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Controlling Pathogens and Meeting Regulatory Requirements for Land Application of Biosolids

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Alternative Treatment Technologies – Working With the Pathogen Equivalency Committee

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ABSTRACT

Under current Federal regulations (40 CFR 503), municipal sludge must be treated prior to land application. The regulations identify two classes of treatment with respect to pathogen reduction: Class B (three alternatives) which provides a minimum acceptable level of treatment; and Class A (six alternatives) which is considered to be free of pathogens. Regardless of the class of treatment, the regulations allow for the use of alternative treatment technologies if they are equivalent to proven technologies with respect to pathogen reduction. EPA's Pathogen Equivalency Committee (PEC) was established to evaluate the treatment technologies on their ability to reduce pathogen densities and to provide recommendations regarding equivalency applications to EPA's Office of Science and Technology and appropriate permitting authorities. In 2008 the PEC updated the criteria it uses to make recommendations of equivalency on innovative or alternative sludge pathogen reduction processes. To assist new applicants through the equivalency recommendation process the pathogen equivalency committee developed a website which provides specific information for applicants. The main steps of the equivalency recommendation process are discussed through the introduction of the website materials.

KEYWORDS

Sludge disinfection, pathogen equivalency committee, PSRP, PFRP, fecal coliform, enteric viruses, helminth ova.

INTRODUCTION

Originally under 40 CFR Part 257 and now under 40 CFR Part 503, one of the accepted options for treating sewage sludge before applying it to land is to use a process that is *equivalent to* the specifically listed processes to significantly or further reduce pathogens. In 1985 the U.S. Environmental Protection Agency (U.S. EPA) created the Pathogen Equivalency Committee (PEC) to oversee this equivalent process alternative by providing guidance and making recommendations on process equivalency to the permitting authorities at the federal and state levels. Since its inception, the PEC has reviewed numerous applications and recommended processes for equivalency to processes to significantly reduce pathogens (PSRPs) which meet Class B pathogen reduction requirements or processes to further reduce pathogens (PFRPs) which meet Class A pathogen requirements. The PEC's approach to equivalency recommendations evolved over this time. There was a degree of flexibility in the way each

application was treated. The differences in review were typically an artifact of the wide variety of process types being considered. Still, these differences may be construed as unequal treatment. Further, over 20 years have passed since the PEC conceived of their equivalency requirements. Since that time negative public perception of the land application of biosolids has grown and the PEC is facing increased scrutiny. The committee is now at a point where the equivalency recommendation process is prescriptive and expected to be rigorously followed. The review procedure for each new application is consistent and thorough. However, innovative approaches to treatment of municipal sludges are currently being developed which may prove to be cost effective and environmentally friendly. Therefore, the PEC encourages alternative technology applicants and is open to working with individuals, municipalities and technology developers as they develop their application and demonstrate process effectiveness. The PEC website (www.epa.gov/ord/nrmrl/pec) is used to disseminate information that will assist new applicants in successfully obtaining a PEC equivalency recommendation.

OBJECTIVES

The purpose of this paper/presentation is to introduce the PEC's website and familiarize the sewage sludge management community with the PEC's rigorous equivalency recommendation process through the use of a hypothetical case study. The PEC's mandate and key concepts involved in the review process will be discussed in an effort to help potential applicants understand what to expect as they embark on the rewarding path to securing an equivalency recommendation for their innovative or alternative sludge pathogen reduction process.

CONCEPTION

Website contents relevant to this stage. Much of the Basic Information page will be helpful during conception. The table of contents of the Basic Information page is shown in Figure 1. This information includes descriptions of many of the terms involved in an equivalency application such as the PEC itself, PSRPs and PFRPs, national and site-specific equivalencies, proof-of-concept, laboratory, pilot, and full scales, and the key organisms; fecal coliform, *Salmonella* spp., enteric viruses, and helminth ova. One link, *What are the benefits of obtaining an equivalency over operating under Alternatives 3 & 4 for Class A, or Alternative 1 for Class B?,* is useful for those who have not yet decided whether seeking equivalency is worth the effort. Once it is determined that a recommendation of equivalency is desired, the *How do I get started?* link on the Basic Information page is a good place to begin.

