3M General Offices

3M Center
St. Paul, MN 55144-1000
651 733 1110

3M

August 21, 2000

CONFIDENTIAL – FOR SETTLEMENT PURPOSES ONLY

Mr. Jesse Baskerville
Director, Toxics & Pesticides Enforcement Division
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N. W.
Suite 4109
Washington, D. C. 20044

Re: **3M Company TSCA Section 8(e) Compliance Audit – Disclosure Of Phase One Findings Pursuant To "Incentives For Self-Policing, Discovery, Disclosure And Correction And Prevention Of Violations," 65 Fed. Reg. 19618 (Apr. 11, 2000)**

Dear Mr. Baskerville:

Pursuant to our recent conversation with Mr. Gerry Stubbs and others from your staff, 3M Company ("3M") is writing to disclose potential violations of TSCA Section 8(e)'s "substantial risk" reporting requirements pursuant to EPA's Self-Audit Policy. See "Incentives For Self-Policing, Discovery, Disclosure And Correction And Prevention Of Violations," 65 Fed. Reg. 19618 (Apr. 11, 2000). We appreciated the opportunity to speak with Mr. Stubbs and the others and their willingness to arrange a meeting with 3M to discuss this matter further. 3M is anxious to arrange a meeting as soon as possible, but has experienced difficulty in finding a mutually convenient time due to summer vacation schedules. 3M would like to propose either September 11 or 13 as meeting dates. We will contact Mr. Stubbs in hopes of confirming a meeting. In this letter, 3M would like to review the background and context for the TSCA Section 8(e) compliance audit under which the potential violations were discovered; to review the specifics of the potential violations; and to close with proposed topics for our upcoming meeting.

I. AUDIT SCOPE, BACKGROUND AND CONTEXT

3M is conducting a systematic and comprehensive TSCA Section 8(e) compliance audit. 3M has retained outside counsel from Latham & Watkins to manage

Exhibit
1734
State of Minnesota v. 3M Co.,
Court File No. 27-CV-10-28862

this audit in accordance with EPA's Self-Audit Policy and other relevant requirements. As presently conceived, this audit will consist of at least three phases. The first two phases will focus on studies and other information that 3M has voluntarily submitted (or will soon submit) on various fluorochemicals (FCs) to the Office Of Pollution Prevention And Toxics ("OPPT"). All of these FC studies and information are now publicly available through the TSCA "For Your Information" docket in FYI No. 1378. For convenience, we will refer to the FC studies and information in this letter as the "FYI Submissions." The third phase of the audit will extend beyond FCs to include other TSCA-regulated chemicals manufactured, processed and used by 3M. Before providing further background on the reasons why 3M undertook this audit and chose to focus initially on the FYI Submissions, it might be useful to review further specifics on the audit scope and timing.

⇒ ***Phase One***: 3M completed the first phase of the audit on July 31, 2000, which included the FYI Submissions on various forms of perfluorooctane sulfonate ("PFOS");[1] on eleven compounds related to PFOS;[2] and on perfluorooctanoic acid ("PFOA"). From the over 600 studies (or pieces of information) in these FYI submissions,[3] 3M identified 30 studies (or pieces of information) that appear potentially to meet EPA's current TSCA Section 8(e) reporting criteria and that are not already contained in the TSCA Section 8(e) docket, published or otherwise "known to the Administrator." 3M also identified an additional two studies (or pieces of information) that would potentially have triggered reporting under the current guidance at the time received by 3M, but for which no present reporting obligation exists due to subsequent publications and 8(e) docket submissions. Further details on the Phase One audit findings will be provided in Section II below.

---

1 Perfluorooctane sulfonates include CAS numbers 1763-23-1 (acid); 29081-56-9 (ammonium salt); 70225-14-8 (DEA salt); 2795-39-3 (potassium salt); 29457-72-5 (lithium salt).

2 These eleven compounds are related to PFOS due to the presence of PFOS in the compounds as an impurity and/or the potential for the compounds to breakdown or metabolize to PFOS. These compounds include CAS numbers: 307-35-7 (Perfluorooctanesulfonyl fluoride (POSF); 754-91-6 (Perfluorooctane Sulfonamide); 2991-51-7 (Perfluorooctane sulfonamido ethyl acetate); 335-77-3 & 67906-42-7 (Perfluorodecane sulfonate); 4151-50-2 (N-ethyl perfluorooctanesulfonamide); 31506-32-8 (N-Methyl perfluorooctanesulfonamide); 1691-99-2 (N-Ethyl perfluorooctylsulfonamido ethanol); 24448-09-7 (N-methyl perfluorooctanesulfonamido ethanol); 423-82-5 (N-ethylperfluorootylsulfonamido ethyl acrylate); 376-14-7 (N-ethyl perfluorooctanesultonamido ethyl methacrylate; 25268-77-3 (N-Methyl perfluorooctanesulfonamido ethyl acrylate).

