of the following guidelines; ECETOC Technical Report No 20 (1986), Annex III to OECD 1992 301 or the ISO Guidance document ISO 10634, or ASTM D6081-98 (Standard practice for Aquatic Toxicity Testing for Lubricants: Sample Preparation and Results Interpretation or equivalent methods).

The acute aquatic toxicity study on algae and daphnia (OECD 201 and 202) does not need to be conducted when:

Assessment of criterion 3.1

Both marine and freshwater toxicity data are accepted. The tests in marine water are carried out according to and using relevant test species mentioned in the following guidelines: ISO/DIS 10253 for algae, ISO TC 147/SC5/W62 for crustacean and OECD 203 for fish. The tests in freshwater are carried out according to and using relevant test species mentioned in the following guidelines: Reg 440/2008/C.3. (OECD 201) for algae, Reg 440/2008/C.2. (OECD 202) for crustacea and Reg 440/2008/C.1. (OECD 203) for fish. Only (72hr)ErC50 for algae, (48hr)EC50 for crustacean and (96hr)LC50 for fish are accepted.

Criterion 3.2 Requirements for each stated substance present above 0.1% (w/w)

No Observed Effect Concentration (NOEC) data are required on two aquatic trophic levels, crustacean and fish for each stated substance present above 0.1% (w/w). In case chronic toxicity test results are missing, additional results shall be stated on acute aquatic toxicity tests on two trophic levels; algae and crustacean.

One or more substances exhibiting a certain degree of aquatic toxicity are allowed in each of the four lubricant categories for a cumulative mass concentration as indicated in Table 1.

Assessment of criterion 3.2

No Observed Effect Concentration (NOEC) data are established by the following test methods; Reg 440/2008/C.20 (OECD 211) for crustacean and Reg 440/2008 (OECD 215) or OECD 210 for fish respectively.

Both marine and freshwater acute toxicity data are accepted on algae and crustacean. The tests in marine water are carried out according to and using relevant test species mentioned in the following guidelines: ISO/DIS 10253 for algae and ISO TC 147/SC5/W62 for crustacean. The tests in freshwater are carried out according to and using relevant test species mentioned in the following guidelines: Reg 440/2008/C.3 (OECD 201) for algae and Reg 440/2008/C.2 (OECD 202) for crustacean. Only (72hr)ErC50 for algae and (48hr)EC50 for crustacean are accepted.

Verification of both criteria 3.1 and 3.2

Test reports or literature data of high quality (testing according to acceptable protocols and GLP) including the references shall be submitted to the competent body demonstrating compliance with the requirements set out for the aquatic toxicity in Table 1.

In the case of slightly soluble substances or preparations (< 10 mg/l) the method of the water accommodated fraction (WAF) can be used in the aquatic toxicity determination. The established loading level, sometimes referred to as LL50 and related to the lethal loading, may be used directly in the classification criteria. The preparation of a water accommodated fraction shall follow the recommendations set out according to one of the following guidelines; ECETOC Technical Report No 20 (1986), Annex III to OECD 1992 301 or the ISO Guidance document ISO 10634, or ASTM D6081-98 (Standard practice for Aquatic Toxicity Testing for Lubricants: Sample Preparation and Results Interpretation or equivalent methods).

In case a UVCB-substance is used the competent body may request additional analytical test results that show that the chemical composition of the UVCB-substance in the marketed lubricant product and in the test protocol is to at least 95% equivalent.

