IN THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REQUEST FOR APPROVAL OF ADDITIONAL USES OF PHOSPHOGYPSUM PURSUANT TO 40 C.F.R. § 61.206

Submitted by: The Fertilizer Institute on Behalf of Its Members

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I. INTRODUCTION

The Fertilizer Institute¹ (TFI) submits this petition in support of a request for approval of the use of phosphogypsum material (PG) in road construction pursuant to the United States Environmental Protection Agency’s (EPA) rule governing the distribution and use of phosphogypsum for other purposes. See 40 CFR §61.206.² TFI will supplement this submission to include a report interpreting the recent measurements of the radioactivity level of PG in U.S. stacks, an economic report on regulatory cost savings, and, if necessary, other information. Consistent with past approvals, EPA will make the “EPA Approval” publicly available, along with the Petition and any information EPA relied upon for making its determination. EPA may decide to respond to relevant stakeholder comments in connection with the Petition. TFI will provide additional information, where requested or deemed appropriate.

TFI’s application includes the Petition, Appendix 1 (summary of the Risk Analysis), Appendix 2 (radionuclide exposure and risk calculation), Appendix 3 (metals screening report), and Appendix 4 (other documents being submitted for the administrative record).

PG is a byproduct of the phosphate fertilizer production process. At a typical U.S. facility, approximately five tons of PG are generated per ton of fertilizer produced. Prior to 1989, PG was reused in various applications (including, among other uses, in the construction of roads and in agriculture). In 1989, EPA restricted the use of PG based on concern with naturally occurring radioactive material (NORM) in PG. Specifically, EPA’s National Emission Standards for Hazardous Air Pollutants (NESHAP) Subpart R requires that, with very limited exceptions, PG must be placed in engineered above ground impoundments (commonly referred to as “gypsum stacks”).³ The existing approved alternative uses include use of no more than 7,000 pounds of PG for indoor research, use of PG with an average radium-226 concentration not exceeding 10 picocuries per gram (pCi/g) for agricultural application as a soil amendment, and use of PG as landfill cover in a test cell to determine if it can be utilized more broadly as a landfill cover.⁴

Since 1989, scientific studies have been completed in the U.S. and internationally supporting expanded beneficial reuse; these studies demonstrate protectiveness of human health and the environment. PG is reused in many countries outside the U.S. in agriculture, mine restoration, building materials, marine applications, daily landfill cover, and for road construction as

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¹ TFI is the leading voice of the fertilizer industry, acting as an advocate for fair regulation and legislation, a consistent source for trusted information and data, a networking agent, and an outlet to publicize industry initiatives in safety and environmental stewardship. The fertilizer industry contributes $155 billion to the nation’s economy. TFI, available at https://www.tfi.org/policy-center/economic-impact. The fertilizer producers, wholesalers and retailers, along with the businesses that serve them, support nearly half a million U.S. jobs with total annual compensation of $36 billion. Id.


³ 40 CFR §§ 61.200 - 201.

⁴ 40 CFR §§ 61.204 - 61.205.
requested herein. Also over the years, EPA has also developed more specific and scientifically supportable guidance governing risk assessments.

This Petition seeks approval of the use of PG in road construction in light of the new scientific and factual information. The Petition includes an Executive Summary (Section II), explanation of the Relief Requested and the Petition Process (Section III), regulatory history and changing conditions (Section IV), summary of the evaluations performed (Section V), and an application of the risk management factors to the use of PG in road construction (Section VI).

II. EXECUTIVE SUMMARY

Requested Relief

Section III of the Petition requests a waiver of the requirement that PG be placed in stacks and approval of the beneficial use of PG in road construction pursuant to EPA’s rule governing the distribution and use of phosphogypsum for other purposes. In 1989, EPA restricted the use of PG, requiring it to be stacked due to concern with naturally occurring radioactive material (NORM) in PG. Since the 1989 restriction, scientific studies have been completed in the U.S. and internationally supporting expanded beneficial use and demonstrating protectiveness of human health and the environment. PG is reused in many countries outside the U.S. in agriculture, mine restoration, building materials, marine applications, daily landfill cover, and for road construction as requested herein. EPA has in the same timeframe developed more specific and scientifically supportable guidance governing risk assessments. This petition provides the necessary information regarding safe use of PG for road construction along with economic and other benefits.

Specifically, TFI requests that the EPA Assistant Administrator of the Office of Air and Radiation (OAR) approve a waiver of the requirement that PG must be placed in stacks to allow the use of PG in road construction as road base, paving and various combinations of road base and paving of roadways. Key considerations underpinning this petition include:

1. All reasonable maximum exposures (RMEs) resulting from use of PG are less than the 3 in 10,000 lifetime cancer risk EPA has determined safe for alternative PG uses and well below natural background exposure. Thus, as stated in EPA’s alternative PG use guidance (entitled Applying to EPA for Approval of Other Uses of Phosphogypsum: Preparing and Submitting a Complete Petition under 40 CFR 61.206),5 the use of PG in road construction is at least as protective as placement of phosphogypsum in a stack, consistent with the regulations.

2. This Petition for PG reuse in road construction and the requested EPA approval covers any paved road, i.e., unpaved roads have not been included in the analysis. The risk

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5 EPA Guidance: Applying to EPA for Approval of Other Uses of Phosphogypsum: Preparing and Submitting a Complete Petition under 40 CFR 61.206: A Workbook, at 13 (2005) (EPA PG Workbook), available at https://www.epa.gov/sites/production/files/2015-05/documents/wrkbk_sub_r_appl_1105.pdf. The Office of Radiation and Indoor Air Workbook’s purpose is “to provide information on how to prepare a complete petition to the U.S. EPA for the distribution and use of phosphogypsum for ‘other purposes’ that is consistent with the requirements of our regulations for radon emissions from phosphogypsum stacks.” Id. at 1.
analysis conducted to support this Petition uses an average radioactivity level (radium-226) of 27 pCi/g that is similar to levels EPA has previously used. To account for some potential variability (~30 percent) that has been observed in past testing, the relief sought in this petition seeks approval to use PG containing radioactivity levels of up to an average of 35 pCi/g in road construction materials. EPA’s past PG testing indicates that the average per stack is bound by this value. As a point of illustration, the radioactivity level would have to be 148 pCi/g to be equivalent to EPA’s “safe” risk level of 3 in 10,000 (see Appendix 2). The average level of 35 pCi/g sought in this petition is over 4 times less than this equivalent safe level.

3. This Petition proposes self-implementation by the owner or operator with notice to EPA. Specifically, this means that the owner or operator of the PG stack from which PG is removed for road construction will submit a certification to EPA on a project by project basis. This requires the owner/operator to notify EPA that a local, state or federal transportation agency or company has requested to use PG in its road construction project. The notice will include: certification that the PG removed from the stack is consistent with EPA’s approved limit under this Petition, and the location where the PG will be used in road construction (i.e., GIS coordinates of the road location). No sampling is required since the existing data demonstrates that the average radioactivity level does not exceed 35 pCi/g, and that this level is far below a safe level of 148 pCi/g.

The petition is supported by a Risk Analysis that examines radiological risks of the proposed use of PG in road construction and ultimate disposition of PG in newly constructed roads, along with a screening evaluation that concludes a numerical risk assessment of metals within the PG is not necessary.

The Risk Management Decision

Section IV provides TFI’s justification for approval of this Petition. The decision to approve a new use for PG must be made by the Assistant Administrator for Air and Radiation. As a matter of policy, the decision involves weighing results of a risk assessment, technical analyses, and other factors. This Section summarizes these factors as TFI submits they should apply to EPA’s risk management decision.

The justifications detailed within the petition include:

1. The Risk Management limit of 3 in 10,000 is consistent with other NESHAP risk limits.

2. The highest Reasonably Maximum Exposure (RME) for the use of PG in road construction, 0.5 in 10,000 (0.5 in 10,000 is 5 in 100,000), is well below the NESHAP radionuclide risk management limit of 3 in 10,000.

3. For ease of calculation, this Risk Assessment used a nominal average radioactivity level in PG of 27 pCi/g. By “nominal average” we mean this is the

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6 The Petition seeks approval of up to an average of 35 pCi/g because this average level represents the highest average level identified in prior testing by EPA.
average radioactivity level we used in our initial calculation. This number is reasonable and is similar to numbers EPA previously used. Once the risk from the initial calculation is determined, EPA can then estimate the risk from higher and lower radioactivity levels. For example, if the average radioactivity level for a stack is 13.5 pCi/g, then the risk is one half of that calculated for 27 pCi/g.

4. At EPA’s request, TFI members recently sampled PG from multiple gypstacks (up to approximately 10 composite samples per stack). A summary report (including any other appropriate data and evaluations) will be submitted. We expect this report will confirm that the existing data supports the use of the PG stacks in the U.S for use in road construction. In summary, the average radioactivity level for each stack tested to-date was significantly lower than 27 pCi/g. Furthermore, the risk assessment performed for this Petition demonstrates that 27 pCi/g corresponds to a cancer risk of 0.5 in 10,000 for the highest RME use of PG in road construction (i.e., the road construction worker), therefore the risk from these stacks is less than 0.5 in 10,000.

5. Based on the risk assessment performed for this Petition, EPA’s PG risk management safe risk level of 3 in 10,000 corresponds to a radioactivity level in the PG of 148 pCi/g (see Appendix 2). Thus, PG materials in TFI’s member’s stacks may be safely used as road construction material. It is extremely unlikely if not impossible for random variation in the PG radioactivity levels to exceed an average 148 pCi/g, the radioactivity level that corresponds to a 3 in 10,000 risk management level.

6. EPA performed extensive modeling of the likely migration of radionuclides from PG used in road construction in a 1992 assessment discussed below. The EPA concluded that the radionuclide “doses from the groundwater pathways are all zero.” EPA’s assessment demonstrates that the radionuclide risks were found to be zero.

7. Screening evaluation of the potential impact of metals in PG shows that PG can be used safely by workers in road construction. Paving limits direct contact by the community and also limits water contact with PG isolated in the base layer.

8. Care has been taken in the assessment process to manage scientific uncertainties by choosing values and approaches that are likely to overestimate rather than underestimate risks. These result in an RME value, which serves as a reasonable upper bound on the risk distribution and is a readily accepted approach for representing maximum exposures (see Appendix 2). It also provides insight into risks to the population. RMEs overestimate risks for highest exposure situations such that actual risks would be lower.

9. For perspective on exposure magnitudes, radiation levels from use of PG are compared to naturally occurring background. Each exposure scenario has incremental radiological doses that are well below naturally occurring background levels. Exposures to the public using the road or living immediately adjacent to the road are likely to be indistinguishable from the natural variability in background.
10. There are naturally occurring background radiation and metals in other non-PG construction material including coal ash, fly ash, bottom ash, and other common construction materials. These materials have been deemed safe to use in road construction and other applications. Similarly, this Petition demonstrates the same is true for PG.

11. The reuse of PG for road construction is consistent with EPA policy on recycling of wastes and waste residuals.

12. The use of PG for roadway construction provides a net economic benefit.

13. Approval of the use of PG for road construction is consistent with the Administration’s Regulatory Reform Policies.

Risk management factors favor approving the use of PG for road construction. The petition and supporting risk analysis demonstrates that this use can be advanced safely.

**Factors Influencing Future Uses of PG**

A number of factors influence the future uses of PG and are the impetus for this petition:

1. The current requirement to obtain regulatory approval for each and every application of a new use is unwieldy and unnecessarily slows the process of implementing new uses; as a result, it impedes innovation and economic efficiencies.

2. The economics of gypstacks have changed. The cost to stack and manage gypstacks has increased beyond original expectations.

3. New data are available on the average level of radioactivity in the PG.

4. There is a better understanding in the scientific community concerning radiation protection and management related to PG reuse. More than a dozen beneficial uses have been analyzed worldwide, resulting in significant, successful PG reuse applications in at least 21 countries.

5. U.S. risk assessment approaches have progressed based on experience, analytical advances, and evolving environmental management policies since the 1980s, along with increased awareness of product lifecycles and sustainability.

6. EPA policies encourage reuse and recovery of high-volume, low-risk waste. This includes increased emphasis on understanding product lifecycles and adopting sustainability policies.

