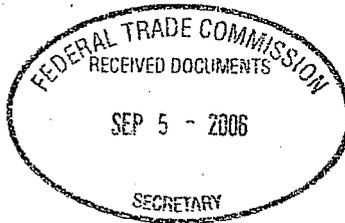




ORIGINAL



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August 31, 2006

**RE : 16 CFR Part 311 Comment – Recycled Oil Rule, Matter No. R511036
Federal Trade Commission request for comments at 71 FR 38321 regarding FTC
regulations at 16 CFR Part 311, “Test Procedures and Labeling Standards for
Recycled Oil”**

Dear Commissioners:

Our company is writing you in regards to a request for public comments issued by the Federal Trade Commission (FTC) and concerning FTC regulations at 16 CFR Part 311, “Test Procedures and Labeling Standards for Recycled Oil.” The request appeared in the July 6, 2006 Federal Register at 71 FR 38321.

These comments are submitted on behalf of Pennzoil-Quaker State Company (“Shell Lubricants”), a wholly owned subsidiary of Shell Oil Company. Shell Lubricants is the manufacturer, marketer and seller of a number of popular brands of engine oil in the United States, including Pennzoil, Quaker State, Q, ROTELLA, Formula Shell, and others that together make Shell Lubricants the largest marketer and seller of engine oil products by volume in this country. Shell Lubricants also owns and either franchises or operates Jiffy Lube stores in many states in the United States.

In its request for comments, the FTC asked a number of questions, to which Shell Lubricants is providing its comments to API as follows.

(1) Is there a continuing need for the Rule as currently promulgated?

Yes, though with one modification. Shell Lubricants believes there is a continuing need for technical performance standards for engine oils and other oil products, and continues to support as a technical performance standard for engine oils the most recent edition of “Engine Oil Licensing and Certification System,” American Petroleum Institute Publication

1509 (EOLCS). Engine oils made from virgin and/or recycled base oils should be considered "substantially equivalent" from a technical performance standpoint if they can meet this certification standard.

Since the FTC's October 31, 1995 Rule, though, Shell Lubricants has recognized that the "substantially equivalent" criterion is solely performance-based and does not include a consideration of the possible health effects of engine oils and other products manufactured with recycled base oils rather than virgin petroleum base oils (virgin oils).

Used gasoline engine oil presents a skin cancer hazard due to impurities that accumulate during use. Recycled base oils vary in terms of how well these impurities are removed during their manufacture. Health-based criteria are needed to determine if these impurities have been sufficiently removed.

Therefore, Shell Lubricants is recommending that the FTC extend its current performance-based criteria to determine "substantial equivalency" for engine oils to also include health-based criteria. A supporting discussion for this recommendation is provided in Attachment 1 to this letter.

- (2) What benefits has the Rule provided to purchasers of the products or services affected by the Rule?

The Rule has eliminated the requirement that engine oils made with recycled base oils be so labeled. Thus, consumers can shop for engine oils with the assurance that the technical performance of an engine oil product that meets API's EOLCS will be sufficient for their vehicles whether the base oil used in its manufacture was virgin or recycled. It is our position that a health-based equivalency standard should also be included in the rule so qualified recycled oils can carry health and safety equivalency assurances.

- (3) Has the Rule imposed costs on purchasers?

Shell Lubricants is not aware of any additional to purchasers due to this Rule.

- (4) What changes, if any, should be made to the Rule to increase the benefits of the Rule to purchasers? How would these changes affect the costs the Rule imposes on firms subject to its requirements? Has the Rule provided benefits to such firms? If so, what benefits?

Shell Lubricants recommends the FTC include health-based criteria in addition to the performance-based criteria contained in the API EOLCS. Purchasers would thereby be assured through an appropriate health-based testing protocol and EOLCS performance testing that recycled engine oil products were indeed "substantially equivalent." Otherwise, purchasers would almost certainly not be aware that potential health hazards of engine oil products manufactured with recycled base oils are not as well characterized as those manufactured with virgin oils.