— the substance is unlikely to cross biological membranes MM > 800 or molecular diameter > 1,5 nm (> 15 Å), — or the substance is highly insoluble in water (water solubility < 10 µg/l), as such substances are not regarded as toxic for algae and daphnia in the aquatic system. Similarly, the acute aquatic toxicity study on daphnia (OECD 202) does not need to be considered when a long-term toxicity study on Daphnia's according to OECD 211 or equivalent one is available. The water solubility of substances shall be determined where appropriate according to OECD 105 (or equivalent tests). If chronic toxicity data are available (results of OECD 210 and 211 tests or equivalent methods), these may be used instead of acute aquatic toxicity data. Absence of chronic toxicity data shall be stated in writing and signed by the applicant.	*An*-aquatic toxicity study does not need to be conducted when: — *the classification of the substance, base fluid or additive is already stated on the Lubricant Substance Classification list (Annex I) or* — *a valid letter of compliance from a competent body can be submitted or* — the substance is unlikely to cross biological membranes MM > 800 g/mol or molecular diameter > 1,5 nm (> 15 Å) or, — *the substance is a polymer and its molecular weight fraction of 1000 g/mol is below 1% or* — the substance is highly insoluble in water (water solubility < 10 µg/l), as such substances are not regarded as toxic for algae and daphnia in the aquatic system. The water solubility of substances shall be determined where appropriate according to OECD 105. *The molecular weight fraction below 1000 g/mol of a polymer shall be determined according to Reg 440/2008/A.19 (OECD 119).*

- Lors de la seconde réunion du groupe de travail ad-hoc:
    1. Il a finalement été proposé de supprimer le point sur les subtsances UVCB au motif que ces dernières sont définies par REACH et ne doivent donc pas être traitées différemment des autres substances.
    2. Des participants ont évoqué le fait qu'il serait difficile d'obtenir des huiles à engrenages ayant une concentration en masse cumulée de substances considérées comme très toxiques de 0.1% (à cause nottamment de l'additivation extrême pression de ces huiles). Pour les huiles à engrenages, il a donc été proposé que la concentration en masse cumulée des susbtances considérées comme très toxiques soit conservée à 1%.

Critère 3 – Biodégradabilité et potentiel bioaccumulatif

- Lors de la première réunion du groupe de travail ad-hoc, les modifications suivantes ont été proposées pour le critère 3 (devenant critère 4):
    1. Rendre possible l'utilisation du test 302B en plus du test 302C pour évaluer la biodégradabilité intrinsèque d'une substance afin d'être en ligne avec les méthodes utilisées pour l'évaluation des substances PBT (persistantes, bioaccumulables et toxiques) et vPvB (très persistantes et très bio-accumulatives) dans REACH.
    2. Rendre possible l'utilisation des tests utilisant de l'eau de mer (tests OECD 306 et OECD 310).
    3. Simplifier les méthodes utilisées pour la détermination du potentiel de bioaccumulation.

Texte actuel	Modifications proposées suite à la première réunion
Criterion 3. The product shall not contain substances that are both: — non-biodegradable, and — (potentially) bioaccumulative. However, the product may contain one or more substances with a certain degree of degradability and potential or actual bioaccumulation up to a cumulative mass concentration as indicated in Table 3. *Table 3* **Requirements for biodegradability and bioaccumulative potential** *Insert Table 3* *Assessment and verification of criterion 3* Conformity shall be demonstrated by providing the following information: — Reports including the data on the biodegradability of each constituent substance if this is not adequately shown on the safety data sheets provided for each substance, — reports including the data on the bioaccumulative potential of each constituent substance: — for non-biodegradable substances, and	**Criterion 4.** The product shall not contain substances that are both: — non-biodegradable, and — (potentially) bioaccumulative. However, the product may contain one or more substances with a certain degree of degradability and potential or actual bioaccumulation up to a cumulative mass concentration as indicated in Table 1. *Assessment and verification of criterion 4* Conformity shall be demonstrated by providing the following information: — Test reports or literature data of high quality (testing according to acceptable protocols and GLP) including the references on the biodegradability and when required on the (potential) bioaccumulation of each constituent substance. The biodegradability shall be determined for each stated substance present above 0.1%(w/w) by test methods specified below. A substance is considered **ultimately biodegradable** (aerobic) if:

— for toxic and very toxic substances that are readily biodegradable (for classification purposes).
The biodegradability shall be determined for each constituent substance in the product separately by test methods specified below (or equivalent tests).

A substance is considered **ultimately biodegradable** (aerobic) if:

1. In a 28-day biodegradation study according to OECD 301 A-F or equivalent tests the following levels of biodegradation are achieved:
— in OECD 301 tests based upon dissolved organic carbon ≥ 70 %,
— in OECD 301 tests based upon oxygen depletion or carbonic dioxide generation ≥ 60 % of the theoretical maxima.

