Some Guidance on Applying for Approval for Other Uses of Phosphogypsum

We refer to the information on this page as “some guidance” in recognition that we will continue to add more guidance in response to your questions about how to apply for approval of other uses for phosphogypsum. If you need guidance on a topic that is not addressed here, please contact us.

GETTING STARTED

At what point should I contact EPA regarding my idea/application?
The earlier the better. Even if you’re just thinking about an idea, wondering if it’s been done before, or even feasible, we encourage you to call. It may save you a lot of time and trouble. Remember: You must have EPA approval before you do anything with phosphogypsum.

What do I have to do to obtain approval of ‘other uses?’
The primary thing you must do is to prepare and submit an application for approval of “other” uses for phosphogypsum. Generally speaking, your application must provide EPA with two kinds of information:

• First, a detailed description of your idea for using phosphogypsum and how you plan to implement it.
• Second, proof that your idea for using phosphogypsum won’t be more hazardous to people than leaving it on a stack.

We will look over your application and contact you regarding any questions or omissions that you must address. Once the application is complete, we will review it and, if it meets the requirements, we will approve it.

May I proceed with my project on an “application pending” basis?
No.

Will EPA provide funding for my project?
No. However, we will share any information we have about organizations or companies that may provide funding.

APPLICATION CONTENTS

What should I include in the description of my idea and how I plan to implement it?
Your application must provide the information requested in 40 CFR 61.206, Distribution and Use of phosphogypsum for other purposes. We are looking for specific pieces of information about the applicant, whether you are applying for yourself or another person. The information required includes the following:
1. The name of the applicant.
2. A description of the applicant’s intended use of the phosphogypsum. You must provide a description of how the applicant will be handling and processing it. Be specific for each phase or step. Remember we may not be familiar with the technology.
3. The complete street address (and mailing address, if different) of any facility the applicant may use to handle or process phosphogypsum.
4. How much phosphogypsum the applicant plans to use at each facility. Remember, each application is for a specific amount, which may not be exceeded. If you aren’t sure, estimate on the high side. This will save you from having to call us later for approval of a larger amount.
5. The average radium concentration of the phosphogypsum the applicant will be using. This information may be available from the owner of the stack. The sampling must have been done within the past 12 months.
6. How the applicant plans to prevent the release of any phosphogypsum into the environment. This could be done using barrels, tarps, indoor storage, for example. Please be specific when you provide this information!
7. How will the applicant dispose of any unused phosphogypsum.
8. The signature of a corporate officer on the application. If the applicant isn’t part of a corporation, please call us to discuss how to respond to this requirement.

What must I do to prove that the idea won’t be any more hazardous than storing phosphogypsum in stacks?
You must include in your application, the results of a risk assessment proving that the idea won’t be any more hazardous than storing phosphogypsum in stacks.

THE RISK ASSESSMENT

The requirements include a risk assessment. What is a risk assessment?
A scientific analysis that examines the ways that your proposed use could expose people and the environment to phosphogypsum, how great the exposure would be, and what health effects can be expected.

When do I have to do a risk assessment?
You should do the assessment before making your application.

How do the results of the risk assessment affect the decision on approval?
The risk assessment must prove that the proposed other use will not cause a threat to the public or environment greater than if the phosphogypsum were left on the stack. This means that the risk assessment must show that the chance of developing a fatal cancer in people who are exposed to phosphogypsum as a result of the use for which you are applying use must not increase more that one in ten thousand (1 x 10^-4). To put this number in perspective and allow you to see how little increase in risk is permitted, the risk in the US of developing a fatal cancer is about 1 in four.
Should I, or can I, do the risk assessment myself?
That determination must be made by you. Generally speaking, the analysis involves the use of a computerized model, which is a series of mathematical equations that combine the impact of many different factors that determine the health effects of your use. For example, if your involves making a product that goes in the ground, the potential for the phosphogypsum to affect the health of people near it will depend on how dry or wet the soil is, how close it will be to drinking wells, whether there are people living near where you propose to use it, etc. Depending on the complexity of the idea and model, you may require assistance. Whether you do the assessment yourself or have someone else do it for you, we will require that you submit all your information, and we will attempt to duplicate your results.

Will EPA do the risk analysis for me?
No. While we will do many of the calculations in our review of your application, this is only to ensure technical accuracy.

RISK ASSESSMENT MODELS

Does EPA tell me which model to use?
No. Although we include some information about models on this Web site. Also, please feel free to contact us for help; we may be able to provide some additional guidance on selecting appropriate models.