Used gasoline engine oil presents a skin cancer hazard due to impurities that accumulate during use. Recycled base oils vary in terms of how well these impurities are removed during their manufacture. Health-based criteria are needed to determine if these impurities have been sufficiently removed. This, in turn, requires testing the recycled base oils.

The costs associated with meeting the health-based criteria will depend on the testing protocol adopted. Shell Lubricants is not proposing a specific testing protocol here. However, it is our position that repeated exposure testing of a recycled base oil comparable to that conducted previously for virgin oils is needed to establish "substantial equivalency" of that recycled base oil in terms of potential health effects. Please note that short-term tests (designated as IP346 and Modified Ames) that were validated for and are currently used to assess virgin oils for their potential carcinogenicity have not been validated for recycled base oils. Furthermore, these tests are not designed to identify potential non-cancer health hazards that may be posed by recycled base oils.

As we are not aware of an appropriate health-based testing protocol for recycled oils, we do not know what the costs of completing such testing would be.

- (5) What significant burdens or costs, including costs of compliance, have the Rule imposed on firms subject to its requirements? How would these changes affect the benefits provided by the Rule?

Shell Lubricants does not have data regarding the compliance costs for manufacturers of re-refined oil.

- (6) What changes, if any, should be made to the Rule to reduce the burdens or costs imposed on firms subject to its requirements? How would these changes affect the benefits provided by the Rule?

Shell Lubricants recommends that no changes be made to the performance-based criteria used to determine whether engine oils manufactured from recycled base oil are "substantially equivalent" to engine oils from virgin base oil. Further, we recommend that the FTC preferably require "substantial equivalency" to include health-based criteria in addition to the performance-based criteria in the API EOLCS. Please see Attachment 1 for additional discussion of this matter and the basis for Shell Lubricants's recommendation.

Further supporting this recommendation is the stated position of the European Petroleum Industry Association in its 2003 report, *Recycle of Used Oils: Legal and Technical Considerations*: "There are limited health and environmental data available on re-refined base oils compared to virgin base oils. The majority of the available screening tests for carcinogenic activity have not been validated for use with used or re-refined oils. Other components that are likely to be present in the used or re-refined oils may interfere with the test outcomes and introduce human health issues other than carcinogenicity. Uncertainties still exist over the potential environmental and health hazards of re-refined oils that suggest the need for a case by case evaluation before their use in lubricants."

- (7) Does the Rule overlap or conflict with other federal, state or local laws or regulations?

Shell Lubricants is not aware of any such conflict or overlap, if it exists.

- (8) Since the Rule was issued, what effects, if any, have changes in relevant technology or economic conditions had on the Rule?

Since the October 31, 1995 rule was established, additional work has been done and more stringent specifications developed for new engine oils, primarily as a result of vehicle manufacturers' efforts to improve engine performance, increase gasoline mileage and extend oil change intervals. During this time, the API EOLCS has evolved from its thirteenth to its fifteenth edition. This and other standards have necessitated improvements in virgin oil quality and additive formulations by Shell Lubricants and other manufacturers of engine oils made from virgin oils.

It is likely that manufacturers of recycled oils have made concurrent quality improvements; however, Shell Lubricants does not have specific data regarding these possible improvements.

- (9) Since the Rule was issued, the American Petroleum Institute has published the Fifteenth Edition of Publication 1509. Should this updated version of Publication 1509 be incorporated by reference into the Rule?

Shell Lubricants supports updating the reference in the Rule to reflect the current API EOLCS publication edition, and suggests a mechanism be added to the Rule to automatically update this reference as subsequent editions are issued. For example, the FTC might state that the edition it is referencing shall be considered the most recent update to the API edition six months after API's publication of the newer edition.

