

## JRC TECHNICAL REPORTS

# Revision of the European Ecolabel Criteria for Lubricants

Technical Report 1.0: Draft criteria proposal for revision of EU Ecolabel criteria

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### **1** INTRODUCTION

The objective of this project is to revise the existing EU Ecolabel criteria (Commission Decision 2011/381/EU<sup>1</sup>) for lubricant products. The criteria were for the first time established in 2001 and are valid until end of December 2018.

The following technical report is intended to provide background information for the revision of the existing EU Ecolabel criteria for lubricants. The study has been carried out by the Join Research Centre (JRC) with the technical support from LEITAT. The work is being developed for the European Commission's Directorate General for the Environment.

The main purpose of this document is to summarise the results of the preliminary analysis of the current criteria and to discuss the criteria are still appropriate and up-to-date or if they should be revised, restructured or some of them removed; and if new criteria should be added.

This first technical report (TR1.0) constitutes an input for the first technical meeting, called first Ad-hoc Working Group meeting (AHWG1) and is supported and complemented by the preliminary report<sup>2</sup> published along with this document. The preliminary report includes scope and definition, market analysis, and technical analysis.

Updated versions of this technical report will be produced during the revision process based on new information collected during the revision process and provided by the involved parties (i.e. through stakeholders' discussion at the AHWG meetings, further stakeholders' input following the meetings and additional desk research).

The report consists of:

- **Introduction** (Chapter 1): this section describes the goal and content of the document, the sources of information and the coming steps in the project. Also summarizes the preliminary report and the main conclusions obtained, regarding the scope definition and the key environmental aspects related to the product group of lubricants.
- Assessment and verification (Chapter 2): this section includes information on the type of documentation required to show compliance with the criteria that shall be provided by applicants and recognised by Competent Bodies.
- **Criteria proposal** (Chapter 3): this section presents the first draft of the proposed revised EU Ecolabel criteria for the product group lubricants. The proposal is written in a blue box and subsequently a rationale is given.
- **Impact of changes to criteria** (Chapter 4): this section consists on a summary of the main changes proposed for the revised criteria and potential implications on current licence holders and applicants.
- **Appendix I** includes the existing EU Ecolabel criteria for Lubricants in order to allow the reader to consult current text within this document

<sup>&</sup>lt;sup>1</sup> Commission Decision No 2011/381/EU of the European Parliament and of the Council of 24 June 2011 establishing the ecological criteria for the award of the EU Ecolabel to lubricants, available online at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32011D0381

<sup>&</sup>lt;sup>2</sup> Preliminary Report. Revision of European Ecolabel Criteria for Lubricants. December 2016. See: <u>http://susproc.jrc.ec.europa.eu/Lubricants/documents.html</u>.

#### 1.1 METHODOLOGY AND SOURCES OF INFORMATION

The approach followed in the revision of the EU Ecolabel for lubricants consists of the following elements:

- analysis of the current scope, the current criteria and review of any relevant legislation;
- analysis of the lubricant market from a world and European perspective;
- technical analysis, in which environmental and health impacts are studied.

A brief description of these above-mentioned elements is given below:

**Revision of the scope and definition**: an overview of existing technical categories, and relevant legislation and standards has been done in order to identify aspects of the current criteria, which may require revision. Moreover, stakeholder feedback was obtained through a questionnaire on the current scope and definition. Other labelling schemes and other initiatives related to lubricants have been analysed in order to identify potential areas for harmonization.

*Market analysis*: the trend of global and European lubricant market has been analysed. Key figures and data have been gathered in order to properly understand the current markets of lubricants and the potential intake of the EU Ecolabel. The main source used for this work has been *Lubricants Market Analysis and Segment Forecasts to 2022<sup>3</sup>*.

**Technical analysis:** the aim of the technical analysis is to provide information about potential impact of lubricants on the environment and human health. The entire life cycle of a lubricant has been assessed in order to recognize the life cycle stages with the highest environmental impacts and those with the highest improvement potential. In addition, analysis of the main hazardous substances used in the lubricant sector has been done, and an identification of their environment and human health impacts has been conducted.

For this task, a critical review of published LCA studies has been performed. 12 Life Cycle Assessment studies (LCAs) have been screened in order to evaluate the quality of the reports and classify them depending on four parameters: the scope, data, impacts evaluated and conclusions/findings. Supplementary information has been searched about the sustainability considerations in the different cycle stages in order to cover all key aspects of the life cycle of lubricants. Moreover, the software Ecoinvent 8.0. and its database have been used for analysing some of the cycle stages of lubricants.

According to the Regulation (EC) No 66/2010, the EU Ecolabel promotes products with reduced impacts during their entire life cycle. Article 6 highlights the importance of taking a whole life cycle perspective to the evaluation of the most significant environmental impacts, including:

- Impacts on climate change, nature and biodiversity
- Energy and resource consumption
- Generation of waste
- Emissions to all environmental media, pollution through physical effects
- The use and release of hazardous substances

<sup>&</sup>lt;sup>3</sup> Lubricants Market Analysis and Segmented Forecasts to 2022. Grand view Research, Inc. 2015

Thus, the EU Ecolabel covers both aspects related to environmental impacts conventionally evaluated through the LCA methodology and other "non-LCA" aspects related to health and hazards inherent to the products.

Some impact assessment categories conventionally included in LCA studies are directly (e.g. human toxicity) or indirectly (e.g. ozone depletion) related also to health issues. However, the LCA methodology typically characterises environmental burdens attributed to inputs and outputs from the product system and it does not analyse the hazards associated to a product, as done for instance in risk assessment. In this sense, REACH and LCA have been integrated, to identify all relevant environmental and human health impacts.

In addition, it has been designed a **prioritisation methodology** in order to consider all the multidimensional (e.g market, technical, environmental) aspects that influence this revision. The prioritisation methodology will serve as a basis to prepare a proposal of the revised scope attending to aspects described previously including market, technical and environmental aspects, as well as to help us to identify the environmental hotspots associated to the categories included in the scope in order to set the revised criteria that target the main relevant environmental hotspots associated to this product group.

Two questionnaires have been released so far in the revision process. A first questionnaire has been done about the current scope and definition, including also questions about the current criteria. The answers of the stakeholders (44 in total) have been presented in the preliminary and technical reports. In addition, a survey on data requirements for criteria 3, 4 and 5 has been sent to stakeholders with the aim to obtain information on the current values of aquatic toxicity, biodegradation and bioaccumulation, and removability for current and potentially labeled products.

The information obtained during this preliminary phase of the revision process has been included in the preliminary report2 published along with this technical report, and is the basis of the criteria proposal included in the present report.

Both documents (preliminary report and technical report) will serve for discussions with stakeholders in the Ad-Hoc Working Group (AHWG) meetings. The opinions of the stakeholders will be considered and their comments will be included in the future versions of the technical report.

## 1.2 Summary of the preliminary report and link to the EU ecolabel criteria

The preliminary report summarises the analysis conducted in the initial stage of the revision of the criteria for the product group lubricants. This includes updating and revision of the scope and definitions, analysis of the lubricants market, and a review of the scientific evidence to identify the main environmental impacts of lubricants. The sections below provide a summary of the findings from the preliminary report. Further details can be found in the report available at the project website: <a href="http://susprcc.jrc.ec.europa.eu/Lubricants/documents.html">http://susprcc.jrc.ec.europa.eu/Lubricants/documents.html</a>.

#### **1.2.1 Product group name, scope and definitions**

**Product group name:** 

#### **Product group name:**

Lubricants

#### **Product group definition proposal:**

A lubricant means a substance or mixture capable of reducing friction, adhesion, heat, wear and corrosion when introduced between two solid surfaces in relative movement and capable to transmit power. The most common constituent substances are base fluids and additives.

#### **Complementary definitions:**

'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 additive(s);

'substance' means a chemical element and its compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the products and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;

'thickener' means one or more substances in the base fluid used to thicken or modify the rheology of a lubricating fluid or grease;

'main component' means any substance accounting for more than 5 % by weight of the lubricant;

'additive' means a substance or mixture whose primary functions are the improvement of the flow, ageing, lubricity, anti-wear properties or of contaminant suspension;

'grease' means a solid to semi-solid mixture which consists of a 'thickener' and may include other ingredients imparting special properties in a liquid lubricant.

#### Scope proposal:

- Category 1: Hydraulic systems (ISO Family H) and metalworking fluids (ISO Family M)
  - **Category 2**: Greases (ISO Family X)
  - **Category 3**: Total loss systems (ISO Family A), turbines stern tube (ISO Family T), concrete mould release (ISO Family B), temporary protection against corrosion (ISO Family R)
  - **Category 4**: 2-T stroke oils, 4-T stroke oils (ISO Family E)
- **Category 5**: Gears (ISO Family C)

#### Rationale of proposed name, scope and proposed definitions

The existing **definition** [i.e. 'lubricant' means a preparation consisting of base fluids and additives] is quite broad, nevertheless there exist more complex lubricant compositions, which do not consist on base fluids and additives but on emulsions (e.g. metal working fluids,

demoulding agents...) or on solid state compounds (e.g fine powders to reduce friction), and therefore are not covered by the existing EU Ecolabel definition based on composition. The definition is suggested to be amended to include a reference to the functionality of the product. The proposed change will allow better explanation on which products are meant.

The complementary definitions have not been modified, since they are still valid.

- '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 additive(s);
- 'substance' means a chemical element and its compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the products and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;
- 'thickener' means one or more substances in the base fluid used to thicken or modify the rheology of a lubricating fluid or grease;
- 'main component' means any substance accounting for more than 5 % by weight of the lubricant;
- 'additive' means a substance or mixture whose primary functions are the improvement of the flow, ageing, lubricity, anti-wear properties or of contaminant suspension;
- 'grease' means a solid to semi-solid mixture which consists of a 'thickener' and may include other ingredients imparting special properties in a liquid lubricant.

#### ISO 6743 "Lubricants, industrial oils and related products":

For the lubricant types to be covered in the scope during this revision it is suggested to harmonise to the nomenclature of the lubricant families used in the ISO 6743 classification aiming to establish unambiguously what are the types of lubricants considered under the scope and to set clearer minimum technical performance requirements (to define a standard test per family or sub-family).

With regard the **scope**, in the first survey it was proposed to extend the scope to cover the categories of the ISO 6743 currently not covered under the existing criteria (to increase the market share of the potential EU Ecolabel products). The preliminary report revealed that the existing scope only represents a **16% of the total lubricants market**.

For this revision, it is suggested to keep a focus on the **total loss** (lubricants physically exposed to the surroundings, their entry into environment is unavoidable and they are irretrievable) and **high risk** (of accident) **lubricants** (lubricants used in confined systems which are susceptible to accidental losses) and to extend the scope in order to cover a higher market share. In addition, the environmental impacts of a lubricant product can be caused in any life stage of its life cycle (e.g. during raw material extraction or at the end of life), and not only from its potential release to the environment.

For this reason, it is considered reasonable to extend the scope to other lubricants not currently covered and that presents risk off accidental losses (accidental loss lubricants), and to other risks lubricants which are those lubricants associated to other environmental impacts than those associate to its potential release.

The approach proposed is to maintain the current lubricants included in the EU Ecolabel, and to extend the scope taking into account the potential impact on the environment and human health during use or end-of-life, and the market share of each ISO family. The inclusion of all lubricant

families in the same revision was considered impracticable due to the feasibility of developing criteria for such a wide number of categories. In the light of the technical analysis, to set scope proposal, a **prioritizing methodology** has been defined in order to select the lubricants to be included in the new scope. The criteria followed are:

The relevant points of the prioritization methodology are the following:

- **Total loss lubricants** where a major environmental impact is expected. This category is in line with previous revision.
- Accidental loss lubricants potentially release to environmentally sensitive areas. This type of lubricants corresponds to lubricants which are often released into the environment due to accidental releases. Although the possibility of spillage is lower, the amount of impact generated could be important.

Although it is considered reasonable to focus on lubricant loss and potential impact to the environment (environmental impacts of a lubricant product can be caused in any stage of its life cycle (e.g. during raw material extraction or at the end of life), and not only from its potential release to the environment. Following lubricant types are also considered relevant:

- **Lubricants with concerns regarding human health.** The scope of the revised EU Ecolabel is proposed to be enlarged in order to include health and safety issues concern.
- Lubricants with concerns regarding disposal. i.e., lubricants with high potential environmental impacts at their end-of-life (waste lubricants). According to the environmental considerations on end-of-life, used lubricating oils represent the largest amount of liquid, non-aqueous hazardous waste in the word. Severe contamination can result from waste oils being left on the ground or released to aquatic ecosystems. Thus, it is crucial to collect as much as possible this very valuable resource, in order to avoid the contamination of the environment and to be able to profit from the very high recovery potential of this waste stream<sup>4</sup>. Therefore, it is suggested to keep a focus on rerefined oils, as well as information on handling and disposal information and packaging requirements.
- **Lubricants with high market share and/or target end-consumer** according to the market analysis in order to extend the scope and cover most of lubricants available on the market (e.g. engine oils currently not covered by the EEL).

According to the market analysis, only the 16% of the lubricants market are included on the current EU Ecolabel scope. Therefore, it is considered reasonable to analyse for potential scope extension on engine oils, i.e. on 4-T stroke oil currently not covered under EEL, which represents the 40% of the lubricants market. This recommendation on the potential scope extension from 16% to 56% (16% + 40%) can be made on the basis of the market analysis and the feasibility to include this type of oils. In addition, most of the current categories covered mostly encompass professional and industrial products. However, the EU Ecolabel is a label that mainly target consumers and it is therefore suggested to include categories of lubricants that are usually sold to **private end consumers** as well (e.g. automotive lubricants).

Moreover, in addition to the environmental assessment, following issues are considered relevant for guidance on the criteria revision:

<sup>&</sup>lt;sup>4</sup> More information available online at: http://ec.europa.eu/environment/waste/oil\_index.htm

- **Harmonisation** between the criteria for this product group and the criteria from other lubricants categories on the most recognized labelling schemes in order to ensure a general more horizontal approach. A comparison of the scope and specifications criteria established for the most recognized labelling schemes has been prepared. Moreover, the success, i.e. the number of certified products in each ecolabel and environmental schemes applicable to lubricants have been taken into account as far as possible.
- **Current penetration of EU Ecolabel for lubricants**, i.e. the number of licenses obtained in each category and type of product in order to analyse and/or revise the possible problems of the industry to obtain the Ecolabel.
- The revision of the current EEL in order to **update** it in compliance with new EU **regulations** on chemicals policy.

According to the prioritization methodology the lubricant families that are currently excluded from the EU Ecolabel scope and were identified as being susceptible to be included during the revision process are: metalworking fluids (MWFs), 4-stroke engine oils and temporary protection against corrosion lubricants.

Regarding other labelling schemes:

- Metalworking fluids are addressed in Nordic Ecolabel and Korea Ecolabel
- Temporary protection against corrosion lubricants are addressed in the Korea Ecolabel, named as "anti rust lubricating oil"
- Four-stroke engine oils: it is to notice that in Europe there are no eco-labels addressing 4T engine oils. Moreover, Korea Eco-Label addresses 4T engine oils but in a Product Category apart from the one of Lubricants. Korea Eco-Label has three Product Categories for engine oils apart from the one of Lubricants (each one for: 4T engine oils, 2T engine oils, diesel gasoline oils) which criteria are different from those of Lubricants, and are related to emissions of air pollutants and resource consumption. The Korea Eco-Label for 2T also includes a biodegradability criterion.

In the light of the prioritisation methodology the initial proposal on scope broadening has been further defined and the following product groups and the potential inclusion into the new proposed scope are discussed below:

- Total loss systems: are those that entry into environment unavoidably and are irretrievable. They are included into the current classification on the category 3 as <u>chainsaw oils</u>, wire rope lubricants, marine gear oils and <u>other total loss lubricants</u>. They are proposed to be maintained into the scope due to their total release to the environment and their potential impacts.
- Mould release: currently only the <u>concrete release agents</u> (Category 3) are included since they are classified as total loss. The inclusion of the industrial release agents is not proposed in this revision due to the low problematic associated and the lack of data.
- Gears: previous revisions and current criteria considered gear oils as total loss. Although this revision considers industrial gear lubricants as Accidental/Partial loss, it is proposed to maintain them within the scope. It should be noticed that, according to ISO, <u>marine gear oils</u> are classified as Family A: total loss systems (as open system gears).

- Internal combustion engine oils: the category includes the 2-stroke oil and the 4-T stroke oil lubricants. 2-stroke oil lubricants are included in the current scope since they are considered as total loss. Moreover, 2-stroke have a severe impact in the atmosphere due to the emission to air with burnt combustible. In this revision, the 4-T stroke oil will be also analysed because of the high market share and the problematic on collecting waste oil produced (especially at particular level).
- Hydraulic systems: they correspond with category 1 of the existing classification: hydraulic fluids and <u>tractor transmission oils</u>. On the current revision they have not been considered as total loss, however the environmental impact could be relevant if they are used in sensitive areas and they are proposed to be maintained within the scope.
- Metalworking: despite they are classified as accidental loss, the metalworking fluids could be important due to the impact on human health for the worker exposure. Also the impacts linked with waste could be relevant from an environmental point of view. Temporary protection against corrosion: They are proposed to be included since they are often used on open systems and in environmentally sensitive areas. Sometimes they are not recovered after use and waste lubricant can be lost into the environment, for this reason they are classified as total loss.
- <u>Stern tube</u>: they are included in family T: turbines of the ISO. They are currently included into the scope of the current criteria as they are total loss. They are proposed to be included into the new scope as well, because they can be used on environmental sensitive areas in direct contact with marine water. Industrial turbines are proposed to be left out of the scope for this revision process.
- Greases: included in the category 2, <u>greases</u> and <u>stern tube greases</u>. They are proposed to be maintained within the scope of the product group since they could generate an important environmental impact depending on the use (they have a broad set of possible applications).

According to the aspects described above, the updated scope proposal includes the following lubricant categories:

ISO Family	ISO 6743-99 Description		Current EEL	Proposal for the revised EEL
Α	Total loss systems		Included	Included
В	Mould release	Concrete	Included	Included
С	Gears		Included	Included
Б	Internal	4-T stroke oil	Excluded	Included
Ľ	oils	2-T stroke oil	Included	Included
Н	Hydraulic systems		Included	Included
Μ	Metalworking		Excluded	Included
R	Temporary protection against corrosion		Excluded	Included
Т	Turbines Stern tube		Included	Included

## Table 1: Included and excluded categories following ISO 6743 classification in the current and revised EU Ecolabel

X	Greases	Included	Included

Three new categories are proposed to be included in the current scope:

- the 4-stroke oils have been considered because of the market share,
- the metalworking fluids could cause an important impact on human health;
- and finally, the temporary protection against corrosion lubricants are usually used in environmental sensitive areas and are considered to be total loss.

The rest of lubricant categories that are currently excluded from the EU Ecolabel scope are proposed to be left out of this revision process following the criteria: they do not have a high market share, they are partial/accidental loss without special potential impacts during use, they do not have specific environmental problematic linked to waste since controlled collection and treatment is normally done at industrial level.

Questions to stakeholders

The existing and revised definitions do not exclude water base lubricants, however no awarded licenses due to that the existing criteria is mainly designed to be accomplished by biobased lubricants.

Stakeholders are asked to provide relevant information on the potential limitations on water base lubricants to comply with the criteria and in the potential features that could addressed in the revised criteria to reflect the environmental performance of such products.

# 1.2.2 Key environmental aspects and relation with the criteria proposal

A robust quantification of the overall environmental impact of lubricants would entail a detailed Life Cycle Assessment (LCA), with a scope covering manufacturing, use and fate at end of life, and with system boundaries encompassing petroleum, petrochemical, oleochemical and engineering industry activities. This would be a complex process, due to the very broad scope required, and also to some particular issues which are characteristic of the industry and the applications. One complication is that lubricants are typically manufactured as co-products in integrated product networks, based on petroleum refining, oleochemical refining or chemical processing.

In spite of the limitations above the environmental assessment described in the preliminary report<sup>5</sup> allowed finding the main areas of environmental concern from a life cycle perspective of the lubricant product group. This section summarises the main conclusions that can be extracted from the results revealed by LCA literature review and the supplementary environmental evidence.

