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January 4, 2021
BY FEDEX

Administrator
U. S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460

Re: Notice to the Administrator pursuant to 15 U.S.C. § 2619(b)(1)(A), re:
Casten v. DuPont de Nemours, Inc., an action pending in the United States
District Court for the Western District of New York at C. A. No. 21-CV-4

Dear Sir/Madam:

Gary R. Casten hereby gives notice to the Administrator of the United States Environmental Protection Agency that on or after sixty (60) days from the service of this notice on you that Gary R. Casten will move to amend his Complaint in the matter of Casten v. DuPont de Nemours, Inc., et al., C. A. No. 21-CV-4, in order to restrain defendant DuPont de Nemours, Inc. (hereinafter, "DuPont") from further violations of 15 U.S.C. § 2607(e), pursuant to 15 U.S.C. § 2619(a)(1). A copy of the filed Complaint is attached at Ex. 1¹.

Section 8(e) of the Toxic Substances Control Act (TSCA) provides as follows:

(e) Notice to Administrator of substantial risks

Any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information.

15 U.S.C. § 2607(e). Since April 20, 1993, DuPont, a chemical manufacturer, has been in possession of substantial risk information regarding the health hazards posed by occupational exposure to the chemical substance ortho-toluidine that should have been reported to the Administrator pursuant to Section 8(e).

¹ All exhibits are attached in pdf form on the DVD which accompanies this letter. A copy of this letter in pdf form is also contained in the DVD.

The significance of this unreported information is that it clearly demonstrated that the Federal standard for occupational exposure to ortho-toluidine does not protect workers against the cancer-causing effects of this chemical. In addition, after DuPont obtained this information, this manufacturer continued to assure the public and this Agency that exposure at the amount permitted by the Federal standard was safe.

Violations by DuPont de Nemours, Inc.

1. Since April 20, 1993, DuPont has been in violation of 15 U.S.C. § 2607(e) due to its failure to report to the Administrator the results of scientific research that it privately conducted that concluded that occupational exposure to the chemical substance ortho-toluidine (CAS No. 95-53-4), at the legally permissible exposure limit of 5 parts per million for an 8-hour work day, would result in a concentration of ortho-toluidine in an exposed worker's urine in the amount of 20 milligrams per liter. See Ex. 2. Prior to DuPont making this finding, this effect of exposure was unknown. DuPont's information demonstrated that the permissible level of occupational exposure to ortho-toluidine in the United States would result in a urinary concentration that was significantly greater than the urinary levels detected in workers who had been found to have a statistically significant excess risk of developing bladder cancer after exposure to ortho-toluidine.
2. On February 2, 1995, DuPont knowingly misinformed the Administrator, in a Section 8(e) submission on ortho-toluidine at Document Control Number 88950000128, that: “[b]ased on all available toxicity data. . .the existing worker exposure limit (Acceptable Exposure Limit, AEL) was reviewed and its validity at 5 ppm, 8- and 12-hr. time weighted average, confirmed.” See Exs. 3 and 4.
3. Since April 24, 2018, DuPont has willfully violated 15 U.S.C. § 2614 by its continued failure to inform the Administrator of the substantial risk of injury to health. On that date, DuPont was put on notice of its violation by Plaintiff Douglas J. Moss, in a pleading filed in the United States District Court for the Western District of New York, in the matter of Moss v. E. I. du Pont de Nemours and Company, et al., at C. A. No. 16-CV-539-LJV-HKS. See Ex. 5.

Significance of DuPont's violations to human health

Ortho-toluidine is “known to be a human carcinogen based on sufficient evidence of carcinogenicity from studies showing that it causes urinary-bladder cancer in humans.” *The Report on Carcinogens*, Thirteenth Edition, National Toxicology Program (NTP), U.S. Department of Health and Human Services (2014). See Ex. 6.

The International Agency for Research on Cancer (IARC) has classified ortho-toluidine into its highest category, Group 1, because it “is carcinogenic to humans.” According to the IARC, “ortho-toluidine causes cancer of the urinary bladder.” *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*, Volume 99 (2010). See Ex. 7.

The human carcinogen classifications of ortho-toluidine by the NTP and IARC are primarily based on epidemiological and industrial hygiene studies of a Goodyear Tire & Rubber Company chemical plant in Niagara Falls, New York. These studies have been performed by the National Institute for Occupational Safety and Health (NIOSH) since 1988. NIOSH is part of the U.S. Centers for Disease Control and Prevention, within the U.S. Department of Health and Human Services. From 1957 through 1995, DuPont annually supplied millions of pounds of ortho-toluidine to this Goodyear plant for use as a raw material.

