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Re: Guidance on Notification Requirements for Spills, Discharges, and other Incidents of a Substance Causing or Threatening Pollution to Waters of the Commonwealth Under Pennsylvania's Clean Streams Law (DEP ID: 383-4200-003): Comments of Merck Sharp & Dohme Corp. ("Merck")

Via eComment: www.ahs.dep.pa.gov/eComment or via e-mail to ecomment@pa.gov

Dear Ms. Shirley,

Merck Sharp & Dohme Corp. ("Merck") appreciates the opportunity to submit these comments on draft Technical Guidance Document No. 383-4200-003 (the "Draft Guidance") published in the Pennsylvania Bulletin, 50 Pa.B 4091 (August 8, 2020).

1. The Draft Guidance Would Perpetuate Uncertainty Regarding Whether A Spill Must Be Reported.

The current spill reporting regulation, 25 Pa. Code § 91.33(a), requires reporting of pollution and threatened pollution. It does not, however, provide any standards from which to determine whether an accidental spill has caused or threatened pollution. The uncertainty created by the absence of a clear standard informing the regulated community and the public which spills must be reported creates a compelling need for clarification of the spill reporting rule.

On its face, the language of Section 91.33(a) requiring reporting of spills that cause or threaten pollution would appear to require reporting only of spills of substances in quantities or with toxicity or other characteristics that pose a threat of harm. But to date, the Pennsylvania Department of Environmental Protection ("PADEP") has taken conflicting positions on whether spills posing no threat of harm must be reported to PADEP, and has not established a clear, workable spill reporting standard. As

a result, PADEP has applied spill reporting obligations across the Commonwealth in an inconsistent manner.

Unfortunately, rather than offer clear guidance on this key issue, the Draft Guidance merely recites the language of Section 91.33(a), thereby offering little of practical value. Whether a spill that is considered benign in light of its quantity, toxicity, and other characteristics must be reported is unstated. Merck recommends that PADEP clearly state that pollution or threatened pollution does not occur in the absence of harm or threatened harm. Merck further recommends that PADEP articulate clear standards for determining whether harm has occurred or is likely to occur. Indeed, as discussed herein, commencing with the amendments to The Clean Streams Law in 1945, setting such standards is precisely what The Clean Streams Law has continuously directed PADEP (and its predecessor agency) to do.

In these comments, Merck will explain why to comply with the General Assembly's directive to PADEP in The Clean Streams Law, an amendment to Section 91.33(a), not a technical guidance document, is the proper approach to clearly informing the regulated community and the public of their spill reporting obligations. Merck will also suggest a workable standard to reduce the uncertainty and inconsistency in how legal requirements are stated and applied. If PADEP rejects Merck's request for a regulatory change and instead proceeds by guidance, then at a minimum the suggestions in these comments should be incorporated in the guidance.

2. 78Clear, Practical and Environmentally Protective Standards Are Needed to Guide the Spill Reporting Obligations of Owners and Operators of Businesses in the Commonwealth Such as Merck.

For more than a century, Merck has been a global health care leader. Merck manufactures prescription medicines, vaccines, biologic therapies, and animal health products to deliver innovative health solutions to consumers in more than 140 countries. We also demonstrate our commitment to increasing access to health care through far-reaching policies, programs, and partnerships. Corporate responsibility is at the heart of our company's mission to discover, develop and provide innovative products and services that save and improve lives. It underscores our commitment to developing and

rewarding our employees, protecting the environment, and operating with the highest standards of ethics and transparency.

Merck's West Point Facility ("Facility") in Montgomery County, Pennsylvania serves as a principal location for pharmaceutical and vaccine research and development, and for the manufacture of vaccines and other biologics. Among the vaccines manufactured are measles, mumps and rubella (M-M-R® II) and varicella (VARIVAX®) vaccines, human papillomavirus (HPV) 9-valent vaccine (Gardasil® 9), rotavirus vaccine (Rota Teq®), hepatitis B vaccine (RECOMBIVAX HB®) and pneumococcal vaccine (PNEUMOVAX 23®).

