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July 16, 1991

RWE-DEA Aktiengesellschaft
für Mineralöl und Chemie
Chemische Werke Newbock
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Umweltschutz und
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403

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Re: Your July 5, 1991 Letter; TSCA PMN Filings;
Our File No. OE9012

Dear Dr. Strehlke and Mr. Bornemann:

The purpose of this letter is to respond to your July 5, 1991 letter regarding Keller and Heckman's expertise in the filing of Premanufacture Notices (PMN's) under Section 5 of the United States Toxic Substances Control Act (TSCA). You indicated that RWE-DEA AG plans to export a new chemical substance into the United States. It is our understanding that on June 26, 1990, RWE-DEA AG filed appropriate "notification" regarding the manufacture of the chemical in conformity with Section 4, 6, and 7 of the German Chemical Substances Act. You asked:

- (1) whether Keller and Heckman would be in a position to file a Premanufacture Notice to the U.S. Environmental Protection Agency (EPA);
- (2) what the costs would be for filing the PMN;

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- (3) what time period would be required once Keller and Heckman is retained by RWE-DEA AG to conduct the work?

As you may be aware, Section 720.22(b)(1) of Title 40 of the Code of Federal Regulations requires that any person who intends to import a new chemical substance into the United States for a non-exempt commercial purpose must submit a Premanufacture Notice (PMN) unless the substance is imported as a part of an article. Only manufacturers that are incorporated, licensed, or doing business in the United States may submit a PMN. 40 C.F.R. § 720.22(a)(3).

With regard to your first question, yes, we would be happy to assist RWE-DEA AG in preparing appropriate documents for filing with EPA's Office of Toxic Substances. If RWE-DEA AG has an office in the United States that will be the importer, we could file the notice on its behalf. Otherwise, all we could do is supply the importer with a substantially completed PMN. If amenable to the importer and you, we could, of course, represent both companies in these transactions and file the notice on behalf of the importer.^{1/}

I thought it might be useful if I briefly introduced you to Keller and Heckman's Toxic Substances Control Act (TSCA) staff, each with significant expertise in TSCA matters. Our TSCA team consists of three of Keller and Heckman's law partners, three associates, two Ph.D. scientists that were responsible for reviewing PMN's when they were employed by the Environmental Protection Agency (EPA) and one law clerk who has a chemistry degree and worked at EPA's Inventory Branch before joining Keller and Heckman (initially as a scientific assistant).

Enclosed are our firm brochure's biographical sketches of myself, Dr. Justin Powell, and Dr. Jan Houk. If there is any additional information you require regarding our TSCA expertise, please feel free to call me or Catherine Roemer Nielsen at 202-956-5640.

As to your second question regarding costs, the following estimate is based on our assumption that the PMN's needed do not present issues of out-of-the-ordinary complexity. Our

^{1/} If RWE-DEA has an office in the United States and will be providing substantial support for the product to customers, it is possible that EPA would agree that RWE-DEA AG would be the appropriate notice submitter even though actual importation to the U.S. may be accomplished by a third party.

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bills are based principally on the number of hours required on your behalf at the hourly rate(s) of the professional(s) involved. The rates range from \$65-\$90 for paralegals, to \$90-\$110 for law clerks, \$110-\$195 for associates, \$220-\$245 an hour for partners, and \$350 an hour for Jerry Heckman's services (in each case, the rate is dependent upon the experience of the professional involved). The rates for our staff scientists are \$130-\$200 per hour. Justin Powell's time is billed at \$180 an hour; Jan Houk's is billed at \$160 an hour. These rates are subject to periodic review and revision. In addition to charges for time actually spent on a client's matter, our bills include charges for out-of-pocket expenses such as long-distance telephone calls, photocopying, and travel. Our practice is to render bills on a monthly basis.

On average, the review and filing of a PMN will cost \$2,000. (This does not include the EPA filing fee of \$2,500 per PMN.) We have been able to reduce the impact of the filing fees significantly for filings that involve related chemicals. For example, we were able to negotiate and come to agreement with EPA on behalf of one client to accept a "Consolidated PMN" for a sequence of related chemicals. Our discussions with EPA's Office of Toxic Substances resulted in our client saving some \$30,000. Drs. Houk and Powell are particularly adept at gaining EPA's agreement to accept consolidated PMN's because of their intimate knowledge of how PMN's are reviewed within the Agency.

Finally, with respect to your last question, we can assure you that we are prompt and efficient at preparing and reviewing PMN's. Ideally, we would like to have input into the preparation of a PMN at its early stages to assure that effort is not wasted gathering information that is not relevant to the review that EPA will conduct. Our review of even complicated PMN's is unlikely to take more than two weeks. Simple PMN's are routinely reviewed in a matter of days.

We look forward to receiving more information about the product and its uses from you. In the meantime, if there is anything further I can do to be of service in this or any other matter, please do not hesitate to call or write.

Cordially yours,


John B. Dubeck

Enclosures

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Justin Christopher Powell With a doctorate in Organic Chemistry and over 20 years' experience combining about equal parts of chemical regulation with chemical innovation, Justin assists clients in effectively resolving a diversity of complex technical issues in the U.S. and many other countries. As a former Senior Research Chemist with Texaco Inc., Dr. Powell holds 18 patents for new products and processes. He was Special Assistant for Compliance and Enforcement to the Director of the Office of Toxic Substances at the U. S. Environmental Protection Agency (EPA). Dr. Powell also managed EPA's chemistry review of over 15,000 new chemical Premanufacture Notifications (PMN's) under the Toxic Substances Control Act. In 1982, Dr. Powell devised polymer regulation concepts for EPA which are being used throughout the world. For both established and emerging chemical technologies, Dr. Powell has provided new insights into the interplay between regular chemistry and regulatory chemistry.

Carnegie Mellon University (B.S., 1965); University of Delaware (Ph.D., 1969).

John B. Dubeck Mr. Dubeck has a scientific background (chemical engineering and nuclear propulsion systems) and thus comes easily to a science-based practice. He represents clients and trade associations before the Food and Drug Administration and the Environmental Protection Agency. Mr. Dubeck also advises clients on the Toxic Substances Control Act, the Resource Conservation and Recovery Act and issues related to the use of hazardous substances. Mr. Dubeck teaches courses in food law and medical device regulation.

Cornell University (B.S., Chem. Eng., with distinction, 1971); Georgetown University (J.D., 1976).

Jan tte Houk Dr. Houk obtained her Ph.D. in Organic Chemistry from the Massachusetts Institute of Technology in 1986. She then spent four years in the Office of Toxic Substances at the U.S. Environmental Protection Agency (EPA) working as a review chemist and as a Section Chief. At the EPA, Dr. Houk was involved primarily in Toxic Substances Control Act (TSCA) Section 5 and Emergency Planning and Community Right-to-Know (EPCRA) Section 313 activities. Dr. Houk has prepared hazard and risk assessments for a wide variety of chemicals, and has authored several papers on the regulation of chemicals under TSCA. Dr. Houk is involved primarily with TSCA matters at Keller and Heckman.

California State University at Fullerton (B.S., 1981, with honors); Massachusetts Institute of Technology (Ph.D., 1986)