2. The BOD5/ThOD or BOD5/COD ratio is larger than 0,5.

In the OECD test the 10-day window principle will not necessarily apply. If the substance reaches the biodegradation pass level within 28 days but not within the 10-day time-window, a slower degradation rate is assumed.

A substance is considered **inherently biodegradable** if it shows:
— a biodegradation > 70 % in the **OECD 302 C** test for inherent biodegradation or equivalent test method, or
— a biodegradation > 20 % but < 60 % after 28 days in the OECD 301 tests based on oxygen depletion or carbon dioxide generation, or
— biodegradation ≥ 60 % in ISO 14593 (CO2 headspace test).

A substance whose primary function is thickening shall be considered inherently aerobically biodegradable if it shows a biodegradation higher than 20 % in the OECD 302 C for inherent biodegradation or equivalent test methods. All of the aquatic toxicity requirements shall then apply also to the degradation products, which have been scientifically proven to be derivates of the thickener, after exposure to the aquatic environment.
A substance is non-biodegradable if it fails the criteria for ultimate and inherent biodegradability.

A substance does not bioaccumulate if its MM > 800 or has a molecular diameter > 1,5 nm (> 15 Å).
A substance with MM < 800 or molecular diameter < 1,5 nm (< 15 Å) does not bioaccumulate if:
— the octanol-water partition coefficient log Kow < 3 or > 7, or
— the measured BCF is ≤ 100. Since most substances used in lubricants are quite hydrophobic the BCF-value should be based on the lipid weight content and care must be shown to ensure a sufficient exposure time.

Test methods

The tests to be applied for the determination of ready biodegradability are the OECD 301 A-F series, or ISO and ASTM equivalents. or the BOD5/(ThOD or COD) ratio. The BOD5/(ThOD or COD) ratio can only be used if no data based on the OECD 301 or any other equivalent test methods are available. The BOD5 shall be assessed according to C.5 (Commission Directive 92/69/EEC (1)) or equivalent methods while the COD according to C.6 (Directive 92/69/EEC) or equivalent methods. For the determination of the inherent biodegradability the OECD 302 C or equivalent test methods are to be applied.

The applicant may also use read-across data to estimate the biodegradability of a substance. 'Read-across' for the assessment of the biodegradability of a substance shall be acceptable if the reference substance differs by only one functional group or fragment from the substance applied in the product. If the reference substance is readily or inherently

1. In a 28-day biodegradation study according to Reg 440/2008/C.4 (OECD 301 A-F), OECD 306, OECD 310 or or any other suitable internationally accepted protocol the following levels of biodegradation are achieved: — in the ultimately biodegradable tests based upon dissolved organic carbon ≥ 70 %, — in the ultimately biodegradable tests based upon oxygen depletion or carbonic dioxide generation ≥ 60 % of the theoretical maxima.
In these ultimately biodegradable tests the 10-day window principle will not necessarily apply. If the substance reaches the biodegradation pass level within 28 days but not within the 10-day time-window, a slower degradation rate is assumed.

2. The BOD5/ThOD or BOD5/COD ratio is larger than 0.5. The BOD5/(ThOD or COD) ratio can only be used if no data based on the OECD 301, 306 or 310 or any other equivalent test methods are available. The BOD5 shall be assessed according to Reg 440/2008/C.5 or equivalent methods while the COD according to Reg 440/2008/C.6

A substance is considered **inherently biodegradable** if it shows:
— a biodegradation > 70 % in the Reg 440/2008/C.9 **(OECD 302 B) or OECD 302 C** test for inherent biodegradation or or any other suitable internationally accepted protocol., or
— a biodegradation > 20 % but < 60 % after 28 days in the OECD 301, 306 or 310 tests based on oxygen depletion or carbon dioxide generation, or any other suitable internationally accepted protocol.

The biodegradation test does not need to be conducted when:
— the classification of the substance, base fluid or additive is already stated on the Lubricant Substance Classification list (Annex I) or
— a valid letter of compliance from a competent body can be submitted

A susbsance is non-biodegradable if it fails the criteria for ultimate and inherent biodegradability.