Does EPA provide any models I can use?
In some cases, yes. There are certain models that have been approved for use. If we are familiar with an approved model that would meet your needs, we can usually provide it to you or assist you in obtaining it.

If I think there’s a better model than you suggest, what must I do to demonstrate it meets EPA’s requirements?
At a minimum, you must send an electronic copy of the model, a users manual, and verification and validation information to be sure it’s a “legitimate” model. We will review the information and let you know if it is appropriate for conducting a risk assessment.

What if I can’t find a model to meet my needs?
It is likely that there is a model that will meet your needs. Contact us for assistance in helping you find it.

How can I find out if there is an earlier application someplace that is similar enough to mine I could use its risk assessment?
All applications that may be released to the public will be included in this Web page. You may also contact us at radiation.questions@epa.gov if you need additional information.

APPLICATION FORMAT
What format should I use for the application?
You may use any well organized format you choose. Just be sure to number sequentially the pages in the body of the application as well as the pages in any appendices. However, we request that you do not permanently bind your application, since we often have to make additional copies for the review process.

How many copies should I send?
One original (marked as such) and four copies.

Do I need to make a fancy presentation package for it?
No. Our review is made on technical merit rather than presentation. However, we do prefer simple, well organized applications.

OTHER REQUIREMENTS

Are there any other EPA requirements than those related to the application?
It depends on the nature of the idea. In some cases, we may require the applicant to take special precautions. For example, if you were proposing to use phosphogypsum in a way that would bring it into contact with the surface of the ground, such as using it for a road base, we would probably require you to establish a ground water monitoring program.

If I meet EPA requirements, do I have to consider state and local requirements?
EPA approval of your application does not supercede any local or state requirements. Before you send in your application it would be wise to talk to the local regulators to ensure you can proceed. If you aren’t sure whom to contact, we may be able to help you.

Is there a limit on how much phosphogypsum would be available for the use I propose?
No, although there is a 7,000 pound limit on the amount that may be used for research, there is no limit on the amount that may be used for production. But, we need to know how much the applicant plans to use when you submit the application. If you find that you need more, please contact us.

APPLICATION REVIEW PROCESS

How long will it take EPA to review my application?
The way we conduct the application review and how long it takes really depend on the application itself. Because of this, we can’t give you a specific time frame. However, you can expect our review of complete applications to be finished within about 2 - 4 months

Will I be required to demonstrate my process, or travel to DC to make any presentations?
No. We should be able to make a decision based on the information you provide in the application. If we have any questions, we will contact you.

Will my application be made public? What if there is business sensitive information I wish to protect?
Unless there is material, such as details about your proprietary process, that you have marked “business sensitive,” we will make the application available to the public. If we have any questions or are uncertain about the sensitivity of any information, we will contact you as a courtesy. However, you are responsible for clearly indicating which information is business sensitive.

What role does my local EPA Regional office play in the review of an application?
EPA staff in the Regional Offices review the applications that affect their region. In some circumstances, we also provide copies to local and state officials for their comments. We will notify you before we release the application outside of EPA.

AFTER USE APPROVAL

What sort of progress reports do I have to make if my application is approved?
None, unless we specifically require you to in our approval. We may contact you from time to time for an update, though.

Can my application, if approved, be revoked?
Yes, if you violate the approved process. For example, if you say you are going to be making your product in State A, then shipping it to State B for testing, and we discover you have sent it to State C for testing, we may revoke your approval. It is also possible that we could involve our Office of Enforcement and Compliance Assurance for further penalties. It is much easier to contact us beforehand and discuss any needed changes to your approved application.

How do I close out my application once I have completed my project?
There really is no “official” closeout. Your application includes information regarding final disposition. A letter or phone call would be welcome so we can make a note in your application file.

Are other uses approved for a few years or permanently?
Other uses are approved for as long as nothing in the application changes. If some piece of information changes, you must notify EPA. You probably won’t be required to do any additional work unless the change is in one of the factors that was considered in the risk analysis. When factors that affect the risk of the use change, you may have to redo part or all of the risk analysis.

If an application comes in from my competitor for an idea identical to mine, will EPA contact me?
No. Each application is considered unique and is reviewed on its own merits.

If I submit an application to manufacture a specific product, and later realize it can be used for another purpose must I submit a new application?
Yes. A new use-specific risk analysis must be done.