7. Perceptions of gypstacks have changed. EPA’s 1989 final rule did not anticipate the range of public sentiment regarding the long term presence of gypstacks, public pressure to cease this practice is growing.
Beneficial Use of PG in Road Construction

PG may be used as road base when mixed (e.g., at or less than 50%) with other materials such as soil, sand or aggregate or in the surface pavement (e.g. at approximately 2.5%). The calculation is based on equal amounts of PG and soil in roadbed. This is an upper bound because industry practice recommends similar ratios or less and EPA’s 1992 risk assessment used 33.3 percent PG to 66.6 percent soil (see Appendix 2). As shown in Figure 1, road base is a supporting layer of material approximately 0.25 m thick beneath the pavement and above underlying sub-grade. The design of new roads is as depicted in Figure 1. The potential for direct exposure is limited by placing the PG road base under the surface pavement, which isolates it from groundwater and surface water, i.e., it prevents the PG from directly contacting people or water (groundwater or surface water). The constructed road also affords a degree of radiation shielding for people driving on the road or for residents living nearby. Section IV describes the use of PG in road construction in detail.

Figure 1 provides a conceptual view; municipal roads can vary in width and structure.

The risk analysis shows that PG can be used safely for road construction. Opening this possibility for PG use brings a number of benefits consistent with now accepted environmental philosophies of emphasizing reuse and sustainable infrastructure. The petition details the factors for EPA to consider as it evaluates this petition.

TFI’s Petition and supporting risk analysis were developed consistent with the EPA PG Workbook, prior Petitions, and a series of working meetings with EPA staff, with EPA input and
direction on key elements of the analysis. The complete analysis for PG reuse in road
collection, including methodologies and other aspects, is provided in this Petition and attached
appendices.

Consideration of Risks

This text box provides some basic concepts and definitions to aid the reader's understanding of
the Petition.

Many substances (often naturally occurring substances) are radioactive. The basic concepts relevant to this Petition are:

- **Radioactivity** is a measure of the amount of gamma rays, alpha or beta particles, x-rays, or neutrons that
disintegrate from a gram of the substance being measured (in our situation, in each gram of PG). The amount of
radioactivity in a gram of a substance is measured in curies (Ci) or Becquerels (Bq). One curie is $3.7 \times 10^{10}$
radioactive decays per second, roughly the amount of decays that occur in 1 gram of radium per second. A
Becquerel is one disintegration per second. Historically, scientists originally used units of Ci. The International
System of Units (ISU) now uses Bq.

A picocurie (pCi) is one-trillionth of a curie.
1 Bq = $2.70 \times 10^{11}$ curies = 0.027 pCi

- **Dose:** Dose measures the amount of radiation absorbed by a person. The terms radiation absorbed dose (rad)
and gray (Gy) describe measurements of the absorbed dose.

1 gray (Gy) is equivalent to 100 rad; 1 rad = 0.01 Gy

Dose equivalent (or effective dose) adjusts the absorbed dose to include the relative medical effects of gamma
rays, alpha or beta particles, x-rays, or neutrons, e.g., the effects of alpha and neutron radiation are more
damaging to the human body than gamma radiation.

The dose equivalent is measured in rems (roentgen equivalent man) or 1/1000th of a rem (millirem or mrem). A
rem for each type of radiation is equal to the absorbed dose (in rads) times a quality factor that reflects the fact
that some types of radiation cause more damage than others [see “Units of Radiation Dose,” 10 CFR § 20.1004].
The scientific community is shifting to use the nomenclature developed for the international system unit, so the
term sievert (Sv) is often used.

1 rem = 0.01 sievert (Sv); 1 sievert (Sv) = 100 rem; 1 millisievert (mSv) = 0.1 rem or 100 mrem.
100 rem is equivalent to 1 Sv or 0.1 rem (or 100 mrem) equals 1 mSv; and

- **Risk:** The regulatory risk assessment process converts a dose equivalent (in mrem) into an upper bound risk (or
probability) of developing fatal cancers. It is based on a regulatory assumption that the dose equivalent may
cause harmful effects and as the magnitude of this dose increases or decreases, the risk increases or decreases,
respectively, linearly (e.g., if the dose is halved, the calculated risk is halved). The risk assessment performed for
this Petition concludes that an effective dose of 600 millirem corresponds to a risk of 3 in 10,000 (i.e., if all of the
protective assumptions are valid, 3 in 10,000 people may develop a fatal cancer). The actual risk is likely to be
lower.

Generally, the sources for this explanation include EPA, *Radiation Terms and Units*, available at
rad, rem, sieverts, becquerels A guide to terminology about radiation exposure*, available at
http://news.mit.edu/2011/explained-radioactivity-0328; National Aeronautics and Space Administration, *Radiation Math,
available at https://www.nasa.gov.
Radiological Risks Associated with Using PG for Road Construction

Five relevant and appropriate exposure scenarios were defined based on discussions with EPA and knowledge of how exposures might occur to workers and the public from using PG in road construction: Truck Driver (transporting PG), Road Construction Worker, Utility Worker, Road User (auto, motorcyclist, or bicycle), and Nearby Resident. The risk assessors chose exposure values such that each exposure scenario represented an RME (exposures are expressed in terms of millirems (mrem)) (see Appendix 2 and text box above). Exposure estimates are developed for each scenario by considering the activities within each group, distance from the potential source, duration of exposure, and physical barriers that serve to shield or reduce exposure.

This information is used as input in one of two accepted radiological exposure models as appropriate to the scenario — MicroShield and RESRAD (as agreed to with EPA). Exposure estimates are converted to cancer risk by using an accepted dose-response relationship (i.e., a linear no-threshold (LNT) dose-response relationship established by the International Commission on Radiological Protection (ICRP)). This is used to evaluate potential health effects from low-level radiological exposure associated with using PG in road construction. The LNT model presumes a straight line slope relationship between exposure and risk with the straight line passing through 0 and as a result any exposure no matter how small, is assumed to have a corresponding risk estimate; this is why it is referred to as “no-threshold” (see Uncertainty Analysis in Section VI). Utilizing an exposure-risk relationship derived with the LNT model helps ensure that risk estimates are more likely to be overestimated than underestimated.

The exposures can also be compared to the level in mrem associated with the RME, which is a value of 600 mrem (dose equivalent to a risk of 3 x 10,000). The level of exposure serves to indicate whether a dose or risk estimate is above or below a risk management level. Exposures below the risk management level of 600 mrem are deemed safe by EPA. The PG reuse exposure scenarios examined for radiological risks were lower than the EPA risk management limit of 3 in 10,000 (Table ES-1).

Of the scenarios evaluated, the highest estimated dose and risk is for the road construction worker who lays down the road base containing PG. The RME for such individuals results in a dose of 22 mrem/year while engaged in road construction and 110 mrem for the total exposure period. This estimated annual exposure of 22 mrem is a fraction of naturally occurring background radiation (310 mrem/year national average with a range of 100 to 1,000) (see Appendix 2). The exposure dose is also over 5 times less than the risk management safe dose of 600 mrem and risk limit of 3 in 10,000.
Risks to the public using the road or living immediately adjacent to the road were much lower than those for a road worker. These results indicate that PG can be used safely for road construction.

Naturally occurring background radiation varies geographically in a broad range of 100 to 1,000 mrem/year for the various states. The average background radiation (generally 310 mrem per year, although background varies locally) is also used to gauge exposures. For example, a 5-year exposure at average natural background corresponds to 1,550 mrem of cumulative background radiation exposure. Similarly, 26 years of exposure corresponds to a cumulative background radiation of 8,060 mrem. These naturally occurring average values are well above the exposure dose calculated in the Risk Assessment for use of PG in road construction.

**Ultimate Disposition of Roads Containing PG**

The Risk Analysis includes a calculation of exposure for a realistic ultimate disposition of a new road constructed with PG. New roads serve as an established part of municipal (county, state and/or federal) infrastructure and as such would require periodic repair and expansion as needed. These activities could include removing the surface and grinding and reusing or disposing of the materials consistent with federal and state and local regulations. Exposures and risks associated with maintenance of roads and reuse of construction materials are expected to be comparable to or less than those detailed in the risk assessment for road construction.

**“Reclaimer Exposure Scenario”**

EPA requested that the risk analysis report include a “Reclaimer Exposure Scenario” (i.e., the road is abandoned, the land cleared for construction, and a house constructed on land containing a mixture of PG, soil, and fill). The length of exposure is 26 years (i.e., 90% of the population lives in their house 26 years or less). This was the RME length of residency used for the residential exposure in EPA’s 1992 Risk Assessment and in EPA guidance. The Risk Analysis concludes that the reclaimer scenario is not an appropriate RME exposure (it is not reasonably realistic in the real world). The in-place abandonment of municipal infrastructure and allowance for construction of residences on top of these abandoned roads runs counter to current road and homebuilding construction practices. Despite this, the Reclaimer Exposure Scenario was evaluated with improvements to the 1992 assumptions. First, a home would not be constructed on an abandoned road without first removing the surface layer and regrading, which would mix and dilute the PG. Second, the house would also not be built on the remixed PG without inclusion of a foundation and vapor layer. Thus, although the Reclaimer Exposure Scenario is
not expected to occur, the refined assumptions and calculations in the Risk Analysis represent an extreme upper bound, and not an RME, on future hypothetical exposure. The Reclaimer Exposure Scenario therefore should not be used for an EPA risk management decision concerning whether to approve the road construction use of PG. However, even this extreme bound on the hypothetical future exposure presents a risk below the EPA risk management safe level limit of 3 in 10,000.

From a screening-level perspective, although not a RME exposure, this extreme hypothetical scenario (undertaken at EPA’s request) demonstrates that a numerical risk on the ultimate disposition scenarios need not be calculated.

**The Screening Level Analysis of the Potential for Radionuclides in PG Impacting Groundwater**

EPA performed extensive modeling of the likely migration of radionuclides from PG used in road construction in its 1992 Background Information Document (BID) assessment. The BID concluded that the radionuclide “doses from the groundwater pathways are all zero.” The soil partition coefficient was arbitrarily decreased and still “no radionuclides are calculated to reach the onsite well via the groundwater pathway” nor are any “radionuclides calculated to reach the off-site river or well via groundwater.” This assessment demonstrates that the radionuclide risks were found to be zero.

Since this extensive modeling found no impact, no additional evaluation was deemed necessary in this Petition.

**Screening Level Risk Analysis of Metals**

The Risk Assessment’s screening of metals considered two pathways: direct contact and potential for leaching. With regard to worker exposure during construction, a screening-level analysis was performed during which the concentrations of metals within PG were compared to EPA screening-level values. For the most part, all maximum metal concentrations in PG were less than EPA screening levels. The only two that initially exceeded their respective screening levels were lanthanum (La) and zirconium (Zr). The zirconium (Zr) level, however, is still within background levels. Upon mixing in either pavement or road base, the lanthanum (La) values are expected to fall below screening levels. Because the road materials are not accessible upon completion, there is no direct contact pathway from PG construction materials to residents or road users.

The second pathway considered was potential for leaching to or influence on surface water bodies and groundwater. Given that the road base is located above the water table and that the PG material is isolated and not directly exposed to surface runoff, the potential for contact of the road base with water is extremely limited. This minimizes the potential for leaching to

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8 *Id.* at 4-17.

9 *Id.* at 4-17, 4-31, 4-34, Scenarios 8, 11, Tables 4-5, 4-18, Footnote C, among other sources.
groundwater. Nevertheless, the Risk Analysis considered the nature of roads and available information on leaching of metals from the PG.

For comparison, we looked at the metals content in PG, other road construction material (such as fly ash), and metals in biosolids continuously applied on agricultural fields (see Appendix 3). All road construction materials have some level of naturally occurring radioactive materials and metals/metalloids. The maximum concentrations reported in the literature for PG were compared with reported median concentrations in fly ash and Portland cement. Approximately half the median concentrations of metals in fly ash are higher than the maximum concentrations reported for PG. Aluminum and iron concentrations are approximately 16 times higher in fly ash than in PG. Boron, barium, beryllium, lead, and vanadium are between approximately 3 to 7 times higher in fly ash compared with PG and other constituents such as arsenic, chromium and manganese are slightly higher in fly ash.

Potential for leaching of metals and associated potential for groundwater impacts from agricultural lands receiving biosolids have already been addressed in other EPA assessments and found not to be a significant source of risk.

