State of New Jersey

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RESPONSE TO COMMENTS DOCUMENT

Discontinuation of GP-020 for Research and Development

On July 19, 2021, the Department's Notice of Opportunity for Public Comment on Discontinuation of General Permit GP-020 for Research and Development was published in the New Jersey Register. 53 N.J.R. 1231(a). The comment period was open until September 17, 2021. Written comments on the discontinuation of General Permit (GP) 020 (GP-020) were received from the following:

1. Michael C. Babos, Associate Director, Merck Kenilworth Safety and the Environment
2. Diann Deal, Project Engineer, Weston Solutions, Inc.
3. Dennis Hart, Executive Director, Chemistry Council of New Jersey (CCNJ)
4. Yuk M. Louie, R&D Operations Manager, Exxon Mobile Research and Engineering, Clinton Facility
5. Dean J. Paranicas, President and Chief Executive Officer, HealthCare Institute of New Jersey
6. Bill Wolfe

Comments received and the Department's responses are summarized below.

General

1. Comment: The Department should not discontinue GP-020. Although the number of facilities that hold a GP-020 may be small, the GP-020 is extremely important to the R&D industry. GP-020 has given industry the flexibility needed for effective research operations, which require the ability to quickly adopt new technologies and techniques, while ensuring compliance with the State's laws and regulations. GP-020 was made available based in part on the recognition of the vital role that research plays in the State's economy. Discontinuing GP-020 would be a significant action that could delay research and development progress in the State. (1, 2, 3, 4, 5)

2. Comment: In proposing to discontinue GP-020, the Department did not properly evaluate the performance of the existing program in meeting the Department's goals while allowing operational flexibility in R&D facilities, which is critical in developing life-saving and life-enhancing products. Nor did the Department consider alternative approaches or conduct a risk-benefit analysis of the significant changes proposed. The Department should reconsider its proposed discontinuation and instead, propose revisions to its existing GP-020 program to address any concerns. (1, 3, 4, 5)

3. Comment: The Department's justifications for the proposed discontinuation of GP-020 support amending, not removing, the GP-020 program. The Department should propose revisions to the existing GP-020 that resolve the regulatory deficiencies outlined and make the changes effective for facilities with an existing GP-020 at the time of renewal. (1)

4. Comment: The Department and local industry collaboratively developed GP-020 more than 15 years ago to give industry necessary operational flexibility for R&D operations, such as short durations, variable configurations, and confidentiality of processes and raw materials,

while protecting public health. GP-020 streamlines the permitting process while authorizing relatively small emissions levels, effectively avoiding hundreds of unnecessary traditional permits and ineffective permitting actions each year.

Rather than discontinue GP-020 and require R&D facilities to apply for a preconstruction permit (PCP), which requires a case-by-case review, the Department should revise GP-020 with updated rule citations and any revised hazardous air pollutant (HAP) emission limits deemed necessary through a transparent stakeholder process. Alternatively, the Department should consider a subchapter 8 R&D documented permitting procedure that effectively provides the same conditions and flexibility as the GP-020 with a simplified health risk assessment process for HAPs above reporting thresholds. Requiring R&D facilities to obtain a PCP permit will not provide any additional environmental benefit or emissions reduction, and in fact could lead to an increase in allowable emissions because sites may need to account for a wider range of potential R&D activities over a longer period of time. The Department will also expend time and resources in reviewing multiple PCP applications, which could be utilized on other environmental initiatives with a larger impact to the State's residents and environment. (3, 4, 5)

5. Comment: GP-020 provides critical flexibility and predictability for the R&D industry, while providing appropriate environmental and health protections. Discontinuing GP-020 would result in unjustified administrative burdens and delays. The Department should withdraw its proposal and consult with stakeholders on a path forward. (5)

   Response to Comments 1 through 5: The Department acknowledges and agrees with the importance of research and development operations to the State, and that one reason the Department developed GP-020 was to give the R&D industry the simplicity and flexibility needed for their operations, while protecting public health and the environment. However, as explained in the notice, GP-020 is outdated and therefore no longer includes the conditions necessary to protect public health and safety and ensure compliance with the Department's current rules. As a result, GP-020 will not be renewable on or after May 16, 2022, when the notice of discontinuation and administrative change is published in the New Jersey Register. A current permit holder may continue to operate under its GP-020 until it expires or until a source registered in its GP-020 is replaced or modified, whichever occurs earlier.