NIOSH reported its first epidemiological study of the Goodyear plant (Interim Report No. 1) in December 1989.

There were 14 cases of bladder cancer observed and 3.54 expected based on New York State incidence rates among the 1749 individuals ever employed at the plant. The ratio of observed to expected cases (also known as the Standardized Risk Ratio or SIR) of 3.95 was found to be highly statistically significant ($p=0.00002$) indicating that this risk was very unlikely to have occurred by chance. There were 8 cases observed and 1.20 (SIR=6.64; $p=0.00004$) expected among 795 workers ever employed in an area of the plant where workers were definitely exposed to o-toluidine.

See Ex. 8 at 1-2. NIOSH also reported that:

worker exposure monitoring data that Goodyear industrial hygiene staff have collected since 1982 show that air concentrations of all chemicals present in Department 245 have been consistently less than one part per million (ppm).

Id. at 11. Department 245 was the area of the plant where ortho-toluidine was used. The NIOSH investigators also performed their own air sampling in the plant and confirmed that "the results for all the area air samples collected were less than 1 ppm." Id. The U. S. Department of Labor's Occupational Safety and Health Administration (OSHA) permits workers to be exposed up to 5 part per million (ppm) based on an average over an 8 hour work day. See 29 C.F.R. 1910.1000 Table Z-1.

NIOSH noted that because ortho-toluidine has the potential for absorption through the skin, which would not be measured by air sampling, "it is important to assess whether workers are adequately protected from exposure via this route" and announced plans to obtain urine samples in order to measure skin absorption. Id. at 15-16.

During the period of February 27 to March 9, 1990, NIOSH conducted an industrial hygiene study of ortho-toluidine exposure at the Goodyear plant. The results of the study were issued in a 114-page report entitled "Interim Report No. 2" in March, 1992. See Ex. 9.

NIOSH conducted both air and urine sampling of workers exposed to ortho-toluidine. Urine samples were taken from the Goodyear workers, both before the work-shift and after the work-shift, and the results were compared in order to determine their ortho-toluidine exposure. In its 1992 report, NIOSH reported that the highest post-shift urinary ortho-toluidine level in the Goodyear workers was 527 micrograms of ortho-toluidine per liter of urine. Id. at 67. NIOSH stated: "This provides conclusive evidence that Department 245 workers were absorbing o-toluidine. . .into their bodies during the workshift." Id. at 2.

When NIOSH released its report in 1992, the mathematical correlation between the amount in the air and the resulting amount in the urine was unknown.

DuPont, however, conducted scientific research which answered this question, and the result was reported within the corporation by April 20, 1993. This information should have been reported immediately under Section 8(e). Such a report would have enabled NIOSH to recommend a new airborne exposure limit for ortho-toluidine that took into consideration the excess incidence of cancer at the Goodyear plant.

DuPont's failure to inform the Administrator

At all times relevant to this matter, DuPont was acutely aware of these NIOSH studies. Beginning in 1985, Goodyear workers who had developed bladder cancer began filing third-party product liability claims against DuPont for its failure to provide adequate warnings of the health hazards of its ortho-toluidine. By the close of 1992, a total of eight Goodyear workers had filed claims against DuPont.

In addition, DuPont was acutely aware of two major deficiencies in the permissible exposure limit (PEL) of 5 parts per million for occupational exposure to ortho-toluidine. First, the 5 ppm PEL had been adopted by OSHA in 1971 from a threshold limit value (TLV) set by a voluntary association called the American Conference of Governmental Industrial Hygienists (ACGIH). The 5 ppm TLV was based on research last conducted in the 1960's and carcinogenicity was never considered by the ACGIH. See Ex. 10.

Second, the 5 ppm OSHA standard was based on air sampling, even though skin absorption was a major route of exposure. Air sampling does not measure absorption of ortho-toluidine through the skin. However, urine sampling for ortho-toluidine can measure exposure from both inhalation and skin absorption. DuPont had been well-aware of this fact since at least 1951, and had, in fact, always relied upon urine sampling to protect its employees from the hazards of ortho-toluidine. See Dawson deposition at 44, Ex. 11.