In general, considering a cradle-to-grave approach, studies indicate that the release to the environment during use and disposal stages can be critical from an environmental point of view.

<sup>&</sup>lt;sup>5</sup> Chapter 3, Preliminary Report

Nevertheless most LCAs studied only cover cradle-to-gate scope and for this reason a quantification of the relevance of these last stages are not feasible.

The overall findings indicate that the main environmental impact of lubricant life cycle is produced at the use stage and the end of life and that the impact is highly dependent on the raw materials used. Bellow a summary of the main impact according the life cycle stages are detailed:

#### Raw material extraction, transport and processing of components

The raw materials can be of high importance, since the extraction and processing (especially due to energy consumption) of these materials can have relevant impacts. Moreover the composition of lubricants will condition the potential impact to the environment during and after their use, since formulation is related to inherent biodegradability and toxicity of the product.

#### Comparing different base fluids:

- In general **vegetable oil** brings advantages due its renewable origin and higher biodegradability. The highest impacts for vegetable oils are due to agriculture stage, so impacts highly depend on the crop operations. LCA comparative studies indicate lower energy consumption during processing and lower impacts for the global warming potential than mineral and synthetic oils.
- Regarding **synthetic oils**, the refining/synthesis phase is the main contributor of impacts. In the production stage they have higher impacts than mineral oil due to more complex processing and higher energy consumption. However they have a longer life and lower impact during use.
- For mineral base oil, the highest contribution is due to the extraction phase.
- $\circ$  **Re-refined oils** bring environmental advantages. With modern re-refining technologies, CO<sub>2</sub> emissions can be reduced by more than 50% as compared to the conventional production of base oil.
- The environmental impact of water base fluid could occur mainly during the disposal of waste fluids.

In relation to **additives** (being between 7-20% of formulation by weight), despite not being covered in most of LCA studies, they can have relevant contribution to life cycle impacts of lubricants for some impact categories where impact from additives can be up to 50% of the total impacts (in particular for carcinogens and mineral extraction).

With regard the **transport**, the relative impacts seem to be of low relevance.

#### Manufacturing of lubricant, packaging and distribution

**Manufacturing** comprises the blending of substances and it is a less complex process and with lower environmental impact than the processing of raw materials (where energy consumption is more relevant), although it can have relevant impacts in some categories.

The **packaging** of lubricants can have a broad range of types, due to the different applications and typologies of lubricants. Packaging is less covered in LCA studies, and the relevance of the

potential impacts is not known however there are sustainability measures such as using environmentally friendly materials, design for a correct use/application/resistance to spillage and correct disposal that might be of easy implementation while bringing environmental benefits.

#### <u>Use phase</u>

The **use** stage of a lubricant product will highly condition its potential environmental impact, considering the probability of release to the environment (application and loss during use and management of used oil) and the consequences in terms of toxicity and impact on human health and the different environmental systems (especially for losses in sensitive areas). This impact is highly important since approximately 50% of all traditional lubricants are released into the environment during use, spills, or disposal. Any release of used oil to the environment, by accident or otherwise, threatens ground soil and surface waters with oil contamination there by endangering drinking water supply and aquatic organisms.

#### End-of-life

LCA studies emphasize used oil disposal as the critical phase of the lube to be paid greater attention to reduce environmental impact. Uncontrolled disposal of lubricant has adverse effect on the soils, aquatic life and drinking water. The 50% of used oils will become waste oils potentially recoverable (the rest is lost during use; through leakages, exhaust emissions, etc.). Waste oils (WO) are hazardous waste as they display some hazardous properties. In addition to additives, waste oil is also likely to contain metals from engine wear; unburned fuel; PAH (polyaromatic hydrocarbons) from polymerisation and incomplete combustion of fuel; particulates and water. Proper collection and posterior re-refining is the best option from an environmental point of view; it has lower impacts than disposal (burning) and also it has associated environmental savings with respect to using new lubricant as raw material.

In the light of the environmental impact assessment, the hazardous substances analysis and the guidelines established in the prioritisation methodology for the revision, it is summarised in the following table the main environmental areas of relevance and the areas of improvement of the existing criteria that will be further investigated and addressed in more detail in this report:

Existing EU Ecolabel criteria	Criteria proposal		Environmental aspects
Criterion 1. Excluded or limited substances and mixtures Criterion 2. Restricted substances	Criterion 1. Excluded and limited substances		It limits the hazardous substances and mixtures that can be included in the product, limiting environmental and health risks for users.
Criterion 3. Additional aquatic toxicity requirements	Criterion 2. Aquatic toxicity	Hazardous substances Emission to soil/ water	It ensures that the overall aquatic toxicity is limited.
Criterion 4. Biodegradability and bioaccumulative potential	Criterion 3. Biodegradability and Bioaccumulative potential		It ensures that the ingredients are biodegradable and will not persist in water.
Criterion 5. Renewable raw material	Criterion 4. Raw materials	Pay materials extraction	It promotes more sustainable alternatives to mineral oils (bio-based, re-refined, synthetic).
	Criterion 5. Origin and traceability of vegetable oils	and processing	It ensures that the vegetable oils used for the lubricant manufacturing comes from a sustainably management plantation.
	Criterion 6.Exhaust emissions	Emissions to air	It limits the air emissions of 2-stroke engine oils.
	Criterion 7. Packaging	Raw materials extraction and processing Spillage during use phase Waste generation and disposal	Recycled content for packaging materials. It ensures prevention of spillage during use. It ensures that a limited amount of waste will be generated and that the packaging can be recycled, as far as possible.
Criterion 6. Minimum technical performance	Criterion 8. Minimum technical performance	Efficiency during use	It guarantees that the product meets certain quality (technical performance) requirements foreseen for the different applications.
	Criterion 9. Consumer information	Waste generation and disposal	It reminds consumers to dispose of the packaging in a responsible manner.

#### Table 2. Link between the environmental aspects identified (LCA and non-LCA impacts) and the EU Ecolabel criteria

Criterion 7. Information on EU Ecolabel	Criterion10. Information on EU Ecolabel	It informs consumers that the product has a limited amount of undesired substances and therefore also a lower environmental impact, in order to encourage the purchase of the product.				

### 1.3 PROPOSED FRAMEWORK FOR THE REVISION OF THE EU ECOLABEL CRITERIA AND MAIN CHANGES

The proposed criteria are aimed to be structured covering the different life stages and assessing the hot spots and key parameters identified in the preliminary report.

Some criteria are suggested to be merged due to technical reasons, whereas other criteria have been modified in content but maintaining the structure. Moreover, some additional criteria are proposed in order to cover certain aspects not addressed through the current criteria and to be consistent with the revised scope. Following table presents the changes in the criteria structure:

Existing EU Ecolabel criteria	Criteria proposal
Criterion 1. Excluded or limited substances and mixtures Criterion 2. Restricted substances	Criterion 1. Excluded and limited substances
Criterion 3. Additional aquatic toxicity requirements	Criterion 2. Aquatic toxicity
Criterion 4. Biodegradability and bioaccumulative potential	Criterion 3. Biodegradability and Bioaccumulative potential
Criterion 5. Renewable raw	Criterion 4. Raw
material	materials
	traceability of vegetable oils
	Criterion 6.Exhaust emissions
	Criterion 7. Packaging
Criterion 6. Minimum	Criterion 8. Technical
technical performance	performance
technical performance	performance Criterion 9. Consumer information
technical performance Criterion 7. Information on	performance Criterion 9. Consumer information Criterion10. Information

Table 3. Comparison of the criteria structure

### 2 ASSESSMENT AND VERIFICATION

#### Assessment and verification

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

Competent bodies shall preferentially recognise attestations which are issued by bodies accredited in accordance with the relevant harmonised standard for testing and calibration laboratories and verifications by bodies that are accredited in accordance with the relevant harmonised standard for bodies certifying products, processes and services. Accreditation shall be carried out in accordance with Regulation (EC) No 765/2008 of the European Parliament and of the Council<sup>6</sup>.

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

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

As a prerequisite, the product shall meet all applicable legal requirements of the country or countries in which the product is intended to be placed on the market. The applicant shall declare the product's compliance with this requirement.

The list of all ingredients present at or above the concentration of 0,010% weight by weight shall be provided to the competent body, indicating the trade name (if existing), the chemical name, the CAS no., the ingoing quantity, the function and the form present in the final product formulation.

All ingoing substances present in the form of nanomaterials shall be clearly indicated in the list with the word 'nano' written in brackets.

For each ingoing substance listed, the Safety Data Sheets (SDS) in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council<sup>7</sup> shall be provided. Where an SDS is not available for a single substance because it is part of a mixture, the applicant shall provide the SDS of the mixture.

#### (b) Measurement thresholds

Compliance with the ecological criteria is required for the final product and its constituent substances that are intentionally added and/or are formed intentionally after any chemical reaction in the applied lubricant, as specified below:

- to the applied lubricant for criteria xxx (to be completed in a later stage);
- to each stated substance intentionally added or formed at or above 0,010 % (w/w) for criteria xxx (to be completed in a later stage);
- to each stated substance intentionally added or formed above 0,10 % (w/w) for

<sup>&</sup>lt;sup>6</sup> Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

<sup>&</sup>lt;sup>7</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 396, 30.12.2006, p. 1).

Assessment and verification

criteria xxx (to be completed in a later stage).

In addition the total fraction of the stated substances where the formulated criteria x and y do not apply shall remain below 0.5 % (w/w).

#### Rationale of proposed General text on Assessment and Verification

The assessment and verification text refers to the different type of evidence that is considered relevant as a proof of compliance for each criterion. The text has been revised harmonizing it, as far as appropriate, with the text which is included in the most recently adopted EU Ecolabel criteria.

The EU Ecolabel Regulation (EC) No 66/2010 indicates that competent bodies shall preferentially recognise verifications performed by bodies which are accredited under the EN 45011. However, this standard is nowadays phased-out since it has been substituted by ISO/IEC 17065:2012: Conformity assessment - Requirements for bodies certifying products, processes and services. For this reason certification bodies are no longer accredited in accordance with these requirements. A new statement has been included in the text doing reference to the Regulation (EC) 765/2008 of the European Parliament and of the Council.

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

The section of the measurement threshold will be updated in the next version of this report, when the decision on the formulation of each criterion is in a more advanced stage.

### 3 CRITERIA PROPOSAL

### 3.1 CRITERION 1: Excluded or limited substances

#### Proposal for criterion 1: Excluded or limited substances

#### 1 (a) Hazardous substances

#### (i) Final product

The final product shall not be classified and labelled as being acutely toxic, a specific target organ toxicant, a respiratory or skin sensitiser, carcinogenic, mutagenic or toxic for reproduction, or hazardous to the aquatic environment, as defined in Annex I to Regulation (EC) No 1272/2008 and in accordance with the list in Table 1.

#### FOR DISCUSSION: (ii) Substances

The final product formulation, including all intentionally added ingredients present at a concentration limit of or above 0,010 % weight by weight (in the final product), shall not contain substances that meet the criteria for classification as toxic, hazardous to the aquatic environment, respiratory or skin sensitisers, carcinogenic, mutagenic or toxic for reproduction in accordance with Annex I to Regulation (EC) No 1272/2008 and in accordance with the list in Table 1.

Where stricter, the generic or specific concentration limits determined in accordance with Article 10 of Regulation (EC) No 1272/2008 shall take precedence.

Carcinogenic, mutagenic or toxic for reproduction			
Category 1A and 1B	Category 2		
H340 May cause genetic defects	H341 Suspected of causing genetic defects		
H350 May cause cancer	H351 Suspected of causing cancer		
H350i May cause cancer by inhalation			
H360F May damage fertility	H361f Suspected of damaging fertility		
H360D May damage the unborn child	H361d Suspected of damaging the unborn child		
H360FD May damage fertility. May damage the	H361fd Suspected of damaging fertility. Suspected of		
unborn child	damaging the unborn child		
H360Fd May damage fertility. Suspected of	H362 May cause harm to breast fed children		
damaging the unborn child			
H360Df May damage the unborn child. Suspected			
of damaging fertility			
Acute toxicity			
Category 1 and 2	Category 3		
H300 Fatal if swallowed	H301 Toxic if swallowed		
H310 Fatal in contact with skin	H211 Toyic in contact with skin		
115101 atal ili contact with skill	H511 TOXIC III COIItact WITH SKIII		
H330 Fatal if inhaled	H331 Toxic if inhaled		
H330 Fatal if inhaled H304 May be fatal if swallowed and enters	H331 Toxic if inhaled EUH070 Toxic by eye contact		
H330 Fatal if inhaled H304 May be fatal if swallowed and enters airways	H331 Toxic if inhaled EUH070 Toxic by eye contact		
H330 Fatal if inhaled H304 May be fatal if swallowed and enters airways Specific target organ toxicity (STOT)	H331 Toxic if inhaled EUH070 Toxic by eye contact		
H300 Fatal if inhaled H304 May be fatal if swallowed and enters airways Specific target organ toxicity (STOT) Category 1	H311 Toke in contact with skin H331 Toxic if inhaled EUH070 Toxic by eye contact Category 2		
H310 Fatal in contact with skill         H330 Fatal if inhaled         H304 May be fatal if swallowed and enters airways         Specific target organ toxicity (STOT)         Category 1         H370 Causes damage to organs	H311 Toke in contact with skin H331 Toxic if inhaled EUH070 Toxic by eye contact Category 2 H371 May cause damage to organs		
H330 Fatal if inhaled         H304 May be fatal if swallowed and enters airways         Specific target organ toxicity (STOT)         Category 1         H370 Causes damage to organs         H372 Causes damage to organs through prolonged	H311 Toxic in contact with skin H331 Toxic if inhaled EUH070 Toxic by eye contact Category 2 H371 May cause damage to organs H373 May cause damage to organs through prolonged		
H330 Fatal if inhaled         H304 May be fatal if swallowed and enters airways         Specific target organ toxicity (STOT)         Category 1         H370 Causes damage to organs         H372 Causes damage to organs through prolonged or repeated exposure	H311 Toxic in contact with skin         H331 Toxic if inhaled         EUH070 Toxic by eye contact         Category 2         H371 May cause damage to organs         H373 May cause damage to organs through prolonged or repeated exposure		
H310 Fatal in contact with skill         H330 Fatal if inhaled         H304 May be fatal if swallowed and enters airways         Specific target organ toxicity (STOT)         Category 1         H370 Causes damage to organs         H372 Causes damage to organs through prolonged or repeated exposure         Category 3	H311 Toxic in contact with skin         H331 Toxic if inhaled         EUH070 Toxic by eye contact         Category 2         H371 May cause damage to organs         H373 May cause damage to organs through prolonged or repeated exposure		
H310 Fatal in contact with skill         H330 Fatal if inhaled         H304 May be fatal if swallowed and enters airways         Specific target organ toxicity (STOT)         Category 1         H370 Causes damage to organs         H372 Causes damage to organs through prolonged or repeated exposure         Category 3         H336 May cause drowsiness or dizziness	H311 Toxic in contact with skin         H331 Toxic if inhaled         EUH070 Toxic by eye contact         Category 2         H371 May cause damage to organs         H373 May cause damage to organs through prolonged or repeated exposure		

Table 1. Restricted hazard classifications and their categorisation

Proposal for criterion 1: Excluded or limited substances				
Category 1A	Category 1/1B			
H317: May cause allergic skin reaction	H317 May cause allergic skin reaction			
H334: May cause allergy or asthma symptoms or	H334 May cause allergy or asthma symptoms or			
breathing difficulties if inhaled	breathing difficulties if inhaled			
Skin corrosion/irritation				
Category 1	Category 2			
H314 Causes severe skin burns and eye damage	H315 Causes skin irritation			
Serious eye damage/eye irritation				
Category 1	Category 2			
-	H319 Causes serious eye irritation			
Hazardous to the aquatic environment				
Category 1 and 2	Category 3 and 4			
H400 Very toxic to aquatic life	H412 Harmful to aquatic life with long-lasting effects			
H410 Very toxic to aquatic life with long-lasting	H413 May cause long-lasting effects to aquatic life			
effects				
H411 Toxic to aquatic life with long-lasting effects				
Hazardous to the ozone layer				
H420 Harms public health and the environment by				
destroying ozone in the upper atmosphere				
Supplemental hazard information – Health haza	ırds			
EUH029 Contact with water liberates toxic gas				
EUH031 Contact with acids liberates toxic gas				
EUH032 Contact with acids liberates very toxic				
gas				
EUH066 Repeated exposure may cause skin				
dryness or cracking				

FOR DISCUSSION: Substances or mixtures which change their properties upon processing (e.g. become no longer bioavailable, undergo chemical modification) so that the identified hazard no longer applies are exempted from the above requirement.

This criterion does not apply to ingoing substances covered by Article 2(7)(a) and (b) of Regulation (EC) No 1907/2006 which set out criteria for exempting substances within Annexes IV and V to that Regulation from the registration, downstream user and evaluation requirements. In order to determine whether that exclusion applies, the applicant shall screen any ingredient present at a concentration above 0,010% weight by weight.

Substances and mixtures included in Table 2 are exempted from point (a)(ii) of Criterion 1.

Table 2. Derogated substances (to be completed in a later stage if requirement ( <i>u</i> ) Substances is kept)					
Substance	Category 1	Category 2	Category 3	Category 4	Category 5
					0.

Assessment and verification: FOR DISCUSSION: the applicant shall demonstrate compliance with this criterion for the final product and for any substance present at a concentration greater than 0,010 % weight by weight in the final product. The applicant shall provide a signed declaration of compliance supported by declarations from suppliers, if appropriate, or SDS confirming that none of these substances meets the criteria for classification with one or more of the hazard statements listed in Table Xin the form(s) and physical state(s) in which they are present in the product.

For substances listed in Annexes IV and V to Regulation (EC) No 1907/2006, which are exempted

#### Proposal for criterion 1: Excluded or limited substances

from registration obligations under points (a) and (b) of Article 2(7) of that Regulation, a declaration to this effect by the applicant shall suffice to comply.

The applicant shall provide a signed declaration of compliance supported by declarations from suppliers, if appropriate, or SDS confirming the presence of ingoing substances that fulfil the derogation conditions.

#### 1 (b) Specified excluded and restricted substances

#### (i) Excluded substances

The substances listed below shall not be included in the product formulation regardless of concentration:

(to be completed if considered necessary along the revision process)

#### (ii) Restricted substances

The substances listed below shall not be included in the product formulation above the concentration of 0,010% (w/w) of the final product:

- substances appearing in the Union List of priority substances in the field of water policy in Annex X to Directive 2000/60/EC of the European Parliament and of the Council<sup>8</sup> as amended by laid in Decision No 2455/2001/EC of the European Parliament and of the Council<sup>9</sup> and the OSPAR List of Chemicals for Priority Action (<u>http://www.ospar.org/work-areas/hasec/chemicals/priority-action</u>);
- 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;

Assessment and verification: the applicant shall provide a signed declaration of compliance supported by declarations from suppliers, if appropriate, confirming that the listed substances are not present in the product formulation above the limits set.

#### 1 (c) Substances of very high concern (SVHCs)

The final product shall not contain any substances that have been identified in accordance with the procedure described in Article 59(1) of Regulation (EU) No 1907/2006, which establishes the candidate list for substances of very high concern.

(if derogation requests are received for SVHC presence in the final product below 0.010% w/w, reformulation should be considered)

Assessment and verification: the applicant shall provide a signed declaration of compliance supported by declarations from their suppliers, if appropriate, or SDS confirming the non-presence of all the candidate list substances.

Reference to the latest list of substances of very high concern shall be made on the date of application.

#### Rationale of Proposed Criterion text

Technical analysis performed as part of the revision showed that the chemicals used in the formulation of the product significantly contribute to the overall environmental impacts. The aim of this criterion is to exclude or limit toxic or harmful substances, thus ensuring that the EU Ecolabel is only awarded to the least environmentally impacting products.

For the revised criteria, it is proposed the existing criteria 1 Excluded or limited substances and *mixtures* and 2 Exclusion of specific substances to be merged in order to present only one criterion related to excluded or limited substances.

<sup>&</sup>lt;sup>8</sup> OJ L 327, 22.12.2000, p. 1.

<sup>&</sup>lt;sup>9</sup> OJ L 331, 15.12.2001, p 1.