The (potential) bioaccumulation does not need to be established when
— the substance has a MM > 800 g/mol or has a molecular diameter > 1,5 nm (> 15 Å) and in case of a polymer its molecular weight fraction of 1000 g/mol is below 1%
— the octanol-water partition coefficient log Kow is < 3 or > 7,
— the measured BCF is ≤ 100 L/kg. Since most substances used in lubricants are quite hydrophobic the BCF-value should be based on the lipid weight content and care must be shown to ensure a sufficient exposure time.

The applicant may also use read-across data to estimate the biodegradability of a substance. 'Read-across' for the assessment of the biodegradability of a substance shall be acceptable if the reference substance differs by only one functional group or fragment from the substance applied in the product. If the reference substance is readily or inherently biodegradable and the functional group has a positive effect on the aerobic biodegradation then the applied substance may also be regarded as readily or inherently biodegradable. Functional groups or fragments with a positive effect on the biodegradation are: aliphatic and aromatic alcohol [-OH], aliphatic and aromatic acid [-C(=O)-OH], aldehyde [-CHO], Ester [-C(=O)-O-C], amide [-C(=O)–N of -C(=S)–N]. Adequate and reliable documentation of the study on the reference substance should be provided. In case of a comparison with a fragment, not included here above, adequate and reliable documentation of the studies should be provided on the positive effect of the functional group on the biodegradation of structurally similar substances.

The bioconcentration factor (BCF) shall be assessed according to Reg 440/2008/C.13 (OECD 305).

biodegradable and the functional group has a positive effect on the aerobic biodegradation then the applied substance may also be regarded as readily or inherently biodegradable. Functional groups or fragments with a positive effect on the biodegradation are: aliphatic and aromatic alcohol [-OH], aliphatic and aromatic acid [-C(=O)-OH], aldehyde [-CHO], Ester [-C(=O)-O-C], amide [-C(=O)–N of -C(=S)–N]. Adequate and reliable documentation of the study on the reference substance should be provided. In case of a comparison with a fragment, not included here above, adequate and reliable documentation of the studies should be provided on the positive effect of the functional group on the biodegradation of structurally similar substances. The log octanol/water partition coefficient (log Kow) shall be assessed according to OECD 107, 117 or the draft 123 or any other equivalent test method. The bioconcentration factor (BCF) shall be assessed according to OECD 305. Log Kow values are applicable to organic chemicals only. To assess the bioaccumulation potential of non-organic compounds, some surfactants, and some organo-metallic compounds, BCF measurements shall be carried out. If the test cannot be performed (e.g. the substance has a high surface activity or does not dissolve in water or in octanol), a calculated value for log Kow as well as details of the calculation method shall be provided. The following calculation methods are allowed for the log Kow: CLOGP for a log Kow between 0 and 9, LOGKOW (KOWWIN) for a log Kow between – 4 and 8, AUTOLOGP for a log Kow greater than 5 as laid down in Commission Regulation (EC) No 1488/94 (1), which is supported by a technical guidance document (TGD).	The log octanol/water partition coefficient (log Kow) shall be assessed according to Reg 440/2008/A.8 (OECD 107 or OECD 117) or OECD 123. In case of an organic substance other than a surfactant where no experimental value is available, a calculation method can be used. The following calculation methods are allowed for the log Kow: CLOGP, LOGKOW (KOWWIN) and SPARC If none of the estimated log Kow values by any of these calculation methods lay in-between the range of 3 to 7 the substance is not expected to bioaccumulate. Log Kow values are applicable to organic chemicals only. To assess the bioaccumulation potential of non-organic compounds, surfactants, and some organo-metallic compounds, BCF measurements shall be carried out.

- Lors de la seconde réunion du groupe de travail ad-hoc, aucune objection n'a été faite concernant ces modifications.