By November 8, 1991, DuPont's Haskell Laboratory for Toxicology and Industrial Medicine acknowledged the need to develop a more precise "urinary biomonitoring method for exposure to o-toluidine" and establish a "safe workplace exposure criteria for o-toluidine, such as a biological exposure index, to be used in conjunction with an

AEL." See Ex. 12.

An "AEL" is an in-house DuPont term for an "acceptable exposure limit." Henry Trochimowicz, ScD, a staff toxicologist at the Haskell Laboratory and chairman of DuPont's AEL Committee, defined an AEL as "a level of exposure believed to be safe for an individual to, let's say, breathe a chemical for eight hours a day, five days a week for his working lifetime without experiencing any serious adverse effect -- or any adverse effect." See Trochimowicz deposition at 53, Ex. 13.

As of April 6, 1990, DuPont had determined that an AEL of 5 ppm (the same as the OSHA PEL) "would provide a sufficient margin of safety," even though DuPont had calculated that an average 70 kilogram worker exposed for eight hours would take in "a maximum of 3 mg/kg" of ortho-toluidine at a 5 ppm airborne exposure. See Exs. 14 and 15. However, the resulting urinary concentration of ortho-toluidine, after 8 hours of exposure at the legal limit of 5 ppm, was unknown at the time.

By March 1993, two studies had been completed by scientists with DuPont's Haskell Laboratory. See Exs. 16 and 17. The data from these two studies was reviewed by Thomas J. Nelson, a certified industrial hygienist with DuPont's corporate level industrial hygiene division. Nelson was working on a DuPont epidemiological study of bladder cancer and had been assigned the task of determining the amount of past exposure to ortho-toluidine at DuPont facilities that had manufactured and used ortho-toluidine.

In a report dated April 20, 1993, Nelson concluded, based on "[u]npublished Haskell data," that

a dose of 220 mg (5 ppm inhalation for a day) would yield an OT [ortho-toluidine] urine level of 20 mg/liter (220 mg * excretion rate of .6 * prevalence of 0.08/500 cc urine volume = 0.02 mg /cc = 20 mg/l.

See Ex. 2 at page KDH01094. In a deposition taken on January 14, 2016, Nelson confirmed the conclusion that he had reached in 1993:

Q. We've established earlier today that 5 parts per million was the DuPont AEL for ortho-toluidine; right?

A. Um-hum.

Q. So here you're saying that if you are exposed for 5 parts per million inhalation over a day, you're going to end up with an OT urine level of 20 milligrams per liter; right?

A. Yes.

See Ex. 18 at 109-110. Nelson's written report was distributed to other members of the DuPont committee that was conducting the epidemiological study, including Charles F. Reinhardt, MD, Director of DuPont's Haskell Laboratory.

Barbara J. Dawson is DuPont's Globally Deployed Occupational Health Resource. In 1993, Dawson was an industrial hygienist assigned to DuPont's Chambers Works in Deepwater, New Jersey, the plant where DuPont had manufactured ortho-toluidine. Dawson testified for DuPont at a deposition on April 7, 2016 as a Federal Rule of Civil Procedure 30(b)(6) witness. Dawson testified that she first saw Nelson's finding in 1993 when she reviewed his report. See Dawson transcript at 117, Ex. 11. Dawson further testified as follows:

Q. Is it fair to say that DuPont had developed data which allowed a calculation of the resulting ortho-toluidine urine level after an exposure of 5 parts per million for an eight-hour day?

MR. WISHNOFF: Object to the form.

A. It looks like it's a calculated number. I think they had determined the excretion rate and then, you know, did some other math there to get to that result, yes.

Q. Okay. And they determined that if there was inhalation exposure at the permissible exposure limit of 5 parts per million for one eight-hour day, would result in a urinary concentration of 20 milligrams of ortho-toluidine per liter of urine; correct?

MR. WISHNOFF: Objection to form.

A. That's what it says.

Id. at 117-118.

As of April 20, 1993, both Nelson and Dawson were well aware of the ortho-toluidine urinary concentrations in the Goodyear workers that NIOSH had reported in March 1992. In fact, on August 24, 1992, Nelson had written a memorandum summarizing the NIOSH data to Dawson and five other DuPont employees and managers. See Ex. 19.

In her deposition, Dawson acknowledged that 20 milligrams per liter would be 37 times higher than the highest urinary levels that had been found by NIOSH in the Goodyear workers. See Ex. 11 at 119. Dawson admitted that at the time when Nelson presented this data, "It was the first time anyone in DuPont had done it." Id. at 122.

