pennsylvania
DEPARTMENT OF ENVIRONMENTAL PROTECTION

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION

COVID-19-Emergency Request to Temporarily Suspend Regulatory Requirements and/or Permit Conditions

In accordance with Governor Wolf's Proclamation of Disaster Emergency of March 6, 2020 and the Governor's powers pursuant to the Emergency Management Code, 35 Pa.C.S. §7301, the Governor has authority to suspend regulatory obligations and other legal obligations within his jurisdiction where strict compliance will prevent, hinder, or delay necessary action in coping with the COVID-19 emergency.
*If you are requesting suspension of a Federal requirement, under only Federal authority, please contact US EPA Region III and refer to the US EPA March 26, 2020 Memorandum (COVID-19 Implications for EPA's Enforcement and Compliance Assurance Program). To the extent the request relates to a federal program delegated to Pennsylvania, Pennsylvania will review requests submitted in this format.

Submit completed and signed requests to the email resource account:
RA-EPCOVID19SuspReq@pa.gov

Background
A. Identify the Regulated Entity or Permittee, including an address for the location of the permitted or regulated activity (if no address, DEP Permit No. can be used), and a point of contact for this request with email and phone number. Sanofi Pasteur, Discovery Drive, Swiftwater, PA 18370-0187, aka "Sanofi" Technical Contact: Jeffery Smith, Deputy Director HSE | jeffery.smith2@sanofi.com Office (570) 957-3871 | Cellular (570) 269-4260
B. Describe what permitted or regulated activity you are engaged in. Sanofi Pasteur manufactures and distributes vaccines for use in humans against a number of deseases, including: Influenza, Diphtheria, Meningitis, Pertussis, Tetanus, and Yellow Fever. The facility, which is located on Route 611 in Swiftwater, Monroe County, Pennsylvania, is owned by parent company, Sanofi, headquartered in Paris, France. The Swiftwater site employs approximately 2500 employees and several hundred contractors and temporary workers. The property is divided into "Main Campus" and "South Campus" totaling nearly 600 acres with over 50 structures. Operations on Main Campus include research, manufacturing, formulation, filling, inspection and packaging. As part of these activities, reguated medical waste (RMW) is generated; some of which is decontaminated on-site. The focus of this request, are the processes and inactivation activities for RMW related to supporting R&D vaccine development for SARS-CoV-2, aka corona virus - the visrus that causes COVID-19.
C. If you were issued a permit by DEP for the permitted or regulated activity described above, identify the type of permit and permit number. Please list the DEP Office, Conservation District, Oil and Gas District Office, or District Mining Office that issued the permit or authorization. The site operates in agreement with a number of PADEP issued permits. Of particular interest to this request is the General Permit for Processing/Disinfection of Regulated Medial Waste - WMGI005D003 (Date Issued: July 27, 2017). This permit was issued by the Department's Bureau of Waste Management, Division of Municipal and Residual Waste; with oversight by both the Central (Harrisburg) and Northeast Regional (Wilkes-Barre) offices. However, this current general permit and associated

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Facility Specific Reference Table for processing of RMW does not encompass the specific inactivation procedures discussed here-in.

D. Identify what regulatory requirement(s) or permit condition(s) or other requirement(s) you seek a temporary suspension of. Please cite the specific regulatory requirement(s), condition(s) and/or other requirement(s).
Sanofi requests suspension of requirements of 25 Pa. Code Chapter 284 as it relates to the inclusion of additional facility specific conditions into the existing site permit. To this end, Sanofi seeks authorization prior to obtaining the approval of the amended permit for chemical and/or thermal inactivation to satisfy disinfection requirements (as detailed in the specified regulated medical waste requirements). Sanofi will continue to use qualified and scientifically valid decontamination processes that are equally effective as current operating procedures for these requested activities.

This request is for the immediate approval of activities as detailed in the forthcoming addendum to the Facility Specific Reference Table for processes and inactivation activities for RMW related to supporting R&D vaccine development for SARS-CoV-2, aka corona virus - the visrus that causes COVID-19.

[NOTE: This addendum is being separately transmitted to Bureau of Waste Management staff within the Department's Central and Northeast Region offices.)