Critère 4 – Exclusion de substances spécifiques

- Lors de la première réunion du groupe de travail ad-hoc, les modifications suivantes avaient été proposées pour le critère 4 (devenant critère 2):
    1. Spécifier que l'exclusion des substances spécifiques concerne toute substance ajoutée intentionnement dans le produit à plus de 0.01% dans le produit final (au lieu de 0.1% dans la version actuelle).
    2. Inclure les substances CMR1[3] et 2[4] (substances mutagènes, toxiques pour la reproduction) dans la liste des « substances exclues » pour être en ligne avec le règlement REACH.
    3. Inclure les nanosubtsances dans la liste des « substances exclues ».

Texte actuel	Modifications proposées suite à la première réunion
Criterion 5. Substances appearing in the Community list of priority substances in the field of water policy and the OSPAR List of Chemicals for Priority Action, both referred to the version applicable in December 2004, shall not be intentionally added in a eligible for the Community eco-label. Organic halogen compounds and nitrite compounds shall not be intentionally added as an ingredient in a product eligible for the Community eco-label. Metals or metallic compounds shall not be intentionally added as an ingredient in a product eligible for the Community eco-label with the exception of sodium, potassium, magnesium and calcium. In the case of thickeners, also lithium and/or	**Criterion 2.** The following stated substances (cf. Art 3c) are not allowed in quantities exceeding 0.01% (w/w) of the final product: • Substances appearing in the Community list of priority substances in the field of water policy and the OSPAR List of Chemicals for Priority Action, both referred to the version applicable in December 2004 • Organic halogen compounds and nitrite compounds • Metals or metallic compounds with the exception of sodium, potassium, magnesium and calcium. In the case of thickeners, also lithium and/or aluminium compounds may be used up to concentrations limited by the other criteria included in this Annex. **• Substances included in Annex XIV of Regulation 1907/2006 (REACH)**

[3] CMR de catégorie 1: substances et préparations que l'on sait être CMR pour l'homme ;
[4] CMR de catégorie 2: substances et préparations pour lesquelles il existe une forte présomption que l'exposition de l'homme à de telles substances et préparations peut provoquer ou augmenter la fréquence d'apparition des effets CMR cités ci-dessus.

aluminium compounds may be used up to concentrations limited by the other criteria included in this Annex. *Assessment and verification of criterion 4* Conformance with these requirements shall be stated in writing and signed by the applicant.	**• CMR-substances of the 1st and 2nd category (substances classified by R45, R46, R60 or R61)The lubricant product is not a nanoproduct.** **• Engineered or manufactured nanoparticules ;** *Assessment and verification of criterion 2* Conformance with these requirements shall be stated in writing and signed by the applicant.

- Pas de remarque lors de la seconde réunion du groupe de travail ad-hoc concernant ce critère.

Critère 5 – Matières premières renouvelables

- Lors de la première réunion du groupe de travail ad-hoc :
  1. La question de la durabilité des matières premières renouvelables utilisées pour formuler les lubrifiants a été soulevée. En effet, le caractère renouvelable des matières premières n'est pas suffisant que pour attester de leur durabilité et de ce fait une relation de cause à effet ne peut être directement établie entre le caractère renouvelable de ces matières premières et un effet de réduction des émissions de CO2, comme cela est déclaré dans l'article 7 de la version actuelle de l'écolabel. Il a donc été proposé que chaque demandeur fournisse un rapport décrivant les étapes qu'il mettrait en place pour pouvoir évaluer l'impact des procédés primaires de production des matières premières renouvelables sur la biodiversité, les gaz à effet de serre et la pollution environnementale.