In closing, Shell Lubricants recommends that no changes be made to the performance-based criteria used to determine whether engine oils from recycled base oil are "substantially equivalent" to engine oils from virgin base oil. Further, we recommend that the FTC require "substantial equivalency" to include health-based criteria in addition to the performance-based criteria in the API EOLCS.

Thank you for considering these comments among those that may be received from other API members that manufacture and/or market lubricant products. If you have any questions about this information or wish to discuss it further, please do not hesitate to contact me. I can be reached by telephone at 713-241-4275 or by e-mail at jeffrey.conklin@shell.com.

J. J. Conklin to FTC
August 31, 2006
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Sincerely,
Shell Lubricants

Jeffrey J. Conklin, Dr. P.H.
Global Product Stewardship Manager

c: File

Attachment 1: Discussion Supporting Response to FTC Questions (NOTE: Numbering of discussion points below has no relation to FTC question numbers.)

1. Unrefined petroleum vacuum distillates and used engine oils are potentially carcinogenic

It has been recognized since the early 1900s that repeated use of inadequately refined mineral oils was associated with an increased incidence of skin cancer in humans. As a result, an experimental testing method was developed using mice to identify mineral oils that were potentially carcinogenic. This test, which became known as the mouse skin-painting test, involved applying a sample of oil to mouse skin several times a week for approximately 1.5 to 2 years and measuring the skin tumor incidence in exposed animals at study termination. This test, now usually conducted for two years, continues to be recognized as the definitive test for determining carcinogenic potential of petroleum base oils.¹ Some used engine oils have undergone this long-term testing and were found to be carcinogenic.^{2, 3, 4} Accordingly, most new gasoline engine oil containers and Material Safety Data Sheets in the U.S. state that used gasoline engine oil is potentially carcinogenic.

Using this and other tests, it became evident that the carcinogenic potential of crude petroleum vacuum distillates correlated with and was attributable to the amount of alkylated 3-7 ring polycyclic aromatic compounds (PACs) present in these virgin oil distillates.^{5, 6, 7} Vehicle engine oils accumulate similar, potentially carcinogenic PACs during use, due largely to engine exhaust blow-by past the engine cylinders.⁸ However, these are non-alkylated or "naked ring" PACs and differ structurally, and perhaps in terms of cancer potency, from the alkylated PACs in virgin petroleum oils. Used engine oils also accumulate lubricant additive breakdown substances, metals, halogenated solvents and other substances that may be deposited into used oil collection containers either at automobile repair facilities, engine oil change shops, or by consumers depositing collected used oil for recycling. These foreign substances, not found in "severely refined" (defined in the next discussion point) virgin petroleum base oils, may also present cancer or other health hazards.

2. Severely refined virgin petroleum base oils have been established to be non-carcinogenic by definitive, long-term testing

¹ Mackerer, C.R. et al, 2003. Petroleum Mineral Oil Refining and Evaluation of Cancer Hazard. Applied Occupational and Environmental Hygiene, 18:890-901.

² API, 1983 The carcinogenicity of new and used lubricants. American Petroleum Institute. Washington DC. Publication No. 30-32847.

³ Grimmer, G. et al. 1982. Quantification of the Carcinogenic Effect of Polycyclic Aromatic Hydrocarbons in Used Engine Oil by Topical Application onto the Skin of Mice. Int Arch Occup Environ Health, 50 (1): 95-100.

⁴ McKee, R.H. and Plutnik RT 1989 Carcinogenic potential of gasoline and diesel engine oils. Fundam Appl Toxicol 13(3): 545-553.

⁵ Mackerer, C.R. et al, op cit.

⁶ Bingham, E. et al. 1965. The Carcinogenic Potential of Certain Oils, Arch Env Health, 10:449-451.

⁷ Doak, S.M.A. 1983. Carcinogenic Potential of Hydrocarbon Petroleum Aromatic Extracts, Brit J. Ind Med. 42:380-388.

⁸ API, op cit.

