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3M

June 13, 2001

CONFIDENTIAL – FOR SETTLEMENT PURPOSES ONLY

Ms. Ann Pontius
Acting 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 Two Findings**

Dear Ms. Pontius:

3M Company ("3M") has been engaged in communications with your office regarding disclosure of potential violations of TSCA Section 8(e)'s "substantial risk" reporting requirements pursuant to EPA's Self-Audit Policy, 65 Fed. Reg. 19618 (Apr. 11, 2000). These communications have included an August 21, 2000 disclosure of 30 potential violations identified by 3M during Phase One of its Section 8(e) Compliance Audit; a September 22, 2000 letter addressing the relationship of the Compliance Audit to the "Agreement For TSCA Compliance Audit" entered into by 3M and EPA in June 1999; and a December 1, 2000 letter reviewing the facts and circumstances supporting application of the EPA Self-Audit Policy to the Compliance Audit.

3M understands from Kathy Clark and Tony Ellis of your office that EPA has been evaluating the situation and has reached a preliminary decision which will be communicated in writing to 3M within the next few weeks. 3M looks forward to receiving EPA's written preliminary decision. In the meantime, 3M submits this letter to disclose potential violations identified during Phase Two of its Compliance Audit.

I. REVIEW OF AUDIT SCOPE, BACKGROUND AND CONTEXT

By way of brief review of the background and context, Phases One and Two of 3M's 8(e) Compliance Audit are focused on studies and other information that 3M has voluntarily submitted on various fluorochemicals (FCs) in response to two e-mails from Mr. Charles Auer of the Office Of Pollution

Prevention And Toxics ("OPPT") requesting information on various forms of perfluorooctane sulfonate ("PFOS"); on eleven compounds related to PFOS; and on perfluorooctanoic acid ("PFOA"). OPPT subsequently placed these FC studies and information in the TSCA "For Your Information" docket AR-226 (FYI No. 1378). As a shorthand reference, we will refer to the FC studies and information in this letter as the "FYI Submissions."

Phase One of the Compliance Audit included the FYI Submissions made through May of 2000. From the over 600 studies in these FYI submissions, 3M had identified 30 studies that appeared 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 first disclosed and then provided further details regarding these Phase One findings to EPA in the communications identified above.

Phase Two of the Compliance Audit reviewed the FYI submissions made from May 30 through December 31, 2000. As with Phase One of the Compliance Audit, 3M assembled an audit team for Phase Two led by legal counsel from 3M and Latham & Watkins and also comprised of Company scientists and other technical experts. The audit team employed the same two-tier process. Latham & Watkins conducted an independent initial review of the studies. Following this initial review, Latham & Watkins then worked with 3M scientists and technical experts to examine the studies requiring further consideration. Specifically, this further consideration involved (i) consulting with 3M scientists to resolve toxicological and other technical questions as to certain studies; (ii) receiving information from 3M experts relevant to the potential exposure profile of the various compounds; and (iii) examining prior 8(e) filings, FIFRA filings and other sources, including publications, which would make information "known to the Administrator", and hence not 8(e) reportable.

Phase Two covered more studies than Phase One -- over 700 studies -- and the majority of these studies were performed on various formulations dating back to the 1970's of 3M's aqueous fire fighting foam (AFFF) products, which are chemical mixtures comprised primarily of non-fluorochemical components, but containing 0.5 to 6.6 percent PFOS in the formulation. The auditing of the AFFF mixture studies added several additional complexities to Phase Two as compared to Phase One of the Compliance Audit.

First, EPA's current 8(e) reporting guidance does not contain any specific analytical framework for evaluating data on mixtures. For Phase Two, 3M developed a rigorous approach based on the general principles from EPA's current guidance. Under this approach, 3M evaluated the studies based on the reporting triggers for severity of effects and potential for exposures that apply under the guidance to studies on individual chemicals. To assess whether any of

the mixture studies that would otherwise meet these reporting triggers were "corroborative" of information already submitted to the 8(e) docket, published or otherwise "known" to the EPA Administrator, 3M examined whether the effects in any study were reasonably attributable to a particular component of the mixture, and if so, whether the effects of such component are "known" to occur at the levels of the component present in the mixture.

Second, to apply this rigorous approach for evaluating the potential reportability of studies on mixtures, 3M had to compile precise formulation information from historical records. To put this task in perspective, Phase Two involved hundreds of mixture studies, and it was necessary in each case to verify the identities and levels of each mixture component.