The proposed formulation of all three sub-criteria is aligned with the recently voted EU Ecolabel criteria for detergents, with specific changes related to the lubricants product group introduced:

#### 1 (a) Hazardous substances

This first sub-criterion -(a) Hazardous substances - is directly linked to the requirements given in the EU Ecolabel Regulation (EC) No 66/2010 which states that:

"The EU Ecolabel may not be awarded to goods containing substances or preparations/mixtures meeting the criteria for classification as toxic, hazardous to the environment, carcinogenic, mutagenic or toxic for reproduction (CMR), in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, nor to goods containing substances referred to in Article 57 of Regulation (EC) No 1907/2006 of the European parliament and the Council of 18 December 2006 concerning the Registration, evaluation, authorization of chemicals (REACH) establishing a European Chemicals Agency".

The Regulation allows derogations to be included for specific substances under strictly defined conditions:

"For specific categories of goods containing substances referred to in paragraph 6, and only in the event that it is not technically feasible to substitute them as such, or via the use of alternative materials or designs, or in the case of products which have a significantly higher overall environment performance compared with other goods of the same category, the Commission may adopt measures to grant derogations from paragraph 6".

The currently used interpretation of the grouping of hazards<sup>10</sup> is presented below (as per Regulation (EC) No. 1272/2008 and the Task Force document<sup>11</sup>):

- Group 1: Hazards subject to complete restriction

Substances present in mixtures, in an article or in any homogenous part of a complex article that meet the criteria of Article 57 of REACH regulation or that are identified according to the procedure described in Article 59 (1) of that Regulation. This shall include the hazards listed below, as well as, endocrine disruptors, neurotoxins and sensitisers of equivalent concern.

- Group 2: Priority hazards for restriction to which stricter conditions shall apply Substances that, in combination with these hazards, are also very persistent, persistent, very bioaccumulative or bioaccumulative, as defined according to Annex XIII of the REACH Regulation, shall be treated as Group 1 substances.
- Group 3: Hazards to which greater flexibility may be applied
   Flexibility may be applied for instance if the fate of the product is not in the aquatic environment.

Carcinogenic, mutagenic or toxic for reproduction				
GROUP 1:Category 1A and 1B	GROUP 2:Category 2			
H340 May cause genetic defects	H341 Suspected of causing genetic defects (R68)			
H350 May cause cancer	H351 Suspected of causing cancer (R40)			
H350i May cause cancer by inhalation (R49)				

#### Table 4. List of hazard statements.

 <sup>&</sup>lt;sup>10</sup> According to 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>11</sup> Findings of the EU Ecolabel Chemicals Horizontal Task Force - Proposed approach to hazardous substance criteria development. 24th February 2014. Available online at: <a href="http://ec.europa.eu/environment/ecolabel/documents/Chemicals%20HTF\_Approach%20paper.pdf">http://ec.europa.eu/environment/ecolabel/documents/Chemicals%20HTF\_Approach%20paper.pdf</a>

H360F May damage fertility (R60)	H361f Suspected of damaging fertility (R62)
H360D May damage the unborn child (R61)	H361d Suspected of damaging the unborn child (R63)
H360FD May damage fertility. May damage the unborn	H361fd Suspected of damaging fertility. Suspected of damaging
child (R60, R60/61)	the unborn child (R62/63)
H360Fd May damage fertility. Suspected of damaging the	H362 May cause harm to breast fed children (R64)
unborn child (R60/63)	
H360Df May damage the unborn child. Suspected of	
damaging fertility (R61/62)	
Acute toxicity	
GROUP 2:Category 1 and 2	GROUP 3:Category 3
H300 Fatal if swallowed (R28)	H301 Toxic if swallowed (R25)
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)
H304 May be fatal if swallowed and enters airways (R65)	EUH070 Toxic by eye contact (R39-41)
Specific target organ toxicity (STOT)	
GROUP 2:Category 1	GROUP 3:Category 2
H370 Causes damage to organs (R39/23, R39/24, R39/25,	H371 May cause damage to organs (R68/20, R68/21, R68/22)
R39/26, R39/27, R39/28)	
H372 Causes damage to organs through prolonged or	H373 May cause damage to organs through prolonged or repeated
repeated exposure (R48/25, R48/24, R48/23)	exposure (R48/20, R48/21, R48/22)
Respiratory and skin sensitisation (where applicable	e)
GROUP 2:Category 1	
H317: May cause allergic skin reaction (R43)	
H334: May cause allergy or asthma symptoms or breathing	
difficulties if inhaled (R42)	
Hazardous to the aquatic environment	
GROUP 2:Category 1 and 2	GROUP 3: Category 3 and 4
H400 Very toxic to aquatic life (R50)	H412 Harmful to aquatic life with long-lasting effects (R52/53)
H410 Very toxic to aquatic life with long-lasting effects	H413 May cause long-lasting effects to aquatic life (R53)
(R50/53)	
H4111 Oxicto aquatic life with long-lasting effects (R51/53)	
GRUUP 2: Hazardous to the ozone layer	
H420 Harms public health and the environment by	
destroying ozone in the upper atmosphere (R59)	

Moreover, according to the current EU Ecolabel, this criterion shall also include the following hazard statements:

Hazard statement
EUH29 Contact with water liberates toxic gas
EUH031 Contact with acids liberates toxic gas
EUH032 Contact with acids liberates very toxic gas
H314 Causes severe skin burns and eye damage
H319 Causes serious eye irritation
H315 Causes skin irritation
EUH066 Repeated exposure may cause skin dryness or cracking
H336 May cause drowsiness and dizziness

The 2<sup>nd</sup> Adaptation to Technical Progress (2<sup>nd</sup> ATP) to the CLP Regulation<sup>12</sup> included the revision related to the hazard class for substances and mixtures hazardous to the ozone layer, consequently the hazard statement 'EUH059' has been replaced by 'H420': Harms public health and the environment by destroying ozone in the upper atmosphere.

According to the EU Ecolabel Chemicals Horizontal Task Force, the inclusion of skin and respiratory sensitizer hazards in the EU Ecolabel hazard list for a product group has been based on whether there is potential for consumer exposure, either through extended periods of skin contact with the product or the potential for respiratory exposure to particles, vapours or fumes

<sup>&</sup>lt;sup>12</sup> Commission Regulation (EU) No 286/2011 of 10 March 2011 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures.

during use (e.g. lubricants). Where, according to Article 57 (f) of REACH sensitisers, are shown to be of equivalent concern to  $SVHC^{13}$  they shall be subject to strict requirements. Therefore, respiratory or skin sensitisers (hazard classes H317 and H334) shall not be allowed in quantities exceeding 0,01% (w/w) of the final product.

#### **<u>1 (b) Specified excluded and restricted substances</u>**

The sub-criterion (b) Specified excluded and restricted substances mentions several groups of substances which are restricted above specified concentrations in the final product, namely:

- substances appearing in the Union List of priority substances in the field of water policy in Annex X to Directive 2000/60/EC of the European Parliament and of the Council as amended by laid in Decision No 2455/2001/EC of the European Parliament and of the Council and the OSPAR List of Chemicals for Priority Action (http://www.ospar.org/work-areas/hasec/chemicals/priority-action);
- 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;

The EU directive on the aquatic policy and the OSPAR treaty have generated lists of priority substances whose emission to the water compartment should be ended. It is important to explicitly include these lists in these criteria and it is suggested to maintain the specific restriction in the revised criterion. The same approach for is suggested for organic halogens and nitrite compounds. Most criteria of national ecolabels exclude organic halogen compounds for reasons related to the incineration of used lubricants, due to the formation of dioxins and furans. Nitrite compounds are excluded in most criteria of national ecolabels since they form nitrosamines that are carcinogenic.

According to the Aquatic Toxicity Reference Values<sup>14</sup>, metals or metallic compounds, lithium and/or aluminium compounds exhibit high toxicity to aquatic organisms while sodium, potassium, magnesium and calcium are exempted based on their relatively low toxicity. It is suggested to maintain this specific restriction in the revised criterion.

Additional information on relevant substances in the lubricants sector can be found in the preliminary report. Relevant information it is summarised below for further discussion:

#### Biocides

Only biocidal products containing biocidal active substances approved by European Commission and authorized for use in lubricants are allowed for use.

Chloromethylisothiazolinone (CMIT) and methylisothiazolinone (MIT) are widely used in lubricants due to their effectiveness within such wide pH range. The dosage of CMIT+MIT added to the products is usually very low.

Mixture of CMIT+ MIT15 (3:1) has already harmonized classification and labeling in Annex VI of CLP regulation with the following H-statements: Acute Tox.3 H331, Acute Tox.3 H311, Acute Tox.3 H301, Skin Corr. 1B H314, Skin sens.1 H317, Aquatic Acute 1 H400, Aquatic Chronic 1 H410, which would exclude its use from the ecolabelled products above certain concentration.

<sup>&</sup>lt;sup>13</sup> SVHC: Substances of Very High Concern

<sup>&</sup>lt;sup>14</sup> Environmental Restoration Division. 1999. Aquatic Toxicity Reference Values (TRVs). Manual ERD-AG-003. More information available online at: http://www.srs.gov/general/programs/soil/ffa/rdh/p76.PDF

<sup>&</sup>lt;sup>15</sup> Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2*H*-isothiazol-3-one [EC no. 220-239-6] (3:1).

CMIT+ MIT are usually used and sold as a mixture of CMIT/MIT in ratio (3:1) because because of their wider effectiveness in combating bacteria, fungi and yeasts and also their cheaper price. The pH of the product to be preserved is one of the main factors that limit the use of preservatives. Depending on the stabilization and other compounds present in the formulation, the CMIT/MIT can be almost with no pH restrictions comparing with other preservatives. If only CMIT separately is used, the CMIT component begins to degrade quickly. CMIT degradation also occurs in systems containing small amounts of reducing agents such as sulphites, sulphides or sulphur containing amino acids. That's one of the reason why CMIT/MIT is almost always used in a mixture.

According to the CLP classification, if the concentration of CMIT/MIT (3:1) is  $\geq 0,0015\%$  (15 ppm), the final mixture must be classified as Skin Sens 1; H317. This explains why the mixtures of CMIT/MIT are found in a concentration below 15ppm as then a classification is avoided.

#### Questions to stakeholders

Stakeholders are asked to provide information on the biocides used in their products, in particular the ones carrying harmonised classification.

#### Nanomate rials

Currently, nanomaterials are covered by the definition of a "substance" under REACH, although there is no explicit reference to nanomaterials and the same REACH provisions apply to all chemical substances. Nanomaterials are not intrinsically hazardous per se but there may be a need to take into account specific considerations in their risk assessment. It is only the results of the risk assessment that will determine whether the nanomaterial is hazardous and whether or not further action is justified.

The use of two nanomaterials of possible concern that could be considered to be specifically excluded or limited in the product group is presented below for further discussion:

Silver nanoparticle: The product G-OIL<sup>TM</sup> MARINE TC-W3 2 CYCLE GREEN ENGINE OIL, currently on the market, is engineered for all models of outboard engines and personal watercraft. Silver nanoparticles (AgNP) reveal high ecotoxicity even at very low effect concentrations. AgNP are classified as very toxic towards aquatic organisms (very low values of EC50, e.g. for algae of 4 µg/l and also for crustaceans – far below 1 mg/l have been reported). Another important aspect is that at low concentrations inhibition of nitrifying bacteria can occur and the function of wastewater treatment plants may be affected due to the presence of AgNP<sup>16</sup>.

Boron-based nanoparticulate: Boric acid is used to be a common additive in metal-working fluid (MWF) formulations thanks to its excellent EP/AW properties and bacteriostatic and bactericidal actions. Nowadays, it has been largely phased out from MWFs because of HSE concerns. However, some recent studies mention "boron-based nanoparticulate lubrication additives that can drastically lower friction and wear in a wide range of industrial and transportation applications", indicating renewed interest in boric acid. Boric acid is identified as a substance meeting the criteria of Article 57 (c) of REACH regulation (substance of very high concern (SVHC), and included in the candidate list for authorization) owing to its classification as toxic for reproduction.

#### 1 (c) Substances of very high concern (SVHCs)

<sup>&</sup>lt;sup>16</sup> Mikkelsen et al.: Survey on basic knowledge about exposure and potential environmental and health risks for selected nanomaterials, Danish Environmental Protection Agency, 2011.

Similarly to sub-criterion (a), sub-criterion (c) is directly linked to the EU Ecolabel Regulation (EC) No 66/2010, which states that no substances of very high concern (SVHC) can be present in EU Ecolabel products. It also specifies that:

"no derogation shall be given concerning substances that meet the criteria of Article 57 of Regulation (EC) No 1907/2006 (REACH) and that are identified according to the procedure described in Article 59(1) of that Regulation, present in mixtures, in an article or in any homogeneous part of a complex article in concentrations higher than 0,1 % (weight by weight)".

Article 57 defines the criteria for the inclusion of substances in Annex XIV of the REACH Regulation (in relation to their classification according to the CLP Regulation) as follows:

(a) substances meeting the criteria for classification in the hazard class carcinogenicity category 1A or 1B;

(b) substances meeting the criteria for classification in the hazard class germ cell mutagenicity category 1A or 1B;

(c) substances meeting the criteria for classification in the hazard class reproductive toxicity category 1A or 1B, adverse effects on sexual function and fertility or on development;

(d) substances which are persistent, bioaccumulative and toxic;

(e) substances which are very persistent and very bioaccumulative;

(f) substances — such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) or (e) — for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59.

Article 59 sets the procedure for the identification of substances referred to in Article 57. The updated list of SVHCs is available on the European Chemicals Agency website: <u>http://echa.europa.eu/web/guest/candidate-list-table</u>. The applicant is asked to refer to the latest version of this list at the date of application.

It is suggested align the wording to detergents product group restricting totally the presence of SHVC in the final product. However, if derogation requests are received for SVHC presence in the final product below 0.010% w/w (which is current limit in force for lubricants), reformulation of the requirement should be considered.

#### Derogations from sub-criterion (a) and (c)

In the criterion (a) in force, there is no derogation to specific substances but a general derogation to the lowest classification limit in Regulation (EC) No 1272/2008 or Directive 1999/45/EC applies to the lubricant that would trigger the classification of the final product. In summary, this means that existing criterion 1 (a) Hazardous substances and mixtures only applies to the candidate lubricant (mixture) irrespective of the classifications of its components (i.e., substances included within the candidate lubricant), except for SVHC substances (Cat 1A/Cat 1B CMRs) which are subject to a maximum threshold of 0,010%. Therefore, as long as the final lubricant (mixture) is not assigned to any of the restricted hazard statement/risk phrases set out in Criterion 1(a), it would be eligible for the EU Ecolabel. According to the current criteria, substances with health or environmental hazards statements are allowed but only under

the limit concentration for which the final product (lubricant) would be classified. Thus in practice Criterion 1(a) applies to the final product and not to the components.

In order to establish a stricter interpretation of the EU Ecolabel regulation, it is suggested to align the text to the recently voted detergents product group:

No derogations shall be given concerning substances that meet the criteria of Article 57 of REACH regulation and that are identified according to the procedure described in Article 59 (1) of that regulation (sub-criterion (c)), when present in the final product in concentration higher than 0.010% w/w per substance.

Other derogations can be only granted following a thorough analysis. The derogation request which industry can provide along the revision process shall be screened based on the nature of the hazards, the functional need and performance benefit from the derogation and the availability of substitutes. According to the existing criterion, no derogation to specific substances is granted.

#### Rationale of proposed verification text

The verification text for each of the sub-requirements is aligned to the recently voted detergents product group. However the text is subject to further discussions on the approach to be followed for this criterion.

#### Questions to stakeholders

Stakeholders are asked to provide their views on the potential implication of the strict interpretation of the article 6(6) and 6(7) of the EU Ecolabel regulation.

Would setting of restrictions at **substance level** (instead of product level as existing criterion *1 (a) Hazardous substances and mixtures*) lead to an ambition level that is not achievable by candidates and therefore to a significant loss of licenses?

Or it is still possible to apply a similar approach than detergents product group and restrict all hazardous substances unless those are explicitly derogated during the revision process?

In the case that **substance level** criteria is finally proposed, it would be crucial that Competent Bodies/industry provide information on the hazardous substances or functional groups of substances which require derogations.

### 3.2 CRITERION 2: Aquatic toxicity

Proposal for criterion 2: Aquatic toxicity

The applicant the applicant shall demonstrate mandatorily compliance by meeting the requirements of criterion 2.2, except category 2, greases (ISO Family X), where the applicant shall demonstrate compliance by meeting the requirements of either criterion 2.1 or criterion 2.2 depending on the toxicity data available for the components in the mixture (freshly prepared lubricant):

#### Proposal for criterion 2: Aquatic toxicity

- When unknown substances are present in the mixture for more than 5% by weight in the lubricant or reliable aquatic toxicity data of the mixture exists, **criterion 2.1** can be applied.
- When adequate toxicity data are available for all the components in the mixture, **criterion 2.2** shall be applied.

#### Criterion 2.1. - Requirements for the lubricant and its main components

The critical concentration<sup>17</sup> for the acute aquatic toxicity shall not exceed values specified in Table 3 for both the lubricant and for each main component.

Table 3 Proposed aquatic toxicity values for both freshly prepared lubricant and for each main component when unknown substances are present in the mixture for more than 5% by weight.

Aquatic toxicity								
CATEGORY 2								
Aquatic toxicity for the freshly	Acute aquatic toxicity or	>200 mg/L						
prepared lubricant <sup>18</sup>	Chronic aquatic toxicity	> 20 mg/L						
Aquatic toxicity for each main	Acute aquatic toxicity or	>100 mg/L						
component	Chronic aquatic toxicity	> 10 mg/L						

Assessment and verification: the applicant shall provide toxicity data of the main components or the final product.

Acute aquatic toxicity tests results shall be provided for all the following three trophic levels:

- fish,
- crustacean,
- and algal species.

Acute aquatic toxicity is normally determined using a fish 96 hour LC50, a crustacea species 48 hour

<sup>17</sup> 'Critical concentration for the acute aquatic toxicity' means the concentration of a substance at and above which injurious to an aquatic organism in a short-term aquatic exposure to that substance.

'Critical concentration' means the concentration of a substance at and above which adverse functional changes, reversible or irreversible, occur in a cell or an organ.

'Acute aquatic toxicity' means the intrinsic property of a substance to be injurious to an aquatic organism in a short-term aquatic exposure to that substance.

'Chronic aquatic toxicity' means the intrinsic property of a substance to cause adverse effects to aquatic organisms during aquatic exposures which are determined in relation to the life-cycle of the organism.

<sup>18</sup> 'Freshly prepared lubricant' means lubricant recently formulated. This term is widely used in relation to lubricant performance requirements. Lubricants are often exposed to severe conditions while in use including extremes of temperature that necessitates that the lubricant remains in a fluid state even at extreme temperatures. These conditions can cause degradation of the lubricant and damage to the metal surfaces by wear and corrosion. Additives (lubricant protection, metal surface protection and flow protection) when correctly formulated into lubricants enable them to 'stay in grade'. It addresses the need that the lubricant remains fit for purpose both freshly prepared and throughout its specified lifetime.

#### Proposal for criterion 2: Aquatic toxicity

EC50 and an algal species 72 or 96 hour EC50. These species cover a range of trophic levels and taxa and are considered as surrogate for all aquatic organisms. Data on other species (e.g. Lemna spp.) shall also be considered if the test methodology is suitable. The aquatic plant growth inhibition tests are normally considered as chronic tests but the EC50s are treated as acute values for classification purposes.

Chronic aquatic toxicity tests results shall be provided for all the following three trophic levels:

- fish,
- crustacean,
- and algal species.

For determining chronic aquatic toxicity data generated according to the standardised test methods referred to in Article 8(3) of CLP regulation shall be accepted, as well as results obtained from other validated and internationally accepted test methods. The NOECS or other equivalent L(E)Cx (e.g. EC10) shall be used.

In circumstances where the basis of the EC50 is not specified or no ErC50 is recorded, classification shall be based on the lowest EC50 available.

According to Annex XI of REACH regulation, if no experimental data exists, results of (Q)SARs<sup>19</sup> may be used.

#### Criterion 2.2. – Requirements for each substance present above 0,10 % (w/w)

Substances exhibiting a certain degree of aquatic toxicity are allowed up to a cumulative mass concentration indicated in the table 4.