The Facility consists of about 100 buildings situated on a 400-acre campus and employs approximately 7,000 people in Pennsylvania. The heating and cooling system used at the Facility provides a good illustration of the extensiveness and complexity of operations. Temperature control is provided in part by a closed-loop chilled water system consisting of, among other equipment, eight chiller plants, numerous building-specific air handling units and approximately twenty-five miles of external chilled water piping. The chilled water/cooling tower operation removes over 85 million ton-hours, or 1.02 trillion BTUs, of heat from Merck buildings each year. Cooling towers evaporate over 200 million gallons of water each year to keep Merck's buildings and vital research and production processes cool. Merck also owns and operates a pharmaceutical manufacturing facility in Riverside, Northumberland County, Pennsylvania which likewise conducts complex operations.

Despite stringent procedures and controls in place at the Facility, on rare occasions a spill may occur which may pose a threat of harm to a water of the Commonwealth. Upon discovery of any such release at the Facility, Merck's trained environmental, health and safety professionals immediately employ the Facility's Environmental Emergency Response Plan to assess the threat posed by the spill and make any necessary notifications to PADEP and others. In light of their familiarity with the materials, environmental controls and systems utilized at the Facility, and their qualifications to evaluate the potential effects of a spill, in most instances these professionals can quickly determine whether a genuine threat of harm exists.

More commonly, in light of the size and complexity of the Facility and the large number of people employed, releases from various sources occur that plainly pose no threat of harm. For example, spills

may consist of drops of motor oil discharged from one or more employee or commercial vehicles, remnants of cut grass or a lawn fertilizer falling on a roadway, or small amounts of cooling water or chilled water that may drip or discharge from an outside valve subjected to the winter freeze-thaw cycle. These releases pose no threat of harm due to their small size, low toxicity, and other characteristics, and the ability of Merck's stormwater management system to capture them at the discharge location or contain them in a detention basin. It would be impossible for Merck to discover and report each such release internally or to PADEP.

Merck's situation is not unique. Although Merck's facility is larger and more complex than many, thousands of facilities across the Commonwealth ranging from industrial manufacturers to gas stations experience small, benign spills daily. Homeowners do as well. Requiring each facility and homeowner to report every spill would create an overwhelming administrative burden on PADEP without any environmental benefit. A clear standard focused on harm and injury to the waters of the Commonwealth is needed to distinguish spills causing or threatening "pollution" from those that do not.

3. Merck Recommends that to Comply with the Mandate of The Clean Streams Law, PADEP Establish Standards for Determining Whether A Spill Constitutes Pollution by Adopting a Regulation following the Public Notice and Comment Process.

The Pennsylvania Clean Streams Law, 35 P.S. § 691.1 et. seq. ("The Clean Streams Law" or "CSL"), does not contain a reporting requirement. The obligation to report spills is set forth in 25 Pa. Code § 91.33(a), which uses the term "pollution," but does not define it.

The term "pollution" is defined in Section 1 of the CSL. The statutory definition identifies various scenarios that "will create or [are] likely to create a nuisance or render such water harmful, detrimental or injurious."¹ By using the words "harmful, detrimental or injurious," the General Assembly made clear that

¹ The definition of "pollution" in Section 1 of the CSL provides: "Pollution" shall be construed to mean contamination of any waters of the Commonwealth such as will create or is likely to create a nuisance or to render such waters harmful, detrimental or injurious to public health, safety or welfare, or to domestic, municipal, commercial, industrial, agricultural, recreational, or other legitimate beneficial uses, or to livestock, wild animals, birds, fish or other aquatic life, including but not limited to such contamination by alteration of the physical, chemical or biological properties of such waters, or change in temperature, taste, color or odor thereof, or the discharge of any liquid, gaseous, radioactive, solid or other substances into such waters. The department shall determine when a discharge constitutes pollution, as herein defined, and shall establish standards whereby and wherefrom it can be ascertained and determined whether any such discharge does or does not constitute pollution as herein defined. 35 P.S. § 691.1 (definition of "pollution").

only the discharges causing harm, or those interfering with the public's use of the waterbody (a nuisance), result in "pollution." Had the General Assembly intended all discharges of any substance to constitute "pollution," it would have used very different language.² See *also*, Section 501 of The Clean Streams Law authorizing PADEP to promulgate regulations prohibiting pollution of domestic water supplies rendering them "inimical and injurious."