Moreover, the footprint of a road on the landscape is very small compared to agricultural lands upon which biosolids and amendments containing higher metals than those in PG are permitted for use. The smaller areal footprint and lower likelihood of leaching from a constructed road compared to an agricultural field indicates that the influence on groundwater from PG in the road is likely to be comparatively very small. PG in road base is expected to be negligible in comparison and thus can be used safely in road construction given the lower metals content in PG and the smaller spatial footprint and confinement of the base layer above the water table. In any case, environmental and highway construction practices already address these risks.

Conclusion of Risk Analysis

The road construction scenarios discussed herein were evaluated for numerous risks (e.g., a broad scope of RME radiological exposures and non-radiological constituents present in PG). The analyses clearly demonstrate that:

- Use of PG in road construction presents no greater risk than stacking of the material; and

- PG can be safely used in road construction. In scientific terms, the use presents a risk of < 3 x 10,000, a level deemed by EPA to be safe (see discussion below).
III. RELIEF SOUGHT AND THE PETITION PROCESS

A. Specific Relief Sought

This PG reuse Petition requests the following:

U. S. Environmental Protection Agency (EPA) action, pursuant to 40 CFR § 61.206, on the Petition submitted by The Fertilizer Institute (TFI). The requested action includes granting a waiver of the requirement that phosphogypsum (PG) be placed in stacks and an approval to allow the use of PG containing up to an average of 35 pCi/g in road base, paving, and various combinations of road base and paving of roadways.

TFI’s Petition demonstrates that with PG used as construction material, the highest RME dose (i.e., the amount of radiation received) to a construction worker placing road base containing PG is ~22 millirem per year (mrem/yr) or 110 mrem total dose during the period that the worker is exposed (22 mrem/yr times five years for the total use dose). The definitions of dose, mrem, and other technical terms are set forth in Appendices 1 and 2. A dose of 110 mrem corresponds approximately to a cancer risk of 5 in 100,000 (or 0.5 in 10,000, to use the same units as EPA’s PG risk management safe level). Most actual exposures are less than those received by the RME and hence the associated risk would also be lower. The risk to the RME is significantly less than EPA’s cancer risk limit of 3 in 10,000 during the alternative PG uses. Thus, consistent with the requirement in EPA’s alternative PG use guidance (Applying to EPA for Approval of Other Uses of Phosphogypsum: Preparing and Submitting a Complete Petition under 40 CFR 61.206), the use of PG in road construction is at least as protective as placement of phosphogypsum in a stack.

This Petition for PG reuse in road construction (and, therefore, any EPA approval) applies solely to paved roads; unpaved roads have not been evaluated and are not the subject of this Petition. PG containing average radiation levels equal to or lower than 148 pCi/g meets EPA’s risk management safe risk level of 3 in 10,000 and, therefore, such PG may be safely used as road construction material. The risk assessment submitted with this Petition used a nominal average 27 picocuries per gram (pCi/g) which corresponds to a construction worker risk of 0.5 in 10,000.

TFI members measured the radioactivity level in the PG from some of their stacks. A summary of this data will be provided to EPA to support this Petition in a separate report. In summary, results to date reflect that average radiation levels from the composite samples taken from stacks

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10 The risk assessment performed in support of this Petition used a nominal average radium -226 concentration of 27 picocuries per gram (pCi/g). The estimated risk from average radium -226 concentrations greater than 27 pCi/g can be scaled linearly from the road construction work risk (Appendix 2) (i.e., if an average radioactivity level of 27 pCi/g corresponds to 0.5 in 10,000 risk, then the EPA risk management limit of 3 in 10,000 corresponds to a radioactivity level of 148 pCi/g). The variation in the average radioactivity levels in the PG demonstrates that it is exceedingly unlikely that any randomly selected amount of PG will have an average radium-226 concentration above 27 pCi/g and thus, exceedingly unlikely that use of PG in road construction would result in a risk exceeding 3 in 10,000. The Petition seeks approval of up to an average of 35 pCi/g because this level represents the highest average level identified in prior testing by EPA.

11 EPA PG Workbook, supra note 5, at 13.
do not exceed the nominal radioactivity level used in the risk analysis (i.e., 27 pCi/g) and, more importantly, 148 pCi/g, the radioactivity level that corresponds to 3 in 10,000 risk management level that EPA has designated as safe.  

B. **Process Used To Develop the Petition**

TFI’s Petition and supporting risk analysis were developed by reviewing the EPA PG Workbook and prior Petitions, and through a series of working meetings with EPA staff to obtain EPA input and direction on key elements of the analysis. Throughout this process, the methodologies and technical issues utilized in the technical evaluations benefited from EPA’s input. The complete analysis for PG reuse in road construction, including methodologies and other aspects, is provided in this Petition and attached appendices.

C. **Specific Requirements for a Petition**

40 CFR § 61.206 requires that a Petition include the following:

- A submission in writing.
- The name and address of the person(s) making the request.
- A description of the proposed use, including any handling and processing that the phosphogypsum will undergo.
- The location of each facility, including suite and/or building number, street, city, county, state, and zip code, where any use, handling, or processing of the phosphogypsum will take place.
- The mailing address of each facility where any use, handling, or processing of the phosphogypsum will take place, if different from paragraph (b) (3) of this section.
- The quantity of phosphogypsum to be used by each facility.
- The average concentration of radium-226 in the phosphogypsum to be used.
- A description of any measures which will be taken to prevent the uncontrolled release of phosphogypsum into the environment.
- An estimate of the maximum individual risk, risk distribution, and incidence associated with the proposed use, including the ultimate disposition of the phosphogypsum or any product in which the phosphogypsum is incorporated.
- A description of the intended disposition of any unused phosphogypsum.

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12 A more detailed interpretation of the data will be provided in a separate submission to EPA.
The Petition must be "signed and dated by a corporate officer or public official in charge of the facility."

Since multiple companies that own and operate PG stacks are making this request, this Petition was prepared and submitted to EPA by TFI on behalf of its members. A representative of TFI is included on the signature page.

The rule provides that the Petition include the "location of each facility, including suite and/or building number, street, city, county, state, and zip code, where any use, handling, or processing occurs." TFI believes this requirement can be satisfied in a two-step process in this case.\(^\text{13}\)

Step 1 constitutes the first part of the approval process; submission of the Petition and EPA's determination that a particular use of PG is no less protective than storing it in stacks.\(^\text{14}\)

Step 2 constitutes the notice to EPA of intent to use PG consistent with the Step 1 determination, including location and other required information. This occurs when a local, state or federal transportation entity (or its contractors) decides to utilize PG on specific road construction projects.

No sampling is required for the reasons discussed below.

IV. REGULATORY HISTORY AND CHANGING CONDITIONS

A. Regulatory History

1. The Original 1989 NESHAP Rule

Prior to 1989, PG in the United States was used for beneficial purposes, such as constructing roadways and agricultural soil amendments. The 1989 NESHAP rule required that all PG must be placed in engineered above ground impoundments (commonly referred to as "gypstacks") or in phosphate mines where it can be used as backfill. 40 CFR § 61.202. EPA's 1989 regulatory analysis was based on an estimate of 66 stacks located in 12 states with two-thirds located in Florida, Texas, Illinois, and Louisiana.\(^\text{15}\)

2. Post-1989 Regulatory Developments

In 1992, in response to TFI's petition for reconsideration, EPA approved the use of PG as an agricultural soil amendment as long as the average concentration of radium-226 in the PG does

\(^{13}\) 40 C.F.R. § 61.201(a) addresses the approval of new uses and provides that PG may not be removed from stacks for any new use "without prior approval." Subsection (b) details the information that a petitioner must submit.

\(^{14}\) There are practical reasons for pursuing this approach and there are no risks to EPA. First, in this case, neither TFI nor its members will know with certainty at the time a Petition is filed the actual location of the use. Notice of a project location prior to an EPA determination is unworkable in practice since it would expect potential users to request to use a product in a manner not permitted by law at the time of the statement. Second, there is no risk to EPA or the public because no newly approved use will be implemented without notice to EPA with the location and other information.

\(^{15}\) 1989 Rule, supra note 2.
not exceed 10 pCi/g (based on a maximum individual risk of 3 in 10,000 due to the use) and use of PG for research in amounts not to exceed 7,000 pounds. 40 CFR § 61.204-205.\(^{16}\)

The regulations were also amended to allow EPA’s Assistant Administrator of the Office of Air and Radiation (OAR) to approve, on a case-by-case basis, a new use if it is as protective of public health, in both the short and long term, as disposal in a stack or a mine. 40 CFR § 61.206(a)-(c).\(^{17}\) In 1992, EPA rejected the use of PG in road construction based on an analysis that assumed a roadway constructed with PG might be abandoned in the future, with a home constructed directly on top of the abandoned roadway with no site preparation (i.e., mixing). This hypothetical scenario included several extreme assumptions that resulted in unrealistic levels of exposure.\(^{18}\)

3. **Prior Petitions**

On December 22, 2004, EPA “conditionally” approved the Petition of the Florida Institute of Phosphate Research (FIPR) to use PG as cover material in a demonstration landfill test cell project (discussions with EPA on this project were initiated in 2002 and the petition submitted December 9, 2003).\(^{19}\) PG, however, was never used as cover material in a landfill test cell. As TFI understands it, by the time the petition was approved, conditions had changed and the landfill owner withdrew its request.

In 2010, Louisiana State University prepared a proposal to allow the use of PG testing to determine if PG could be used to make coastal zone protection devices.\(^{20}\) TFI’s understanding is that this effort has been deferred for the time being.

These examples illustrate the unwieldiness of EPA’s current approach to approvals for PG reuse. This has resulted in continued stacking, which has been subject to criticism as an unsustainable practice. Meanwhile, in most other countries, there are either few or no restrictions (allowing unrestricted use up to 27 pCi/g on PG reuse, or the radiation level restrictions do not limit use).

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\(^{17}\) Id. at 23,319.

\(^{18}\) Id. at 23,312.

\(^{19}\) Letter from Jeffrey R. Holmstead, Assistant Administrator of the Office of Air and Radiation, EPA to Michael Lloyd, Jr., Research Director Chemical Processing, Re: FIPR Petition (December 22, 2004).

\(^{20}\) Louisiana State University, Preparation Of An Application For Approval To Use Stabilized Phosphogypsum As A Fill Material For Coastal Protection Devices, FINAL REPORT (prepared for Florida Institute Of Phosphate Research Institute, 2010).
B. Factors Influencing Future Uses of PG

A number of factors influence the future uses of PG:

1. Current requirements to obtain regulatory approval prior to each individual new use slow the process of implementing beneficial, safe new uses. In many other countries, PG reuse is encouraged over storage and there are little or no regulatory restrictions on the use of PG up to an average radium content of 35 pCi/g, a level consistent with EPA’s assessments of safe exposure.21

2. The size, costs and complexity of gypstacks have increased beyond original expectations. When the stacking solution was developed, two key factors were not fully recognized: (1) the significant volume of PG material that would be involved over time for storage in stacks, and (2) the beneficial reuses for which PG could safely be employed. Today, active stacks are concentrated in Florida, Idaho, Louisiana, and North Carolina and contain at least 1.7 billion tons of stored PG. EPA’s final rule did not anticipate the significant increase in production that would occur, creating a need for new storage capacity at the rate of 30 million tons per year. As a result, EPA’s 1989 final rule and its underlying analysis are not consistent with the environmental impact and cost of long-term stack storage on a scale compatible with modern fertilizer production facilities.

3. New data are available on the average level of radiation in gypstacks. Historically, EPA considered the radium-226 concentrations in phosphogypsum as ranging from 1.4 to 46 pCi/g.22 At EPA’s request, TFI members performed radiation sampling on gypstacks across the U.S. to provide updated information. Multiple stacks owned and operated by three companies were sampled. Up to approximately ten samples per stack were taken. The data reviewed to date demonstrates that the average radioactivity level for each stack is significantly lower than the 27 pCi/g used in the risk assessment (i.e., less than 0.5 in 10,000).23

4. The scientific community has developed an updated understanding of relative risks associated with PG.24 This Petition has been prepared to enable EPA’s regulatory decision to be based on the current, best scientific understanding of

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21 International Fertilizer Industry Association, Phosphogypsum: Sustainable Management and Use at Chapter 5, 52-63 (2016) (IFIA Sustainable PG Management Report), which reviews international and U.S. roads constructed with PG. Other chapters address other uses.