Reasons for Requested Suspension

For each regulatory requirement or permit condition or requirement listed above, please state clearly why you are seeking the temporary suspension, addressing at least the following in detail:

A. How will strict compliance with the subject requirement(s) prevent, hinder, or delay necessary action in coping with the COVID-19 emergency? Be as specific as possible.
Not being able to secure the requested suspension of the applicable regulations will likely delay and/or lead to greater risks in the anticipated COVID-19 vaccine development research activities. With the requested expedited approval of the amended facility specific general permit conditions, Sanofi will be allowed to implement necessary viral inactivation practices for the management of regulated medical wastes generated from future COVID-19 clinical studies. The temporary suspension will not apply to non-COVID-19 related wastes.

B. How has COVID-19 restricted your ability to comply with the environmental regulatory requirement, permit condition or other requirements for which you are seeking a suspension?
Critical need and timing does not allow for completion of normal processing of the permit application.

C. What other aspects or parts of your operation(s) are being shut down or are not functioning due to the COVID-19 restrictions? And, are you requesting any

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suspensions or waiver(s) from other government agencies? If so, from what agencies and for what requirements? N/A
D. What alternate compliance options have you explored to address the issues or environmental compliance hurdles with which you are confronted? The primary alternative compliance option is not to undertake the planned research & development activities for the purposes of supporting world-wide efforts in the licensure of a vaccine for SARS-CoV-2, aka corona virus - the visrus that causes COVID-19.
E. Do you believe cost gouging or supply hoarding is negatively effecting your ability to comply? If so, please explain and provide cost information and/or availability information from your supply chain history. N/A
F. How long do you expect to be unable to comply with the regulatory requirement(s), permit condition(s) or other requirement and identify what circumstances must exist for you to return to compliance. Specify the period of time for which you are requesting the suspension. Suspensions will not be issued initially beyond June 30, 2020. As discussed with representatives from PADEP in conference on 03 Apr 2020, suspension of permit requirements for work with COVID-19 should be extended/continue until such time as the associated permit modification request (transmitted to PADEP on 19 Mar 2020) is approved.
G. If applicable, identify how you will account for all reporting obligations for the period of noncompliance. Sanofi will continue to operate within the terms of the existing infectious waste general permit as it regards recordkeeping and reporting. Compliance with these existing conditions will continue.

Evaluate Risk to Public Health and the Environment
A. Will the temporary suspension, if granted, result in an increase in the risk of additional pollution (e.g. increased emissions, increased concentrations of any pollutant and/or releases of new or more pollutants) and/or will it result in less monitoring, reporting, and/or supervision of pollution incidents, accidents or equipment failures? No
(i) If yes, please identify what pollutants and the nature of the risk.

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(ii) If yes, please identify the potential extent of increased pollution, including any increases in risk to human health, safety or the environment.

(iii) If no, explain how increased pollution will be avoided.
Use of the designed and qualified viral inactivation systems will minimize the risk to both employees and the general public. By allowing use of such systems, including the effluent decontamination system and decontamination autoclaves, Sanofi will be able to safely process the expected quantities of generated COVID-19 related waste (both solids and liquids).

B. What public health and/or safety benefits will result if the temporary suspension is granted?
Use of the designed and qualifed viral inactivation systems will minimize the risk to both employees and the general public. Completion of the planned vaccine activities will have a significant impact on the nation's health and safety while contributing to worldwide efforts to develop a vaccine for the prevention of COVID-19.

C. Is the restriction on your ability to comply generally applicable to others engaged in your industrial classification or industry? If no, please explain why your situation is unique.
N/A - limited number of facilities with the capabilities required.

D. Would you possess a unique advantage over your competitors, or others in the same industry, if a suspension is granted?
N/A

E. What would be the negative consequences to your operation if the temporary suspension is not granted? What would be the negative consequences to the Commonwealth's response to the COVID-19 emergency if your requested temporary suspension is not granted?
Denial of the approval for suspension of the noted regulatory requirements will significantly limit Sanofi's ability to achieve the mission to reduce or eliminate suffering for millions around the world through vaccination. Timely progress for the completion of planned clincal studies will contribute to vaccine development that is of importance for the Commonwealth and nation.

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CERTIFICATION

Pursuant to the prohibition against unsworn falsification to authorities, 18 Pa.C.S.A. §4904, I am an authorized representative of the requestor and have personal knowledge of the facts set forth in this temporary suspension request.

I hereby certify that the information provided herein is true and accurate.

Mark Nemitz, Sr. Director HSE

Signature and title of Certifier

Mark Nemitz, Sr Director HSE

Print Name and Title

Note: Electronic signatures are not accepted.

Submit completed and signed requests to the email resource account:
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