Third, for those mixture studies requiring further consideration under the two-tier auditing process, it was necessary for 3M to assess the results of the studies from the standpoint of each component of the formulation. This assessment entailed conducting a toxicological evaluation and literature review of each non-fluorochemical component of each particular mixture formulation. Over 50 mixture studies were identified for further consideration, and thus, required such an assessment.

II. DISCLOSURE OF PHASE TWO AUDIT RESULTS

Phase Two of the Compliance Audit was completed in May of 2001. Based on the audit findings and recommendations, 3M has identified three studies that appear potentially to meet EPA's current reporting guidance. 3M also identified one additional study 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. As to these three studies, 3M has followed the same procedure as recommended by EPA for the Phase One studies identified as potentially reportable. On June 13, 2001, 3M submitted a request that EPA redesignate these three studies now contained in AR-226 (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).

As discussed with the Agency in the context of Phase One of the Compliance Audit, 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[1], the March 2000 Environmental White Paper[2] and the extensive FYI Submissions. In all cases, the three studies identified as potentially reportable in Phase Two are consistent with prior 8(e) submissions and information in the published literature, but it appears that these studies may not qualify, strictly speaking, as "corroborative" under current EPA guidance, and for this reason, may qualify as potentially reportable under the guidance. Further details regarding these three studies follow below.

⇒ ***Range Finding Rat Teratology Study***: One of the three studies is a range finding rat teratology study on N-EtFOSE which was completed in 1983. Although 3M did submit to the 8(e) docket the results of the definitive study which was completed the following year, the definitive study did not involve the high end dose of 75 mg/kg/day of the range finding study and some of the fetal effects observed at this dose (*e.g.*, cleft palates; incompletely descended testes) do not appear, strictly speaking, corroborative of the results from the definitive study.

⇒ ***Eye Irritation Studies***: Two of the three studies are eye irritation studies on different formulations of AFFF products containing di-ethyl glycol butyl ether (DEGBE) -- a 1991 study with 10 percent DEGBE and a 1975 study with 12 percent DEGBE. The eye irritation observed in these studies -- significant corneal opacity effects -- would appear attributable to DEGBE. Although DEGBE has been reported in the published literature to cause such effects, the lowest level that 3M could locate in the published literature involving significant corneal opacity effects for DEGBE was 25 percent in solution. These two studies showed the same effects, but at lower DEGBE concentrations, and thus, do not appear, strictly speaking, corroborative of the studies in the published literature.

One final noteworthy aspect of Phase Two of the Compliance Audit relates to environmental monitoring data. 3M has been conducting a multi-faceted environmental monitoring program for PFOS and other FCs. This program is ongoing and will not be completed until early in 2002. Phase Two encompassed interim data from one facet of this monitoring program -- measurement of PFOS and other FCs in limited surface water samples at very low part per billion levels -- which had been provided to OPPT through the August

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

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

31, 2000 FYI Submission . EPA's 8(e) reporting guidance for environmental monitoring data is quite limited and has been a continuing source of industry uncertainty. 3M conducted Phase Two applying EPA's existing guidance in a rigorous manner and determined that these interim surface water data should not trigger 8(e) reporting. Nevertheless, in the spirit of full disclosure, we wanted to make the Agency aware of the inclusion of these data in Phase Two of the Compliance Audit and would be willing to answer any questions with regard to our reporting determination.

* * *

Again, 3M looks forward to receiving EPA's written preliminary decision regarding its 8(e) Compliance Audit and to working cooperatively towards a successful resolution of this matter. In the meantime, please do not hesitate to contact Mr. Thomas DiPasquale of 3M's Office Of General Counsel if you have any questions regarding this Phase Two Compliance Audit disclosure.

Very truly yours,

Katherine E. Reed

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

Enclosure

cc: Gerald B. Stubbs, EPA Toxics and Pesticide Enforcement Division, Case Development, Policy And Enforcement Branch
Kathy M. Clark, Esq., EPA Toxics and Pesticide Enforcement Division, Office of Regulatory Enforcement
Tony Ellis, EPA Toxics and Pesticide Enforcement Division, Case Development, Policy And Enforcement Branch
Julia A. Hatcher, Esq., Latham & Watkins
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REVISED DRAFT