23 The Risk Assessment found that the nominal level of radium-226 assumed for calculation purposes to be contained in PG (27 pCi/g) corresponds to a maximum risk of 0.5 in 10,000. Thus, the EPA PG risk management limit of 3 in 10,000 corresponds to a level of 148 pCi/g in PG (using the non-rounded risk for the construction worker). Therefore, PG may be safely used as road construction material. The Risk Assessment submitted with Petition used a nominal average 27 picocuries per gram (pCi/g) which corresponds to a construction worker risk of 0.5 in 10,000.

radiation protection and management related to PG reuse. The International Atomic Energy Agency (IAEA), an international organization which the U.S. helped establish to provide a scientific source of recommendations on radiation issues, has determined that radionuclide activity concentrations in PG material are less than 1 Bq per gram (Bq/g) (which corresponds to 27 pCi/g) “implying that it is not necessary to regulate.” Section IV below summarizes this updated understanding. U.S. and international research, as well as data from uses in developed nations, are now available to support various PG uses and demonstrate that PG reuse is at least as protective of public health as storage in stacks. More than a dozen beneficial uses have been analyzed worldwide, resulting in significant, successful PG reuse applications in at least 21 countries.

Further, U.S. risk assessment approaches have changed based on experience and evolving environmental management policies since the 1980s, along with increased awareness of product lifecycles and sustainability. These changed conditions enable a more thorough and appropriate evaluation of PG reuse in road construction, and a demonstration that this reuse is protective of human health and the environment.

5. EPA policies encourage reuse and recovery of high-volume, low-risk waste. EPA’s 1989 and 1992 risk management decisions concerning PG reuses acknowledge, but do not provide, an effective mechanism to implement PG reuse decisions that are consistent with the Agency’s overarching policy of supporting recycling. Since 1992, EPA has increased its emphasis on understanding product lifecycles and has adopted sustainability policies and encouraged sustainable practices.

6. The economics of gypstacks have changed. The cost to stack and manage gypstacks is increasing. These rising costs are a concern to phosphate fertilizer producers that must maintain a competitive advantage in a global marketplace. Fertilizer companies outside the U.S. may reuse their PG material safely utilizing the IAEA standards. This puts U.S. companies at a significant economic disadvantage. The international community has actively moved in the direction of safe PG use and recycling, creating an increasing competitive disadvantage for U.S. industry, particularly when one considers the costs associated with gypstack maintenance, closure, and long term care.

7. Perceptions of gypstacks have changed. EPA’s final rule did not anticipate a range of public sentiment regarding the long-term presence of gypstacks. Inactive stacks that are already closed (or in closure) exist in various locations. There are also concerns about long-term gypstack aesthetics. Some local governments and

25 id. at 56. This statement does not in any way preclude a risk based determination that higher levels might also be acceptable.


communities have expressed a preference for reuse of PG in a manner that encourages redevelopment, because such reuse increases economic development by generating jobs associated with the transportation and reuse of PG, and frees up land for other uses.

8. It should be noted that TFI’s proposal represents a significant regulatory burden reduction that will create new commercial markets, industries and jobs. This is in the context of the dramatic increase in PG use worldwide since 2008, from a baseline of close to 35-40 million tons consumed worldwide by 2015. To make comparable advancements, the U.S. phosphate industry, led by TFI’s Petition, requests approval for certain PG reuses. If successful, approval would support the industry’s sustainable development goals by expanding the list of PG beneficial uses and ameliorate substantial, avoidable regulatory burdens and costs imposed by the NESHAP Subpart R regulations.

With this background in mind, Section V summarizes the Risk Analysis and metals screening evaluation that have been completed (see Appendices 2 and 3) and demonstrate the safety of PG reuse in road construction. Key exposure and risk calculations and application of EPA’s risk management criteria are described. The complete exposure and risk analyses are provided in appendices to this Petition.

V. SUMMARY OF THE EVALUATIONS CONDUCTED FOR THE PETITION

A. Overview

The Petition process is governed by EPA’s document, titled “Applying to EPA for Approval of Other Uses of Phosphogypsum: Preparing and Submitting a Complete Petition under 40 CFR 61.206, A Workbook” (EPA PG Workbook). The key requirement expressed in this guidance is that in responding to any proposed petition, EPA must decide whether the radiological risk associated with the alternative use poses no greater risk than placement in stacks.

The decision concerning whether the radionuclide risk associated with PG in alternative uses is acceptable depends upon many risk analysis elements, including:

- The specific exposure scenarios that are determined to be appropriate. This Petition seeks approval of the use of PG in road construction based on a risk analysis for a series of specific exposure scenarios;

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29 See e.g., EPA holds meeting about Mississippi Phosphate Site, St. Louis Post-Dispatch, Jan. 11, 2018, available at https://www.stltoday.com/news/world/epa-holds-meeting-about-mississippi-phosphate-site/html_0a41c1fa-96cf-54bb-a825-8fcaeb4bf463.html (comment of Pasagoula Mayor, Dane Maxwell, at an EPA public meeting regarding the Mississippi Phosphate site cleanup: “We want it clear and ready for development as soon as possible”).


31 EPA PG Workbook, supra note 5, at 13.

32 Id. at 12.
• The RME exposure assumptions or parameters that are selected to estimate a high end radiation dose estimate during the alternative use of PG, i.e., an assumption likely to overestimate exposure. This Petition developed RME exposure assumptions for each exposure scenario and receptor and calculated a high end RME dose;

• The radiation dose (see text box, above) to risk conversion factor used;

• The cancer risk estimate based on RME exposure assumptions and the radiation dose to risk conversion factor of 5 in 10 million mrem;

• EPA’s cancer risk limit for new PG uses of 3 in 10,000 during the use;

• A comparison of the estimated cancer risk to EPA’s risk limit for new PG uses; and

• EPA’s Risk Management Decision considering economic and other risk management factors.

EPA did not assess chemical risk in its 1992 risk assessment and review of new uses, including agricultural uses.\textsuperscript{33} Thus, petition development and consideration by EPA are primarily focused on exposure analyses associated with radiological risks from the proposed new use. For this Petition, EPA requested that TFI perform a screening level evaluation for chemical risks (i.e., metals). It should be noted that PG contains naturally-occurring radioactivity and metals. This chemical risk screening is provided as a supplement to the radiological risk assessment (Appendix 3).

B. Exposure Scenarios

1. Overview

PG reuse was considered for road construction. This led to the development of the following RME exposure scenarios evaluated in the risk assessment:

• Road Construction Worker who builds roads exclusively with PG material for five years;

• Road User who routinely commutes on the constructed roadway by vehicle, motorcycle or bicycle for 26 years (motorist/bicyclist was deemed most conservative);

• Nearby Resident who lives in a home located 50 feet or more from a PG roadway for 26 years. To illustrate the amount of exposure reduction with distance, exposure to a resident who resides 20 feet from the PG roadway for 26 years was also calculated;

• Truck Driver who delivers PG for road base material to a construction site for five years; and

• Utility Worker who excavates across a PG roadway during utility maintenance projects and is exposed in a trench for 160 hours in a year.

These exposure scenarios were selected based on a review of prior regulatory submissions as well as discussions with EPA personnel, and the best professional judgment of the scientists assisting in the preparation of the Petition. This analysis includes receptors added at EPA’s request during the working sessions to fully evaluate public health.

This Petition also includes, at EPA’s request, a hypothetical future “Reclaimer” scenario which the risk analysis concludes is an extreme exposure (Extreme Reclaimer), i.e., the exposure is much higher than a RME exposure scenario. This scenario, therefore, should not be utilized to determine if the risk from the use of PG in the construction of roads meets the EPA risk management limit of 3 in 10,000.

In TFI’s view, the design and construction of roadways will be governed by policies and constraints on future land use associated with public infrastructure. In light of this, the reclaimer scenario of building a house on top of an abandoned roadway is not a reasonably anticipated future land use. Nevertheless, at EPA’s request, this report separately assesses the risk of this hypothetical scenario.

2. Reasonable Maximum Exposure (RME)

In order for there to be a risk, there must be exposure. EPA uses an RME metric to assess exposure risk. The “intent of the RME is to estimate a conservative exposure case (i.e., well above the average case) that is still within the range of possible exposures.” Each exposure factor used to estimate the RME should be selected “so that the resulting estimate of exposure is consistent with the higher end of the range of plausible exposures” (citing EPA’s 1991 guidance).

A National Academy of Science (NAS) Committee reviewing EPA’s regulation of technologically enhanced naturally occurring radioactive material (TENORM) recommended

34 Arcadis (a firm specializing in design and consultancy for natural and built assets) and Exponent (an engineering and scientific consulting firm).


36 Id.
that EPA “should use exposure and dose risk assessments that are ‘reasonably realistic’” in developing standards for exposure to the various types of low level naturally occurring radiation.\textsuperscript{37} “The Committee defined ‘reasonably realistic’ as ‘not....intended to greatly overestimate or underestimate actual effects for the exposure situation of concern,’” and EPA agreed with the Committee’s recommendations.\textsuperscript{38}

The exposure calculations in the Petition use currently accepted radiation modeling methods such as RESRAD and MicroShield. State regulators, citing to EPA guidance, note that “if high-end values are chosen for every exposure factor, then the resulting exposure estimate may no longer be consistent with the RME and may exceed the realm of possibility altogether.”\textsuperscript{39}

The use of reasonable exposure assumptions is supported by the courts, which have long held that exposure assumptions “must bear some rational relationship” to actual conditions, and disallowed unduly conservative approaches. For example, a court rejected EPA’s use of an extreme assumption - that a child eats sludge applied to roadside cemeteries every day for a five year period.\textsuperscript{40}

Scenario-specific exposure assumptions were selected for this analysis in accordance with EPA guidance and methodology (see Table 1 below). These exposure assumptions are contained in appendices and accompanied by detailed scientific support, citations to guidance, discussion of best professional judgment and prior precedent used to make the selections. A summary of key exposure assumptions is provided in Table 1 below.

Table 1: Summary of Key Exposure Assumptions

<table>
<thead>
<tr>
<th>Person</th>
<th>Description</th>
<th>Years</th>
<th>Model</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Road Worker</td>
<td>Builds roads exclusively with PG material</td>
<td>5</td>
<td>RESRAD</td>
<td>The worker who uses PG to build a road is closest to the PG mixtures in road base and/or paving. Used Florida Department of Transportation construction project data and EPA guidance.</td>
</tr>
<tr>
<td>Truck Driver</td>
<td>Delivers PG to the construction site to be used in road base and/or paving materials</td>
<td>5</td>
<td>MicroShield</td>
<td>A truck driver hauls PG to the road construction site for 5 years (the truck body provides some shielding).</td>
</tr>
<tr>
<td>Nearby Resident</td>
<td>Resident lives in a home located 50 feet or more from</td>
<td>26</td>
<td>MicroShield</td>
<td>EPA guidance on exposure values. To illustrate the amount of exposure</td>
</tr>
</tbody>
</table>


\textsuperscript{38} Id.

\textsuperscript{39} ITRC, Decision Making at Contaminated Sites, supra note 35, at 6.1.1.

\textsuperscript{40} Leather Indus. of America v. EPA, 40 F.3d 392, 405 (D.C. Cir. 1994).
<table>
<thead>
<tr>
<th>Road User</th>
<th>Resident drives on the road in a vehicle, or on a motorcycle or bicycle (the motorist/bicyclist is evaluated as the most conservative)</th>
<th>26</th>
<th>RESRAD</th>
<th>EPA guidance on exposure values.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Utility Worker</td>
<td>Worker in trench dug across a PG roadway (e.g., utility work)</td>
<td>160 days</td>
<td>MicroShield</td>
<td>Best professional judgment, based, in part, on limited time trenching occurs (since, among other reasons, it obstructs traffic).</td>
</tr>
</tbody>
</table>

At EPA’s request, the Petitioner provided a “reclaimer scenario” (an assessment of the extreme hypothetical exposure if the road is abandoned and a house is constructed on the abandoned roadbed (see Table 2)).

Table 2: Reclaimer Scenario Exposure Assumption

<table>
<thead>
<tr>
<th>Hypothetical Extreme Exposure Reclaimer Use Scenario</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reclaimer Resident</td>
</tr>
</tbody>
</table>

The RME is used to calculate the dose (i.e., the amount of radiation that the individual in the exposure scenario receives over a particular unit of time.) In our situation, the annual and total doses depend on the length of time exposure occurs for that exposure scenario. Different exposure scenarios have different lengths of exposure. Risk is assumed to increase in direct proportion to the RME dose (i.e., if the RME dose increases by a factor of two, the risk increases by a factor of two).