Petroleum base oil manufacturers and API tested a wide range of oils using this long-term test method and used the results to establish processing conditions that result in noncarcinogenic base oils.^{9,10} In other words, conditions were established that reduced PACs such that the resulting base oils were not carcinogenic in the long-term mouse skin-painting bioassay. The International Agency for Research on Cancer (IARC) evaluated this information and classified petroleum base oils for carcinogenic potential based on how they have been refined (i.e., processed).^{11,12} Base oils processed to sufficiently reduced PAC levels to have tested noncarcinogenic in mouse skin painting tests are designated by IARC as “severely refined.” Unrefined vacuum distillates or those processed insufficiently to eliminate PACs and carcinogenic potential are designated as “untreated” or “mildly refined.”

3. Short-term tests were developed and validated to determine the carcinogenic potential of virgin oils

Virgin oil manufacturers recognized the practical utility of rapid or short-term tests that could predict the outcome of the long-term cancer bioassay without the time and expense of the long-term test. However, for any such predictive screening tool, it is necessary to validate the predictive screening tool results against the actual definitive test results that the tool is being designed to predict. Fortunately, a considerable number of virgin petroleum vacuum distillates subsequently processed to varying degrees by various methods permitted several such tests to be developed and validated, primarily during the 1980s, for virgin oils. Two of these tests are now commonly employed by virgin oil manufacturers to verify their base oils have been “severely refined,” are not be expected to be carcinogenic, and need not be so classified. One is an analytical test commonly referred to as the IP346 test.^{13,14} This test was developed and applied to a considerable number of virgin oils that had undergone the long-term animal skin-painting test. Based on the results of this testing, it was determined that virgin oils containing < 3% dimethyl sulfoxide (DMSO) -extractable material would not be expected to be carcinogenic in the long-term bioassay. This test is now a regulatory requirement in the European Union, in that virgin oils must be classified as carcinogenic unless they pass the IP346 test.

The second commonly employed short-term screening test is the Modified Ames test, which was developed in the mid-1980s by investigators at Mobil Oil and was more recently

⁹ API, op cit.

¹⁰ Kane, M.L. et al. 1984. Toxicological Characteristics of Refinery Streams Used to Manufacture Lubricating Oils. *Am J. Ind Med.* 5:183-200.

¹¹ IARC Monographs – Mineral Oils, Vol. 33, pp. 87-168. IARC, Lyon France (1984)

¹² IARC Monographs, Supplement 7. IARC, Lyon, France (1987)

¹³ Institute for Petroleum: Determination of Polycyclic Aromatics in Unused Lubricating Base Oils and Asphaltene Free Petroleum Fractions – Dimethyl Sulphoxide Extraction Refractive Index Method IP 346/92. In: *Standard Methods for Analysis and Testing of Petroleum and Related Products*, Vol. 2. Chichester – John Wiley and Sons. (1993)

¹⁴ Briefly, this is an analytical, gravimetric test in which the base oil is extracted with dimethyl sulfoxide (DMSO) and the mass of DMSO extractable material is determined gravimetrically (i.e., it is weighed). PACs (as well as certain other polar substances if present) will tend to partition into the DMSO fraction.

adopted as an ASTM Standard.^{15,16,17} This is a biologically based mutagenicity test that measures the potential for PACs present in virgin oil to induce “reverse mutations” that can then easily be measured in the TA98 test strain of *Salmonella typhimurium* bacteria.¹⁸ Mutagenic activity as determined by this test correlates closely with measured PAC content, and with carcinogenic activity in mice.¹⁹ The test result is expressed in terms of “Mutation Index” (MI). Virgin oils with an MI < 1 are predicted to be noncarcinogenic in the long-term mouse skin-painting bioassay.²⁰