Not only does the definition of "pollution" require harm, it also directs PADEP to specify standards for determining when a harm constitutes "pollution." The definition of pollution provides in part: "**The department shall... establish standards** whereby and wherefrom it can be ascertained and determined whether any discharge does or does not constitute pollution as herein defined." (emphasis added). In other words, not every discharge is pollution, and PADEP is directed to establish standards by which polluting discharges and non-polluting discharges may be distinguished. The binding standards necessary to fulfill the legislative mandate must be established through regulation. A guidance document which does not carry the force of law does not establish enforceable standards. For this reason, a regulation, not a guidance document, should be promulgated.³

In addition, unlike a guidance document, a regulation would create a uniform requirement throughout the Commonwealth. Businesses and the public rarely report minor spills. To do so would subject them to enforcement by PADEP, EPA and citizens, even though the CSL neither considers these spills to constitute pollution nor requires them to be reported. Yet PADEP responds inconsistently to this practice. As an illustration, PADEP's Southeast Regional Office ("SERO") instructed Merck to report all spills regardless of quantity, toxicity or potential to cause harm. Merck is unaware of any other company being similarly instructed. Even though SERO's untenable interpretation conflicts with PADEP's existing

² The 1970 Amendment to the CSL expanded the types of harms encompassed by the term "pollution." Significantly, the General Assembly chose to expand, not eliminate, the element of harm.

³ As noted above, although Merck strongly encourages PADEP to proceed with public notice and comment rulemaking, if PADEP rejects this approach, Merck suggests that the changes recommended in these comments be incorporated into the Draft Guidance.

guidance (the Spill Fact Sheet), SERO does not follow this guidance.⁴ A regulation would eliminate this lack of uniformity and the risk of arbitrary enforcement.

4. A Spill Reporting Standard Should be Based on the Threat Posed by a Spill to the Uses of the Receiving Waters.

Ample precedent exists for establishing a standard for pollution, and thereby for reporting pollution, tied to the potential effect of a spill on the uses of the receiving waterbody. In *People United to Save Homes*, 1999 EHB 457, *aff'd*, 789 A.2d 319 (Pa. Commw. Ct. 2001) (“PUSH”), based on PADEP’s brief and argument, the Pennsylvania Environmental Hearing Board held that pollution does not occur absent an adverse impact upon “uses” of the waters of the Commonwealth. 1999 EHB at 562. On appeal, PADEP continued to assert that pollution occurs only when the uses of the waterbody are adversely affected. The Commonwealth Court agreed: “Because the Clean Streams Law requires that pollution affect the ‘uses’ of the water and the EHB clearly applied that standard, PUSH’s argument is without merit.” 789 A.2d at 329. *Accord*, *UMCO Energy, Inc. v. DEP*, 2006 EHB 489, *aff'd*, 938 A.2d 530 (Pa. Commw. Ct. 2007).⁵

Accordingly, Merck recommends that PADEP clearly state that pollution or threatened pollution occurs, and must be reported, only when there is an actual or threatened adverse impact to uses of the waters of the Commonwealth.

5. PADEP Should Utilize its Water Quality Criteria as the Standard for Determining Whether a Spill Constitutes or Threatens “Pollution” and Must Be Reported.

As discussed above, Pennsylvania courts and the Environmental Hearing Board have held that discharges that do not interfere with the uses of a waterbody do not constitute pollution. PADEP’s regulations have established water quality standards which are based on water uses to be protected.

⁴ See deposition testimony of Jennifer Fields, former manager of water programs in SERO, in *Merck Sharp & Dohme Corp. v. PADEP*, EHB Docket No. 2015-001-L.

⁵ In contrast, in a case involving Merck, PADEP contended that any discharge of any substance to a waterbody causes pollution regardless of any resulting harm or threatened harm. *Merck Sharp & Dohme Corp. v. PADEP*, EHB Docket No. 2015-001-L. In that case, PADEP stated that it could not approve Merck’s proposed spill reporting criteria contained in its Environmental Emergency Response Plan which provides for the evaluation of spills using federal and state standards and other clear criteria. The Environmental Hearing Board declined to resolve the dispute over the meaning of “pollution” under the circumstances of that case.

