



UEIL HSE comments concerning the draft criteria proposal for revision of EU Ecolabel criteria for lubricants (Technical Report 3.0)

The following are critical issues that still need to be addressed by JRC/Commission before finalising the EU ecolabel criteria:

1. Scope: Introduction of a statement that impurities are to be considered as intentionally added

UEIL HSE understand what the regulators are trying to do here and of course appreciate their recent concession on the no 'de minimis' limit for SVHCs, which now appears to be back to the amount indicated in the current standard. However, adding text that considers impurities to be intentionally-added (which of course they are not in the strictest sense) creates an additional practical anomaly. This is because in some cases applicants will be expected to generate/submit test data on impurities separate from the actual intentionally-added ingredients. The ingredients that additive manufacturers and lubricant formulators use necessarily contain low levels of impurities because we do not operate in a pharmaceutical-like manufacturing environment. Additionally, when test data is developed on those ingredients, the impurities are present and so generating data on the impurities themselves seems to be disproportionate. Some regulators may consider that REACH data should exist for raw materials used to make the ecolabel fluid ingredients (and which typically exist in the finished product as impurities) but they misunderstand that REACH data may not be available to formulators for non-REACH purposes without them having to pay for access to the data again. A practical solution that does not reduce the level of protection provided by having robust test data would be to waive aquatic toxicity and environmental fate data from applicants where they can provide the same data on an ingredient containing the impurity.

2. Criterion 1. Excluded or Limited Substances

a) Omission of the current derogation for excluded or limited substances based on the overall product classification

UEIL HSE members continue to highlight the risk of the potential loss of current licenses if the Criterion 1 is implemented as proposed in the Technical Report 3.0. We specifically refer to the impact assessment made regarding Part II of the LuSC list where approximately 30% of the currently approved products would be adversely affected by this change, and which would effectively be disqualified from use in an ecolabel lubricant because their treat rate would be significantly reduced. We believe that the assessment seriously under-estimates the impact on current LuSC listed substance/products, and therefore on the ability of formulators to develop a lubricant. This is because the impact assessment on Part II of the LuSC list includes a high proportion of base stock fluids, which by their nature rarely carry any Hazard phrases compared to other ingredients such as thickeners, performance additives and polymer systems. We therefore request that the impact assessment should be repeated separately for base stock fluids and 'other additives', to illustrate the true potential impact on these 'other

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additives'. We believe that this is necessary because these 'other additives' are critical parts of a finished lubricant, enabling it to meet the necessary technical performance. Even if the hazard profile of LuSC listed additives does not automatically disqualify them from being used, the proposed Criterion may result in the treat rate being reduced to a level where it is not possible to produce a lubricant giving the required technical performance

b) Setting a limit on the content of skin sensitising ingredients in the finished fluid that is 50% lower than that allowed by Blue Angel (RAL UZ-178)

According to previous comments made by JRC the limits set in Table 1 are based on a hazard grouping defined by the EU Ecolabels Chemical Horizontal Task Force. As such JRC appears to consider sensitisers to be a Group 1 substance (i.e. subject to complete restriction in ecolabel products), which places them in the same grouping as CMRs, PBTs/vPvBs and endocrine disruptors. Confusingly 'allergens' are also indicated in the 3rd Technical Report as being in Group 2 and JRCs response to comments made after the 2nd Technical Report suggests that they still consider skin sensitisers to be a member of the 'priority concern' group (either 1 or 2). Recently, however, at least one competent body (ANSES) has produced a paper confirming that skin sensitisers do not meet the REACH Article 57(f) 'equivalent concern' criteria and so we request that the limit for skin sensitisers in the finished product should be harmonised with that found in the Blue Angel and should be changed from less than 0.5 x final product classification limit for H317 to less than the classification limit for H317 (i.e. < 1.0% for Category 1 and Category 1B sensitisers and < 0.1% for Category 1A sensitisers).

c) Setting a low limit on the content of ingredients classified as an aspiration hazard without consideration of the overall classification of the finished lubricant for this hazard end point