4. Few if any long-term animal test data on re-refined oils are available

As stated by EUROPIA, “There are limited health and environmental data available on re-refined base oils compared to virgin base oils. The majority of the available screening tests for carcinogenic activity have not been validated for use with used or re-refined oils. Other components that are likely to be present in the used or re-refined oils may interfere with the test outcomes and introduce human health issues other than carcinogenicity. Uncertainties still exist over the potential environmental and health hazards of re-refined oils that suggest the need for a case by case evaluation before their use in lubricants.”²¹

To the best of our knowledge, sufficient toxicity test results to permit correlating long-term skin-painting bioassays with short-term tests are not available for re-refined oils. No such data were found in the published scientific literature. Furthermore, we were unable to locate any other repeated-exposure toxicity tests of re-refined oil designed to detect potential health hazards other than cancer. Material Safety Data Sheets from two of the major re-refined oil manufacturers that supply the U.S. were reviewed and were not found to indicate any repeated-exposure tests of re-refined oils had been conducted.

Therefore, Shell Lubricants believes that engine oils made with re-refined base oils -- even the most thoroughly processed -- cannot yet be claimed in terms of toxicity to be “substantially equivalent” to engine oils made with their virgin oil counterparts. They may eventually be demonstrated to be substantially equivalent in terms of toxicity, but the data necessary to demonstrate this have not yet been developed.

¹⁵ Blackburn, G.R. et al, 1984. Estimation of the Dermal Carcinogenic Activity of Petroleum Fractions Using a Modified Ames Assay. *Cell Biol & Toxicol.* 1:67-80.

¹⁶ Blackburn, G.R. et al. Predicting Carcinogenicity of Petroleum Distillation Fractions Using a Modified Salmonella Mutagenicity Assay. *Cell Biol Toxicol* 2:63-84 (1986)

¹⁷ American Society for Testing and Materials: Designation E 1687-95 (1996)

¹⁸ Notably, this assay was also validated using virgin petroleum base oils that had previously undergone the definitive long-term cancer bioassay test in mice. Also notable is that this assay is very specifically designed to detect genetic damage caused by a mechanism that is elicited by PACs that are metabolically activated by yet another specifically developed liver enzyme suspension. The reader is referred to these references for details regarding this test.

¹⁹ Roy et al. 1988. Correlation of Mutagenic and Dermal Carcinogenic Activities of Mineral Oils with Polycyclic Aromatic Compound Content. *Fund Appl Toxicol.* 10:466-476.

²⁰ Blackburn, G.R. et al. 1984. *op cit.*

²¹ European Petroleum Industry Association (EUROPIA). *Recycle of Used Oils: Legal and Technical Considerations.* p. 22. Brussels, 2003.

5. No short-term tests have been validated for re-refined base oils

As noted above, it is critical to consider that the short-term predictive tests for virgin oil carcinogenic activity, including the IP346 test and Modified Ames test, have both been validated against the definitive long-term cancer bioassay database for virgin oils. As there is no similar database for re-refined oils, this validation does not exist for such oils. Absent these data, it can only be presumed that the same test predicts potential carcinogenicity of re-refined oils, and if they do, it can only be presumed that the same correlations and the same cutoffs (<3% DMSO-extractables measured by IP346, and MI < 1 in the Modified Ames test) distinguish carcinogenic from noncarcinogenic oils.

However, these presumptions have not been confirmed by empirical data and, as noted above, there is good cause to question how well these relationships would hold. As the mixture of substances in re-refined base oils may be substantially different than those in virgin oils, the experimental methods and carcinogenic thresholds established through testing of virgin oils may be inappropriate for re-refined base oils.²² Furthermore, these tests are not designed to detect potential health safety hazards other than skin cancer.

6. FTC cannot and should not consider re-refined oils to be toxicologically equivalent to severely refined virgin oils

There are insufficient grounds for the FTC to conclude that re-refined oils and virgin oils should undergo identical short-term testing protocols and interpretation criteria for carcinogenic potential. These short-term tests have been validated only for virgin oils.