   The Department has already engaged stakeholders in developing a new general permit for R&D, which the Department anticipates being available for public comment in summer 2022, in accordance with N.J.A.C. 7:27-8.8(m). The Department will review all comments received and take final action, as the Department determines is appropriate, as expeditiously as possible. If the Department finalizes a new general permit, based on the Department's records, the Department does not expect a gap between the date a current GP-020 expires, and the date a new general permit for R&D would be available.

6. Comment: The Department did not explain why the Department is proposing to rescind GP-020 rather than amend the GP-020 requirements to incorporate the new regulatory requirements. The Department also did not indicate which regulatory language will be changed to facilitate the change proposed. (1)

Response: As explained in Response to Comments 1 through 5, the Department is developing a new general permit for R&D, after discussions with stakeholders. By discontinuing GP-020, owners/operators who hold a GP-020 are allowed to operate under its GP-020 until it expires, or until a source registered in its GP-020 is replaced or modified, whichever occurs earlier. The Department is not rescinding any currently held GP-020. Rather, discontinuation of GP-020 means it is no longer available for renewal and as provided in the notice of administrative change published in the May 16, 2022 New Jersey Register, N.J.A.C. 7:27-8.8(c)19 has been deleted.

7. Comment: The Department did not engage with holders of GP-020 at any time leading to its decision to move forward and publish its proposal to discontinue GP-020. The Department's only engagement with stakeholders was during the February 5, 2021 Industrial Stakeholder Group (ISG) meeting, at which time concerns were raised and the Department was requested not to take any final action on GP-020 until discussion of alternatives could take place. The Department did not hold any subsequent formal stakeholder meetings with permittees and impacted industries prior to publishing its notice. (3, 5)

   Response: The Department disagrees with this comment. The Department also briefed stakeholders at the June 4, 2021 ISG meeting about the Department's intent to propose discontinuing GP-020, and the proposed discontinuation was discussed at the October 1, 2021 ISG meeting. The Department also separately met with representatives of the R&D industry to discuss their concerns prior to taking this final action.

Health risk from all HAPs consistent with the new reporting thresholds and new risk factors

8. Comment: In the notice of proposed discontinuation, the Department stated that GP-020 does not address health risk from all HAPs consistent with the new reporting thresholds and new risk factors. Every GP-020 must contain a limitation of total HAPs with the maximum amount allowed of 5 tons per year. Each GP-020 also requires annual reporting of HAP emissions from any equipment operated under the GP-020. These emissions show that R&D operations that currently operate in the State and hold a GP-020 are small-scale in nature with extremely low HAP emissions, and do not use the most toxic chemicals on the health risk list. Therefore, these operations do not demonstrate an unacceptable health risk. (1, 2, 3, 4, 5)

9. Comment: In addition to the low HAP emissions from R&D operations, R&D facilities also have Best Management Practices (BMPs) and other protections in place to ensure their operations are not impacting public health. (3, 4, 5)

10. Comment: R&D facilities with a GP-020 calculate their emissions to ensure that total permitted emissions are not exceeded. Facilities also certify their emissions annually. (2, 4)

11. Comment: In developing GP-020, the Department performed a risk assessment and included a method in GP-020 to ensure that the risk assessment remains valid. See GP-020, Section VI, Table 3, which contains limits for over 40 toxic compounds. Although the Department

may need to update Table 3 and conduct a risk assessment again, this does not justify discontinuing GP-020. Without demonstrating how the current GP-020 process is resulting in unacceptable risk, the Department's proposal is unsupportable. Significant investments have been made in research in the State in part because of the Department's streamlined permitting process. The Department should not arbitrarily eliminate this program. (1)

12. Comment: Understanding that the risk from HAPs and toxic substances (TXS) in N.J.A.C. 7:27-17.9, Table 2, is a concern, the Department could revise the list in GP-020 to be consistent with the updated Risk Assessment Worksheet or allow facilities to conduct risk screening to ensure there will be no significant risk to the public and the environment. (2)

13. Comment: The Department has not evaluated the health risk associated with the annual emission reports submitted by GP-020 holders. If the Department had done this analysis, the Department would have realized it cannot claim that GP-020 does not address health risk. (3, 5)

    Response to Comments 8 through 13: Air pollution control permits, including GP-020, are based on potential to emit, not actual emissions. As explained in the notice, GP-020 is not consistent with the Department's current rules. Therefore, as explained in Response to Comments 1 through 5, the Department is discontinuing GP-020 and developing a new general permit for R&D.