3 The FYI Submissions covered by phase one were submitted to EPA on the following dates: April 21, 2000; May 4, 2000; May 12, 2000; May 18, 2000; and May 25, 2000.

⇒ ***Phase Two***: The second phase of the audit will address the remaining FYI Submissions, which include studies and information on PFOS mixtures as well as additional studies and information on PFOS, the PFOS-related compounds and PFOA. 3M already has commenced the second phase of the audit and expects to complete this phase of the audit by October 1, 2000 or shortly thereafter.

⇒ ***Phase Three***: In light of the phase one results, 3M has decided to perform a third phase of the audit to address studies and information not encompassed by the FYI Submissions. For the most part, phase three will focus on non-FC studies and information, but it may also include other materials relating to FCs not covered by the FYI Submissions, such as, for example, studies and information on perfluorocarbon gases. Although scoping for phase three is not yet complete, 3M anticipates that phase three could involve as many studies and pieces of information as the first two phases of the audit combined, and thus, may require additional time and resources. 3M has targeted to complete phase three by March of 2001.

As we indicated to Mr. Stubbs and the others in our recent telephone conversation, there is some background behind 3M's decision to undertake the audit and to focus initially on the FYI Submissions. Although we look forward to providing the details at our meeting, some preliminary background may be useful in advance of the meeting.

3M has been involved in an ongoing dialogue with Dr. Charlie Auer, Dr. Oscar Hernandez and others from OPPT for nearly two years regarding FCs. This dialogue stems from a series of TSCA Section 8(e) submissions by 3M beginning in May of 1998, which reported the measurement of PFOS and other FCs in general population human serum and in wildlife at low parts per billion (ppb) levels. The measurement of PFOS and other fluorochemicals at such low levels became possible only due to state-of-the-art analytical developments. 3M had previously reported to the TSCA Section 8(e) docket the detection of FCs in the serum of its production workers at low parts per million (ppm) levels.

Early on in this dialogue, 3M submitted a paper to OPPT in January of 1999 -- often referred to as the "Health Effects White Paper" -- which summarized the toxicological, epidemiology and serum data on PFOS and provided a risk characterization based on these data.[4] OPPT placed this White Paper into the TSCA Section 8(e) docket as a supplement to the FC-related docket numbers 373/374. In

---

[4] "Perfluorooctane Sulfonate: Current Summary Of Human Serum Health & Toxicology Data" (January 1999) (contained in TSCA 8(e) docket number 8EHQ-0299-373).

March of 2000, 3M submitted as a supplement to these same docket numbers a paper -- often referred to as the "Environmental White Paper" -- which summarized the environmental fate and effects data on PFOS and other FCs.[5] Both of these White Papers were intended by 3M to facilitate OPPT's consideration of FCs. As discussed further in Section II below, the White Papers review either the specific data or similar data for all of the 30 studies identified by 3M as potentially reportable under the current EPA guidance.

In late March 2000, Dr. Auer requested that 3M make available additional studies and other information on FCs not previously submitted to the TSCA Section 8(e) docket. The FYI Submissions comprise 3M's voluntary response to this request. The first FYI Submission occurred on April 21, 2000, and submissions have occurred thereafter on a periodic basis under an informal schedule. 3M's file search is continuing, and at least one more submission will occur at the end of August 2000.

Shortly after the first FYI Submission, 3M initiated the current TSCA Section 8(e) compliance audit. Over the years, 3M has made a significant number of TSCA Section 8(e) submissions on FCs. Nevertheless, questions have arisen about the application of EPA's TSCA Section 8(e) reporting guidance to some of the studies and information in the FYI Submissions as well as about which of these studies and information had been either published or made available to EPA through other reporting mechanisms, such as FIFRA registration. 3M felt that it was important under the circumstances to undertake a retrospective assessment of all of the studies and information in the FYI Submissions against EPA's current TSCA 8(e) reporting guidance and to place into the 8(e) docket any material that potentially meets the reporting guidance.