The risk is then compared to the EPA risk management levels. EPA has long utilized (and courts have long upheld) the principle that a 1 in 10,000 risk level is “safe.” As a unanimous en banc ruling of the Court of Appeals for the District of Columbia Circuit candidly noted, the basis for claiming harm from exposure to chemicals at extremely low environmental levels is more a function of “the rules of arithmetic rather than because of any knowledge” and there was “no particular reason to think that the actual line of the incidence of harm is represented” by the assumption selected by EPA.41

This acknowledgment is also apt for the risks from radionuclides. EPA’s guidance for new uses of PG states unequivocally that for new PG uses to be approved, petitioners must demonstrate

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that the cancer risk to those exposed to phosphogypsum as a result of proposed reuse “must not be more than three in ten thousand (3 \times 10^{-4}, \text{i.e., 3 in 10,000}).” In the radionuclides NESHAP, EPA primarily, but not exclusively, evaluated the maximum individual risk (MIR) (which is the added chance of a cancer) and compared it to the NESHAP risk management level of 3 in 10,000.

The use of the 3 in 10,000 “risk threshold is consistent with the determination of a ‘safe’ level first announced in the NESHAP for certain benzene source categories (54 FR 38044, September 13, 1989).” As noted above, in the 1989 radionuclide rulemaking, EPA determined that six radionuclide source industries presented a cancer risk higher than 1 in 10,000 but that nonetheless was “essentially equivalent” to EPA’s safe risk level “in light of the numerous uncertainties.” Similarly, EPA reaffirmed in 1992 that a 3 in 10,000 risk level was protective of human health and consistent with EPA’s long-standing risk management goals. In particular, EPA “determined” that the 3 in 10,000 risk level provided “an ample margin of safety, considering the cost, scientific uncertainty, and technological feasibility of control technologies needed to further reduce the radon emissions from [the PG] stacks.”

In summary, EPA explicitly has determined that the 3 in 10,000 cancer risk for radionuclides (including PG) is safe, consistent with overall EPA risk management policy. EPA has concluded that the “proposed other use will not cause a threat to the public or environment greater than if the phosphogypsum were stored in the stack,” if the risk is not “more than three in ten thousand [3 in 10,000].”

The relationship between exposure dose and risk is further elaborated on in Appendices 1 and 2.

C. ICRP Dose to Risk Relationship

The risk assessment selected in this Petition is the ICRP dose to risk conversion factor. The ICRP sets out the basis for evaluating health effects from radiological exposure along with recommendations for using specific values for regulatory purposes. While there are broad uncertainty bounds at low-dose exposures, the assumption of a linear relationship between exposure and risk is maintained regardless of the possibility of a threshold below which there is

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42 EPA PG Workbook, supra note 5, at 13.

43 1989 Rule, supra note 2, at 51,654, 51,659, 51,660. In this context, the risk distribution (i.e. the range of risks to which the population is exposed) decreases as distance to the road increases, for PG use in road construction. Relatively quickly the dose falls below the dose that corresponds to background. The exposure to the residents is below the 3 in 10,000 safe level.

44 EPA PG Workbook, supra note 5, at 5.

45 1989 Rule, supra note 2, at 51,654, 51,664, 51,666, 51,668-69, 51,669, 51,677, 51,682 risks ranged between 1 in 10,000 and 3 in 10,000. Id.


47 EPA PG Workbook, supra note 5, at 5.

48 Id. at 13.
no risk. In Publication 103, ICRP provides an analysis of the exposure values considered in that analysis. On the basis of model uncertainty and epidemiological evidence, the ICRP recommends a dose-to-risk coefficient of 5% per Sievert. (one Sievert is equivalent to 100 rems or 100,000 mrem, see explanation of terms text box, above). This coefficient is the basis for current international radiation safety standards, and is considered by ICRP to be “appropriate for the purposes of radiological protection.” Although it is based on cancer mortality as the endpoint, it is also approximate for all calculated detrimental effects.

For our risk analysis, we use a dose conversion expressed in terms of millirems or mrem. Translating the 5% risk per Sievert recommended by the ICRP for regulatory purposes yields 5 x 10^{-7} risk per mrem.

The risk assessment submitted as part of this Petition estimates the annual dose for each of the exposure scenarios, summed over the associated years of exposure, to provide a total dose that is then converted to a cancer risk using a dose-to-risk conversion factor of 5x10^{-7} risk per mrem (i.e., 5/10,000,000).

Our use of 5 x 10^{-7} as a conversion factor is consistent with EPA risk assessment procedures. The EPA’s 2011 guidance provides cancer risk factors for uniform whole-body exposures of low-dose gamma radiation to the entire population, and reports an estimated 90% confidence interval for cancer mortality of 2.8% to 10% per Gy (i.e., from 2.8 x 10^{-7} to 10 x 10^{-7} per mrem). This range is essentially the same dose to risk conversion range derived by ICRP.

The value we use is also consistent with the perspective of the National Council on Radiation Protection and Measurements (NCRP) (the U.S. organization chartered by the U.S. Congress in 1964 to, among other things, “develop … recommendations about …protection against radiation” (i.e., NCRP uses the same dose to risk conversion factor as in the 2007 ICRP)).

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50 The mrem is a common unit of radiation dose. In this report, “dose” refers to effective dose, which simply means that when a person is exposed to a uniform radiation (e.g., external gamma radiation), all of the doses to the different organs are weighted by their radiosensitivity and added together. See Appendices 1 and 2 for more detailed discussion of the definitions and application of these factors.

51 Similarly, the international community has widely adopted the International Atomic Energy Agency (IAEA) determination that 1 millisievert (1 mSv) per year is the acceptable level of radiation exposure (for example, the European Union [EU] regulations). See Radiation Protection and Management of NORM Residues in the Phosphate industry, supra note 24, at 165. The IAEA and EU determinations are also based on the International Commission on Radiological Protection, The 2007 Recommendations of the International Commission on Radiological Protection, supra note 49, at 55, 97 Table 5, 116 Table 8.

52 For practical purposes as to gamma radiation, 1 Gy = 1 Sv = 100 rem = 100,000 mrem.


The ICRP analysis was also relied upon by the European Union (EU) in selecting its general population acceptable dose level. The EU appointed a group of experts to provide advice on the basic safety standards, taking into account the 2007 recommendations of the ICRP (specifically, ICRP Publication 103 since the ICRP reflected “new scientific evidence and operational experience.”).\(^{56}\)

The most recent report of the NCRP (2018) (Report No. 180) provides a detailed discussion of the risks from exposure to ionizing radiation and states that “[t]he value of 5 \text{ Sv} \dagger \text{ [i.e., 5/10,000,000 per rem]}\text{ is a rounded value for radiation detriment used to inform all the NCRP recommendations regarding stochastic effects},”\(^{57}\) (emphasis added).

In summary, the use of the ICRP dose to risk relationship is scientifically sound and supported by many independent governmental entities, including EPA and NCRP. We elaborate further in Appendices 1 and 2. The “conservative” nature of the assumptions underlying the dose to risk relationship and associated uncertainties are discussed below.

For the reasons noted above, the risk estimates derived for PG using the ICRP dose to risk conversion factor are based on a linear relationship between dose and risk for the very low dose exposures derived for this report. Therefore, they are appropriate for use in the Petition and can be relied upon by EPA in its decision making.

D. Calculation of Risk that Corresponds to the RME

This section summarizes the RME doses calculated in the Risk Assessment and explains generally how they are derived.

1. Deriving Dose for the Period of Use

A dose is the cumulative amount of radioactivity absorbed (weighted to take into account the different medical impacts of different types of radiation). The dose is calculated using the RME associated with each scenario.

Duration is specific to the exposure scenario. For a resident, the exposure period is 26 years based on standard EPA guidance.\(^{58}\) For a road construction worker, the length of exposure is

\(^{53}\) ICRP is an international expert advisory body that offers its recommendations to regulatory and advisory agencies, mainly by providing guidance on the fundamental principles on which appropriate radiological protection is based. The 2007 recommendation was produced “after eight years of discussions, involving scientists, regulators, and users all around the world.” The 2007 Recommendations of the International Commission on Radiological Protection, supra note 49, at 3.


five years based on data from roadway construction projects and EPA guidance. The risk assessment determined that the 3 in 10,000 risk level corresponded to a total cumulative dose of 600 mrem and this value can be used to judge the magnitudes of exposure for each scenario. Table 2 below summarizes the exposure doses calculated in the risk assessment on an annual and scenario basis.

Table 3: Total Dose Summary

<table>
<thead>
<tr>
<th>Person Exposed</th>
<th>Annual Dose</th>
<th>Years</th>
<th>Total Use Exposure Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Road Worker</td>
<td>22 mrem</td>
<td>5</td>
<td>110</td>
</tr>
<tr>
<td>Truck Driver</td>
<td>18.6 mrem</td>
<td>5</td>
<td>93</td>
</tr>
<tr>
<td>Nearby Resident</td>
<td>multiple exposures over 26 years</td>
<td>26</td>
<td>16</td>
</tr>
<tr>
<td>Road User</td>
<td>1 mrem</td>
<td>26</td>
<td>28</td>
</tr>
<tr>
<td>Utility Worker</td>
<td>0.8</td>
<td>160 hours in 1 year</td>
<td>0.8</td>
</tr>
</tbody>
</table>

2. Converting the Total Use Dose to Risk

Radiation risk for cancer is calculated as the product of the RME exposure dose for each scenario and the dose-to-risk conversion factor. The distance from the road and durations of exposure are key considerations in calculating the total dose risk. While the RME is designed to bound these, most residents would be located at greater distances from the road and/or experience shorter durations of exposure than the RME individual. Thus, actual doses for the populations would be less than those presented here.

As noted above, using a dose-to-risk conversion factor of $5 \times 10^{-7}$ risk per mrem, 600 mrem corresponds to a 3 in 10,000 risk level. From this relationship, one can calculate the risk for a particular dose. The result of the risk calculations are summarized in Table 3 below. The results of the calculations are provided in Appendices 1 and 2 of this Petition.

Table 4: Total Use Dose and Risk Table Compared to Background

<table>
<thead>
<tr>
<th>RME Exposure Scenario</th>
<th>Total Use Dose (mrem)</th>
<th>Years</th>
<th>Risk From the Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Road Construction Worker</td>
<td>110</td>
<td>5</td>
<td>0.5 in 10,000</td>
</tr>
<tr>
<td>Truck Driver</td>
<td>93</td>
<td>5</td>
<td>0.5 in 10,000</td>
</tr>
<tr>
<td>Road User</td>
<td>28</td>
<td>26</td>
<td>0.1 in 10,000</td>
</tr>
<tr>
<td>Nearby Resident</td>
<td>16</td>
<td>26</td>
<td>0.08 in 10,000</td>
</tr>
<tr>
<td>Utility Worker</td>
<td>0.8</td>
<td>160 hours in 1 year</td>
<td>0.004 in 10,000</td>
</tr>
</tbody>
</table>

3. Road Construction Worker Risk

Based on the assessments provided in this Petition, the highest estimated RME exposure is for the road construction worker placing road base containing PG that contains radium-226 at 27

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picocuries per gram. The exposure dose amounts to ~22 mrem/year (which results in a 110 mrem total dose for the exposure period of five years). This dose corresponds approximately to an incremental cancer risk of 0.5 in 10,000, which is over 5 times less than the PG use risk management level of 3 in 10,000.

4. **Risk to the Nearby Resident**

In addition to the highest risk individual (a road construction worker), the risk assessment also evaluated the exposure doses and risk to local residents who may live immediately adjacent to the road. Consideration was given to all stages of life from childhood through adult. Exposure depends on distance, with exposures dropping off quickly as distance from the road increases. Nevertheless, for people living immediately adjacent to the road, the exposures and risks are well below the risk management level of 3 in 10,000.

The exposure doses and risks were estimated without considering shielding during the period of construction; shielding was included when estimating doses following construction of the road. Shielding of residents was afforded by the road surface as well as by embankments and other structures that cover the sides of the road base.

The cumulative incremental dose associated with living in a house adjacent to a road with a PG base is 16 mrem and the associated risk is 0.08 in 10,000. These RME exposure dose and risk estimates to nearby residents are well below the EPA risk management levels.