Texte actuel	Modifications proposées suite à la première réunion
Criterion 5. The formulated product shall have a carbon content derived from renewable raw materials that shall be: — ≥ 50 % (m/m) for hydraulic oils, — ≥ 45 % (m/m) for greases, — ≥ 70 % (m/m) for chainsaw oils, concrete release agents and other total loss lubricants, — ≥ 50 % (m/m) for two-stroke oils. Carbon content derived from renewable raw material means the mass percentage of component A × [number of C-atoms in component A, which are derived from (vegetable) oils or (animal) fats divided by the total number of C-atoms in component A] plus mass percentage of component B × [number of C-atoms in component B, which are derived from (vegetable) oils or (animal) fats divided by the total number of C-atoms in component B] plus the mass percentage of component C × [number of C-atoms in component C], and so on.	**Criterion 5.** The formulated product shall have a carbon content derived from renewable raw materials that shall be: — ≥ 50 % (m/m) for Category 1, — ≥ 45 % (m/m) for Category 2, — ≥ 70 % (m/m) for Category 3, — ≥ 50 % (m/m) for Category 4. Carbon content derived from renewable raw material means the mass percentage of component A × [number of C-atoms in component A, which are derived from (vegetable) oils or (animal) fats divided by the total number of C-atoms in component A] plus mass percentage of component B × [number of C-atoms in component B, which are derived from (vegetable) oils or (animal) fats divided by the total number of C-atoms in component B] plus the mass percentage of component C × [number of C-atoms in component C], and so on. *The applicant shall make a report in what way the company will assess the influence of the production, transport and use of the renewable raw material on the biodiversity, greenhouse gas balance and environmental pollution of the primary production process. Assessment and verification of criterion 5* The applicant shall provide the competent body with a declaration of compliance with this criterion.

- Lors de la seconde réunion du groupe de travail ad-hoc :
  1. La discussion s'est penchée sur la possible introduction d'autres critères de durabilité en tenant compte des travaux menés actuellement au niveau européen. Le représentant de l'UE a rappelé qu'il s'agissait d'un point crucial pour le Bureau de l'écolabel (EUEB).
     a. L'UE a publié une directive sur la promotion de l'utilisation de l'énergie produite à partir de sources renouvelables. Cette dernière établit un cadre commun d'utilisation des énergies provenant des sources renouvelables afin de limiter les émissions de gaz à effet de serre et de promouvoir un transport plus propre. À cet effet, des critères de durabilité ont été introduits pour les biocarburants et les bioliquides. Ces développements seront probalement étendus à d'autres secteurs et l'écolabel doit y prêter attention.

b. Le contenu en matières premières renouvelables ne peut être directement relié à l'affirmation « émissions de CO2 limitées ». Il est donc proposé de supprimer cette phrase dans le critère 7 (ou alors d'introduire des critères supplémentaires pour pouvoir soutenir cette affirmation).
c. Certains participants ont soulevé le fait que, comparés aux biocarburants, les biolubrifiants représentent un tout petit volume et que de plus, la chaîne de production des biolubrifiants est beaucoup plus complexe.
d. Le consultant IVAM propose que dans le rapport demandé, le demandeur précise pour toutes les matières premières renouvelables utilisées dans les fluides de base :
    - Si la matière première renouvelable est une ressource primaire ou secondaire?
    - Le type de ressource primaire ou secondaire de la matière première renouvelable.
    - Le pays/la région d'origine de la ressource primaire et/ou
    - Le pays du fournisseur de la ressource secondaire.

Critère 6 - Performance technique

- Lors de la première réunion du groupe de travail ad-hoc, les changements suivants avaient été proposés:
    1. Changer l'intitulé du critère pour « Performance technique minimale ».
    2. Suivre les changements de la norme ISO 15380 qui demande maintenant à ce que seulement 2 élastomères soient testés (au lieu de 4 auparavant).
    3. Pour les huiles à engrenages, introduire la norme DIN 51517-3 comme critère de performance technique à atteindre.