Other notable FC-related developments have occurred in recent months. 3M announced on May 16, 2000 its intention substantially to phase out production of all perfluorooctanyl-based chemistries – including PFOS, PFOA and the other FCs addressed by the FYI Submissions -- by the end of 2000. 3M made this decision because of its commitment to responsible environmental management and sound business principles. 3M has continued to work with OPPT since its May 16, 2000 announcement on the specifics of the phase out plan. In addition, 3M is currently preparing a screening level risk assessment for PFOS in coordination with OPPT and other regulators through the Organization For Economic And Community Development ("OECD").

---

5 "Sulfonated Perfluorochemicals In The Environment: Sources, Dispersion, Fate And Effects" (March 2000) (contained in 8(e) docket number 8EHQ-0300-0373).

II. DISCLOSURE OF PHASE ONE AUDIT RESULTS

Phase one of the audit was completed on July 31, 2000. Based on the audit findings and recommendations, 3M has submitted a request that EPA redesignate 30 studies (or pieces of information) out of the over 600 studies now contained in FYI Docket Number 1378 as a supplement to the TSCA Section 8(e) dockets for PFOS and related FCs -- Docket Numbers 373/374. (See Attachment A).

In our upcoming meeting, 3M would like to take the opportunity to review the details of our audit protocol and results and to address any specific questions that the Agency may have regarding the audit. As background prior to our meeting, it is important to emphasize that 3M has submitted a substantial body of data on FCs to the TSCA Section 8(e) docket over the years. These submissions reflect the seriousness with which 3M regards its reporting obligation. We have voluntarily augmented these data through the January 1999 Health Effects White Paper, the March 2000 Environmental White Paper and the extensive FYI Submissions. Out of the over 600 FC studies audited so far in phase one, 3M identified 30 studies that appear potentially reportable under a strict application of the current EPA guidance. In all cases, these 30 studies are consistent with prior 8(e) submissions and information in the published literature; also, some of these studies are of questionable reliability, and in several cases, subsequently have been (or are being) performed under more sound methods. Nevertheless, it appears that these studies may not qualify, strictly speaking, as "corroborative" or "unreliable" under current EPA guidance, and for this reason, may qualify as potentially reportable under the guidance. To place these studies in further perspective, 3M reviews the studies below on a categorical basis.

⇒ ***Animal Data -- Acute Toxicity***: Four acute toxicity studies appear potentially to meet EPA's current reporting guidance. All four of these studies fall into the "moderate" toxicity category under EPA's reporting guidance. These data are consistent with published data and/or previous 8(e) submissions on other, structurally similar FCs. For example, one study addresses the acute toxicity of one form of PFOS, whereas comparable published acute toxicity data are for a salt form of PFOS. Moreover, acute toxicity data were included in the January 1999 Health Effects White Paper placed by OPPT in the 373/373 8(e) dockets.

⇒ ***Animal Data – Subchronic and Chronic Toxicity***: Four studies appear potentially to meet EPA's current reporting guidance due to liver weight changes and liver effects. Three of these four studies are on PFOS, and the data is consistent with previous 8(e) submissions and/or published information on PFOS. Moreover, toxicology data on PFOS, including liver weight changes and liver effects, were addressed in the January 1999 Health Effects White Paper. Similarly, the fourth study is on N-methyl FOSE, which is structurally similar to N-

ethyl FOSE, for which 3M has already submitted information to the TSCA Section 8(e) docket showing comparable effects.

⇒ ***Animal Data -- Neurotoxicity***: Two studies -- a two-week rangefinding study on PFOS in rats and a 28-day study on N-ethyl FOSE in rats -- appear potentially to meet EPA's current reporting guidance due to the observation of effects identified in the guidance as being potential indicators of neurotoxicity. The extensive data base on both PFOS and N-ethyl FOSE suggests, however, that neither of these compounds is a neurotoxin.

⇒ ***Animal Data – Developmental Toxicity***: Four studies -- one study on PFOS in rabbits and three studies on N-ethyl FOSE -- appear potentially to meet EPA's current reporting guidance due to the observation of developmental effects, even though these effects occurred in conjunction with maternal toxicity. The January 1999 Health Effects White Paper reviewed some of this data as well as similar data; prior 8(e) submissions also have covered similar data on these chemicals.

⇒ ***Animal Data – Dermal/Eye Irritation***: Four studies -- one on PFOS; one on N-ethyl FOSE; and two on PFOA-related compounds -- appear potentially to meet EPA's current reporting guidance due to observation of continued irritation effects 21 days after cessation of dosing. Prior 8(e) submissions have covered similar data on these and other FCs.