November 28, 2001

Summary of Disclosures made under the 3M/EPA Audit Agreement

35 Disclosures Made:

- 12 No actions warranted
- 12 Audit Policy met (No Penalties)
- 8 Economic Benefit determinations for $ 109,608
  - $ 10,700 (I-98-60)
  - $ 19,682 (L99-235)
  - $ 14,863 (P99-1002)
  - $ 9,520 (P99-1229)
  - $ 2,542 (L99-456)
  - $ 24,949 (CSA #13) Avoidance
  - $ 13,430 (CSA # 14) Avoidance
  - $ 13,922 (L00-248)
- 3 Stipulated penalties for $ 242,000
  - $ 20,000 (NOC violations)
  - $204,000 (8(e) Phase 1)
  - $ 18,000 (8(e) Phase 2)
- Total Penalty Assessment $ 351,608

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REVISED DRAFT: Working Papers
Updated November 28, 2001

DRAFT: Working Papers

3M Company

Disclosure Type	Date Disclosure made	Type of Violation	Proposed Penalty	Violation corrected?	Audit Policy Conditions Met?	Economic benefit?	Disposition or Status
SMMD	2/20/98	§ 5 PMN	$ 40,000	Yes - Company ceased commercial mfg. and submitted a mock PMN for review (I-98-60)	Yes	Yes - $10,700 (See Ben report)	Company requested and was granted enforcement discretion to distribute existing stocks. Although the company did submit a "mock" PMN, the company is subject to the delayed cost of submitting a PMN.
SMMD	4/8/99	§ 5 LVEA	$186,000	Yes - Company submitted a LVEA, L-99-235.	Yes	Yes - $19,682 (See Ben report)	Company did submit a LVEA but is subject to the delayed costs of submitting the LVEA.
SMMD	10/27/98	§ 8 IUR	$ 0 No action warranted	Company omitted two chemicals to their 1994 IUR submission (Decatur, AL facility and Cordova, IL facility)	Yes	No	The Agency considers the economic benefit from non-compliance to be de-minimus.
CSA #1 and CSA #2	11/6/98	§ 8 IUR/ § 8 PAIR	$ 0 Previous NOD Issued	Company submitted their 1994 IUR form and PAIR form for carbon disulfide (Tonawanda, NY facility)	Yes	No	This disclosure was forwarded to Region II for action on 12/1/98. The Region issued a NOD for the violations on 3/17/99.
CSA #3 and CSA #4	11/24/98	§ 8 IUR	$ 0 No action warranted	Company omitted one chemical to their 1994 IUR submission (Bedford Park, IL, and St. Paul, MN)	Yes	No	The Agency considers the economic benefit from non-compliance to be de-minimus.

CSA #5	12/10/98	§ 13 Improper cert. for a R&D product	$ 1,430	Company corrected negative certification with a positive certification.	Yes	No	The Agency considers the economic benefit from non-compliance to be de-minimus.
CSA #6	12/22/98	§ 5 illegal use	$ 62,700	Company stopped illegal use. A PMN was subsequently submitted by another company.	Yes	No	The Agency considers the economic benefit from non-compliance to be de-minimus
CSA #7	1/6/99	§ 5 SNUN	$ 215,600	Company now complying with SNUR requirements.	Yes	No	The Agency considers the economic benefit from non-compliance to be de-minimus
CSA # 8	4/26/99	§ 13 False cert.	N/A	No violation occurred.	N/A	N/A	Company submitted a negative certification when none was needed.
CSA # 9	4/29/99	§ 5 PMN	N/A	No violation occurred.	N/A	N/A	Chemical is on the TSCA Inventory as of 1994.
SMMD	5/6/99	§ 8 IUR	$ 18,700	Company failed to submit the 1994 and 1998 IUR form for one chemical at the Decatur, AL site)	Yes	No	The Agency considers the economic benefit from non-compliance to be de-minimus
CSA #10	5/11/99	§ 13 False cert.	N/A	No Violation occurred.	N/A	N/A	Company submitted a negative certification when none was needed.
CSA #11	5/20/99	§ 5 SNUN	$ 495,000	Failed to comply with R&D requirements under 40 C.F.R. 721.47.	Yes	No	The Agency considers the economic benefit from non-compliance to be de-minimus