5. **RME Risk from the Other Exposure Scenarios**

Doses and associated risks for all other RME exposure scenarios (the truck driver delivering the PG, the users of the road, and the utility worker in a trench near the road) are lower than those for the road construction worker (see Table 3).

6. **RME Exposures/Risks, by Definition, are the Highest Exposures**

All exposure scenarios have doses and risks that are less than the EPA’s risk management levels. The RME risks are constructed to overestimate rather than underestimate the actual risks and this provides confidence for making decisions that are health protective.

Other workers who are more distant from the PG have lower exposures than the construction worker (and, therefore, lower risk). Similarly, most residents living near roadways are exposed to lower risk levels and most PG will contain lower radiation levels used in this calculation. Moreover, the dominant source of dose is gamma radiation which decreases with distance and hence, residents who live more than 50 feet from a road will receive a lower dose (and consequent risk) than the RME at a distance of 50 feet from the edge of the road.

7. **Comparison to Background**

Because radiation is always present naturally, it is helpful to compare the incremental radiological exposures to background levels to provide perspective. While natural background varies geographically (between states and even within states), a value of approximately 310 mrem a year was used for comparison because it is a widely used national background level. Background radiation varies naturally from ~100 mrem to 1,000 mrem. Thus, the ratio of total
use exposure to background will vary depending upon the location of the road (see Table 4 below). Given the conservative nature of the exposure estimates, these incremental exposures would likely be within the variability of measurement for ambient radiation.

Table 5: Dose, Risk, and Background Summary for All RME Scenarios

<table>
<thead>
<tr>
<th>Receiver</th>
<th>CSAs</th>
<th>Exposure Duration (years)</th>
<th>Exposure Dose (rem)</th>
<th>Estimated Cancer Risk</th>
<th>Background Dose from Exposure Duration (rem)</th>
<th>Exposure Dose Percentage of Background Dose (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reasonable Maximum Exposure Scenarios</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Road Construction Worker</td>
<td>PG in Road Base</td>
<td>5</td>
<td>110</td>
<td>0.5 in 10,000</td>
<td>1550</td>
<td>7%</td>
</tr>
<tr>
<td>Road User (Motorist/Bicyclist)</td>
<td>PG in Road Base &amp; Surface</td>
<td>26</td>
<td>28</td>
<td>0.1 in 10,000</td>
<td>8060</td>
<td>0.3%</td>
</tr>
<tr>
<td>Truck Driver</td>
<td>PG-containing material for Road Base</td>
<td>5</td>
<td>93</td>
<td>0.5 in 10,000</td>
<td>1550</td>
<td>6%</td>
</tr>
<tr>
<td>Nearby Resident</td>
<td>PG in Road Base &amp; Surface</td>
<td>26</td>
<td>16</td>
<td>0.08 in 10,000</td>
<td>8060</td>
<td>0.2%</td>
</tr>
<tr>
<td>Utility Worker</td>
<td>PG in Road Base</td>
<td>1</td>
<td>0.8</td>
<td>0.004 in 15,000</td>
<td>310</td>
<td>0.3%</td>
</tr>
<tr>
<td><strong>EPA Cancer Risk Management Goal</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>600</strong></td>
</tr>
</tbody>
</table>

*Estimated cancer risk below this goal.

Figure 2: Estimated Cancer Risks

8. Disposition Scenario

The EPA PG use regulations require an assessment of the risk from the ultimate disposition of PG for any product in which the PG is incorporated.\(^{59}\) The RME for the ultimate disposition of a

\(^{59}\) 40 C.F.R. § 61.602.
new road constructed with PG is that it serves as an established part of municipal (county, state, or federal) infrastructure and as such would require periodic repair and expansion as needed.

All public roadways and associated rights of way are owned and operated by the government and are all subject to governmental jurisdiction with zoning and land use requirements that support continued roadway use. Maintaining public roadways and associated rights of way into the future is consistent with current trends in community plans to maintain and expand roadway infrastructure and utility services (buried within right of ways) and to provide access (e.g., ingress/egress to surrounding parcels). Converting a roadway to a residential property would complicate or eliminate access to surrounding parcels in addition to the redeveloped residential property and is not a realistic assumption.60

The sustainability of roads and reuse of road construction materials are key aspects of guidance and plans for roads under the jurisdiction of the Federal Highway Administration and state departments of transportation. The in-place abandonment of municipal infrastructure and allowance for construction of residences on top of these abandoned roads runs counter to sustainable infrastructure projects involving road construction.

Road maintenance activities include removing the surface, grinding and reusing or disposing of the materials consistent with federal, state, and local regulations. Exposures and risks associated with maintenance of roads and reuse of construction materials are expected to be comparable to or less than those detailed in the risk assessment for road construction.

E. **Extreme Hypothetical Reclaimer Requested By EPA (> RME)**

Our evaluation is that, in light of current policies and known constraints on future land use for public infrastructure, a hypothetical reclaimer scenario does not represent a reasonably foreseeable future use for inclusion in the risk analysis for this Petition.61 Thus, a Reclaimer Exposure Scenario should not be utilized to determine whether to approve the use of PG for road construction.62

Since EPA requested that the risk analysis include the extreme hypothetical reclaimer scenario, it is summarized below. The annual total radiation dose is 3 mrem, which converts to 78 mrem.

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60 The determination that the reclaimer scenario is also not a reasonably anticipated future land use for public roadways is also supported by EPA policy published after the 1992 BID. EPA published its Superfund Land Use Directive in 1995 (EPA, Land Use in the CERCLA Remedy Selection Process, OSWER Directive No. 9355.7-04 (May 25, 1995)) and reaffirmed the policy in 2001 (EPA, Reuse Assessments: A Tool To Implement The Superfund Land Use Directive, OSWER 9355.7-06P (June 4, 2001)). EPA's Land Use Directive acknowledges that "EPA has been criticized for too often assuming that future use will be residential" and identifies several evaluation factors to identify reasonably anticipated future land use, such as current land use, zoning laws and maps, community master planning, population growth patterns and projections, accessibility to existing infrastructure, site location, federal/state land use designation, and others.

61 Memorandum from TFI to Lee Veal, Director, Radiation Protection Division, U.S. Environmental Protection Agency (April 24, 2019). This detailed memorandum explains the reasons that the Reclaimer Exposure Scenario is not a RME.

62 As a practical matter, if a risk assessment uses extreme enough assumptions, the calculated risk will exceed any risk management safe level. Thus, realistic but high end RME are used.
over 26 years (the total use dose). The resident reclaimer scenario requested by EPA is an extreme exposure duration. Nonetheless, this risk (which is higher than an RME risk) corresponds to about a 0.4 in 10,000 risk, still below the PG use risk management level of 3 in 10,000.

However, this hypothetical scenario can also be considered to be an extreme upper bound screening assessment. Even this extreme hypothetical scenario does not result in exposures and risks that exceed the EPA risk management level of 3 in 10,000. It must be emphasized that the use of the reclaimer scenario does not mean it is a foreseeable ultimate disposition. In any event, the fact that this extreme exposure scenario presents a risk below 3 in 10,000 demonstrates that any conceivable RME scenario related to ultimate disposition will meet the EPA’s risk management level.

F. **Groundwater Pathway Screening Analysis**

EPA’s PG Petition guidance suggests that the Petition should address other potential pathways of exposure, such as the ground water pathway, if they are relevant. The Petition used a screening analysis to address these pathways and, where appropriate, referenced EPA’s prior evaluations. A conservative screening level analysis generally is used to determine at an early stage that no further analysis is warranted.

G. **Radionuclides in Groundwater**

EPA performed extensive modeling of the likely migration of radionuclides in a 1992 assessment of the risk from PG used in agriculture and road construction. Neither concluded that the groundwater pathway supported restrictions on the use of PG. EPA’s risk assessment determined in 1992 that “no radionuclides are calculated to reach the onsite well via the groundwater pathway” nor are any “radionuclide calculated to reach the off-site river or well via groundwater.” The radionuclide risks were found to be zero. The TFI consultants agree with these prior assessments and no additional evaluation was deemed necessary. No monitoring data reviewed indicates a significant groundwater impact from radionuclides.

H. **Screening Evaluation of the Potential Impact of Non-Radionuclides in PG**

The EPA PG Guidance states:

[A petitioner] “must provide information on the other toxic or hazardous constituents of the waste...to assure that the proposed use does not cause non-radiological risks to human health and the environment.”

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63 EPA PG Workbook, supra note 5, at 10.

64 EPA 1992 BID, supra note 7, at Chapter 4. See discussion in Appendix 2.

65 Id., at 4-31, 4-34, Scenario 8, Tables 4-5, 4-18, FN C, Scenario 11, among other sources.

66 EPA PG Workbook, supra note 5, at 9.
To the extent the phosphogypsum is land applied or will remain in place following the test, the risk assessment must examine other potential pathways of exposure, in particular with respect to ground-water and surface water. Consideration of multiple pathways, particularly pathways associated with ground water, are consistent with our review of alternative uses as found in the 1992 rulemaking on phosphogypsum.\footnote{\textit{id}. at \textit{12}.}

Despite this, EPA did not include an assessment of the impact of metals in its review of alternative uses of PG in 1989 or 1992 (see Appendix 3).

However, EPA requested that TFI perform screening analyses of the potential impact of direct contact with PG by road construction workers, and evaluate potential metals leaching on ground and surface water quality. Thus, these assessments were performed and appear in Appendix 3.

These analyses confirm that PG is “safe” for worker handling with respect to non-radiouclides as well. Road construction workers were assumed to come into direct contact with PG (incidental ingestion, inhalation, and dermal contact). The PG concentrations were then compared to health-based screening levels. The chemicals in PG were found to be either a low risk or present at background levels.

Appendix 3 contains an assessment of the potential for metals to leach from a roadbed using PG. The design of new roads affects the potential for exposures by creating a degree of isolation of the base layer from the environment. The PG in the proposed alternative use is placed above the water table and underneath the road’s paved surface. Additionally, the roads are sloped to drain precipitation.\footnote{\textit{Appendix 3}.} This limits water contact with the PG isolated within the base layer. Thus, for purposes of the Petition, leaching of PG to groundwater or surface water is likely not a complete exposure pathway of concern for roadbed use.

state, and local road building agencies will assess whether there is an impact from utilizing material A versus material B and decisions on how to mitigate any impacts is within the discretion of these agencies.

In summary, the presence of other substances that are not radionuclides in PG is unlikely to present an unacceptable worker exposure or adversely impact groundwater or surface water quality. The leaching pathway is likely not a complete pathway of concern for the PG use in road construction proposed in this Petition. Further, federal and state regulations require evaluation of and protection of groundwater prior to implementing road construction projects, regardless of what particular material is used, providing a further dimension of protection to the public.

I. **Comparison of TFI Risk Assessment and Screening Evaluation with EPA's 1992 EPA Background Information Document (BID) Risk Assessment**

Appendix 2 performed a very "high level" and preliminary overview of the main differences that we could readily identify between the dose and risk results provided in EPA's 1992 BID and those previously discussed in this report. The following is a list of comparisons:


- A road thickness of 0.25 m (the same as in 1992).

- The current risk assessment considers the same receptors as did EPA in 1992 as well as two additional receptors suggested by the EPA, namely, the truck driver transporting PG to the construction site and a utility worker who works some time in a trench cutting across a road constructed with PG.

- The EPA (at Table 4-16 for a road base of PG and sand) provided results for a variety of Ra-226 concentrations in PG, the highest of which is 26 pCi/g, comparable to our notional assumption of 27 pCi/g. This difference is not directly relevant since the risk is scalable from the notional assumed pCi/g level used.

- For the road construction worker, the EPA considered workers standing on the road base and unshielded, as was also assumed for the current risk assessment.

- The current risk assessment assumes a worker moves around over the road surface and is exposed at the average of the gamma fields at the center and edge of the road. While not fully clear, the EPA in 1992 may have assumed a worker was always in the center of the road which would largely account for the difference between gamma doses estimated in 1992 and now.
• The road user is assumed in both cases to drive on a road with PG base and a cover (in 1992 asphalt or cement) and in the present analysis, for purpose of illustration, concrete road surface was assumed. Only annual dose and risk are available from the 1992 risk assessment. The 1992 EPA risk assessment used a 0.6 shielding for the road user, but rather than determine the degree to which vehicles have changed in the amount of metal in the under carriage of cars, the current risk assessment takes no credit for shielding provided by the vehicle that would provide some level of shielding which is a conservative assumption and could reasonably be considered.