Many of the newly introduced, alternative base fluids (PAOs, PAGs, synthetic esters etc) are hydrocarbons that have the potential to be classified as an aspiration hazard if they have KV40 < 20.5 cSt, especially less viscous fluids that are also highly degradable. Currently a product formulated from such fluids would qualify for the ecolabel providing the finished fluid has a kv40 > 20.5 cSt and is not classified as hazardous (due to the so-called Table 1 derogation in the current criteria). In future, however, a fluid may meet all the other criteria (including low aquatic toxicity and high degradation) but be disqualified because the final lubricant contains > 5% of an ingredient classified as an aspiration hazard. A practical solution would be to insert a footnote permitting a higher total amount of substances classified as an aspiration hazard (H304) than suggested in Table 1 providing the finished product is not classified as an aspiration hazard.

d) Setting a limit for skin hazard (EUH066) and acute toxicity (H301, H311 and H331)

There is currently no General Concentration Limit for classifying mixtures containing substances that are assigned the EUH066 supplemental hazard statement. CLP Regulation 1272/2008 refers to "practical observations or relevant evidence concerning their predicted effects on the skin", and both hazard criteria are at least semi-qualitative in nature and are not easily verifiable by competent bodies. UEIL HSE members suggest that this hazard statement should be omitted from Table 1, or that the limit should be set to an arbitrary level (e.g. <20%) that is greater than the GCL for substances classified as a skin irritant (H315). Similarly, since the implementation of CLP mixtures are no longer classified for acute hazard based on the percentage content of acutely toxic substances. Instead an acute toxic estimate (ATE) is calculated based on the contribution of all ingredients and this then determines the



classification of the product in terms of acute toxicity. This means that there is no percentage regulatory threshold for classifying mixtures and the final product classification for acute hazard also depends on the other substances present and whether data exists for them or not. We would suggest that the criteria in Table 1 should be that the final product should not be classified as H301, H311 or H313 rather than specifying a fraction of a limit that no longer exists.

3. Criterion 3. Biodegradation

a) Terminology i.e. switching 'ultimate' for 'readily'

It is considered that the change in terminology used to describe the extent of degradation seen and the strict interpretation of this criterion including the 10-day window could significantly impair a lubricant manufacturer's ability to formulate fluids that have the necessary technical performance required by the market and still meets the revised ecolabel criteria. This is despite several concessions being made including the fact that the 10-day window would not apply to base stocks that could demonstrate that they qualified as UVCBs or complex, multi-component substances, and allowing products containing single component base stocks that show > 70% degradation, which does lessen the impact of this criterion.

b) Cumulative amounts of biodegradable, partially degradable and non-degradable substances allowed in products

UEIL HSE believes that the cumulative mass percentage of substances present in the product (Table 4, page 52 of the Technical Report 3.0) should include stricter requirements for the PLL category than for the ALL category rather than the situation proposed which is the opposite situation. UEIL HSE also believes that the new limit of 10% for non-degradable substances for TLL greases- is too strict compared with the limits in the current version of the Ecolabel standard where up to 25% of non-biodegradable materials are permitted. It is the opinion of the UEIL HSE members who are experienced grease manufacturers that it would be very challenging to produce a TLL grease that would meet these stricter requirements, and there is therefore the potential that no TLL greases would qualify for the ecolabel (examples of TLL greases include rail lubrication or rail-based lubrication) Instead of separating different types of grease UEIL HSE suggests that all greases should be required to meet the same criteria concerning the content of biodegradable, partially degradable and non-degradable substances. Furthermore, based on the experience of grease producing members the limits should be revised as follows:

- "> 80%" for the "Readily aerobically biodegradable";
- "< 20%" for the "Inherently aerobically biodegradable";
- "< 20%" for the "Non-biodegradable and non-bioaccumulative".