Table 4. Proposed aquatic toxicity requirements for substances present above 0,10% weight by weitht in the final product

		Cumulative mass percentage (% weight by weight in the final product)					
Aquati	CATEGO RY 1	CATE GORY 2	CATEGOR Y 3	CATEGOR Y 4	CATEGO RY 5		
			PROPOSED LI	MIT			
CHRONIC HAZARD CATEGORY 3 (E)**	Acute aquatic toxicity >10 to ≤ 100 mg/L or 1 mg/L < Chronic aquatic toxicity ≤ 10 mg/L	≤10	≤20	≤2	≤20	≤10	
CHRONIC HAZARD CATEGORY 2 (F)*	Acute aquatic toxicity >1 to ≤ 10 mg/L or 0,1 mg/L < Chronic aquatic toxicity ≤ 1 mg/L	≤2,5	≤0,5	≤0,3	≤0,5	≤2,5	
CHRONIC HAZARD CATEGORY1(G)* ACUTE HAZARD CATEGORY1(G)	Acute aquatic toxicity $\leq 1$ mg/L or Chronic aquatic toxicity $\leq$ 0,1 mg/L	≤0,1/M	≤0,1/M	≤0,1/M	≤ 0,1/M	≤0,1/M	

\* Acute aquatic toxicity tests results shall be provided for one of the following three trophic levels:  $96 \text{ hr } \text{LC}_{50}$  (for fish) and/or  $48 \text{ hr } \text{EC}_{50}$  (for crustacean) and/or  $72 \text{ or } 96 \text{ hr } \text{EC}_{50}$  (for algae or other aquatic plants) (or QSAR estimation if no experimental

<sup>&</sup>lt;sup>19</sup> The OECD QSAR Toolbox for Grouping Chemicals into Categories. QSAR TOOLBOX is a software for grouping chemicals into categories and filling gaps in (eco)toxicity data needed for assessing the hazards of chemicals. More information available on-line at webpage: https://www.gsartoolbox.org/

Practical guide How to use and report (Q)SARs. ECHA-16-B-09-EN. More information available on-line at webpage: <u>https://echa.europa.eu/documents/10162/13655/pg\_report\_gsars\_en.pdf/407dff11-aa4a-4eef-a1ce-9300f8460099</u> and Guidance on information requirements and chemical safety assessment. Chapter R.6: QSARs and grouping of chemicals. More information available on-line at webpage: https://echa.europa.eu/documents/10162/13632/information\_requirements\_r6\_en.pdf/77f49f81-b76d-40ab-8513-4f3a533b6ac9

#### Proposal for criterion 2: Aquatic toxicity

data).

\*\* And the substance is not rapidly degradable and/or the experimentally determined BCF  $\geq$  500 (or, if absent, the log Kow  $\geq$  4) unless the chronic toxicity NOECs are > 1 mg/l.

Assessment and verification: the applicant shall provide acute aquatic toxicity tests results for all the following three trophic levels:

- fish,
- crustacean,
- and algal species.

Acute aquatic toxicity is normally determined using a fish 96 hour LC50, a crustacea species 48 hour EC50 and an algal species 72 or 96 hour EC50. These species cover a range of trophic levels and taxa and are considered as surrogate for all aquatic organisms. Data on other species (e.g. Lemna spp.) shall also be considered if the test methodology is suitable. The aquatic plant growth inhibition tests are normally considered as chronic tests but the EC50s are treated as acute values for classification purposes.

Chronic aquatic toxicity tests results shall be provided for all the following three trophic levels: fish, crustacean and algal species. For determining chronic aquatic toxicity data generated according to the standardised test methods referred to in Article 8(3) of CLP regulation shall be accepted, as well as results obtained from other validated and internationally accepted test methods. The NOECS or other equivalent L(E)Cx (e.g. EC10) shall be used.

According to Annex XI of REACH regulation, if no experimental data exists, results of  $(Q)SARs^{20}$  may be used.

#### **Rationale of Proposed Criterion text**

Due to the fact that lubricants have potential to cause disturbances in aquatic ecosystems when they cause emissions to water during their life cycle or due to accidental spillages, EU Ecolabel criteria include requirements that aim to limit the aquatic toxicity of the ingredients used in lubricant product group.

Existing criterion 2.1 and 2.2 are proposed to be maintained in the revised criteria version. However partial modifications are suggested in order to reduce tests on animals if sufficient information is available on substances present in the mixtures ensuring adequate comparability of results of the classification of such mixtures. Therefore, where alternatives exist, under no circumstances criterion 2 will lead to the use of animal tests.

#### **Criterion 2.1. – Requirements for the lubricant and its main components**

According to REACH and CLP, testing of mixtures does not appear scientifically necessary, where alternative tests are adequate for the purposes of classification and labeling, and the reduction of the number of tests on animals and the use of existing data are a priority<sup>21</sup>.

<sup>&</sup>lt;sup>20</sup> The OECD QSAR Toolbox for Grouping Chemicals into Categories. QSAR TOOLBOX is a software for grouping chemicals into categories and filling gaps in (eco)toxicity data needed for assessing the hazards of chemicals. More information available on-line at webpage: https://www.qsartoolbox.org/

Practical guide How to use and report (Q)SARs. ECHA-16-B-09-EN. More information available on-line at webpage: <a href="https://echa.europa.eu/documents/10162/13655/pg">https://echa.europa.eu/documents/10162/13655/pg</a> report qsars en.pdf/407dff11-aa4a-4eef-alce-9300f8460099</a> and Guidance on information requirements and chemical safety assessment. Chapter R.6: QSARs and grouping of chemicals. More information available on-line at webpage: <a href="https://echa.europa.eu/documents/10162/13632/information\_requirements\_r6\_en.pdf/77f49f81-b76d-40ab-8513-4f3a533b6ac9">https://echa.europa.eu/documents/10162/13632/information\_requirements\_r6\_en.pdf/77f49f81-b76d-40ab-8513-4f3a533b6ac9</a>

<sup>&</sup>lt;sup>21</sup>According to Annex XI" General rules for adaptation of the standard testing regime set out in Annexes VII to X", testing of mixtures does not appear scientifically necessary where alternative tests are adequate for the purposes of classification and labeling such as: bridging principles of existing data, weigh of evidence, Qualitative or Quantitative

Moreover, according to the user manual, nearly all current applicants have used Criterion 2.2. Therefore, the need to maintain Criterion 2.1 needs to be considered since this could go against the main objective of REACH and CLP regulations to reduce the number of tests on animals. In the last revision, it was already suggested to remove this criterion. But this was opposed due to the fact that many types of greases are the result of a direct reaction product. The full composition of the greases is therefore not completely known and a criterion that established the aquatic toxicity based on the testing the product was considered necessary for at least this group of lubricants.

Therefore, it is suggested to maintain Criterion 2.1 but only for Greases category and when unknown substances are present in the mixture for more than 5% by weight in the lubricant or reliable aquatic toxicity data of the mixture exists. Nevertheless, when adequate toxicity data are available for all the components in the mixture, criterion 2.2 shall be applied.

According to the existing EU Ecolabel text, 'main component' means any substance accounting for more than 5 % by weight of the lubricant. The aquatic toxicity requirements for the freshly prepared lubricant should be established considering consistency with the requirements for specific substances defined in Criterion 2.2 for category 2 of lubricants (see also Table 12):

- substances with acute aquatic toxicity values between 1 and 10 mg/L (aquatic toxicity category 2) are proposed to be restricted at levels under 5% (the proposed cumulative mass percentage of substances present within the candidate lubricant is  $\leq 0.5\%$  for category 2 of lubricants).
- substances with acute aquatic toxicity between 10 mg/L and 100 mg/L (aquatic toxicity Category 3) are allowed above 5% (the proposed cumulative mass percentage of substances present within the candidate lubricant is  $\leq 20\%$  for category 2 of lubricants).

Assuming that the toxicity of the mixture is additive, and using the formula below, the estimated acute toxicity of a mixture containing 5% of a material with different potential aquatic toxicity values has been calculated, as summarized in the table below.

structure-activity relationship ((Q)SAR), in vitro methods and/or grouping of substances and read-across approach. Moreover according to CLP Regulation, paragraph 27, "The classification and labelling criteria set out in this Regulation should take the utmost account of promoting alternative methods for the assessment of hazards of substances and mixtures and of the obligation to generate information on intrinsic properties by means other than tests on animals within the meaning of Directive 86/609/EEC as laid down in Regulation (EC) No 1907/2006. Future criteria should not become a barrier to this aim and the corresponding obligations under that Regulation, and should under no circumstances lead to the use of animal tests where alternative tests are adequate for the purposes of classification and labelling". Moreover, according to article 7, "Where new tests are carried out for the purposes of this Regulation, tests on animals within the meaning of Directive 86/609/EEC shall be undertaken only where no or inadequate test data are available for the mixture itself, manufacturers, importers and downstream users should therefore follow the bridging principles to ensure adequate comparability of results of the classification of such mixtures.

Σci	Σ <sup>Ci</sup>
C(E)L <sub>50m</sub>	$\frac{2}{\eta}C(E)L_{50i}$

where:

Ci	= concentration of component i (weight percentage)
L(E)C <sub>50 i</sub>	= (mg/l) $LC_{50}$ or $EC_{50}$ for component i
η	= number of components
L(E)C <sub>50 m</sub>	= L(E) $C_{50}$ of the part of the mixture with test data

### Table 5 Estimated acute toxicity values of a mixture containing 5% of a substance with different potential aquatic toxicity

Aquatic toxicity of a substance at 5% with different potential aquatic toxicity	Resulting mixture aquatic toxicity estimated assuming additivity	Current acute toxicity threshold for the product (mixture) for Categories 2, 3 and 4
1 mg/L	20 mg/L	
10 mg/L	200 mg/L	1000 mg/L
100 mg/L	2000 mg/L	

If the entire unknown fraction (5% of the product) was classified with aquatic toxicity Category 2, Criterion 2.2 would not be fulfilled for the lubricant category 2. According to the table presented above, the criteria 2.1 would not be fulfilled for category 2 of the lubricant (estimated product aquatic toxicity = 200 mg/L <threshold = 1000 mg/L).

If the entire unknown fraction (5% of the product) was classified with aquatic toxicity Category 3, Criterion 2.2 would be fulfilled for the lubricant category 2. According to the values presented in the table above, the current Criterion 2.1 would not be fulfilled for the lubricant category 2 (estimated product aquatic toxicity = 200 mg/L < threshold = 1000 mg/L).

If the current Criterion 2.1 is modified to have a threshold of 200 mg/L for Category 2, this will be more consistent with Criterion 2.2.

Therefore, the revised threshold has been proposed in order to keep balance between criterion 2.1 and 2.2 and maintain coherence in terms of relative restriction among the main components and the prepared lubricant.

Moreover, an analysis of other ecolabels has been performed in order to understand how aquatic toxicity requirements are addressed in respective schemes. A table comparing thresholds in both schemes is given below.

 Table 6 Comparison of aquatic toxicity requirements for the different labeling schemes for the product category of lubricants

Blue Angel	Nordic Ecolabel	Eco Mark Japan	Korea Eco-Label	NF Environment	Swedish Standard

			1	I	I
Blue Angel	Nordic Ecolabel	Eco Mark Japan	Korea Eco-Label	NF Environment	Swedish Standard
Equivalent to EU Ecolabel (the thresholds are also comparable)	(except for Gear/Transmision Oils: No requirement) • Base oil cannot classify for Environmental Hazards nor classify as carcinogenic • Additives classified for Environmental Hazards must not exceed a % depending on the H statement and on the family of the lubricant <sup>22</sup>	<ul> <li>96-hour LC<sub>50</sub> of fish acute test ≥ 100 mg/L</li> <li>48-hour EC<sub>50</sub> of Daphnia inhibition of the mobility ≥ 100 mg/L</li> </ul>	In regards to water and soil contaminants from the product during the disposal phase, the following criteria shall be met: 72-hour $EC_{50}$ algae acute test or 48-hour $EC_{50}$ Daphnia acute test $\geq 100 \text{ mg/L}$ 48-hour $EC_{50}$ of Daphnia inhibition of the mobility $\geq 100$ mg/L	For main components > 5%: Absence of a substances having BCF> 100 or log Pow> 3 and aquatic toxicity between 10 and 100 mg / L. For components < 5%: The sum of components classified with the risk phrases R53 or R52 / R53, should not exceed 3% of weight of the lubricant.	Different cumulative % mass fraction is allowed depending on the Aquatic Toxicity of the compounds (% indicated in the legal text)

#### Criterion 2.2. - Requirements for each stated substance present above 0,10 % (w/w)

In order to define suitable thresholds in the revised criteria, stakeholders and competent bodies were asked to provide information on currently ecolabelled products in order to obtain reliable and representative statistics. The information was asked to all Competent Bodies by e-mail, with the condition that the data will be treated confidentially. The values gathered were referred to:

- Biodegradability and bioaccumulative potential
- Renewable raw materials and
- Additional aquatic toxicity requirements

At the end of the process, data on 47 ecolabelled products from 10 different countries was obtained, which represents the 25% of the total ecolabelled lubricants present in the market<sup>23</sup>. This information is summarized in the tables below.

In the tables:

- HARMFUL means Aquatic toxicity Category 3,
- TOXIC Aquatic toxicity Category 2,
- VERY TOXIC Aquatic toxicity Category 3.

### Table 7. Criterion 2.2 Aquatic toxicity descriptive statistics and current limits – Lubricant Category 1

NUMBER OF ECOLABELLED	AQUATIC TOXICITY	Aquatic toxicit	t <b>y</b> (cumulative ma	uss percentages (%w/w) lubricant)	of substances present v	vithin the candidate	
PRODUCTS INFORMATION	(Criterion 3.2 only)		CATEGORY 1				
RECEIVED		RANGE	AVERAGE	50th PERCENTILE <sup>24</sup>	75th PERCENTILE <sup>25</sup>	CURRENT LIMIT	
23	HARMFUL (E)	0-0,70	0,32	0,27	0,51	$\leq 20$	

<sup>&</sup>lt;sup>22</sup> Components classified with the risk phrases R50 or R50/53 must not exceed 2% in metal cutting fluid and hydraulic oil and 1% in chain oil, mould oil, 2-stroke oil and lubricating grease. Components classified with the risk phrase R51/53 must not exceed 1% in chain oil, mould oil, hydraulic oil, 2-stroke oil and lubricating grease and 2% in metal cutting fluid. Components classified with the risk phrases R52/53 or R53 must not exceed 3% in chain oil, mould oil and hydraulic oil, **17% (15% for thickeners and 2% for others)** in lubricating grease, 5% in metal cutting fluid and 15% in 2-stroke oil.

<sup>&</sup>lt;sup>23</sup> Until now, the EU Ecolabel for lubricants was given to 176 products (and 119 licenses).

 $<sup>^{24}</sup>$  Percentiles show the percentage of values that are at or below a certain value (e.g. the 50th percentile value indicates that 50% of the values are at or below that value)

<sup>&</sup>lt;sup>25</sup> Percentiles show the percentage of values that are at or below a certain value (e.g. the 75th percentile value indicates that 75% of the values are at or below that value)

TO XIC (F)	0-2,26	0,22	0,09	0,2	≤ 5
VERY TO XIC (G)	0-0,08	0,02	0	0,08	$\leq$ 0,1 / M <sup>26</sup>

## Table 8. Criterion 2.2 Aquatic toxicity descriptive statistics and current limits – Lubricant Category 2

NUMBER OF ECOLABELLED	AQUATIC TOXICITY	Aquatic toxicity (cumulative mass percentages (%w/w) of substances present within the candidate lubricant)						
PRODUCTS INFORMATION	(Criterion 3.2 only)	CATEGORY 2						
REC EIVED		RANGE	AVERAGE	50th PERCENTILE <sup>24</sup>	75th PERCENTILE <sup>25</sup>	CURRENT LIMIT		
	HARMFUL (E)	0 - 18,49	7,28	2,8	12,8	≤ 25		
7	TO XIC (F)	0-0,52	0,17	0	0,35	$\leq 1$		
	VERY TO XIC (G)	0	0	0	0	$\leq$ 0,1 / M <sup>26</sup>		

## Table 9. Criterion 2.2 Aquatic toxicity descriptive statistics and current limits – Lubricant Category 3

NUMBER OF ECOLABELLED	AQUATIC TO XICITY	Aquatic toxicity (cumulative mass percentages (%w/w) of substances present within the candidate lubricant)				
PRODUCTS INFORMATION	(Criterion 3.2 only)	Criterion 3.2 CATEGORY 3 nly)				
REC EIVED		RANGE	AVERAGE	50th PERCENTILE <sup>24</sup>	75th PERCENTILE <sup>25</sup>	CURRENT LIMIT
	HARMFUL (E)	0-2,00	0,3	0	0,35	≤ 5
10	TO XIC (F)	0 - 0,50	0,10	0	0,15	$\leq 0,5$
	VERY TO XIC (G)	0	0	0	0	$\leq$ 0,1 / M <sup>26</sup>

## Table 10. Criterion 2.2 Aquatic toxicity descriptive statistics and current limits – Lubricant Category 4

NUMBER OF ECOLABELLED PRODUCTS INFORMATION	AQUATIC TOXICITY	Aquatic toxicity (cumulative mass percentages (%w/w) of substances present within the candidate lubricant)						
	(Criterion 3.2 only)	CATEGORY 4						
REC EIVED	() () () () () () () () () () () () () (	RANGE	AVERAGE	50th PERCENTILE <sup>24</sup>	75th PERCENTILE <sup>25</sup>	CURRENT LIMIT		
1	HARMFUL (E)	-	4	4	4	≤ 25		
	TO XIC (F)	-	0	0	0	$\leq 1$		
	VERY TO XIC (G)	-	0	0	0	$\leq$ 0,1 / M <sup>26</sup>		

## Table 11. Criterion 2.2 Aquatic toxicity descriptive statistics and current limits – Lubricant Category 5

NUMBER OF ECOLABELLED	AQUATIC TOXICITY	Aquatic toxicity (cumulative mass percentages (%w/w) of substances present within the candidate lubricant)							
PRODUC'IS INFORMATION	(Criterion 3.2 only)	CATEGORY 5							
RECEIVED	omy)	RANGE	AVERAGE	50th PERCENTILE <sup>24</sup>	75th PERCENTILE <sup>25</sup>	CURRENT LIMIT			

 $<sup>^{26}</sup>$  M-factor means a multiplying factor. It is applied to the concentration of a substance classified as hazardous to the aquatic environment acute category 1 or chronic category 1, and is used to derive by the summation method the classification of a mixture in which the substance is present.
-	HARMFUL (E)	-	0	0	0	$\leq 20$
6	TO XIC (F)	-	0	0	0	≤ 5
	VERY TO XIC (G)	-	0	0	0	$\leq 1 / M^{26}$

Based on the outcome of the consultation, it was found that generally the current threshold values are higher than the corresponding values for most of the samples investigated. This supports the proposal for stricter aquatic toxicity limits. The revised thresholds have been selected with the following criteria in mind: to cover 10 to 20% of the best performing products available currently, to keep balance between chronic and acute hazards categories limits within each category; and maintain coherence in terms of relative restriction among different categories.

Based on these criteria, the following aquatic toxicity threshold values (cumulative mass percentages (% w/w) of substances present within the candidate lubricant) are proposed for the revised criteria for <u>aquatic toxicity</u> according to table 6. Moreover, taking into account that indications of danger under DSD/DPD have been changed to signal words according to CLP, and in order to be in consonance with this regulation, the following terms have been modified:

- Not toxic for not hazardous to the aquatic environment (D)
- Harmful for chronic hazard category 3 (E)
- Toxic for chronic hazard category 2 (F)
- Very toxic for chronic or acute hazard category 1 (G)

The EU Ecolabel classification (D, E, F and G) has not been changed due to they are explicitly mentioned in the Lubricant Substance Classification list (LuSC-list), thus they have been kept.