• The dose to the nearby resident is dominated by exposure to gamma radiation which decreases rapidly with increasing distance from the edge of the road. The 1992 risk assessment assumed the nearest resident would be at 100 meters (approximately 328 ft) from the edge of the road. The current assessment considers the RME exposure scenario to be a resident whose home is located a distance of 50 feet from the edge of the road (an urban resident whose home is at 20 feet from the edge of the road is also calculated to illustrated the change in exposure levels with distance).

• The 1992 BID mentions the presence of metals, but did not consider any substances other than radionuclides in the 1992 risk assessment. The current risk assessment is relying upon the in-depth assessment performed for radionuclide in 1992. However, the current Petition includes a metals screening evaluation to justify the fact that a quantitative risk assessment is not warranted.

• The EPA BID risk assessments considered a reclamer scenario with exposures from gamma radiation and radon, in which the surface is removed and a house is directly built upon PG, and a resident lives in the house for 70 years.
  
  o At EPA’s request, this Risk Assessment calculated this reclamer scenario, even though such a scenario is an extreme hypothetical case that is not a RME exposure. Both the 1992 and present calculation assume the surface is removed, but the current assessment takes into account the necessary construction site preparation and grading, which reduces the thickness and to a lesser degree, the concentration of residual road base construction activity that would be necessary to construct a house.

  o The 1992 BID does not indicate how the risk from radon was calculated (dose from radon was not reported in the 1992 BID).

  o The 1992 BID assumed 70-years residency and the current assessment assumed a 26-year residency (the upper 90th percentile). The 1992 BID appears to have used for the nearby resident scenarios values that are in the ballpark of 25 to 30 years. Thus, the 70-year residency for the reclamer scenario in the 1992 BID appears to be inconsistent with the residency lengths used by EPA in other parts of the 1992 as well as current EPA guidance.

  o The current assessment also assumes a 6 ml poly layer which is standard as a vapor barrier in current home construction.
These comparisons demonstrate the upper bound nature of the risk assessment. Actual doses and risks are likely to be lower.

VI. RISK MANAGEMENT DECISION

A. Overview

The regulatory decision to approve a new use for PG is a risk management decision that is assigned to the Assistant Administrator for Air and Radiation. Risk management decisions involve weighing the results of a risk assessment with "the results of other technical analyses and nonscientific factors, to reach a decision about the need for and extent of risk reduction to be sought in particular circumstances and of the means for achieving and maintaining that reduction."73

This Petition and its Appendices provide the facts and science necessary to decide whether to approve this Petition. This subsection applies these facts and the science to EPA’s risk management factors and articulates the reasons that TF1 submits support approval.

B. The Risk Management Level of 3 in 10,000 is Consistent with Other NESHAP Goals

The EPA Office of Air and Radiation policy is that it will make a case-by-case decision concerning the acceptability of the risk from exposure to radionuclides.74 However, the PG risk management limit of 3 in 10,000 is consistent with other typical EPA risk management decisions.

C. The Highest RME Risk Scenario for the Use of PG in Road Construction is Below the NESHAP Radionuclide Risk Management Goal of 3 in 10,000

This Petition demonstrates that the risks of using PG material in constructing roads meet the risk management goal for approved alternative uses of PG.

The risks from all exposure scenarios were calculated, but the highest RME risk is calculated for the road construction worker who is involved with paving the road with PG that is mixed with soil (i.e., a cancer risk of 0.5 in 10,000, lower than the PG alternative use risk management goal of 3 in 10,000). EPA has long concluded that 3 in 10,000 is the equivalent of the risk from the existing PG stacks, so this alternative does not present a meaningful difference in the risk from the existing stacks. The focus is on the road construction worker since the risks from all other exposure scenarios fall below 110 mrem during road construction use and are of lower risk, although the road worker's risk falls within EPA exposure limits as well.


74 1989 Rule, supra note 2, at 51,564.
The vast majority of road construction workers have much lower risks than those calculated in this Petition. Highway construction workers not directly working on the road are located further from the PG and have lower risks.

The risk calculation for the highest RME for a worker placing road base assumes that the PG emits 27 pCi/g exposure for five years. Based on the preliminary data on radiation levels from PG stacks, the average level of radioactivity from the PG material in each sampled stack is less than the nominal 27 pCi/g used in the risk assessment, thus, the risk from these sampled stacks is even further below the EPA risk management safe limit of 3 in 10,000 risk level. The calculated risk is scalable, i.e., if the radioactivity level in a stack is 13.5 pCi/g, the risk is one half of the risk calculated for the nominal radioactivity level of 27 pCi/g (i.e., the 12.5 pCi/g stack corresponds to a 0.275 in 10,000 risk level, significantly lower than the EPA PG risk limit of 3 in 10,000). On average, the RME exposure and the dose to risk conversion for road construction workers using PG are likely to overestimate risk.

Similarly, the highest RME to a resident living near a road (assuming the resident lives in a home located 50 feet or more from a road for 26 years) assuming the PG contains 27 pCi/g is approximately a 0.08 in 10,000 cancer risk, again, well below the PG reuse risk management goal of 3 in 10,000. Most residents living near roadways are located further than 50 feet from the edge of the road, and the RME exposure and dose to risk conversion are likely to overestimate risk.

The reclaimer scenario is not a RME since it is such a rare potential event, and should not be used in the risk management decision. Nonetheless, the risk assessment report calculated a risk using RME-type exposure input below the PG reuse risk management goal of 3 in 10,000.

D. **Science Policy Assumptions and Uncertainties are Taken into Account in the Final Risk Management Decision**

1. **Overview**

Each of the factors EPA considers in its risk management decision has sensitivities, variabilities, and uncertainties. EPA specifically considered uncertainties and other nonrisk factors in its 1989 and 1992 decisions on acceptable alternative uses of PG.\(^5\)

A recent NAS report recommended incorporating uncertainty analysis, which was broadly defined to include sensitivities, variability, and various other uncertainties, into EPA decisions.\(^6\) This NAS report recommends that “uncertainty analysis” be “designed on a case-by-case basis.”\(^7\) EPA considered uncertainties in previous risk calculations and decisions concerning

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\(^5\) EPA PG Workbook *supra* note 5, at 5.


\(^7\) *Id.*
alternative uses of PG. However, combining RME with the inherent uncertainties in the dose to risk conversion factors can yield risks that are overly conservative compared to actual risks.

Science policy influences both the exposure calculation and the cancer potency and noncancer risk factors that convert the exposure to risk. The EPA decision makers and the public need to understand how policy influences the risk calculation. Put simply, regulatory risk is not the same as actual harm. Unduly conservative risk calculations do not serve the public, since they divert limited resources to issues that present less risk. Science policy based on accumulations of conservative assumptions, including extra layers based on uncertainties, can distort risk estimates and undermine the value and credibility of risk management decisions.

2. **Measurement Uncertainty**

Each calculated risk depends upon how sensitive the calculation is to changes in the measurements and input values used in any risk assessment. Risk is assumed to be linearly proportional to dose and the length of exposure. For example, if the concentration of radionuclide in PG increases by 10%, the dose (and, therefore, the risk) increases by 10%. Similarly, if the length of exposure increases by 20%, the total dose increases by 20%.

3. **Variation by Location**

Some of the inputs to risk assessments naturally vary. For example, the average radioactivity level in PG stacks depends upon the source of the phosphate ore and other site specific factors. This risk assessment assumed average radioactivity levels of 27 pCi/g. However, the average level of radioactivity in some PG stacks may vary from less than 10 pCi/g to 35 pCi/g, and even at levels of 35 pCi/g, the Risk Assessment shows these doses are safe. Again, dose is directly proportional to the radioactivity level.

4. **The Influence of Exposure Policies**

It is well settled that exposure is not sufficient to support regulation unless there is a significant risk. Because empirical data are often not available, a 2013 National Academies of Science (NAS) report noted that EPA’s risk assessment policies and practices rely heavily on default options or generic approaches. These approaches can introduce high levels of uncertainty into risk assessments.

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78 EPA PG Workbook, supra note 5, at 5.

77 Based on the risk assessment, PG with radiation levels a couple of times greater than 27 pCi/g may still be utilized for road construction. In fact, an average radiation level of 148 pCi/g corresponds to EPA’s risk management goal of 3 in 10,000.

79 “When the administrative record reveals only scant or minimal risk of material health impairment, responsible administration calls for avoidance of extravagant, comprehensive regulation. Perfect safety is a chimera; regulation must not strangle human activity in the search for the impossible.” Industrial Union Dep’t v. API, 448 U.S. 607, 642 (1980). See NRDC v. EPA, 1987, supra note 41, at 1164-65.

As noted above, the "intent of the RME is to estimate a conservative exposure case (i.e., well above the average case) that is still within the range of possible exposures." A NAS Committee reviewing EPA's regulation of technologically enhanced naturally occurring radioactive material (TENORM) recommended that EPA "should use exposure and dose risk assessments that are 'reasonably realistic'" in developing standards for exposure to the various types of low level naturally occurring radiation. The Committee defined "reasonably realistic" as "not...intended to greatly overestimate or underestimate actual effects for the exposure situation of concern" and EPA agreed with the Committee's recommendations. Thus, by definition, RME exposures should be intentionally set at levels that are at the high end, but not an extreme worst case.

The use of defaults has been criticized by independent commentators for: (a) "lack of an adequate scientific basis;" (b) the fact that default "can mask the uncertainty;" (c) observations that defaults can be "overly conservative;" (d) the fact that cumulative impact of uncertainties is not well defined; and (e) concerns "whether there is any basis for believing that the upper-bound estimate for one substance has the same relation to the 'true' risk as it does for another substance."

5. **Risk Factor Policies and Uncertainties**

EPA has long utilized (and courts have long upheld) the principle that a 1 in 10,000 risk level is "safe." As a unanimous en banc ruling of the Court of Appeals for the District of Columbia Circuit candidly noted, the basis for claiming harm from exposure to chemicals at extremely low environmental levels is more a function of "the rules of arithmetic rather than because of any knowledge" and there was "no particular reason to think that the actual line of the incidence of harm is represented" by the assumption selected by EPA. This acknowledgment is also apt for the risks from radionuclides.

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n5 Risk Assessment Guidance for Superfund, supra note 35, at 7-2.

n3 EPA Report to Congress Re: TENORM, supra note 37, at 15.

n4 Id. at 15 of 22, citing the NAS Report at p. 245. "If high-end values are chosen for every exposure factor, then the resulting exposure estimate may no longer be consistent with the RME and may exceed the realm of possibility altogether." EPA, Human Health Evaluation Manual, Supplemental Guidance: Update of Standard Default Exposure Factors, OSWER Directive 9200.1-120 (Feb. 6, 2014) available at https://www.epa.gov/sites/production/files/2015-11/documents/oswer_directive_9200.1-120_exposurefactors_corrected2.pdf.

n5 Uncertainty in Environmental Decisions, supra note 76, at 58, available at https://www.nap.edu/read/12568/chapter/4#58. The RME and other factors utilized in the risk assessment are documented in the literature (see RESRAD documentation, EPA guidance or as justified in the various Appendices to this Petition).

n6 NRDC v. EPA, 1987, supra note 41, at 1165.
The 2013 NAS noted that:

EPA originally selected the linear, no-threshold default as a “conservative” or “health-protective” policy choice because it assumes that there is no dose below which risks are not increased. It is likely to generate the highest, or upper-bound, risk estimate consistent with the data; the actual risk almost certainly will not exceed the upper bound and will likely fall below it.87

Use of the ICRP value (the value proposed by the international institution whose purpose is to provide such advice) is supported by several factors:

First, ICRP is an expert advisory body that offers its recommendations to regulatory and advisory agencies, mainly by providing guidance on the fundamental principles on which appropriate radiological protection is based. The 2007 recommendation was produced “after eight years of discussions, involving scientists, regulators, and users all around the world.”88

Second, the Petition’s use of the ICRP dose to risk conversion factor is consistent with EPA’s radiation risk assessment factors and procedures. For example, the EPA 2011 radiation guidance89 provides cancer risk factors for uniform whole-body exposures of low-dose gamma radiation to the entire population, essentially the same dose to risk conversion range derived by the ICRP.