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CSA #12	6/4/99	§ 12(b)	N/A	Company disclosed a potential 12(b) violation for an export that occurred on May 26, 1999 for Cas # 74-87-3	N/A	N/A	No Violation occurred. The 12(b) export notification requirement for this chemical was sunset on 7/30/94.
SMMD	6/8/99	§ 8 IUR	$18,700	Company omitted one chemical to their 1998 IUR submission (Cottage Grove, MN)	Yes	No	The Agency considers the economic benefit from non-compliance to be de-minimus.
SMMD	6/28/99	§ 5 PMN	$4,059,000	Yes - 3M submitted a PMN (P-99-1002).	Yes	Yes - $14,863 (See Ben report)	Company requested and was granted enforcement discretion to distribute existing stocks. Although the company did submit a PMN, the company is subject to the delayed cost of submitting the PMN.
SMMD	7/22/99	§ 8 (NOC)	$20,000	Company reported two late NOCs.	No* *Repeat violator $20,000 Stip	N/A	Company had a previous TSCA violation (see TSCA 97-H-34). Company subject to stipulated penalties per the Audit Agreement Section 3(a)(vi).
SMMD	7/22/99	§ 5 PMN	$ 33,000	Yes - 3M submitted a PMN (P-99-1229)	Yes	Yes - $9,520 (See Ben report)	Company did submit a PMN and but is subject to delayed costs.
SMMD	9/21/99	§ 5 LVEA	$ 8,800	Yes - 3M submitted a LVEA L99-456 for this chemical.	Yes	Yes - $ 2,542 (see Ben report)	Company requested and was granted enforcement discretion to distribute existing stocks. Although the company did submit a LVEA, the company is subject to the delayed cost of submitting the LVEA.

CSA #13	9/29/99	§ 5 PMN	$ 480,000	Yes – The chemical was placed on the TSCA Inventory by another company (deleted) See P-(deleted) (NOC submitted by (deleted) on 6/17/99)	Yes	Yes - $24,949 (see Ben report)	Company requested and was granted enforcement discretion to distribute existing stocks. Company avoided costs of submitting a PMN.
CSA #14 and CSA #15	11/4/99	§ 5 LVEA	$ 14,300	Company stated that no further manufacture occurred (Final report)	Yes	Yes - $13,430 (See Ben report)	Company avoided cost of submitting an LVEA. No LVEA was filed. All products containing the chemical substance was treated as waste and disposed of by 3M.
SMMD	12/17/99	§ 5 PMN	N/A	Company submitted a LVEA but the Agency determined that the chemical was on the TSCA Inventory (according to company)	N/A	N/A	No Violation occurred.
SMMD	2/10/00	§ 8 IUR	$18,700	Company incorrectly reported the wrong CAS# for a chemical substance to their 1998 IUR (Cottage Grove, MN)	Yes	No	The Agency considers the economic benefit from non-compliance to be de-minimus.
SMMD	4/24/00	§ 5	N/A	No determination has been made that a violation occurred.	N/A	N/A	3M has requested a correction of inventory listings to reflect intended chemical species (IC-5854).
SMMD	5/12/00	§ 5 LVEA	$ 11,000	Yes - Company submitted a LVEA, L-00-248.	Yes	Yes - $13,922 (See Ben report)	Company did submit a LVEA but is subject to the delayed costs of submitting the LVEA.

CSA #16	6/2/00	§ 13 Failure to certify for R&D products	Company was unable to reasonably obtain records to determine penalty.	Company imported numerous R&D products without providing the necessary TSCA certifications to Customs	Yes	No	3M has provided the necessary guidance to personnel for future R&D imports requiring TSCA certifications. No past corrections is deemed necessary.
SMMD	6/12/00	§ 8 (IUR)	$ 56,100	Company incorrectly reported the volume amounts of three chemicals for the 1998 IUR report (Cottage Grove, MN)	Yes	No	The Agency considers the economic benefit from non-compliance to be de-minimus
CSA # 17	7/7/00 3/30/01	§ 8(c)	$1,804,000	Company reported 164 8(c) allegations that were not contained in the central file.	Yes	No	Economic gains from non-compliance is unknown.
POST FINAL REPORT	11/20/00	§ 5 (polymer exemption)	$ TBD	Company failed to submit an exemption notification requirement.	Yes	No	The Agency considers the economic benefit from non-compliance to be de-minimus
POST FINAL REPORT	12/26/00	§ 5 (polymer exemption)	$ TBD	Company failed to submit an exemption notification requirement.	Yes	No	The Agency considers the economic benefit from non-compliance to be de-minimus

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TSCA 8(e) PHASE I	8/21/00	§ 8 (e)	$ TBD To be calculated	29 animal studies ($6,000) 2 human health ($15,000)	No $ 204,000* *Stipulated penalties	N/A	Company did not meet the terms of the audit policy and are subject to the stipulated penalties of the 3M audit agreement.
TSCA 8(e) PHASE II	6/13/01	§ 8 (e)	S TBD To be calculated	3 animal studies ($6,000)	No $ 18,000* *Stipulated penalties	N/A	Company did not meet the terms of the audit policy and are subject to the stipulated penalties of the 3M audit agreement.