The comparison of the proposed and the current thresholds is given in Table 12

					Cumula	tive mass p	ercentage	s (%w/w)	of substance	s present v	within tl	he candidate	lubricant)			
		(	CATEGORY	71	C	ATEGORY	2	(	CATEGORY	3		CATEGORY	7 <b>4</b>	CATEGORY 5		
Aquatic toxicity (	Aquatic toxicity (Criterion 3.2 only)		PROPOSED LIMIT	NUMBER OF CURRENT EU ECOLABELLE D PRODUCTS AFFECTED	CURRE NT LIMIT	PROPOSE D LIMIT	NUMBER OF CURRENT EU ECOLABEL LED PRODUCTS AFFECTED	CURREN T LIMIT	PROPOSED LIMIT	NUMBER OF CURRENT EU ECOLABELL ED PRODUCTS AFFECTED	CURR ENT LIMIT	PROPOSED LIMIT	NUMBER OF CURRENT EU ECOLABELL ED PRODUCTS AFFECTED	CURRE NT LIMIT	PROPOSED LIMIT	NUMBER OF CURRENT EU ECOLABELL ED PRODUCTS AFFECTED
NOT HAZARDOUS TO THE AQUATIC	Acute aquatic toxicity <sup>27</sup> >100 mg/L or								NOT LIMIT	ED						
(D)	Chronic aquatic toxicity <sup>28</sup> >10 mg/L															
CHRONIC HAZARD CATEGORY 3 (E) <sup>29</sup>	Acute aquatic toxicity <sup>27</sup> >10 to $\leq$ 100 mg/L or 1 mg/L < Chronic aquatic	≤ 20	<b>≤</b> 10	0	≤ 25	<b>≤ 20</b>	0	≤ 5	≤ 2	0	≤ 25	<b>≤ 20</b>	0	≤ 20	<b>≤</b> 10	0
CHRONIC HAZARD CATEG ORY 2 (F) <sup>29</sup>	to xicity $^{27} \le 10 \text{ mg/L}$ Acute aquatic toxicity $^{27} > 1$ to $\le 10 \text{ mg/L}$ or0,1 mg/L < Chronic aquatic	≤ 5	≤ 2,5	0	≤ 1	≤ 0,5	1	≤ 0,5	≤ 0,3	1	≤1	≤ 0,5	0	≤ 5	≤ 2,5	0
CHRONIC CATEGORY 1 (G) <sup>29</sup> ACUTE CATEGORY 1 (G)	Acute aquatic toxicity <sup>27</sup> $\leq 1$ mg/L or Chronic aquatic toxicity <sup>28</sup> $\leq $ 0,1 mg/L	≤ 0,1/M	≤ 0,1/M	0	≤ 0,1/M	≤ 0,1/M	0	≤ 0,1/M	≤ 0,1/M	0	≤ 0,1/ M	≤ 0,1/M	0	≤ 1/M	≤ 0,1/M	0

#### Table 12. Criterion 2.2 Proposed threshold values for the aquatic toxicity, current limits and number of EU ecolabelled products affected

 $<sup>^{27}</sup>$  Acute aquatic toxicity tests results shall be provided for all the following three trophic levels: fish, crustacean and algal species. Acute aquatic toxicity is normally determined using a fish 96 hour LC50, a crustacea species 48 hour EC50 and an algal species 72 or 96 hour EC50. These species cover a range of trophic levels and taxa and are considered as surrogate for all aquatic organisms. Data on other species (e.g. Lemna spp.) shall also be considered if the test methodology is suitable. The aquatic plant growth inhibition tests are normally considered as chronic tests but the EC50s are treated as acute values for classification purposes.

 $<sup>^{28}</sup>$ Chronic aquatic toxicity tests results shall be provided for all the following three trophic levels: fish, crustacean and algal species. For determining chronic aquatic toxicity data generated according to the standardised test methods referred to in Article 8(3) of CLP regulation shall be accepted, as well as results obtained from other validated and internationally accepted test methods. The NOECS or other equivalent L(E)Cx (e.g. EC10) shall be used.

<sup>&</sup>lt;sup>29</sup> And the substance is not rapidly degradable and/or the experimentally determined BCF  $\geq$  500 (or, if absent, the log Kow  $\geq$  4) unless the chronic toxicity NOECs are > 1 mg/l.

It is worth to note that when classifying substances as Acute Category 1 and/or Chronic Category 1 it is necessary at the same time to indicate then appropriate M-factor(s) according to table below.

MULTIPLYING	FACTORS FOR	HIGHLYTOXIC COMPONE	NTS						
ACUTE TO XICITY	Multiplying	CHRONIC	TO XICITY						
L(E)C50 value mg/L	factor (M)	NOEC value mg/L	NRD <sup>30</sup>	RD <sup>31</sup>					
$0,1 < L(E) C50 \le 1$	1	$0,01 < \text{NOEC} \le 0,1$	1	_					
	1		1	_					
$0,01 < L(E) C50 \le 0,1$	10	$0,001 < \text{NOEC} \le 0,01$	10	1					
$0,001 < L(E) C50 \le 0,01$	100	$0,0001 < \text{NOEC} \le 0,001$	100	10					
$0,0001 < L(E) C50 \le 0,001$	1 000	0,00001 < NOEC ≤ 0,0001	1 000	100					
$0,00001 < L(E)C50 \le 0,0001$	10 000	0,000001 <noec 0,00001<="" td="" ≤=""><td>10 000</td><td>1 000</td></noec>	10 000	1 000					
(continue in factor 10 intervals)									

Table 13. Multiplying factors for highly toxic components of mixtures

**Rationale of proposed "Assessment and verification"** According to the existing criterion 3.1 and 3.2, aquatic toxicity shall be stated on two trophic levels: algae and daphnia for each main component in criterion 3.1 and daphnia and fish (or algae and daphnia in case chronic toxicity test results are missing) for criterion 3.2. Nevertheless, according to section 4.1 of Annex I to CLP regulation "Classification and labelling requirements for hazardous substances and mixtures", the lowest of the available toxicity values between and within the different trophic levels (fish, crustacean, algae/aquatic plants) shall normally be used to define the appropriate hazard category. Therefore, it is suggested that information on toxicity using data on aquatic organisms shall be provided for all three trophic levels.

According to Annex XI of REACH regulation "General rules for adaptation of the standard testing regime set out in Annexes VII to X", if no experimental data exists, results of (Q)SARs<sup>32</sup> may be used ensuring adequate comparability of results of the classification of such substances and/or mixtures.

# 3.3 CRITERION 3: Biodegradability and bioaccumulative potential

Proposal for criterion 3: Biodegradability and bioaccumulative potential

Requirements for the biodegradability and bioaccumulative potential shall be fulfilled by each substance present above 0,10 % weight by weight in the final product.

The lubricant shall not contain substances that are both: non-biodegradable and (potentially) bioaccumulative. However, the lubricant may contain one or more substances with a certain degree of degradability and potential or actual bioaccumulation up to a cumulative mass concentration as

<sup>&</sup>lt;sup>30</sup> NRD: Not rapidly degradable

<sup>&</sup>lt;sup>31</sup> RD: Rapidly degradable

<sup>&</sup>lt;sup>32</sup> <u>The OECD QSAR Toolbox for Grouping Chemicals into Categories. QSAR TOOLBOX is a software for grouping chemicals into categories and filling gaps in (eco)toxicity data needed for assessing the hazards of chemicals. More information available on-line at webpage: https://www.qsartoolbox.org/</u>

Practical guide How to use and report (Q)SARs. ECHA-16-B-09-EN. More information available on-line at webpage: <a href="https://echa.europa.eu/documents/10162/13655/pg">https://echa.europa.eu/documents/10162/13655/pg</a> report qsars en.pdf/407dff11-aa4a-4eef-alce-9300f8460099</a> and Guidance on information requirements and chemical safety assessment. Chapter R.6: QSARs and grouping of chemicals. More information available on-line at webpage: <a href="https://echa.europa.eu/documents/10162/13632/information\_requirements\_r6\_en.pdf/77f49f81-b76d-40ab-8513-4f3a533b6ac9">https://echa.europa.eu/documents/10162/13632/information\_requirements\_r6\_en.pdf/77f49f81-b76d-40ab-8513-4f3a533b6ac9</a>

Proposal for criterion 3: Biodegradability and bioaccumulative potential

indicated in following table:

	Category 1	Category 2	Category 3	Category 4	Category 5
Readily aerobically biodegradable	> 95	> 80	> 95	> 75	> 90
Inherently aerobically biodegradable	≤ 5	≤ 15	≤ 5	≤15	≤ 5
Non- biodegradable and non- bioaccumulati ve	<i>≤</i> 5	≤ 15	≤ 5	≤ 10	<i>≤</i> 5
Non- biodegradable and bioaccumulative	≤ 0,1	≤ 0,1	≤ 0,1	$\leq 0,1$	≤ 0,1

#### a) Biodegradation

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 or a valid letter of compliance from a competent body can be submitted,
- a substance is non-biodegradable if it fails the criteria for ultimate and inherent biodegradability.

The applicant may also use read-across data to estimate the biodegradability of a substance.

#### b) Bioaccumulation

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), or
- has an octanol-water partition coefficient, log  $K_{ow}$ , value of  $\leq 4$ , or
- has a measured BCF of  $\leq 100$  L/kg, or
- is a polymer and its molecular weight fraction below 1.000 g/mol is less than 1 %.

Assessment and verification: the applicant shall provide a declaration of compliance with this criterion supported by a high quality test reports or literature data (testing according to acceptable protocols and GLP) including the references on the biodegradability and when required on the (potential) bioaccumulation of each constituent substance.

#### **Rationale of Proposed Criterion text**

#### a) Biodegradation

Current EU criterion of biodegradability covers different biodegradability: ultimately aerobically biodegradability and inherently aerobically biodegradability. Moreover, the criterion establishes a limit value for the non-biodegradable substances.

An analysis of other ecolabels and certification systems has been performed in order to understand how the issue of biodegradability and bioaccumulation is addressed in respective schemes.. A brief summary is given below:

#### Blue Angel:

Blue Angel made the last revision of lubricant criteria in 2014. The biodegradability and bioaccumulation potential criterion has similarity with the EU Ecolabel criterion. However, the threshold for Blue Angel is more restrictive. In Table 14 a comparison between both Ecolabel categories has been done in order to compare the limit value of each biodegradation test. The

EU Ecolabel Category 4: two-stroke oils are not included in the scope of the Blue Angel Ecolabel.

The thresholds for the ultimately aerobically biodegradability within Blue Angel are higher (5 points) than current values of EEL for all the categories; for the non-biodegradable and non-bioaccumulative potential the limit value in Blue Angel are more restrictive than EEL as well (for categories 1, 3 and 5 being 2% for Blue Angel and 5% for EEL).

A table comparing thresholds in both schemes is given below.

Table 14 Comparison	of biodegradability	and bioaccumulation	potential	for the	different	lubricant
C	ategories of the EU	Ecolabel and the Blu	e Angel Ed	colabel		

	Categ	ory 1	Categ	ory 2	Categ	gory 3	Category 4	Cate	gory 5
	DDL	Blue Angel	EEL	Blue Angel	EEL	Blue Angel		EEL	Blue Angel
Ultimately aerobically biodegradable	> 90	≥ <b>9</b> 5	> 75	> 80	> 90	≥ 95	> 75	> 90	≥ 95
Inherently aerobically biodegradable	≤ 5	< 5	≤ 25	-	≤ 5	< 5	$\leq 20$	≤ 5	< 5
Non- biodegradable and non- bioaccumulative	≤ <b>5</b>	≤ 2	≤ 25	-	≤ 5	≤ 2	≤ 10	<i>≤</i> 5	≤ 2
Non- biodegradable and bioaccumulati ve	≤ 0,1	≤ 0,1	≤ 0,1	≤ 0,1	≤ 0,1	≤ 0,1	≤ 0,1	≤ 0,1	≤ 0,1

Other ecolabels, like the *NF Environment*, consider different threshold values for the base fluid and the additives. The requirement for the base fluid is more restrictive than for the additives (70% and 20% at 28 days, respectively).

The *Nordic Ecolabel* define only thresholds for base fluids, since it did not have any restriction value for biodegradability of additives.

In addition, *NF Environment*, and also the *Korean Ecolabel* and the *Swedish Standard*, addresses lubricant ingredient which are defined as non biodegradable, as follows:

- The amount of the additives defined as not "readily biodegradable" has to be less than 5% by mass of the lubricant in the NF Environment,
- 5% or more of the raw materials of lubricating oil by weight shall be biodegradable. In the Korean Ecolabel,
- Chemical compounds that are not included in the threshold value defined in the standard, shall not form a total mass fraction  $\geq 5\%$  in the *Swedish Standard*.

EU Ecolabel stakeholders have been asked along the revision process to share information about the respective values for lubricants which are currently awarded with the EU Ecolabel and for those aimed to be evaluated in the future. The information obtained has been used in order to evaluate the level of ambition of the current thresholds. It is presented in below tales.

NUMBER OF		(cumulative mass percentages (% weight by weight) of substances present in the lubricant)									
ECOLABELLED PRODUCTS	<b>Biodegradability and</b>		CATEGORY 1								
INFORMATION RECEIVED	bioaccumulation potential	RANGE	AVERAGE	50th PERCENTILE <sup>[1]</sup>	75th PERCENTILE <sup>[2]</sup>	CURRENT LIMIT	PROPOSED LIMIT	N°of products under the proposed limit			
	Ultimately aerobically biodegradable	90,95 - 99,40	97,4	98,50	96,50	>90	> 95	5 (not currently compliant)			
23	Inherently aerobically biodegradable	0-5	0,45	0	0	≤5	≤ 5	0			
	Non-biodegradable and non- bioaccumulative	0,4 - 4,98	1,86	1,25	2,62	≤5	≤5	0			
	Non-biodegradable and bioaccumulative	0 – 1	0,05	0	0	≤0,1	≤ 0,1	1 (currently under the proposed limit)			

#### Table 15. Criterion 3, Biodegradability and bioaccumulation potential descriptive statistics and current limits – Lubricants Category 1

# Table 16. Criterion 3, Biodegradability and bioaccumulation potential descriptive statistics and current limits – Lubricants Category 2

NUMBER OF		(cumulative mass percentages (% weight by weight) of substances present in the lubricant)									
ECOLABELLED	Biodegradability and				CATEGORY 2						
PRODUCTS INFORMATION RECEIVED	bioaccumulation potential	RANGE	AVERAGE	50th PERCENTILE <sup>[1]</sup>	75th PERCENTILE <sup>[2]</sup>	CURRENT LIMIT	PROPOSED LIMIT	Number of products under the proposed limit			
	Ultimately aerobically biodegradable	81,01 – 92,9	87,7	88,41	83,05	>75	> 80	0			
7	Inherently aerobically biodegradable	0 – 14,5	5,25	3	8,99	≤25	≤ 15	0			
-	Non-biodegradable and non- bioaccumulative	1,1 – 14,35	6,97	6,99	7,67	≤25	≤ 15	0			
	Non-biodegradable and bioaccumulative	-	0	0	0	≤0,1	≤ 0,1	0			

<sup>&</sup>lt;sup>[1]</sup> Percentiles show the percentage of values that are at or below a certain value (e.g. the 50th percentile value indicates that 50% of the values are at or below that value) <sup>[2]</sup> Percentiles show the percentage of values that are at or below a certain value (e.g. the 75th percentile value indicates that 75% of the values are at or below that value)

NUMBER OF		(cumulative mass percentages (% weight by weight) of substances present in the lubricant)									
ECOLABELLED PRODUCTS	<b>Biodegradability and</b>		CATEGORY 3								
INFORMATION RECEIVED	bioaccumulation potential	RANGE	AVERAGE	50th PERCENTILE <sup>[1]</sup>	75th PERCENTILE <sup>[2]</sup>	CURRENT LIMIT	PROPOSED LIMIT	Number of products under the proposed limit			
	Ultimately aerobically biodegradable	91 – 100	96,5	96,03	95,84	>90	> 95	1 ( not currently compliant)			
9	Inherently aerobically biodegradable	0-5	1,71	1,36	2,12	≤5	≤ 5	0			
	Non-biodegradable and non- bioaccumulative	0-5	2,88	2,8	3,95	≤5	≤ 5	0			
	Non-biodegradable and bioaccumulative	-	0	0	0	≤0,1	$\leq 0,1$	0			

#### Table 17. Criterion 3, Biodegradability and bioaccumulation potential descriptive statistics and current limits – Lubricants Category 3

#### Table 18. Criterion 3, Biodegradability and bioaccumulation potential descriptive statistics and current limits – Lubricants Category 4

NUMBER OF		(cumulative mass percentages (% weight by weight) of substances present in the lubricant)									
ECOLABELLED	Biodegradability and				CATEGORY 4						
PRODUCTS INFORMATION RECEIVED	bioaccumulation potential	VALUE				CURRENT LIMIT	PROPOSED LIMIT	Number of products under the proposed limit			
	Ultimately aerobically biodegradable	76				>75	> 75	0			
1	Inherently aerobically biodegradable	14				≤20	≤ 15	0			
	Non-biodegradable and non- bioaccumulative	10				≤10	$\leq 10$	0			
	Non-biodegradable and bioaccumulative	_				≤0,1	≤ 0,1	0			

1		· · · · · · · · · · · · · · · · · · ·	r r	Free Prese							
		(cumulative mass percentages (% weight by weight) of substances present in the lubricant)									
ECOLABELLED	<b>Biodegradability and</b>		CATEGORY 5								
PRODUCTS INFORMATION RECEIVED	bioaccumulation potential	RANGE	AVERAGE	50th PERCENTILE <sup>[1]</sup>	75th PERCENTILE <sup>[2]</sup>	CURRENT LIMIT	PROPOSED LIMIT	Number of products under the proposed limit			
	Ultimately aerobically biodegradable	-	94,55	94,55	94,55	>90	> 90	0			
6	Inherently aerobically biodegradable	-	0	0	0	≤5	≤ 5	0			
6	Non-biodegradable and non- bioaccumulative	-	4,98	4,98	4,98	≤5	≤ 5	0			
	Non-biodegradable and bioaccumulative	-	0	0	0	≤0,1	≤ 0,1	0			

#### Table 19. Criterion 3, Biodegradability and bioaccumulation potential descriptive statistics and current limits – Lubricants Category 5

Taking into account the analysis of the data and the thresholds defined in the Blue Angel the current EU Ecolabel thresholds have been proposed to be modified. For 2-stroke oils and gears a more restricted value in this case will suppose the exclusion of all the current products certified whereas for 4-stroke oils and metalworking a conservative approach has been taken since no data is available for these new categories.

The inherent aerobically biodegradability has been proposed to be modified for the lubricant products greases, 2-stroke oils and 4-stroke oils; according the current threshold values of the products certified.

The Blue Angel defines a more restrictive value for the non-biodegradable and nonbioaccumulative potential. However, the only product group that has been modified is the hydraulic system lubricants. Others modifications would involve the exclusion of an important percentage of the current lubricants classified in the EU Ecolabel.

According to the last version of CLP Regulation, a change of nomenclature is proposed: *Ultimately* is changed by *Readily*.

Substances are considered rapidly degradable in the environment if one of the following criteria holds true<sup>33</sup>:

(a) if, in 28-day ready biodegradation studies, at least the following levels of degradation are achieved:

(i) tests based on dissolved organic carbon: 70 %;

(ii) tests based on oxygen depletion or carbon dioxide generation: 60 % of theoretical maximum.

These levels of biodegradation must be achieved within 10 days of the start of degradation which point is taken as the time when 10 % of the substance has been degraded, unless the substance is identified as an UVCB or as a complex, multi- constituent substance with structurally similar constituents. In this case, and where there is sufficient justification, the 10-day window condition may be waived and the pass level applied at 28 days; or

(b) if, in those cases where only BOD and COD data are available, when the ratio of BOD 5 /COD is  $\geq 0.5$ ; or

(c) if other convincing scientific evidence is available to demonstrate that the substance can be degraded (biotically and/or abiotically) in the aquatic environment to a level > 70 % within a 28-day period.

## b) Bioaccumulation

Biodegradability is extensively covered by the different regional Ecolabels, on the contrary the bioaccumulation potential are not included in other ecolabel criteria with the exception of the Blue Angel.