On February 2, 1995, DuPont made a submission to the USEPA on Section 8(e). The EPA document control number is 88950000128. See Ex. 4. On the EPA website

ChemView collection (<https://chemview.epa.gov/chemview>) of "Substantial Risk Reports" for ortho-toluidine, this submission is dated February 22, 1995. We have also attached the original DuPont submission letter. See Ex. 3. The correct date for this submission should be February 2, 1995.

The submission states that the Agency had made an inquiry to DuPont's Reinhardt dated December 8, 1994. DuPont stated that it was submitting a response to that inquiry. DuPont proceeded to represent to the Agency that "[b]ased on all available toxicity data. . .the existing worker exposure limit (Acceptable Exposure Limit, AEL) was reviewed and its validity at 5 ppm, 8- and 12-hr. time weighted average, confirmed."

According to Trochimowicz, the process of determining an AEL requires consideration of all "human data -- all data that related to the health and safety would have been considered." See Ex. 13 at 80. Yet, in this submission to the Agency, there is no mention of the unpublished Haskell data and Nelson's calculation that determined that a 20 milligram per liter concentration would result after exposure to ortho-toluidine at 5 parts per million for 8 hours. When compared to the NIOSH data available from the Goodyear plant, the resulting urinary concentration from exposure at a 5 ppm AEL could not be deemed protective of workers against cancer.

As shown on the DuPont copy of the February 2, 1995 submission, DuPont provided copies of the submission to Reinhardt and Dawson. See Ex. 3. The Agency's Section 8(e) homepage states:

The discovery of previously unknown and significant human exposure to a chemical, when combined with knowledge that the subject chemical is recognized or suspected as being capable of causing serious adverse health effects (e.g., cancer, birth defects, neurotoxicity), should be reported to EPA under §8(e).

It is anticipated that DuPont will raise two arguments to excuse its failure to report Nelson's finding under Section 8(e).

First, it is anticipated that DuPont will argue that Nelson's calculations were not relevant outside of DuPont and lacked any scientific basis. However, Nelson followed the same formula devised by J. A. Williamson, the scientist who conducted the underlying research at DuPont's Haskell Laboratory. Williamson published his findings in an article entitled the "Development of a biomonitoring assay for ortho-toluidine or its metabolites in human urine," which appeared in the July/August 1995 edition of the Journal of Analytical Toxicology, a peer-reviewed international toxicology journal. See Ex. 20. However, Williamson failed to include the critical data pertinent to ortho-toluidine. As stated above, Nelson based his calculation on "[u]npublished Haskell data" that "o-toluidine was about 8% of the metabolite" in the urine excreted in the first 12 hours after exposure. See Ex. 2.

One court has held that

[u]nder the plain language of the statute, a manufacturer's "belief" about the quality of a study plays no role in determining whether it should have been reported. The only question is whether the study "reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment."

In re Methyl Tertiary Butyl Ether ("MTBE") Products Liab. Litig., 559 F.Supp.2d 424, 438 (S.D.N.Y.2008).

Second, it is anticipated that DuPont will argue that as of 1993 that there was no scientific basis to associate any urinary concentration of ortho-toluidine with any excess risk of bladder cancer. However, the Agency had previously ruled that a

person is not to delay reporting until he obtains conclusive information that a substantial risk exists, but is to immediately report any evidence which "reasonably supports' that conclusion.

Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk, 43 Fed. Reg. 11112 (Mar. 16, 1978).

If such an argument had any credence, it evaporated on December 24, 2013 with the on-line publication of a second NIOSH epidemiological study of bladder cancer incidence at the Goodyear plant. See Carreón T, Hein MJ, Hanley KW, Viet SM, Ruder AM, Bladder cancer incidence among workers exposed to o-toluidine, aniline and nitrobenzene at a rubber chemical manufacturing plant, *Occup Environ Med* 71(3): 175-182 (2014), attached at Ex. 21 (hereinafter, "Carreon (2014)"). This study expanded the 1988 Goodyear cohort assembled by NIOSH and updated its bladder cancer incidence through 2007. The Carreon study recorded fifty cases of bladder cancer.

Carreon estimated bladder cancer risk based on "cumulative relative exposure ranks" developed by another team of NIOSH scientists in Hanley KW, Viet SM, Hein MJ, Carreón T, Ruder AM, Exposure to o-toluidine, aniline, and nitrobenzene in a rubber chemical manufacturing plant: a retrospective exposure assessment update, *J Occup Environ Hyg* 9(8): 478-490 (2012), attached at Ex. 22, (hereinafter, "Hanley (2012)").