Similarly, as noted above, the organization chartered by the U.S. Congress in 1964 to, among other things, “develop ... recommendations about ...protection against radiation” (i.e., the United States National Council on Radiation Protection and Measurements (NCRP)) uses the same dose to risk conversion factor as the 2007 ICRP.90

Third, the international scientific and regulatory communities have widely adopted the ICRP recommendations.91

87 Uncertainty in Environmental Decisions, supra note 76, at 58, available at https://www.nap.edu/read/12568/chapter/4#58.


89 EPA Radiogenic Cancer Risk Models and Projections for the U.S. Population, supra note 53.


91 See Radiation Protection and Management of NORM Residues in the Phosphate industry, supra note 24, at 165. The IAEA was founded to “establish or adopt ... standard of safety for protection of health and minimization of danger to life and property” and while “[r]egulating safety is a national responsibility ... many have decided to adopt the IAEA’s standards for use in their national regulations” (including Sweden, Denmark, the Netherlands, the UK, Japan, Canada, Belgium, Japan, and the EU). IAEA, Governmental, Legal and Regulatory Framework for Safety, 7 (2018) available at https://www-pub.iaea.org/MTCD/Publications/PDF/PUB1798_web.pdf.


Fourth, the International Atomic Energy Agency (an organization in which the U.S. is a member and helped establish) and the European Union (as well as each of its member countries) utilized a 1 millisievert (1 mSv) per year acceptable level of radiation exposure, which has been widely adopted by the international community, such as the IAEA and EU regulations. This corresponds to a 26-year total dose of 26 mSv (i.e., 2,600 mrem).

The ICRP approach is more stringent than the large, and growing, body of scientific literature that radiation risks have a threshold. Also, in 2015, a U.S. Nuclear Regulatory Commission (NRC) Advisory Committee acknowledged that:

> There is a large, and growing, body of scientific literature as well as mechanistic considerations which suggest that 1) the LNT model may overstate the carcinogenic risk of radiation at diagnostic medical, occupational, and environmental doses and 2) such low doses may, in fact, exert a hormetic (i.e., a beneficial or protective) effect.\(^2\)

The United Nations Scientific Committee on the Effects of Atomic Radiation notes that below doses of 100 to 200 mGy (roughly equivalent to 10,000 to 20,000 mrem), “[c]linical and epidemiological studies alone are unlikely to be able to identify significant elevations in risk.”\(^3\)

Because, as a matter of policy, neither EPA nor the Nuclear Regulatory Commission has changed its "no threshold" default assumptions, this Petition does not seek to go beyond the widely accepted ICRP value. In reality, the actual risk may be lower.

E. **Comparison of Radioactivity Levels from Use of PG and Naturally Occurring Background**

Each exposure scenario we assessed results in a radiation dose well below the annual natural background level. The annual background level of naturally occurring radiation is 310 mrem.\(^4\) For a 26 year period, the cumulative dose is 8,060 (310 mrem times 26), thus the total dose for a nearby resident (16 mrem) given this PG use is 0.2% of the cumulative natural background dose levels (16 divided by 8,060). Background levels of radiation are often considered in governmental decisions. For example, EPA’s PG Workbook compares the risk from use of PG to background levels of radiation.\(^5\) When the calculated risk for receptors in a risk assessment is lower than background, it is a relevant factor in the risk management decision.

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\(^3\) UNSCEAR Report, *supra* note 91, at 8.

\(^4\) Appendix 2.

\(^5\) EPA PG Workbook, *supra* note 5, at 13 ("To put this number in perspective and allow you to see how little increase in risk is permitted, the risk in the United States of developing a fatal cancer (from all causes) is about one in four").
F. EPA Policy Supports Recycling of Wastes and Waste Residuals

EPA’s 1989 and 1992 risk management decisions concerning alternative uses of PG took into account the Agency’s overarching policy of supporting recycling. Since 1992, EPA has increased its emphasis on adopting sustainability policies.

EPA has prioritized policies to encourage recycling of byproducts and other materials. Similarly, the U.S. Department of Agriculture also has guidance on using reclaimed materials in road construction. Such recycling decreases raw material costs for companies and government entities that use the PG material, increases beneficial land use, reduces long-term maintenance costs, and avoids with respect to coal ash, site-specific potential environmental risks from long term storage of PG. For example, EPA states that:

Beneficial use is the recycling or reuse of coal ash in lieu of disposal. For example, coal ash is an important ingredient in the manufacture of concrete and wallboard, and EPA supports the responsible use of coal ash in this manner. This final rule supports the responsible recycling of coal ash by distinguishing beneficial use from disposal.

EPA recently concluded that:

[Environmental releases of COPCs from CCR fly ash concrete and FGD gypsum wallboard during use by the consumer are comparable to or lower than those from analogous non-CCR products, or are at or below relevant regulatory and health-based benchmarks for human and ecological receptors. Thus, EPA supports the continued beneficial use of coal fly ash in concrete and FGD gypsum in wallboard. Furthermore, the Agency believes that these beneficial uses provide significant environmental and economic benefits, and opportunities to advance Sustainable Materials Management (SMM).]

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96 1989 Rule, supra note 2.


98 "Sustainable Materials Management (SMM) refers to the use and reuse of materials in the most productive and sustainable way across all their entire life cycle. On a broader scale, SMM looks at social, environmental and economic factors to get a more holistic view of the entire system. The benefits of maximizing this connection include conserving resources, reducing waste, slowing climate change, and minimizing the environmental impacts of the materials we use." EPA, Advancing Sustainable Materials Management: 2016 Recycling Economic Information (REI) Report, 2 (2016), available at [https://www.epa.gov/sites/production/files/2017-05/documents/final_2016_rei_report.pdf].

99 Reclaimed Materials and Their Applications in Road Construction, supra note 71.


The use of CCR for beneficial use in road construction is analogous to and supports the Office of Air and Radiation’s approval of the use of PG in road construction. More generally, approval of the use of PG in road construction is consistent with EPA’s policy of encouraging recycling.

G. Naturally Occurring Background Radioactivity and Metals are Present Widely in the Environment, Including Existing Road Construction Materials

Many consumer products contain radioactive components (smoke detectors, clocks and watches, older camera lenses, older gas lantern mantles, older televisions and computer monitors, sun lamps and tanning salons, ceramic materials such as tiles and pottery, glassware, and some EXIT signs, among other products).102 Most consumer products contain metals. Similarly, “[r]adioactive materials (including uranium, thorium, and radium) exist naturally in soil and rock.”103 Essentially all air contains radon and many types of soil and natural rock emit radiation.104 In addition, virtually all road construction materials contain radioactivity and metals.

Coal ash, fly ash, bottom ash, natural gypsum, and other common construction materials contain radioactive material (see Table below).105

A 2014 evaluation of coal ash beneficial uses concluded that:

All of the existing evaluations identified concluded that radiation exposures from fly ash concrete are not a major source of concern. Several of these existing evaluations compared fly ash concrete to analogous products and found that the potential exposures do not represent an appreciable addition to the background radiation that the general public is subjected to on an annual basis. Naturally occurring radionuclides are present throughout the environment in food, air, water, soil, consumer products, and even the human body. All natural resources used in building construction (e.g., cement blocks, bricks, granite, soil, rocks) contain some trace level of naturally occurring radionuclides. For example, the USGS concluded that “the radioactivity of typical fly ash is not significantly different from that of more conventional concrete additives or other building materials such as granite and red brick.” The NCRP concluded that exposures from living in concrete buildings containing fly ash are “similar to calculations made for individuals living in a brick and masonry home. Consequently, it is assumed that the use of [coal ash] in building materials has not substantially increased the average dose to an individual in the population residing in a building constructed with brick or masonry materials.”106


104 Id.

105 EPA Report to Congress Re: TENORM, supra note 37, at Appendix A.

The United Kingdom Health Protection Agency "concluded that exposures to ‘…members of the public from the use of [fly ash] in building materials is negligible.'"\textsuperscript{107}

Thus, the appropriate risk management consideration is not whether PG has a low level of radioactivity or metals, but whether the risk is below the EPA PG risk management goal of 3 in 10,000.

\textsuperscript{107} Id.
As a comparison to background levels, radium 226 concentrations in soils of the U.S. are shown at the top of the table.

<table>
<thead>
<tr>
<th>TENORM Material</th>
<th>Range of Radioactivity Concentrations, Radium 226</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Low</td>
</tr>
<tr>
<td>Soils of the United States</td>
<td>0.2</td>
</tr>
<tr>
<td>Uranium Mining Overburden</td>
<td>3</td>
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<tr>
<td>Uranium In-Situ Leach Evaporation Pond Solids</td>
<td>300</td>
</tr>
<tr>
<td>Phosphate Ore (Florida)</td>
<td>7</td>
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<tr>
<td>Phosphogypsum</td>
<td>11.7-24.5</td>
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<tr>
<td>Phosphate Fertilizer</td>
<td>5.7</td>
</tr>
<tr>
<td>Coal Ash1-Bottom Ash</td>
<td>1.6</td>
</tr>
<tr>
<td>Fly Ash</td>
<td>2</td>
</tr>
<tr>
<td>Petroleum (oil and gas)</td>
<td>0.1 pCi/l</td>
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<tr>
<td>Produced Water</td>
<td>&lt;0.25 pCi/g</td>
</tr>
<tr>
<td>Pipe/Tank Scale</td>
<td>–</td>
</tr>
<tr>
<td>Water Treatment Sludge Treatment Plant Filters</td>
<td>1.3 pCi/l</td>
</tr>
<tr>
<td>Rare Earths</td>
<td>5.7</td>
</tr>
<tr>
<td>Monazite</td>
<td>–</td>
</tr>
<tr>
<td>Xenotime</td>
<td>–</td>
</tr>
<tr>
<td>Bastnasite</td>
<td>–</td>
</tr>
<tr>
<td>Titanium Ores</td>
<td>3.9</td>
</tr>
<tr>
<td>Rutile</td>
<td>–</td>
</tr>
<tr>
<td>Ilmenite</td>
<td>–</td>
</tr>
<tr>
<td>Wastes</td>
<td>–</td>
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<tr>
<td>Zircon Wastes</td>
<td>–</td>
</tr>
<tr>
<td>Wastes</td>
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<tr>
<td>Aluminum (Bauxite) Ores</td>
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<tr>
<td>Product</td>
<td>–</td>
</tr>
<tr>
<td>Wastes</td>
<td>–</td>
</tr>
<tr>
<td>Copper Wastes</td>
<td>0.7</td>
</tr>
<tr>
<td>Geothermal Energy Waste Scales</td>
<td>10</td>
</tr>
</tbody>
</table>

H. **Use of PG For Roadway Construction Provides a Net Economic Benefit and is Consistent with the Administration’s Regulatory Reform Policies**

A detailed report explaining the various economic benefits to be expected from approval of PG use in road construction will be submitted shortly in support of this Petition.
The Petition is consistent with Presidential Executive Orders that encourage: (a) reducing unnecessarily burdensome and costly regulation,\textsuperscript{108} (b) maximizing the use of goods, products and materials produced in the U.S.;\textsuperscript{109} and (c) encouraging innovative strategies and trade policies.\textsuperscript{110}

I. **Other Benefits to Eliminating PG Stacks**

Construction and maintenance of PG stacks are large engineering projects. There are environmental and actuarial risks presented by any such construction project. The approval of PG for use in road construction will reduce future potential risk by limiting the size of existing and potentially eliminating the need for new PG stacks.

\textsuperscript{108} Presidential Executive Order on Reducing Regulation and Controlling Regulatory Costs, Executive Order 13771 (Jan. 31, 2017).

\textsuperscript{109} Presidential Executive Order on Buy American and Hire American, Executive Order 13788 (April 18, 2017).

\textsuperscript{110} Presidential Executive Order on Establishment of Office of Trade and Manufacturing Policy, Executive Order 13797 (April 29, 2017).
SIGNATURE PAGE

I, Andrew (Andy) T. O’Hare, CAE, am Vice President of Public Policy for The Fertilizer Institute (the national trade association for fertilizer companies, including the companies that own and/or operate phosphogypsum stacks). I coordinated the preparation of this Petition and am signing on behalf of all of the TFI members who own or operate PG stacks.

Andrew (Andy) T. O’Hare
Vice President of Public Policy
The Fertilizer Institute