As described above, the IP346 and Modified Ames test may or may not qualitatively or quantitatively predict carcinogenic potential for re-refined oils as effectively as has been established for virgin oils. In other words, they may or may not be as predictive of carcinogenic potential for re-refined oils, and the same health safety thresholds (i.e., IP346 < 3%, MI < 1) may or may not apply. Furthermore, these substances may differ compositionally from virgin oils, resulting in as yet unknown differences in potential toxicity for other endpoints. For all of these reasons, it would be unwarranted or, at best, premature for the FTC to unconditionally conclude that re-refined oils and virgin oils, and by extension, engine oils formulated from these base oils, are "substantially equivalent" in terms of toxicity.

²² Re-refined base oils may contain substances that are not present in virgin base oils, but that boil in the same range as PACs, potentially resulting in false positive and false negative test results in both methods. Biologically active substances may be present in the oil, but may not extract as well into DMSO, resulting in a false negative test. Alternatively they may contain substances which are noncarcinogenic but which do extract well into DMSO, resulting in a false positive test particularly for IP346. Similarly, the "naked-ring" residual PACs present in a re-refined oil might possess different mutagenic or carcinogenic potency than the alkylated virgin oil counterparts, such that MI < 1 may or may not be the correct threshold measurement for distinguishing likely from unlikely carcinogenic oils. Additionally a re-refined oil may contain non-PAC mutagenic substances acting by a different mechanism than PACs, such that the MI < 1 again may or may not be the correct metric, or the substance may not even be detected by the TA98 *S. typhimurium* bacteria strain used in this test procedure.

7. Re-refined oils vary in terms of feedstock composition, processing methods, product composition, and consequently, toxicity

Used oil recyclers and re-refiners face a number of issues not encountered by manufacturers of virgin oils. The first of these is variability of the collected used oil feedstock, into which other waste materials (e.g., halogenated solvents, metals, new or used engine antifreeze) may have been added and/or mixed. This variability makes routine, comprehensive analysis of the feedstock for all constituents of concern very difficult.

To avoid such variability, re-refiners may combine a certain number of batches or quantities of collected used oil in order to "smooth out" their variability and sufficiently dilute harmful contaminants that may be present. (However, Shell Lubricants is not aware of any standard protocol for this practice among re-refiners.) Additionally, used engine oil contains additives and additive degradation products that may accumulate when the engine oil is in use. To Shell Lubricants's knowledge, concentrations of such additive degradation products would also be variable, but the compounds themselves have not been chemically characterized. Thus, a particularly difficult aspect of assessing re-refined base oil is how to measure variations and unknown impurities that would not be found in virgin base oil.

Recycled oils, including re-refined oils, also differ widely in terms of their severity of processing, further differentiating recycled oils from highly-refined virgin base oils. Shell Lubricants understands "recycling" to be a general term with one aspect of this being re-refining. The re-refining industry, in turn, has many variations in degree of processing, from nominal treatment to vacuum distillation and subsequent high-pressure hydrogen treatment. It is evident that only those recycled oils that have been re-refined to remove biologically active and harmful chemicals that are not present in highly refined virgin oils might be toxicologically equivalent to highly refined virgin oils.

Vacuum distillates of crude oil and of used engine oils both contain potentially carcinogenic PACs.^{23,24} Due to differences in feedstock composition, these two vacuum distillates can differ in other respects. In addition to PACs, other substances that happen to distill in the appropriate boiling range, including contaminants from the aforementioned wastes and additive degradation products, will be present in used oil vacuum distillates. While high-pressure hydrotreatment effectively removes PACs, it may not be effective in removing these other contaminants from vacuum distillate intermediates of used engine oil. As some of these contaminants could be biologically active, these compositional differences suggest the possibility of differences in toxicity between re-refined base oils and virgin oils.

²³ Grimmer, G., Jacob, J., Naujack, K.W. et al. op cit.

²⁴ McKee, R.H. and Plutnik RT. op cit.