Texte actuel	Modifications proposées suite à la première réunion
Criterion 6. Hydraulic fluids shall at least meet the technical performance criteria laid down in ISO 15380, Tables 2 to 5. Greases shall be 'fit for purpose'. Chainsaw oils shall at least meet the technical performance criteria laid down in the RAL UZ 48 of the Blue Angel. Concrete release agents and other total loss lubricants shall be fit for purpose. Two-stroke oils shall at least meet the technical performance criteria laid down in 'NMMA Certification for two-stroke cycle gasoline engine lubricants' of NMMA TC-W3. *Assessment and verification of criterion 6* The applicant shall provide the competent body with a declaration of compliance with this criterion, together with related documentation.	**Criterion 6.** For Hydraulic fluids: at least the technical performance criteria as laid down in the current ISO 15380, Tables 2 to 5. The supplier should list on his product information sheet which 2 elastomers have been tested. For Industrial gear oils: at least the technical performance requirements as in the DIN 51517-3. For chainsaw oils: at least the technical performance criteria as laid down in the RAL UZ 48 of the Blue Angel For two-stroke oils for marine applications: at least the technical performance criteria laid down in "NMMA Certification for Two-Stroke Cycle Gasoline Engine Lubricants" of NMMA TC-W3. For two-stroke oils for terrestrial applications: at least meet the EGD level of technical performance criteria laid down in ISO 13738:2000. For all other lubricants: fit for purpose. *Assessment and verification of criterion 6* The applicant shall provide the competent body with a declaration of compliance with this criterion, together with related documentation.

- Lors de la seconde réunion, les changements suivants ont été proposés :
    1. Pour les huiles à engrenages, les participants ont expliqué que toutes ne pourraient pas atteindre les performances de la norme DIN 51517-3. Il est donc proposé que ces huiles répondent à la norme DIN 51517 et que soit détaillé sur la fiche technique du lubrifiant à quelle partie de la norme (partie 1, 2 ou3).
    2. Pour les huiles de transmission pour tracteurs, il est proposé qu'elles soient « adaptées à l'usage prévu ».

Critère 7 – Informations figurant sur le label écologique

- Lors de la seconde réunion du groupe de travail ad-hoc, il est proposé de retirer la phrase « émissions de CO2 limitées ».

3. Introduction d'une liste LuSC (liste de classification des substances lubrifiantes)

- Lors de la première réunion du groupe de travail ad-hoc, il a été proposé qu'une liste LuSC soit mise en place en remplacement de la liste de l'annexe II présente dans la version actuelle de l'écolabel. Il s'agirait d'une liste positive de substances et de produits commerciaux dans laquelle serait indiquée leur classification en terme de toxicité aquatique et de biodégradabilité. Cette liste constituerait un outil d'aide à la formulation et elle contiendrait :
  - les substances de l'annexe II de la version actuelle de l'écolabel
  - les substances de l'actuelle annexe IV de REACH
  - les susbtances organiques (ou leurs sels de Na, K, Ca ou Mg) qui sont transférées de l'annexe IV à l'annexe V de REACH
  - le carbone et le graphite
  - un certain nombre de systèmes épaississants
- Lors de la seconde réunion du groupe de travail ad-hoc, il a été proposé que la liste LuSC soit publiée sur le site Internet de l'écolabel. Après approbation d'une susbtance ou d'un produit commercial, le compétent body enverra les données au Bureau de l'écolabel qui mettra la liste à jour.

Layout LuSC-list *substances* (exemple)

Substance	CAS no	EINECS no	Biodegradability	Aquatic toxixity	Remarks
Fatty acids C12-14	90990-10-6	292-771-7	Ultimately (A)	Not toxic (D)	Organic substances removed from annex IV to Annex V of regulation 1907/2006 (REACH) by regulation 987/2008
Lithium 12-hydroxystearate, pure, $C_{19}H_{38}O_3Li$	7620-77-9	231-536-5	Inherently aerobically (B)	Harmful €	Assessed by the Dutch Competent Body.

Layout LuSC-list *brands* (exemple)

Brand name	Proposed maximum treat rate				Based on 100% treat rate			Remarks	Assessed by
	Cat 1	Cat 2	Cat 3	Cat 4	EEL biodegradation	EEL aquatic toxicity	Renewability		
					A/B/C/X/-	D/E/F/G(M)			
Base fluids									
Uniflex 939LAN	Not limited by biodegradation ad aquatic toxicity				100% A	100% D	89.6%	/	Dutch CB
Additives									
Irgalube® 353	1%	1%	1%	1%	100% C	100% E	0%	Limited by R43	Dutch CB

4. Agenda

Le vote final sur les critères aura lieu en avril 2010.
Les critères actuels de l'écolabel sont prolongés jusqu'au 31 juillet 2010.