'Bioaccumulation' means the net result of uptake, transformation and elimination of a substance in an organism due to all routes of exposure (i.e. air, water, sediment/soil and food). Bioaccumulation of substances within aquatic organisms can give rise to toxic effects over

<sup>&</sup>lt;sup>33</sup> REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 16 December 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

longer time scales even when actual water concentrations are low.<sup>33</sup> For this reason, bioaccumulation potential, together with toxicity and biodegradability, is a key parameter to deal with in order to minimize the adverse effects to the aquatic environment is minimized.

Blue Angel links this requirement with the requirement on biodegradability. The limit values are similar to the values defined in the EU Ecolabel (see Table 14). The Blue Angel threshold for bioaccumulation potential is the same as the EU Ecolabel threshold.

Stakeholders have been asked to share information also regarding the bioaccumulation potential. The data has shown that the share of bioaccumulative components is usually 0. However, the limit value should be the same in order to allow for applying other lubricant products.

The bioaccumulation criterion is proposed to be updated according to the last version of CLP Regulation, which refers to octanol-water partition coefficient, log  $K_{ow}$ , value of <4 or >7. According to CLP the cut-off value for real potential to bioconcentrate is log  $K_{ow} \ge 4$ .

#### **Rationale of proposed "Assessment and verification"**

OECD 301B (title) and ISO 14593 (title) are the most commonly requested methods in the U.S. and Europe for testing the biodegradation of lubricants<sup>34</sup>. The OECD 301 test is the most extensively used for other ecolabels to evaluate the biodegradability of the substances: Korean Ecolabel, Japan Ecolabel, Nordic Swan and Blue Angel.

Other tests used to define the biodegradability are: ISO 14593, 9439 and 9408 (or equivalent) for Nordic Swan, ISO 10708, 9439 and 9408 for Swedish Standard. Blue Angel also relate to other OECD tests: OECD 306, 310 and 302C to verify the ultimate biodegradability and inherent biodegradability.

In the Regulation (EC) No 440/2008<sup>35</sup> OECD 107 test and the method OECD 305 are referred to for testing of the bioaccumulation potential. The Blue Angel also mentions the same test methods to verify the bioaccumulation potential.

# 3.4 CRITERION 4: Raw materials

#### Proposal for criterion 4: Raw materials

FOR DISCUSSION: Discussion and further research needed in order to define the best options for each category

The formulated product shall have a content from renewable origin, synthetic or re-refined that shall be:

 $\geq 60$  % (m/m) for Category 1

 $\geq$  60 % (m/m) for Category 2

 $\geq$  70 % (m/m) for Category 3 (only renewable and synthetic origin).

 $\geq$  50 % (m/m) for Category 4

 $\geq$  60 % (m/m) for Category 5

For renewable origin, the parameter to be analysed will be the carbon content. carbon content derived from renewable raw material means the mass percentage of component  $A \times [number of C-atoms in$ component A, which are derived from (vegetable) oils or (animal) fats divided by the total number of $C-atoms in component A] plus mass percentage of component <math>B \times [number of C-atoms in component$ B, which are derived from (vegetable) oils or (animal) fats divided by the total number of C-atoms in

<sup>&</sup>lt;sup>34</sup> http://www.situbiosciences.com/lubricant-biodegradation-and-toxicity-testing/

<sup>&</sup>lt;sup>35</sup> COUNCIL REGULATION (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

#### Proposal for criterion 4: Raw materials

component B] plus the mass percentage of component  $C \times [number of C-atoms in component C, which are derived from (vegetable) oils or (animal) fats divided by the total number of C-atoms in component C], and so on.$ 

The applicant shall indicate on the application form the type (s), source(s) and origin of the material(s) of the main components.

#### Assessment and verification

The applicant shall provide the competent body with a declaration of compliance with this criterion supported by a high quality test reports or literature data.

# **Rationale of Proposed Criterion text**

With regard renewable content, the existing criteria (criterion 5. Renewable raw material) only requires a minimum percentage of renewable content in order to enforce renewable ingredients against mineral oils. Nevertheless other options to replace virgin mineral oils are currently in the market such as re-refined and synthetic oils that are proved to have lower environmental impacts than mineral oils.

As stated in the preliminary report several LCAs comparing **different base fluids**: mineral oil, synthetic oil and vegetable oil found that mineral oils present the highest impacts, due mostly to the extraction phase. In general **vegetable oil** brings advantages over mineral oils due its renewable origin and higher biodegradability. LCA comparative studies indicate lower energy consumption during processing and lower impacts for the global warming potential than mineral and synthetic oils.

Regarding **synthetic oils**, the refining/synthesis phase is the main contributor of impacts. In the production stage they have higher impacts than mineral oil due to more complex processing and higher energy consumption. However they have a longer life and lower impact during use.

**Re-refined oils** bring environmental advantages. With modern re-refining technologies,  $CO_2$  emissions can be reduced by more than 50% as compared to the conventional production of base oil. Waste oil regeneration contributes to  $CO_2$  emissions reduction associated with extracting and processing crude oil and is key process for closing the loop of the lubricant lifecycle which is in line with the circular economy strategy. However derogations for toxicity and biodegradability criteria needs to be considered in order to include re-refined oils as an alternative for the categories with **less probability to reach the environment.** 

Differences shall be noticed between the terms: recycled, regenerated and re-refined oils:

- <u>Recycled or regenerated used oil</u>: generally means to take used motor oil and use it for a different purpose, most commonly to be burnt as fuel. In the lube oil industry, "recycling oil" or "regenerating oil" is most commonly referring to using commercial filtration systems to remove insoluble impurities. This method, however, does not remove any of the soluble contaminants. This resulting oil has very limited uses. In some cases, reconditioned oil is mixed with additives in order to prolong its usage. This oil is generally used for fuel and is only good for one-time use. Reconditioned oil is not suitable for use in automobiles.
- <u>Re-refined oil</u>: Re-refining is a process that has been developed over many years. It removes all impurities, both soluble and insoluble, and returns the oil to a quality

suitable for its original use. Re-refined oil has quality that is equal to or better than some virgin base oils. When re-refining using hydrotreating process, the product base oil can meet technical specifications for most uses. In addition, the re-refining process is less severe than the refining of crude oil and uses less energy and oils can be re-refined many times.

In order to recognize that for categories where the lubricant is directly released to the environment (Category 3) the use of re-refined oils is not a good option and therefore it is not allowed as an option in the initial proposal.

#### Questions to stakeholders

In order to allow the presence on re-refined oils as an alternative for the categories with less probability to reach the environment, stakeholders are asked to provide their views on following options:

- Re-refined oils are not allowed for category 3 (current proposal)
- Re-refined oils are only allowed in category 4 (engine oils)

In addition to include re-refined oils as an option for the categories with less probability to reach the environment, derogations for toxicity and biodegradability criteria needs to be discussed.

In addition, a revision of the thresholds has been carried out. In order to set revised limits the current values of EU Ecolabelled products and other ecolabel schemes have been consulted. Regarding the other ecolabel schemes, only Nordic Swan had a similar criterion setting minimum percentages of renewable content. Nevertheless these values have been not taken as a reference since one reason of the unsuccessful intake of the Nordic Swan could be the high values of renewability, according to stakeholders' feedback.

Under consultation of competent bodies and industry stakeholders, the following average values have been gathered for awarded products under the EU Ecolabel or products that have applied but are not currently complying with this or other criteria.

Products	renewa	(cumulative m candidate lubi	nass percenta ricant)	ges (%w/w	) of subst	ances present	within the	Products above	the
information received 23 (5 currently	materia l	range	average	50th percen tile <sup>[1]</sup>	75th perce ntile <sup>[2]</sup>	current limit	proposed limit	proposed limit	
23 (5 currently not compliant)	Cat. 1	50- 98,4	74,75	80	57,48	≥50%	$\geq 60 \%$	17	
7	Cat. 2	54,4-92,82	76,99	81,70	68	≥45%	$\geq 60 \%$	6	
9	Cat. 3	73- 97,4	88,46	91,9	80,50	≥70%	≥ 70 %	9	
1	Cat. 4	67,29	67,29	67,29	67,29	≥50%	≥ 50 %	1	
6	Cat. 5	67,23-82,94	74,20	74,53	70,21	≥50%	≥ 55 %	6	

Table 20.	Existing	criterion 5	. Renewable	raw material.	statistics	current and	proposed limits
Table 200	LAISUNG	criticiton 5	• Itelle manie	I av matting	sausucs	, cui i chi anu	proposed minus

More restrictive thresholds have been proposed, considering the current values for ecolabelled products. Also it is considered that including other alternatives besides renewable substances

(i.e synthetic or re-refined origin), the broader possibilities on the market could facilitate to accomplish with these new limits.

# Rationale of proposed "Assessment and verification"

For the verification of the existing criterion only a declaration of compliance is requested. There are several test methods to measure biomass content:

The USDA Bio-Preferred program use the ASTM D6866 (cost: 400\$) for testing the biobased content of a product<sup>36</sup>. ASTM D6866 standard is a test method that provides accurate biobased/biogenic carbon content results<sup>37</sup>. Similar methods are developing following the methodology of carbon-14 analysis:

ISO 13833: Stationary source emissions - Determination of the ratio of biomass (biogenic) and fossil-derived carbon dioxide - Radiocarbon sampling and determination<sup>38</sup>.

EN 15440: Solid recovered fuels - Methods for the determination of biomass content<sup>39</sup>.

Questions to stakeholders

In order to better define the verification text stakeholders are asked to provide information on availability, cost and use of methods to measure % renewable C, % synthetic oils, % of re-refined oil.

# 3.5 CRITERION 5 (New): Origin and traceability of vegetable raw materials

Proposal for criterion: Origin and traceability of vegetable raw materials

Renewable raw materials must be sourced from plantations and exploitations that meet criteria for sustainable management

Assessment and verification

The applicant shall provide third-party certifications that the vegetable oils used in the manufacturing of the product originates from sustainably managed plantations.

# Rationale of proposed criterion text

Renewable raw materials for lubrications are basically vegetable and animal oils and greases. Vegetable oils used in lubricants are mainly derived from rapeseed, sunflower, palm and coconut. In Europe, rapeseed and sunflower oils are the major vegetable oils used for industrial purposes, including lubricant production, while soybean and corn are mostly utilized in the

<sup>&</sup>lt;sup>36</sup> https://www.biopreferred.gov/BioPreferred/faces/Welcome.xhtml

<sup>&</sup>lt;sup>37</sup> http://www.astm.org/Standards/D6866.htm

<sup>&</sup>lt;sup>38</sup> http://www.aenor.es/aenor/normas/normas/fichanorma.asp?tipo=N&codigo=N0051753#.WAiD3fmLSUI

<sup>&</sup>lt;sup>39</sup> http://www.aenor.es/aenor/normas/fichanorma.asp?tipo=N&codigo=N0049098#.WAiD7PmLSUl

United States<sup>40</sup>. Nevertheless a wide range of types of vegetable oils are used as lubricants and additives for industrial lubricant applications<sup>41</sup>:

Type of oil	Application			
Canola oil	Hydraulic oils, tractor transmission fluids, metalworking fluids, food grade lubes, penetrating oils, chain bar lubes			
Castor oil	Gear lubricants, greases			
Coconut oil	Gas engine oils			
Olive oil Automotive lubricants				
Palm oil Rolling lubricant,-steel industry, grease				
Rapeseed oil	bil Chain saw bar lubricants, Biodegradable greases			
Soybean oil	Lubricants, biodiesel fuel, metal casting/working, hydraulic oil			
Jojoba oil	Grease, lubricant applications			
Crambe oil Grease, intermediate chemicals, surfactants				
Sunflower oil Grease,				
Tallow oil	Steam cylinder oils, ,lubricants,			

Table 21. Applications of different types of oils in the lubricant industry

Biobased lubricants can be utilized in many applications and are classified in several categories or uses including: hydraulic fluids, greases, motor oils, transmission and gear oils, chain and cable lubricants, metalworking fluids, degreaser, corrosion inhibitor, food grade oils, 2-cycle engine oils, penetrating oils, and compressor oils.2

As found in the preliminary report, the main advantages of vegetable oils are that they are readily available, have a lower price than synthetic esters, are 100 % renewable, and are readily biodegradable. The use of bio-based raw materials could be beneficial to face two current problems: fossil resources depletion and climate change<sup>42</sup>. Vegetable oils are biodegradable, in general are less toxic, are renewable and reduce dependency on imported petroleum oils

Despite the potential environmental advantages of using these vegetable oils in comparison with mineral or synthetic oils, some impacts from vegetable oils used should be considered, especially those related to the agriculture stage. In LCA studies2, it was found that sunflower oil had higher environmental impacts for the energy consumption, acidification, eutrophication and global warming than other vegetable oils; followed by rapeseed oil, coconut and palm oil. The high environmental impact of sunflower oil is because of relative low yields per hectare compared to other crops and more fertilizers and pesticides per tonne of oil produced are used.

<sup>&</sup>lt;sup>40</sup> Cuevas, P. (2010). Comparative life cycle assessment of biolubricants and mineral based lubricants (Doctoral dissertation, University of Pittsburgh).

<sup>&</sup>lt;sup>41</sup> Shashidhara YM, Jayaram SR (2010) Vegetable oil as a potential cutting fluid—an evolution. Tribol Int 43:1073–1081

<sup>&</sup>lt;sup>42</sup> CEN/TR 16227:2011 (E)

It is proved that most of the contribution in global warming, eutrophication and acidification potential is due to the agriculture stage.

Since it is proposed to maintain a criterion to promote renewable raw materials in form of vegetable oils in front of mineral oils (criterion 4), it should be guaranteed that vegetable ingredients come from sustainable managed source according to the principle of sustainability for economic, social and environmental aspects in order to guarantee that these vegetable raw materials have the minimum environmental impact during the agriculture stage, with it is the most impactant stage of their life cycle. Since one of the environmental impacts source of vegetable oils is the agriculture operations, oils coming from plantations with good sustainability harvesting practices are desired.

Palm and soyben oils are the oils more controversial, because of the deforestation association with their plantations in Southeast Asia (Palm) and Amazon rainforest (Soy). Some certifications exist for these oils. For instance for Palm oil exist the Roundtable on Sustainable Palm Oil (RSPO) certification, which is the main scheme of initiatives that aims to promote the growth and use of sustainable vegetable oils based on economic, social and ecological criteria. Similar initiatives regarding other renewable products, e.g. soya beans (Round Table on Responsible Soy (RTRS)) and sugar cane, are currently being developed. Some producer countries are being developing their own certificates for palm oil such as Malaysia Sustainable Palm Oil (MSPO) certification and the mandatory Indonesian Sustainable Palm Oil (ISPO) certifications should prove compliance with the ISO Guide 65/66. General criteria:

- Economic criterion: continuous efficiency improvements; documentation on the improvement of production conditions and continuous increases in yield which lead to work and employment
- Ecological criterion: rainforest or other areas of high conservation value may not be destroyed to make way for new plantations
- Social criterion: working conditions must be consistent with industry standards and minimum wages must be paid. The RSPO also addresses health and safety at work.

In the European Union, under the Renewable Energy Directive (RED)<sup>43</sup>, only those vegetable oils that have been verifiably certified as sustainable can receive state support for energy use and may be counted towards national renewable energy targets. The established standards are related to requirements concerning changes in the use of land, Greenhouse Gas Effect calculations and traceability, and they determine if these raw materials may be considered as sustainable or not. To meet this regulation, they have created the RTRS Annex for Biofuels. This Annex includes all the requirements of the directive and, although certification is only optional, it assures that producers will export soy to any of the member states of the European Union in the form of raw material for biofuel production.

On this regard, any ecolabel studied do not have any criterion covering these issues. The Japanese revision of Ecolabel from 2004 did research on this aspect in order to explore the

<sup>&</sup>lt;sup>43</sup> Directive 2009/28/EC of the European Parliament and of the Council of 23 April 2009 on the promotion of the use of energy from renewable sources and amending and subsequently repealing Directives 2001/77/EC and 2003/30/EC.

possibility of setting criteria regarding this issue. The following points were reviewed under this item:

(1) Exotic animal and plant species shall not be used as a raw material

CONCLUSION: since most plant oil raw materials are imported, it is not realistic to prohibit the use of exotic species. Consequently, this item was not selected as a criterion.

(2) Gene-recombinant products shall not be used as a raw material

CONCLUSION: it is not possible to survey whether imported plant oil raw materials are gene-recombinant products. In addition, since no methods exist for evaluating the influence of genetically engineered products on the ecosystem, this item was not selected as a criterion.

In the revision of 2014 of Blue Angel for Biodegradable Lubricants and Hydraulic Fluids (RAL-UZ 178) it is stated that issues related to the renewable origin of renewable substances should be investigated for possible future criteria.

• The possibility of safely excluding the possible negative environmental effects of the cultivation and processing of renewable raw materials using a targeted set of criteria and verification obligations (e.g. via a suitable certificate).

• On this basis and with the goal of preserving resources, substantial requirements would be established for ensuring the minimum content of these types of renewable raw materials.

• If in the course of this investigation, a set of instruments for verifying the sustainability of the renewable raw materials is available at the time of the next examination of the Basic Award Criteria, a corresponding new criterion "renewable raw materials" will be included based on the EU Environmental Label.

Other product groups from EU Ecolabel have set criteria regarding the sustainability of vegetable oils:

- Rinsed-off cosmetics: Criterion for sustainable palm oil
- Detergents and cleaning product groups: Criterion for sustainable palm oil

As conclusion, criterion promoting the sustainable production of vegetable-based ingredients could be proposed to be set, although some difficulties arise in order to define a proper standard and mean of verification. Although some standard exist for some oils (palm oil, soya oil), it is not the case for the oils most widely used in lubricants in Europe (sunflower, rapeseed). **Further research and discussions are expected in order to better define the proposal.** 

# Rationale of proposed "Assessment and verification"

Manufacturers should provide supply-chain-evidence that the product originates 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.

Discussion should be maintained to decide which mechanisms included of current certifications for some oils can be applied to the rest of vegetable oils, since current certifications only cover

some oils such as palm oil and soy oil. No well-established certification exists for the rest of vegetable oils.

Official certifications would be accepted as evidence if is considered sure enough and it is in conformance with ISO Guide 65/66.

# 3.6 CRITERION 6 (New): Exhaust emissions

wo-stroke engine oils shall perform:		
Performance	Criterion	Test procedure
Exhaust smoke	≥ 85	JASO M342
Exhaust system blocking	≥ 90	JASO M343
Assessment and verification The applicant shall provide the informatic	on about the exhaust emis	ssion test results.

# Rationale of proposed criterion text

Engine design changes do require meeting the latest emission regulations, having a great impact on the engine oil degradation process. New regulations with stricter emission limits, especially particulate matter (PM) and nitrogen oxides ( $NO_x$ ) are being introduced not only in Europe with the standards "Euro", but also in Australia, USA and Japan.

Contrary to 4-stroke engine oil, in 2-stroke engines there is no dedicated lubrication system, the lubricant is mixed with fuel. Each time a new charge of air-fuel is loaded into the combusting chamber, a part of it leaks out through the exhaust port. The burning of lubricating oil and the exhaust of un-burnt fuel makes them more polluting than a 4-stroke engine of similar power.

Two-stroke engines are employed widely due to their simple construction and economic production costs. They also provide a good power-to-weight ratio and can operate in any position, which is not possible with the four-stroke engines due to the problems in lubrication. Contrary to their advantages, the thermal efficiency and fuel economy of the two-stroke engines are poor, and total hydrocarbon (THC) and particle mass (PM) emissions are very high. The poor fuel economy and high emission THC and CO rates are predominantly due to the scavenging losses. The high PM emissions result mainly from the mixture of oil and fuel employed in the two-stroke engines. Lubricating oil is less combustible than gasoline; some of the oil that is mixed with fuel is unburned or partially burned, therefore lubricating oil exits the engine with exhaust. Particulate matter, particularly the finer ones, is associated with respiratory problems. Un-burnt hydrocarbons emissions result from the elements of the air-fuel mixture that fail to burn in the engine due to leakage through the exhaust port, weak compressing causing partial combustion and misfiring.

Lubricating oil is suggested to contribute even 95% to the total exhaust particle mass (1). Moreover, the emissions of the gaseous and particulate pollutants can be reduced by improving the fuel and lubricating oil formulation.

This criterion is proposed to be included in the current EU Ecolabel for two-stroke engine oils products. Actually, other ecolabels, for example Korea Eco-label, establishes minimum requirements regarding the emission of air pollutants for two-stroke engine oils.