Potential to emit HAP and PM limits based on the Department's current rules

14. Comment: Although GP-020 is not consistent with the Department's current regulations for HAP reporting thresholds and PM10 and PM2.5 PTE emission limits, the Department could simply update the general permit rather than discontinue GP-020. (1, 2, 3, 4, 5)

    Response: Although revising GP-020 was one option, as explained in Response to Comments 1 through 5, the Department determined to discontinue GP-020 (which allows current holders to continue to operate under their GP-020 until the expiration date, unless equipment is replaced or modified before the expiration date) and develop a new general permit for R&D, which will be subject to public notice and comment.

Preconstruction permits for R&D facilities

15. Comment: The Department stated that R&D facilities can apply for a PCP for equipment or operations, which requires a case-by-case review, and that a PCP could be structured to give R&D facilities flexibility similar to that provided by GP-020. However, the standard PCP format is not an acceptable or practical air permit replacement option for R&D facilities, which is why the GP-020 was developed and is still needed. A PCP requires listing all equipment and pollutants, operating scenarios for all equipment configurations, worst case emissions for all reportable pollutants, and a specific health risk assessment process. Equipment additions and removals for permitted R&D facilities fluctuate significantly, creating a regulatory burden for facilities and the Department when permit modification is needed. For a PCP to provide the flexibility suggested by the Department, the Department

would at least need to issue a guidance document or technical manual, which would be more difficult and time-consuming than to simply revise GP-020. (1, 2, 3, 4, 5)

16. Comment: PCP modifications and approvals will not be addressed in the same timeframe as the current GP-020 allows. Permit review and issuing delays would significantly hinder R&D operations, where adaptability is essential. (2, 3, 4, 5)

17. Comment: Multiple PCPs would be required to cover the same locations, equipment, and emissions to accommodate R&D intermittent and fluctuating needs. Due to the multiple PCP permits submitted to cover possible R&D operations, potential emissions on paper will be artificially inflated. GP-020 provides a more accurate potential emissions estimate and a smaller emissions cap. (4)

18. Comment: Due to confidentiality concerns, owners/operators applying for a PCP may have to submit paper applications, requiring the Department to implement extra security measures and resulting in potentially longer reviews. (2)

19. Comment: GP-020 is an excellent example of a permitting solution that streamlines and protects confidential information in air permit applications. (3, 5)

    Response to Comments 15 through 19: The Department acknowledges the commenters' concerns. Please see Responses to Comments 1 through 5 and Comment 13 regarding the Department's development of a new general permit for R&D.

Miscellaneous

20. Comment: Please provide a list of the 27 active permits and the list of the historical permit holders. (6)

    Response:

Active Permits	Historical permits
Nouryon Surface Chemistry LLC	Appco Pharma LLC
Ingredion Inc.	LTS Lohmann Therapy Systems Cop
Mylan API US LLC	Union Carbide Corp
Revlon Consumer Products Corp	Amneal Pharmaceuticals
Johnson Matthey Inc.	Keystone Industries
Mel Chemicals Inc.	Cedar Brook 2005 LP
MSN Pharmaceuticals Inc.	CMIC CMO USA Corp.
Ascendia Pharmaceuticals Inc.	Austar Pharma Laboratory
Amneal Complex Products Research, LLC	Tulex Pharmaceuticals Inc.
Henkel Corp.	Parsippany Littleton LLC
The Witte Co. Inc.	Novartis Pharmaceuticals Corp.
Abon Pharmaceuticals LLC	Hoffman-La Roche Inc.
Mondelez Global LLC	Coperion K Tron Pitman Inc.
Church & Dwight Co-Armex Facility	FMC Corp.

BASF Corp Catalysts Group Iselin
Coperion K Tron Pitman Inc.
Merck Sharp & Dohme Corp.
Croda Inc. North American HQ
Novitium Pharma LLC
ExxonMobile Research & Engineering Co.
Nucrogene Inc.
Church & Dwight Co.
Bristol-Myers Squibb Co.
Merial Limited
Merck Sharp & Dohme Corp.
Summit West Celgene LLC
Mars Wrigley Confectionary US LLC
Danisco US Inc.
1011 Morris Avenue Urban Renewal LLC

21. Comment: Has the Department reviewed all the other general permits (GPs) to determine if they meet the criteria for discontinuation of this GP? (6)

    Response: The Department provided notice of the opportunity for public comment on the discontinuation of only GP-020 for Research and Development at minor air facilities. The Department did not evaluate other GPs as part of this action.