See 25 Pa. Code § 93.2. In addition to designated uses for each waterbody, PADEP's regulations also establish water quality criteria to protect the designated uses. 25 Pa Code § 93.3. These criteria may be numeric or narrative. See 25 Pa. Code §§ 93.6 and 93.7.⁶

Utilizing water quality criteria as the standard for spill reporting would serve multiple purposes. First, it would satisfy the CSL statutory mandate that PADEP "establish standards whereby and wherefrom it can be ascertained and determined whether any such discharge does or does not constitute pollution as herein defined." CSL § 1, 35 P.S. § 691.1 (definition of "pollution").

Second, use of water quality standards would implement the statutory definition of "pollution" in accordance with the holding in the *PUSH* case discussed above. Because "pollution" requires an interference with the uses of a waterbody, the water quality standards establishing the uses and the criteria necessary to protect them are directly relevant. PADEP utilizes water quality criteria in its wastewater discharge permitting program to establish water quality based effluent limitations. These criteria are equally applicable to spill reporting.

Finally, employing water quality criteria as the threshold for determining whether pollution has occurred would provide a workable standard offering far greater clarity to the regulated community and the public than the current regulation, facilitate uniform administration of the CSL, and serve as a practical tool to inform decisions on whether a spill must be reported.

6. PADEP Should Follow the Lead of Other Jurisdictions Who Establish Clear, Numeric Criteria for Spill Reporting by Employing Water Quality Criteria or Reportable Quantities as the Applicable Standards.

Unlike PADEP which to date has not adopted clear, workable, and uniform reporting standards, other jurisdictions have adopted practical numeric criteria to significantly reduce the uncertainty over whether a spill must be reported. They require reporting of spills only when they will cause a violation of water quality standards or exceed other specific thresholds. For example, at least two states utilize their water quality standards as thresholds for spill reporting. See Mont. Admin. R. 17.30.104-5 (Montana) and

⁶ Narrative criteria include, among others, the discharge of substances "in concentrations or amounts sufficient to be inimical or harmful to the water uses to be protected or to human, animal, plant or aquatic life. 25 Pa. Code §93.6(a).

S.C. Code Ann. Regs. 61-68(E)(4)(b) (South Carolina). Merck recommends this approach as most consistent with the language and objectives of the CSL.

Other jurisdictions utilize reportable quantity thresholds. Pursuant to Section 311 of the Federal Water Pollution Control Act, 33 U.S.C. § 1321, EPA has published reportable quantities for hazardous substances, 40 C.F.R. Part 117, and requires discharges of hazardous substances in excess of their reportable quantities to be reported. 40 C.F.R. § 117.21. See *also* 40 C.F.R. Part 302 (establishing reportable quantities under § 102 of the Comprehensive Environmental Response and Liability Act, 42 U.S.C. § 9602).

Various states have followed the federal model, at times substituting their own reportable quantities as reporting thresholds. See, *e.g.*, 7 Del. C. 1953, 6028 (Delaware), Fla. Admin. Code Ann. r. 62-150.300 (Florida), Haw. Rev. Stat. § 128D-3 (Hawaii), Ill. Admin. Code t.t. 29 § 430.30(a) (Illinois), Mich. Admin. Code r. 324.2007 (Michigan), Or. Rev. Stat. § 466.635 (Oregon), 30 Tex. Admin. Code § 327.3 (Texas), Md. COMAR 26.10.08.04B (Maryland). New York establishes reportable quantities and adds danger of fire, explosion or illness. N.Y. Comp. Codes R. & Regs. tit. 6, §§ 597.3 and 597.4(b)(1). At least two states use both reportable quantities and health and safety thresholds. See, *e.g.*, Ky. Rev. Stat. Ann. § 2241.1-400(4)-(7) (Kentucky), Wis. Admin. Code NR 706.05-706.07 (Wisconsin).

The lack of clarity in Pennsylvania's spill reporting requirements puts Pennsylvania at a competitive disadvantage with each jurisdiction employing clear thresholds and provides Pennsylvanians with no offsetting environmental benefit. Adopting water quality criteria (or reportable quantities) as the spill reporting standard offers the best opportunity for PADEP to become compliant with the CSL and consistent with the spill reporting requirements of other states.

Merck appreciates the opportunity to submit these comments.

Sincerely,



Cassie Gaudiosi
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