## **Rationale for the Assessment and Verification**

Korea Eco-label and ISO 13738:2011 relate to JASO (Japanese Automotive Standards Organization) standards M342 and M343 to verify the exhaust smoke and exhaust blocking, respectively.

# 3.7 CRITERION 7 (New): Packaging requirements

#### Proposal for criterion: Packaging requirements

- a) Packaging materials: Product packaging, including caps and labels, must not contain halogenated plastics.
- b) Ecodesign: for low capacity packaging, a dispenser closure system allowing proper dosage and avoiding spillage shall be made available to the users as part of the packaging.
- c) Recycled content/Recyclability (For further discussion): plastic packaging shall be recyclable, excluding the use of incompatible materials that are not detected and separated during the recycling process and/or packaging shall be made on a minimum of XX% of recycled material

#### Assessment and verification

The applicant shall provide a declaration of non-use halogenated plastics from the manufacturer of the product packaging.

The applicant shall provide a description of the dispenser closure, along with photos or technical drawings of the system.

The applicant shall provide the label of the packaging where the information about the waste disposal appears.

The applicant shall provide a declaration with the % of recycled material and the list of the materials content within the packaging and their recyclability characteristics.

# Rationale of proposed criterion text

The relative impact generated for the packaging is minor compared to the lubricant manufacturing and other stages. However, waste generated due to packaging is an increasing concern: 157 kg of packaging waste per inhabitant was generated during 2013 in the EU, of them 19% is plastic packaging<sup>44</sup>. Considering the extension of the lubricant market, the impact generated due to the waste disposal of packaging could be important.

For this reason, an inclusion of criterion for packaging could be important in order to influence in:

• The restriction of certain substances.

<sup>&</sup>lt;sup>44</sup> Packaging waste by waste operations and waste flow: packaging waste generation. Eurostat (2016).

- The use of recycled material in the packaging manufacturing
- The design of the package to optimize the use and disposal

The Directive on Packaging and Packaging Waste (Directive 94/62/EC) provides measures aimed at reduce the production of packaging waste and encourage the waste recovery promoting recycling and re-use, for example. In this criterion, the restrictions on packaging will be in accordance and will go further the Packaging Directive.

Including technical and scientific arguments/supporting data taken into account to set up specific criteria/ threshold/ restriction or the withdrawn of other proposals discussed during the development/revision process;

# Packaging materials

According to the LCA, it is considered that the environmental impact generated by the packaging would be low in comparison with the rest of life stages. Nevertheless, some materials and substances used in the packaging could be considered important due to its potential environmental impact and its inherent toxicity.

According to the preliminary report, the halogenated waste, when incinerated without precautions, has the potential to form toxic polychlorinated dioxins and furans (Zennegg et al. 2009, Wong et al. 2007) and many show persistent and bioaccumulative properties from the waste incineration plant. Dioxins and furans are commonly regarded as highly toxic compounds that are environmental pollutants and persistent organic pollutants (POPs).

Halogenated compounds are not suited for combustion; however the problem is that halogenated waste may end in the rubbish deposited by consumers, which may be finally combusted. It should be considered that approximately 50% of all traditional lubricants are released into the environment during use, spills, and disposal. For example, during normal use Four-Stroke engine oils are not released to the environment, but their main environmental concerns come from improper disposal of used oil. It is therefore recommended to exclude packaging containing halogenated plastics, especially in the case of lubricants designed to be sold to private end consumers when the lubricant is used for non professional or non industrial users due to it could generate a spillage to the environment.

It is stressed to note that others regional ecolabels include information about the packaging materials:

- The withdrawn Nordic Swan included the following criterion about the product packaging: Product packaging, including caps and labels, must not contain halogenated plastics.
- Eco mark Japan: Packaging shall not contain resins made of halogens and halogenids as constituents.

# Ecodesign:

This sub-criterion is proposed to be included in the EU Ecolabel criteria for products manufactured for particular users. The environmental impact during use of the lubricants is significant when the lubricant is used for non professional or non industrial users due to it could generate a spillage to the environment.

To avoid or minimize the environmental impact during use, the design of the dispenser closure is important and allows the correct dosing of the lubricant fluid.

Others regional ecolabels include information about the design of the packaging:

- The Nordic Swan include the following criterion about the remainder part of the lubricant that could remain in the packaging: in the case of up to five liters an account must be provided of the design used to prevent the retention of oil<sup>45</sup>.
- NF-Environment considers also the importance of the retention of the lubricant in the package and also of the right dose lubricant<sup>46</sup>.

#### **Recycled content and recyclability:**

In order to promote a reduced production of waste from packaging and the circular economy, it is proposed to encourage the use of packaging from recycled sources and the easy recycling of packaging.

The recycling rate of packaging in the year 2013 represented 103 kg per habitant, 65,6% of the total waste packaging<sup>47</sup>.

Some frontrunners have been identified selling lubricants in fully recyclable packaging, such as REPSOL (<u>https://www.repsol.com/es\_en/productos-servicios/lubricantes/principios/seguridad-y-medio-ambiente/gestion-envases/</u>) or SHELL (<u>http://www.greenerpackage.com/additives/bag-box\_provides\_sustainable\_option\_shell\_lubricants</u>).

No other schemes on lubricants include criteria on recycled content. Further research and discussions are needed in order to set criteria on packaging for lubricants.

#### Rationale of proposed "Assessment and verification"

The verification text for each of the sub-requirements is subject to further research and discussions on the approach to be followed for this criterion.

#### Questions to stakeholders

Stakeholders are asked to provide information on the use of recycled content on the lubricants packaging.

In order to better define the verification text, stakeholders are asked to provide information on availability, cost and use of methods to measure/proof recyclability and recycled content of the packaging.

# 3.8 CRITERION 8: Minimum technical performance

Proposal for criterion 5: Minimum technical performance

The quality of the candidate lubricant must be equal to or better than those of reference lubricants, or within the tolerances as specified.

ISO ISO 6743-99 Family Description

Minimum technical performance

<sup>&</sup>lt;sup>45</sup> Nordic Swan

<sup>&</sup>lt;sup>46</sup> NF-Environment

<sup>&</sup>lt;sup>47</sup> Packaging waste by waste operations and waste flow: packaging recycling rate. Eurostat (2016).

Propo	Proposal for criterion 5: Minimum technical performance						
A	Total loss systems	<u>Chainsaw:</u> Based on RAL UZ 48 <sup>48</sup> and AFNOR NF 375 (see Table 24) <u>Wire ropes</u> : Lubricity and corrosion requirements (see Table 23) <u>Other total loss lubricants</u> : Minimum stability requirements					
В	Concrete release agents	Concrete: Minimum stability requirements					
С	Gears	DIN 51517 section (I, II or III)					
Е	Internal combustion engine oils	2-stroke marine: NMMA TC-W3 2-stroke terrestrial: ISO 13738:2000 (EGD) 4-stroke marine: NMMA FC-W 4-stroke terrestrial: ACEA 2016 European Oil Sequences 2016					
Н	Hydraulic systems	ISO 15380 (Tables 2 to 5) <u>Fire resistant hydraulic fluids</u> : ISO 12922					
М	Metalworking fluids	Minimum stability requirements					
R	Temporary protection against corrosion	ISO/TS 12928:1999					
Т	Turbines	<u>Stern tube</u> : ISO 8068:2006					
Х	Greases	<u>Temporary protection against corrosion</u> : ISO/TS 12928:1999 <u>Gears</u> : DIN 51517 section (I, II or III) <u>Other greases</u> : "Fit for purpose"					

#### Assessment and verification

The applicant shall provide a declaration of compliance with this criterion supported by testing laboratories confirming compliance with the requirements.

## **Rationale of Proposed Criterion text**

It is proposed to incorporate a technical performance criterion for the new categories included in the current EEL revision, as four-stroke engine oils or metalworking fluids. Moreover, some categories that are currently considered in the EEL are revised in order to establish a minimum technical performance and to avoid damaging the Ecolabel brand.

This proposal includes a revision of the current technical performance requirements for the existing categories and the addition of minimum technical performance requirements for the new categories, taking into account existing technical standards. Table 22 shows the current minimum technical performance for each proposed category.

ISO Family	ISO 6743-99 Description	Current EEL
А	Total loss systems	<u>Chainsaw:</u> Based on RAL UZ 48 <u>Other total loss lubricants</u> : "Fit for purpose"
В	Concrete release agents	Concrete: "Fit for purpose"
С	Gears	Industrial and marine: DIN 51517 section (I, II or III)
Е	Internal combustion engine oils	2-stroke marine: NMMA TC-W3 2-stroke terrestrial: ISO 13738:2000 (EGD)

Fable	22. Minimum	technical	performance	for	each	category	in	the	current	EEL.	
			Perrormanee			energer,					

<sup>&</sup>lt;sup>48</sup> The product must meet the technical requirements specified in the directives of the Kuratoriums für Waldarbeit und Forsttechnik (KWF) (Committee for Forest Labour and Forest Engineering) on the Testing of Chain Lubricants for Power Saws.

Н	Hydraulic systems	ISO 15380 (Tables 2 to 5)
М	Metalworking fluids	Not included
R	Temporary protection against corrosion	Not included
Т	Turbines	Stern tube: "Fit for purpose"
X	Greases	"Fit for purpose"

#### Total loss systems

The main functions of wire rope lubricants are not only to reduce friction as the individual wires move over each other, but also to provide corrosion protection and lubrication in the core, inside wires, and on the outer surface. A revised minimum technical performance is suggested based on common analysis. EEL pioneer in establishing a minimum technical performance for wire rope lubricants, given that other labeling schemes do include wire rope lubricants within the "other total loss systems" category and they set the technical performance as 'fit for purpose'. For wire ropes lubricants, a new minimum technical performance has been proposed:

Table 23. Minimum technical performance proposed for wire rope lubricants.

Properties	Method	Results
Viscosity	ISO 3104 or ASTM D445	Specify at 40 and 100°C
Corrosion	Salt spray (ASTM B117) Humidity cabinet (ASTM D1748)	>60 hours >60 days
Weld point	ASTM D2783	>200 kg
Load-wear index	ASTM D2783	> 45

For chainsaw oils the current EEL technical performance is based on RAL UZ 48 (Swedish Standards). There are, however, other eco-labels, as NF Environment brand, that are based on other standards as AFNOR 375-0 (certification scheme criteria 7 to 12). In addition, ISO/TC 23/SC 17 has recently defined a new test procedure to evaluate the chainsaw oil lubrication ability, ISO/TS 19858:2015.

For chainsaw oils, the proposed technical performance is based on RAL UZ 48 and AFNOR NF 375 (see Table 24). However some methods to meet some properties required in RAL UZ 48 (like viscosity, flash point or pour point) have been modified following AFNOR NF 375 in order to harmonize the EEL. Moreover a new test method recently developed for evaluating chain saw oil lubricity is proposed to be included, the ISO/TS 19858.

Table	24. Minimum	technical	performance	proposed	for	chainsaw	lubricants.
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Properties	Method	Results
Viscosity	ISO 3104, ASTM D445	Specify at 40 and 100°C
Flash Point	ISO 2592	>200°C
Pour Point	ISO 3016	Temperature lower than: • -10°C: Hot climate (H) • -20°C: Temperate climate (T) • -30°C: Arctic climate (A)
Ageing	Annex 2 of KWF. Heating in glass dishes	Flow time no more than 15s longer than original flow time. No visible changes (separation, flocking or formation of

	at 80°C for 1000h	separation layers)
Lubricity Brugger	DIN 51347	Loading $> 27 \text{ N/mm}^2$
Wear on chains and guide bars	ISO/TS 19858:2015 (E)	Chain extension <2mm Wear depth of the guide bar <1.5mm Surface temperature after 180min <85°C
Non corrosive	Visual inspection	No damage to or signs of material change in paint, plastic components and metal components of chainsaws

For other total loss lubricants, as railway lubricants, a minimum stability requirement, MSR, has been proposed, which guarantees no aspect changes for a short storage time, although for several types technical performance criteria are desired. For example, no changes shall be observed when a product recovers 20°C after being 7 days at 5°C and 50°C.

## Concrete release agents

After completing a deep review, no technical standard has been found that covers a minimum technical performance. Other eco-label programs are also lacking a specific technical performance requirement. As a result, it has been decided to propose a minimum stability requirement (MSR), which takes technical standards into account.

## Gears

Current EEL program for gear lubricants, as well as other eco-label like the Swedish Standard, take the recognized DIN 51517 specification as a basis to define a minimum technical performance. In addition, the standard ISO 12925 has also been taken into consideration as an alternative standard. As a result, the minimum technical performance criterion is not modified and shall meet the DIN 51517, which considers three sections. The supplier shall list within the product information sheet to which specific section (I, II or III) does the gear lubricant fit.

# Internal combustion engine oils

Internal combustion engine oils have been classified in: two-stroke and four-stroke engine oils.

a) 2-stroke

In addition to EEL, Japan Ecolabel and Korea Ecolabel are eco-labels that also include a twostroke engine oils category. The EEL follow s: ISO 13738:2000 for terrestrial applications and NMMA TC-W3 for marine applications. The Japan Ecolabel bases the technical performance criteria on both, the NMMA TC-W3, and the JASO (Japanese Automotive Standards Organization) M345. By contrast, Korea Eco-label considers 2-stroke engine oils for gasoline and diesel two-cycle engine oils used in ship or motorcycle applications. Korea Eco-label includes its own technical criteria based on ILSAC (International Lubricants Standards Accreditation Committee), JASO standards, KS (Korean Industrial Standards), and ASTM.

The existing EEL technical performance for 2-stroke engine oils has not been modified. Oils shall conform to one of the following standards:

- Two-stroke oils for <u>marine</u> applications: at least the technical performance criteria of NMMA TC-W3, "Two-Stroke Cycle Gasoline Engine Lubricants".
- Two-stroke oils for <u>terrestrial</u> applications: at least meet the EGD level of technical performance criteria of ISO 13738:2000.
- b) 4-stroke

For four-stroke engine oils, a minimum technical performance needs to be established. Similarly to the approach taken for two-stroke oils, a distinction is made between marine and terrestrial applications.

For marine applications, the National Marine Manufacturers Associations (NMMA), which has a widespread experience in four-stroke outboard engine technology, has developed testing criteria for the marine four-stroke oil, the NMMA FC-W.

For terrestrial applications, the European Automobile Manufacturer's Association (ACEA) defines a minimum quality level: for service-fill oils for gasoline engines, for light duty diesel engines, for gasoline and diesel engines with after treatment devices, and for heavy duty diesel engines. The ACEA Oil Sequences 2016 has been chosen as the minimum technical performance.

For the new category of four-stroke engine oils:

- Four-stroke oils for <u>marine</u> applications: at least the technical performance criteria as laid down in NMMA FC-W "Four-Stroke Cycle, Water-Cooled Gasoline Engine Lubricant".
- Four-stroke oils for <u>terrestrial</u> applications: at least meet the Engine tests as laid down in ACEA 2016 European Oil Sequences 2016 that define the minimum quality level of service-fill oils that ACEA members demand for using these oils in their vehicles.

# Hydraulic systems

Existing Ecolabel as well as Swedish Standard for hydraulic fluids are both based on the ISO 15380 standard. In the current EEL revision, the minimum technical performance is maintained.

The technical criteria for hydraulic fluids are based in the standard ISO 15380 "Lubricants, industrial oils and related products (class L) – Family H (Hydraulic systems) – Specifications for categories HETG, HEPG, HHES and HEPR", Table 2 to 5. This standard includes an elastomer compatibility test, where at least two elastomers types shall met the specifications. Therefore, it should be indicated on the product information sheet which elastomers have been tested.

Nevertheless, fire-resistant hydraulic fluids are suggested to meet some additional requirements and pass several fire resistance tests. As a result, a new minimum technical performance is proposed for fire-resistant hydraulic fluids; at least shall be performed the criteria of ISO 12922 "Lubricants, industrial oils and related products (class L) – Family H (Hydraulic systems) – Specifications for hydraulic fluids in categories HFAE, HFAS, HFB, HFC, HFDR and HFDU", Table 1 to 3.

## Metalworking fluids

No previous Eco-label records have been found for the metalworking fluid technical performance criteria. Metalworking fluids perform multiple functions in machining processes, like reducing friction, cooling the whole system, or removing chips from the cutting are. Depending on the machining operation, the fluid requirements can be quite different. In this revision, the guideline ISO/TS 12927:1999 "Lubricants, industrial oils and related products (class L) – Family M (Metalworking) – Guidelines for establishing specifications", has been used for classification purposes.

Considering the variety of products and applications for this new category with diverse performance requirements, a minimum stability requirement has been proposed, which guarantees no aspect changes for a short storage time, although for several types technical performance criteria are desired. For example, no changes shall be observed when a product recovers 20°C after being 7 days at 5°C and 50°C.

# Temporary protection against corrosion

Given that no eco-label precedent has been found for this new category, it is proposed to, at least, perform the protection performance (duration) as defined in ISO/TS 12928:1999 "Lubricants, industrial oil and related products (class L) – Family R (Products for temporary against corrosion) – Guidelines for establishing specifications", (Table 1 to 3).

This standard is a guideline that establishes specifications for temporary corrosion protection products for a given application.

## Stern tube

In the current EEL revision, the stern tube greases from the previous Ecolabel scheme has been expanded to include also stern tube oils. For the stern tube greases, the minimum technical performance is maintained as fit for purpose. For the newly included stern tube oil lubricants, they shall be in accordance with the limits of ISO 8068:2006 "Lubricants, industrial oil and related products (class L) – Family T (Turbines) – Specification for lubricating oils for turbines".

# Greases

Greases are classified, as designed in the ISO 6743-9, as "Lubricants, industrial oils and related products (class L) - Classification - Family X (greases)", which is constituted by a group of five letters depending on: the minimum and maximum operating temperatures; the ability of the grease to provide satisfactory lubrication in water prone conditions; the ability to provide the proper level of protection against rust; the ability of the grease to lubricate in high load conditions. In accordance with this standard, ISO/DIS 12924 "Lubricants, industrial oils and related products (class L) - Family X (greases) – Specification" specifies the requirements of greases taking into account these 5-letter designation.

Moreover, other eco-labels, as the Swedish Standard (with SS 15 54 70) and the Japan Ecolabel (with JIS K 2220 "Lubricating grease") do in fact establish several requirements different from "Fit for purpose". On the one hand, the Swedish Standard, similar to ISO/DIS 12924, classifies greases according to their properties: the lower and upper operating temperature; gel strength (oil separation); corrosion preventive abilities of lubricating greases; and lubrication ability under extremely high loads. On the other hand, some characteristics requirements that grease should fulfill in the Japan Ecolabel are the dropping point, the penetration, the oil separation and the water wash-out, just to name several of the most common ones.

There is a wide range of applications for greases, covering lubricating greases used in industrial, automotive and marine applications. It has not been possible to establish simple technical requirements for greases, given that, among other reasons, a grease does not need to fulfill a specific technical requirement in order to properly perform its function. Consequently, in future revisions a minimum technical performance for specific grease applications should be defined.

On the one hand, temporary protection against corrosion grease shall fulfil the specifications of performance duration of ISO/TS 12928:1999 (Table 5) and gear greases shall fulfil the requirements of DIN 51517. On the other hand, stern tube greases shall fulfil the same specifications as other greases, fit for purpose.

## Rationale of proposed "Assessment and verification"

Declaration of compliance and the results of the tests are described in the criterion.

# 3.9 CRITERION 9 (New): Consumer information regarding use and disposal

#### Proposal for criterion: Disposal information

In the case of lubricants designed to be sold to private end consumers, the following information shall be present in the label of the package:

"Lubricating oil may be harmful to health and environment, it must not be deposited in water systems and it must be managed for an authorized waste manager"

#### Assessment and verification

The applicant shall provide a label of the packaging where the criterion information appears.

## Rationale of Proposed Criterion text

The European List of Waste (Commission Decision 2000/532/EC<sup>49</sup>) classify the wastes and provide a common terminology to improve the efficiency of waste management activities. The lubricating oils are included in the category 13: Oil wastes and wastes of liquid fuels.

Waste oils are an important source of environmental impact if they are not collected correctly. The uncontrolled disposal could affect the soils, aquatic life and renders water unfit for drink.