⇒ ***Animal Toxicity – Pharmacokinetics And Metabolism***: Two studies appear potentially to meet EPA's current reporting guidance: one study showing the half-life of PFOS in rabbits to be greater than one month and one study showing PFOS as a metabolite of N-ethyl FOSE in rats. Previous 8(e) submissions have addressed both of these specific aspects of FC metabolism; these aspects of FC metabolism also were discussed in depth in the January 1999 Health Effects White Paper.

⇒ ***Human Serum Data***: 3M has made 8(e) submissions of human serum data over the years. Most recently, as indicated above, 3M reported in May of 1998 its finding of PFOS in general population human serum; this May of 1998 report was followed by a detailed summary of PFOS toxicology, medical surveillance, epidemeology and serum data in the January 1999 Health Effects White Paper. 3M made a further 8(e) submission with human serum data on PFOS and other FCs in May of 1999. Nevertheless, two additional pieces of serum data obtained subsequent to the May 1999 Submission -- a 1999 analytical report on measurements of FC metabolites in 3M worker serum and a 1999 analytical report on measurements of FCs in serum samples from ten children -- appear

potentially reportable under EPA's current guidance because these data are not, strictly speaking, "corroborative" of prior submissions.

⇒ ***Environmental Fate Data***: 3M's May of 1998 8(e) submission with the human serum data also included data on the measurement of PFOS in blood bank animal serum. Subsequently, in May of 1999, 3M made a supplemental 8(e) submission that included measurements of PFOS in the serum of wildlife species. The March 2000 Environmental White Paper also provided a detailed review of the animal serum data. Nevertheless, two additional pieces of serum data -- the 1999 finding of certain FCs in naïve rats and the 2000 finding of FCs in additional wildlife species -- appear potentially reportable under the EPA guidance. In addition, six environmental fate studies on FCs -- four studies from various years measuring an n-octanol/water partitioning coefficient for N-ethyl FOSE and N-methyl FOSE; one study detecting N-ethyl FOSE in a limited number of fish from the Tennessee River; and one study detecting N-ethyl FOSE in various fish tissues under experimental conditions -- appear potentially reportable under the EPA guidance. Notably, all of these studies are of questionable reliability, and 3M is currently conducting state-of-the-art studies to measure an n-octanol/water partitioning coefficient for these compounds.

⇒ ***Environmental Toxicity Data***: One recent acute toxicity study of PFOS in bobwhite produced an LC_{50} at the "high" toxicity category under EPA's current reporting guidance. Although the draft results from this study were included in the March 2000 Environmental White Paper, this study was never identified with particularity in any 8(e) submission.

III. NEXT STEPS

3M has requested the opportunity to meet with the Agency. We believe that a meeting would provide the opportunity to address two principal aspects of this matter.

First, 3M has endeavored to conduct this audit in accordance with the Self-Audit Policy. Given the breadth of 3M's audit, we believe that it is important to develop an understanding of how the Self-Audit Policy applies to our effort and to agree with the Agency on a process for self-reporting on future phases of the audit under the Self-Audit Policy. As we discussed with Mr. Stubbs and others, 3M has been operating over the last one and one-half years under an agreement that provides for auditing of TSCA systems and of PMN nomenclature. (See Attachment B). This agreement expired on July 24, 2000. 3M did not initiate its current TSCA Section 8(e) compliance audit under this agreement for the principal reason that this agreement does not seem to contemplate extensive TSCA Section 8(e) compliance auditing, but rather, only TSCA systems audits with compliance "sampling" to bolster those audits. Thus, 3M initiated

the current compliance audit under the Self-Audit Policy as opposed to this agreement. Nevertheless, 3M believes that this agreement epitomizes the cooperative approach that 3M would like to pursue for this matter and provides a model to govern the compliance audit.

Second, 3M would like to use our meeting to provide further details to the Agency on the FC context for the audit. As we mentioned to Mr. Stubbs and the others, Dr. Auer and Dr. Hernandez from OPPT, in particular, also may be able to provide useful background in this regard. Their attendance at the meeting may be beneficial.

* * *

Thank you again for your willingness to meet with 3M regarding this matter. As we prepare for the meeting, please use our outside counsel from Latham & Watkins, Julie Hatcher, as your central point of contact. You also should feel free to direct any questions regarding this matter to Julie, who can be reached at (202) 637-2238.

Very truly yours,

Katherine E. Reed (4pm)

Katherine E. Reed, Ph.D
Executive Director
Environmental Technology and Safety Services

Enclosure

cc: Gerald B. Stubbs, Chief, Case Development, Policy and Enforcement Branch
Julia A. Hatcher, Esq.

DC_DOCS\321116.2 6vrw02!.DOC [W97]