Hanley performed an exposure assessment revision to the prior studies of the Goodyear plant by assigning an approximate rank of relative exposure level for each department-job-year combination using a ranking scale of 0 to 10. "The assigned rank multiplied by duration (recorded in days) yields a cumulative exposure score for the worker's duration of employment." Id. at 487. For the time period of 1990, Hanley assigned an exposure rank of 8 to workers performing the "rubber chemicals jobs." Id. at 486. The workers in the rubber chemicals jobs were the same group of workers whose urine was sampled and reported in the 1992 NIOSH report.

According to the mathematical formula devised by Hanley and Carreon, a cumulative exposure score for a worker holding a rubber chemical job in 1990 can be determined by multiplying 365.25 calendar days per year by the exposure rank of 8. The result is 2,922 unit-days of exposure per year. See Ex. 21 at 180, Table 3. Based on Table 2 of Carreon (2014), it would only take 5.13 years of exposure at rank 8 to achieve a doubling dose of cancer risk with a SIR of 2.33, which is statistically significant, 95% CI: 1.01 to 4.59 (15,000 unit-days in the unlagged cumulative rank quartile, divided by 2,922 equals 5.13). See Ex. 21 at 179.

In prior litigation, DuPont has contended that Hanley (2012) and Carreon (2014) are “the only reliable and relevant studies for assessing” bladder cancer risk among the workers at the Goodyear plant because they are “the culmination of NIOSH’s investigation of exposure and bladder cancer risk at the Goodyear plant.” See Sarkees v. E. I. du Pont de Nemours and Company, et al., C. A. No. 17-CV-651-JLS-HBS, United States District Court for the Western District of New York, Dkt. No. 75 at 34 and Dkt. No. 84 at 16.

Accordingly, from April 24, 2018 to the present, DuPont has willfully violated 15 U.S.C. § 2614 due to its continued failure to inform the Administrator of the substantial risk of injury to health, because as of April 24, 2018:

- DuPont was on notice of this violation by Plaintiff Douglas J. Moss in a pleading filed in the United States District Court for the Western District of New York in the matter of Moss v. E. I. du Pont de Nemours and Company, et al., at C. A. No. 16-CV-539-LJV-HKS (Ex. 5);
- the depositions of Thomas J. Nelson and Barbara J. Dawson had been completed (Exs. 11 and 18); and,
- Hanley (2012) and Carreon (2014) had been published and obtained by DuPont (Exs. 22 and 21).

Conclusion

Ortho-toluidine is considered to be high-production-volume chemical, based on its importation into the United States in quantities of tens of millions of pounds per year. See https://chemview.epa.gov/chemview. The NIOSH National Occupational Exposure Survey (NOES) conducted between 1981 and 1983 estimated that about 30,000 workers were potentially exposed to ortho-toluidine at that time. See Ex. 23, NTP Report on Carcinogens Monograph on Ortho-toluidine, (2014) at 9.

The Agency has stated that one of the uses of information submitted under Section 8(e) is to “to provide a mechanism for the timely and prioritized dissemination of new information on chemical hazards” to OSHA so that agency can “determin[e] the need for new OSHA workplace standards or revis[e] existing workplace standards.” 1991

Reporting Guide at 18.

The OSHA permissible exposure limit of 5 parts per million does not protect workers against the carcinogenic effects of ortho-toluidine. DuPont's own research proves that legal exposure at 5 ppm is a lethal level of exposure. Governmental action to protect workers should have occurred a long time ago. DuPont's failure to make an adequate and timely reporting under Section 8(e) has contributed to this delay.

On at least four prior occasions, with respect to other chemicals, the Agency has found DuPont in violation of Section 8(e) and that the corporation committed unlawful acts under 15 U.S.C. § 2614. The Agency has obtained more than \$13 million in penalties from DuPont.

There is a direct connection between DuPont's failure to abide by this statute and the continuing cases of bladder cancer in the Goodyear workers in Niagara Falls, New York. We urge the Agency to enforce this statute to its full extent against DuPont by commencing an action within the next sixty days pursuant to 15 U.S.C. § 2619(b)(1)(B). However, if no action is taken by the Agency, we will proceed as permitted by 15 U.S.C. § 2619(a)(1). Please let me know if you have any questions or need any further information.

Sincerely yours,

[REDACTED]
Steven H. Wodka

enc: DVD "Exhibits to Wodka letter to Administrator"