A criterion to reduce the amount of waste lubricant is important to decrease the overall environmental impact, especially in aquatic ecosystems.

Disposal of waste lubricant is a criterion considered in different Ecolabels. Most of them consider the inclusion of a description with the information about the waste disposal. Some references are:

- Nordic Swan: Lubricating oils must be delivered to an approved site or collector of toxic waste.
- NF-Environment: All lubricating oils can present a risk to the environment and health and therefore should not be discharged into sewers, water or soil.
- Swedish Standard specifies that the waste lubricant must not discharge into drains, water courses or onto the ground; and that the applicant should provide recommendations for safe handling of lubricant. The SS introduce a new specification concerning the emergency plan in case of spillage.

Whole industry should do efforts to make an appropriate disposal and separation. In case of the private end consumers, the disposal of the lubricant is not able to control and regulate, nevertheless this use of lubricant presents the higher risk due to the lack of knowledge of the consumer. For this reason, the applicants shall inform users about the disposal needs of the used lubricant.

# 3.10 CRITERION 10: Information appearing on the EU Ecolabel

Proposal for criterion 6: Information appearing on the EU Ecolabel

<sup>&</sup>lt;sup>49</sup> Commission Decision 2000/532/EC: European List of Waste

# Proposal for criterion 6: Information appearing on the EU Ecolabel

The logo shall be visible and legible. The EU Ecolabel registration/licence number shall appear on the product and it shall be legible and clearly visible.

The applicant may choose to include an optional text box on the label that contains the following text:

- Limited impact on the aquatic environment;
- Restricted amount of hazardous substances;
- Tested for lubricating performance

## Assessment and verification

The applicant shall provide a signed declaration of compliance along with a sample of the product label or an artwork of the packaging where the EU Ecolabel is placed.

# Rationale of proposed criterion text

According to Article 8 (3b) of the EU Ecolabel Regulation 66/2010, for each product group, three key environmental characteristics of the ecolabelled product may be displayed in the optional label with text box. The guidelines for the use of the optional label with text box can be found in the "Guidelines for the use of the EU Ecolabel logo" on the website<sup>50</sup>.

Information about the Ecolabel on the product is needed in order to inform the consumer and make easy the environmental friendly decision. For this reason, a requirement about the logo and the number certification shall be included.

The information that appears on the existing EU Ecolabel criterion has partially modified. Main change correspond to the deletion of the claim *contains a large fraction of biobased material* that will not be always the case regarding the introduction of criterion 4. Base fluids origin, and the introduction of the claims:

- Restricted amount of hazardous substances;
- Tested for lubricating performance

Also instructions on the use of logo and licence number are included. with the recently voted detergents product group.

The text is in line with the most recently revised EU Ecolabel criteria of product categories such as detergency product groups.

<sup>&</sup>lt;sup>50</sup> http://ec.europa.eu/environment/ecolabel/documents/logo\_guidelines.pdf

# 4 IMPACT OF CHANGES TO CRITERIA

This section consists on a summary of the main general changes proposed for the revised criteria and potential implications on current license holders and possible applicants. This section will be further developed at an advanced stage of the revision when a more definitive proposal is available.

In relation to the **scope** there are two main aspects proposed:

- Enlargement of the <u>scope</u> to cover a higher market share (including end-consumer products) and to cover all life cycles of lubricant products with the aim of guarantee that ecolabelled products will have the minimum impact on health and environment during all life, from cradle to grave, with especial focus on those life stages with higher potential impacts: raw materials, use and disposal

- Harmonisation of the lubricants families to <u>ISO 6743 "Lubricants, industrial oils and related</u> <u>products":</u> For the lubricant types to be covered in the scope during this revision it is suggested to harmonise to the nomenclature of the lubricant families used in the ISO 6743 classification aiming to establish unambiguously what are the types of lubricants considered under the scope and to set clearer minimum technical performance requirements (to define a standard test per family or sub-family).

These two aspects will have direct implications on possible applicants due to a wider and clearer scope. There would be wider spectra of lubricants (including end-consumer products) that would be able to apply for the EU Ecolabel and in addition it would be clearer the different families covered in the scope thanks to the alignment to ISO definition of families.

In relation to the **criteria**, there is a general raise of ambition level proposed mainly based on data received from competent bodies and information from other labelling schemes.

Regarding the criteria dealing with hazardous substances issues and potential toxicity, bioaccumulation and biodegradability of products (criterion 1, 2 and 3), the requirements have been updated according to current legislation and REACH regulation. For criterion 1, more restrictive requirements and thresholds have been established, harmonizing them with other EU ecolabel product groups. For criteria 2 and 3, more restrictive requirements and thresholds have been established, harmonizing them with other ecolabel schemes and according with actual values of current labeled products within the different categories. According to data provided by Competent Bodies, most of ecolabelled products would accomplished with new proposed requirements (criteria 2 and 3). These changes reflect the evolution of the market and the industry, evolving to more sustainable and less hazardous products.

For **raw materials criteria** (**criterion 4**), the focus have been broad from vegetable oils/subtances to subtances with vegetable origin, synthetic or re-refined (differentiating among categories depending on the lubricant loss). These options have been proved to be more sustainable than mineral origin substances and mineral oils. In recent years, last technology developments have increased the quality of synthetic and re-refined oils for several applications.

With this change proposed, manufacturers have more alternatives to accomplished with more restrictive thresholds proposed.

Regarding oils and substances from **vegetable oils**, **criterion 5** have been proposed in order to ask for traceability of the origin of these substances, in order to assure that these raw materials and harvested and managed with sustainability criteria.

Two new criteria have been formulated for the **use phase and end-of-life**, since in LCA studies was found that these two life stages can have important impacts associated since lubricants can reach the environment compartments. Criteria have been proposed for **packaging (criterion 7) and Consumer information regarding use and disposal (criterion 9)**, covering hazardous materials limitation, design for proper dosage, recycled content and recyclability and end of life of the lubricant.

Regarding the use phase, **minimum technical performance (criterion 8)** have been revised according to updated standards and tests, covering all existing and new categories included within the scope.

Finally, in relation to the emission to air associated to 2 stroke oils a criteria dealing with **exhaust emissions for engine oils (criterion 6)** have been introduced.

An increase of ambition would have an impact on current licenses and possible applicants. Further discussions and further research should be carried out in order to assure that only best environmental products for each category and application are able to comply with the requirements.

# 5 APPENDIX 1. EXISTING CRITERIA

#### Criterion 1 - Excluded or limited substances and mixtures

#### (a) Hazardous substances and mixtures

According to the Article 6(6) of Regulation (EC) No 66/2010 on the EU Ecolabel, the product or any part of it shall not contain substances (in any forms, including nanoforms) meeting the criteria for classification with the hazard statements or risk phrases specified below in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council (1) or Council Directive 67/548/EEC (2) nor shall it contain substances referred to in Article 57 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (1). The risk phrases below generally refer to substances. Nanoforms intentionally added to the product shall prove compliance with this criterion for any concentration.

1	
Hazard Statement (4)	Risk Phrase (5)
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	R26
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; R61; R60-61
H360Fd May damage fertility. Suspected of damaging the unborn	R60-R63
child	
H360Df May damage the unborn child. Suspected of damaging	R61-R62
fertility	
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; R39/24; R39/25; R39/26; R39/27; R39/28
H371 May cause damage to organs	R68/20; R68/21; R68/22
H372 Causes damage to organs through prolonged or repeated	R48/25; R48/24; R48/23
exposure	
H373 May cause damage to organs through prolonged or repeated	R48/20; R48/21; R48/22
exposure	
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

EUH059	Hazardous to the ozone layer	R59
EUH029	Contact with water liberates toxic gas	R29
EUH031	Contact with acids liberates toxic gas	R31
EUH032	Contact with acids liberates very toxic gas	R32
EUH070	Toxic by eye contact	R39-41

This criterion shall also apply to the following hazard statements and risk phrases:

Hazard Statement (6)	Risk Phrase <u>(7)</u>
H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled	R42
H317: May cause allergic skin reaction	R43
H314 Causes severe skin burns and eye damage	R34; R35
H319 Causes serious eye irritation	R36
H315 Causes skin irritation	R38
EUH066 Repeated exposure may cause skin dryness or cracking	R66
H336 May cause drowsiness and dizziness	R67

Substances or mixtures which change their properties upon processing (e.g. become no longer bioavailable, undergo chemical modification) so that the identified hazard no longer applies are exempted from the above requirement.

Concentration limits for substances meeting criteria of Article 57(a), (b) or (c) of Regulation (EC) No 1907/2006 shall not exceed 0,010 % (w/w). If specific concentration limits are referred to for substances meeting criteria of Article 57(a), (b) or (c) they should remain below one tenth (1/10) of the lowest specific concentration value indicated unless this value falls below 0,010 % (w/w).

Derogations from Criterion 1(a) are listed in Table 1.

Assessment and verification of criterion: the applicant shall provide the exact formulation of the product to the competent body. The applicant shall demonstrate compliance with this criterion for substances in the product on the basis of information consisting as a minimum of that specified in Annex VII to the Regulation (EC) No 1907/2006. Such information shall be specific to the particular form of the substance, including nanoforms, used in the product. For that purpose, the applicant shall provide a declaration of compliance with this criterion, together with a list of ingredients and related Safety Data Sheets in accordance with Annex II to Regulation (EC) No 1907/2006 for the product as well as for all substances listed in the formulation(s). Concentration limits shall be specified in the Safety Data Sheets in accordance with Article 31 of Regulation (EC) No 1907/2006.

Sufficient data shall be available to allow for the evaluation of the environmental hazards (indicated by the hazard statements H400 – H413 or R-phrases: R 50, R 50/53, R 51/53, R 52, R 52/53, R 53), of the product in accordance with Regulation (EC) No 1272/2008 or Directive 67/548/EEC and Directive 1999/45/EC of the European Parliament and of the Council.(8).

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 or by the summation method in Section 4.1.3.5.2 of Regulation (EC) No 1272/2008. However, as defined by Part C of Annex III to Directive 1999/45/EC or by Section 4.1.3.3 of Regulation (EC) No 1272/2008, 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 or summation method.

(b) Substances listed in accordance with Article 59(1) of Regulation (EC) No 1907/2006

No derogation from the exclusion in Article 6(6) of Regulation (EC) No 66/2010 may 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, when present in mixtures, in concentrations higher than 0,010 % (w/w).

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

Reference to the list shall be made on the date of application.

Concentration limits shall be specified in the Safety Data Sheets according to Annex II, paragraph 3.2.1(c) of Commission Regulation (EU) No 453/2010\_(9).

#### Criterion 2 - Exclusion of specific substances

The following stated substances are not allowed in quantities exceeding 0,010 % (w/w) of the final product:

- --substances appearing in the Union List of priority substances in the field of water policy in Annex X to Directive 2000/60/EC of the European Parliament and of the Council(10) as amended by laid in Decision No 2455/2001/EC of the European Parliament and of the Council(11) and the OSPAR List of Chemicals for Priority Action (http://www.ospar.org/content/content.asp?menu=00950304450000\_000000\_000000),
- 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 the Annex to this Decision.

Assessment and verification: conformance with these requirements shall be stated in writing and signed by the applicant.

#### Criterion 3 - Additional aquatic toxicity requirements

The applicant shall demonstrate compliance by meeting the requirements of either criterion 3.1 or criterion 3.2.

#### Criterion 3.1. - Requirements for the lubricant and its main components

Acute aquatic toxicity data of the main components and the mixture shall be provided.

Acute aquatic toxicity data for each main component shall be stated on each of the following two trophic levels: algae and daphnia (12). 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 applied lubricant shall be stated on each of the following three trophic levels: algae, daphnia and fish. The critical concentration for the acute aquatic toxicity for a lubricant in Category 1 and 5 shall be at least 100 mg/L and for a lubricant in Category 2, 3 and 4 at least 1 000 mg/L.

Table 2 summarises the requirements for the different lubricant categories according to criterion 3.1.

Assessment and verification: either marine or freshwater toxicity data are accepted. The tests are carried out according to and using relevant test species mentioned in the following guidelines: ISO/DIS 10253 or OECD 201 or Part C.3 of the Annex to Council Regulation (EC) No 440/2008 (13) for algae, ISO TC 147/SC5/WG2 or OECD 202 or Part C.2 of the Annex to Regulation (EC) No 440/2008 for daphnia and OECD 203 or Part C.1 of the Annex to Regulation (EC) No 440/2008 for daphnia and OECD 203 or Part C.1 of the Annex to Regulation (EC) No 440/2008 for daphnia and OECD 203 or Part C.1 of the Annex to Regulation (EC) No 440/2008 for fish. Equivalent test methods as agreed with a competent body are also permitted. Only (72hr)ErC50 for algae, (48hr)EC50 for daphnia and (96hr)LC50 for fish are accepted.

#### Criterion 3.2. - Requirements for each stated substance present above 0,10 % (w/w)

Chronic toxicity test results in the form of No Observed Effect Concentration (NOEC) data shall be stated on each of the following two aquatic trophic levels: daphnia and fish.

In case chronic toxicity test results are missing, acute aquatic toxicity tests results shall be provided for each of the following two trophic levels; algae and daphnia. One or more substances exhibiting a certain degree of aquatic toxicity are allowed in each of the five lubricant categories for a cumulative mass concentration as indicated in Table 1.

Assessment and verification: No Observed Effect Concentration (NOEC) data on the two trophic levels, daphnia and fish, are established by the following test methods: Part C.20 and Part C.14 of the Annex to Regulation (EC) No 440/2008 for daphnia and fish respectively, or equivalent test methods as agreed with a competent body.

Either marine or freshwater acute toxicity data are accepted on algae and daphnia. The tests in marine water are carried out according to and using relevant test species mentioned in the following guidelines: ISO/DIS 10253 or OECD 201 or Part C.3 of the Annex to Regulation (EC) No 440/2008 for algae, ISO TC 147/SC5/WG2 or OECD 202 or Part C.2 of the Annex to Regulation (EC) No 440/2008 for daphnia and OECD 203 or Part C.1 of the Annex to Regulation (EC) No 440/2008 for daphnia and OECD 203 or Part C.1 of the Annex to Regulation (EC) No 440/2008 for daphnia and OECD 203 or Part C.1 of the Annex to Regulation (EC) No 440/2008 for fish. Equivalent test methods as agreed with a competent body are also permitted. Only (72hr)ErC50 for algae and (48hr)EC50 for daphnia are accepted.

Assessment and verification for Criteria 3.1 and 3.2: high quality test reports or literature data (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 addition, demonstration of the absence of toxicity for a substance at its limit of water solubility shall be deemed to have met the requirements of this criterion.

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, 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 below 1 000 g/mol is less than 1 %, or
- the substance is highly insoluble in water (water solubility  $< 10 \mu g/l$ ),

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 or equivalent test methods.

The molecular weight fraction below 1 000 g/mol of a polymer shall be determined according to Part A.19 of the Annex to Regulation (EC) No 440/2008 or equivalent test methods.

#### Criterion 4 – Biodegradability and bioaccumulative potential

Requirements for the biodegradability and bioaccumulative potential shall be fulfilled for each stated substance present above 0,10 % (w/w).

The lubricant shall not contain substances that are both: non-biodegradable and (potentially) bioaccumulative.

However, the lubricant 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: conformity shall be demonstrated by providing the following information:

High quality test reports or literature data (testing according to acceptable protocols and GLP) including the references on the biodegradability and when required on the (potential) bioaccumulation of each constituent substance.

#### 4.1. Biodegradation

A substance is considered ultimately biodegradable (aerobic) if:

1.In a 28-day biodegradation study according Part C.4 of the Annex to Regulation (EC) No 440/2008, OECD 306, OECD 310 the following levels of biodegradation are achieved:

- in the ultimately biodegradable tests based upon dissolved organic carbon  $\geq$  70 %,
- —in the ultimately biodegradable tests based upon oxygen depletion or carbon dioxide generation  $\ge 60$  % 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  $\geq$  0,5. The BOD5/(ThOD or COD) ratio can only be used if no data based on Part C.4 of the Annex to Regulation (EC) No 440/2008, OECD 306 or OECD 310 or any other equivalent test methods are available. The BOD5 shall be assessed according to Part C.5 of the Annex to Regulation (EC) No 440/2008 or equivalent methods while the COD shall be assessed according to Part C.6 of the Annex to Regulation (EC) No 440/2008 or equivalent methods.
- A substance is considered inherently biodegradable if it shows:
- —a biodegradation > 70 % in the Part C.9 of the Annex to Regulation (EC) No 440/2008 or OECD 302 C test for inherent biodegradation or equivalent methods, or
- -a biodegradation > 20 % but < 60 % after 28 days in Part C.4 of the Annex to Regulation (EC) No 440/2008, OECD 306, OECD 310 tests based on oxygen depletion or carbon dioxide generation or equivalent methods.

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 or a valid letter of compliance from a competent body can be submitted,
- a substance is non-biodegradable if it fails the criteria for ultimate and inherent biodegradability.

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 or -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.

4.2. Bioaccumulation

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), or
- has an octanol-water partition coefficient, log Kow, value of < 3 or > 7, or
- has a measured BCF of  $\leq 100$  L/kg, or
- is a polymer and its molecular weight fraction below 1 000 g/mol is less than 1 %.

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 bioconcentration factor (BCF) shall be assessed according to Part C.13 of the Annex to Regulation (EC) No 440/2008 or equivalent test methods.

The log octanol/water partition coefficient (log Kow) shall be assessed according to Part A.8 of the Annex to Regulation (EC) No 440/2008 or OECD 123 or equivalent test methods. 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: CLOGP, LOGKOW, (KOWWIN) and SPARC. Estimated log Kow values by any of these calculation methods < 3 or > 7 indicates that 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.

#### Criterion 5 – Renewable raw materials

The formulated product shall have a carbon content derived from renewable raw materials that shall be:

- $\geq$  50 % (m/m) for Category 1,
- $\geq$  45 % (m/m) for Category 2,
- $\geq$  70 % (m/m) for Category 3,
- --  $\geq$  50 % (m/m) for Category 4,
- $\geq 50$  % (m/m) for Category 5.

Carbon content derived from renewable raw material means the mass percentage of component  $A \times [number of C-atoms in component A, which are derived from (vegetable) oils or (animal) fats divided by the total number of C-atoms in component A] plus mass percentage of component <math>B \times [number of C-atoms in component B, which are derived from (vegetable) oils or (animal) fats divided by the total number of C-atoms in component B] plus the mass percentage of component C c-atoms in component B] plus the mass percentage of component C c-atoms in component C, which are derived from (vegetable) oils or (animal) fats divided by the total number of C-atoms in component C, which are derived from (vegetable) oils or (animal) fats divided by the total number of C-atoms in component C], and so on.$ 

The applicant shall indicate on the application form the type (s), source(s) and origin of the renewable material(s) of the main components.

Assessment and verification: the applicant shall provide the competent body with a declaration of compliance with this criterion.

#### Criterion 6 - Minimum technical performance

- (a)For Hydraulic fluids: at least the technical performance criteria as laid down in the current ISO 15380, Tables 2 to 5. The supplier shall list on his product information sheet which 2 elastomers have been tested.
- (b)For Industrial and marine gear oils: at least the technical performance requirements as in the DIN 51517. The supplier shall list on his product information sheet which Section (I, II or III) was selected.
- (c)For chainsaw oils: at least the technical performance criteria as laid down in the RAL UZ 48 of the Blue Angel.
- (d)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.
- (e)For two-stroke oils for terrestrial applications: at least meet the EGD level of technical performance criteria laid down in ISO 13738:2000.
- (f) For all other lubricants: fit for purpose.

Assessment and verification: the applicant shall provide the competent body with a declaration of compliance with this criterion, together with related documentation.

#### Criterion 7 – Information appearing on the eco-label

Optional label with text box shall contain the following text:

- '— Reduced harm for water and soil during use
- Contain a large fraction of biobased material'.

The guidelines for the use of the optional label with text box can be found in the 'Guidelines for the use of the EU Ecolabel logo' on the website: http://ec.europa.eu/environment/ecolabel/promo/logos\_en.htm

Assessment and verification: the applicant shall provide the competent body with a sample of the product packaging showing the label, together with a declaration of compliance with this criterion.

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