4. Criterion 3. Bioaccumulation

a) Log Kow upper limit = 8 for organic substances

UEIL HSE welcomes JRC being receptive to previous comments explaining why setting the upper limit at 10 was inadvisable from a practical viewpoint. However, they appear to have underestimated the practical impact of setting the upper limit at or above 8. Although an OECD method exists with an upper standard of 8.2, a significant amount of historical testing for Log Kow was carried out with the upper standard at 7. This means that there is a considerable amount of test data around for those ingredients that form the additive concentrate (i.e. the



part of the lubricant which has a significant impact on the technical performance) where results are summarised as Log Kow > 7 (or > 7.5), simply because that was the limit of the test method and standards at the time the testing was conducted. There was logic in this because many experts regard the interval of concern for Log Kow as between 3 and 7 (or at an extreme 7.5). It is noteworthy that the Blue Angel recognises this as a practical matter and includes a derogation for non-degradable substances with Log Kow > 6 that can be demonstrated to be critical to the performance of the lubricant. UEIL HSE suggests that there is a need for a similar provision to be included in the revised ecolabel lubricants criterion to prevent ingredient suppliers having to retest their components just to confirm that they meet this new criterion. If this request for a derogation was rejected, another practical solution would be to only enforce the > 8 upper limit of for a non-degradable substance that didn't have any existing bioaccumulation data at 1st January 2019, when the new requirement came into force. In this circumstance, it is reasonable that the applicant/supplier could develop Log Kow data in full knowledge of the new upper limit. Otherwise requiring applicants (or their suppliers) to retest is completely disproportionate, and could result in a loss from the market of useful additive chemistry.

b) BCF measurement required for some ingredients

The Technical Report 3.0 indicates that BCF measurement is the method of choice for measuring the bioaccumulation potential of non-organic compounds, surfactants, and some organo-metallic compounds, and appears to suggest that no other method would be valid. JRC/Commission may be unaware that in vivo BCF studies are extremely expensive (e.g. due to the need for radiolabelling, very challenging analysis of low levels of test material etc) and typically have to be performed on a discrete chemical structure, not a mixture. Since many lubricant ingredients are characterised as UVCB substances, each constituent would need to be measured separately increasing the cost of this testing to an unrealistic level for qualifying a product for ecolabel. Finally, and perhaps most relevant, the BCF study OECD 305 is a vertebrate study and it is highly likely that regulatory approval would not be granted to an EU company for such testing for the purposes of qualifying for the ecolabel.

5. Criterion 5. Packaging requirements

The UEIL HSE agrees that a reduction in the consumption of fresh plastic is desirable, and fits well with the overall goal of the EU ecolabel scheme. Nonetheless, from a practical standpoint, UEIL HSE members are not aware of any EU packaging suppliers who currently offer the desired content of post-consumer recycled plastic for most common containers. Additionally, for internal logistic reasons B2B products are sometimes packaged in containers that are also suitable for transporting dangerous goods (i.e. have United Nations approval). Again, UEIL HSE members are not aware of any plastic packaging with recycled plastic content that also meet UN container standards, and we consider that there is insufficient time to work with packaging material manufacturers and so we are very concerned that no suitable containers will be available by the implementation date of the new criteria.

6. Other practical implementation issues

a) Transition period for LuSC-substances/mixtures and current ecolabel products containing LuSC-list substances/mixtures:

When the new criteria come into effect on 1st January 2019 it is assumed that it will also be necessary to reassess the LUSC substances. UEIL HSE requests that JRC/Commission should recognise the length of time it takes to develop lubricants, possibly including OEM

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approvals, and the level of investment necessary. In particular, it needs to be recognised that lubricant development has not been stopped whilst the new criteria have been discussed during the past 12 months. It is therefore inevitable that lubricants currently being developed to meet ecolabel are relying on LuSC substances that are approved according to the current criteria, and that at the time of submission may no longer qualify under the new criteria or the required study reports might not be available where repeat testing is necessary (e.g. new Log Kow measurements based on the updated criteria). It is therefore necessary that a review of the substances and products on the LuSC list should be performed quickly after the implementation date and that suitable transitional arrangements should be put in place where a substance/product no longer qualifies for LuSC listing. UEIL HSE suggests that a reasonable transitional period is at least until the end of 2020. We would also suggest that any lubricant that has been submitted for approval under the ecolabel scheme before that transitional date should be allowed to comply with the 'old' criteria and remain on the market until the next revision date.