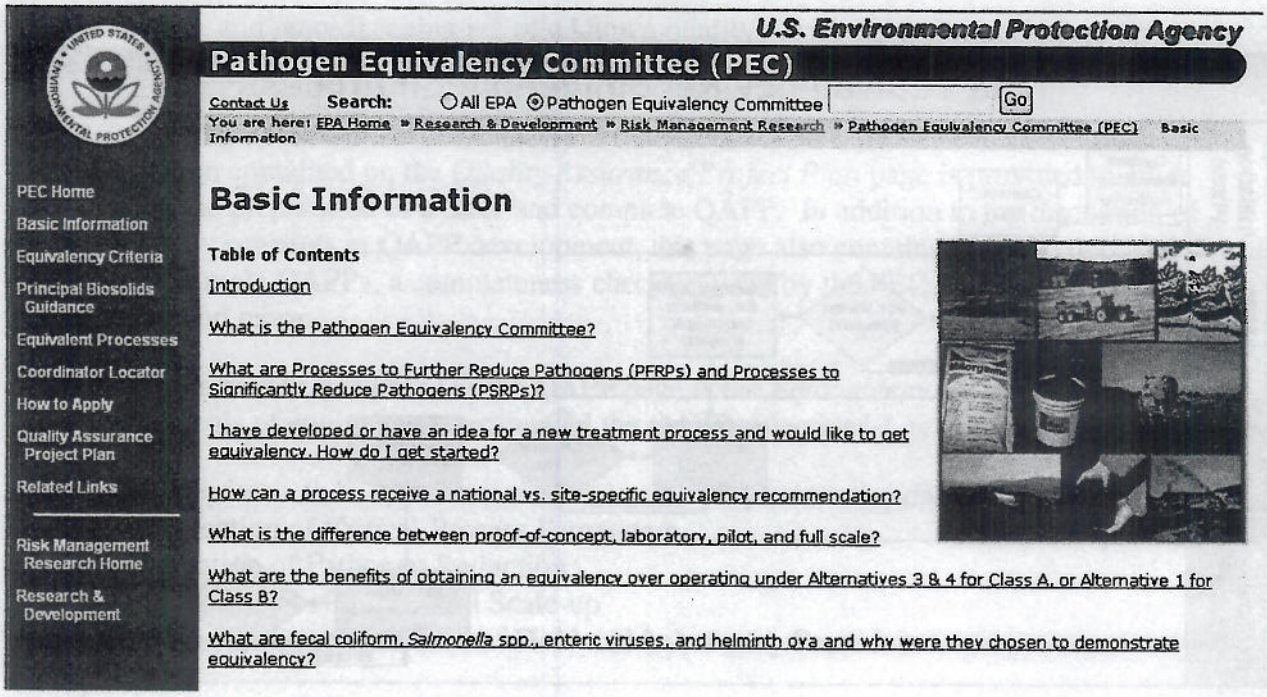

Figure 1: Table of Contents for the Basic Information page of the PEC's Website

For a look at what lies ahead, the *How to Apply* page is helpful. The typical equivalency recommendation process is broken down into four main phases as detailed in Figure 2. The first phase begins with either contacting your permitting authority or the pathogen equivalency committee directly. However, before this initiation phase, the applicant should have answered three basic questions which are detailed in the *How do I get started?* link; (1) Will you be seeking a PSRP or PFRP equivalency?, (2) Do the critical operating parameters of your process like pH, temperature, and time meet or exceed those of an established option?, and (3) Will you be seeking a national or site-specific equivalency?

Throughout the entire website there are frequent references and hyperlinks to the principal biosolids guidance document EPA 625/R-92/013 (2003 Revision) *Control of Pathogens and Vector Attraction in Sewage Sludge* (better known in the field as the white house document). One page of the PEC website is dedicated to the white house document. The entire document and its table of contents are accessible from this page. Notes on updated information since the latest revision of the white house document (EPA, 2003) are also listed, including a link to the *Equivalent Processes* page, which describes all the processes which have been recommended as equivalent to date.

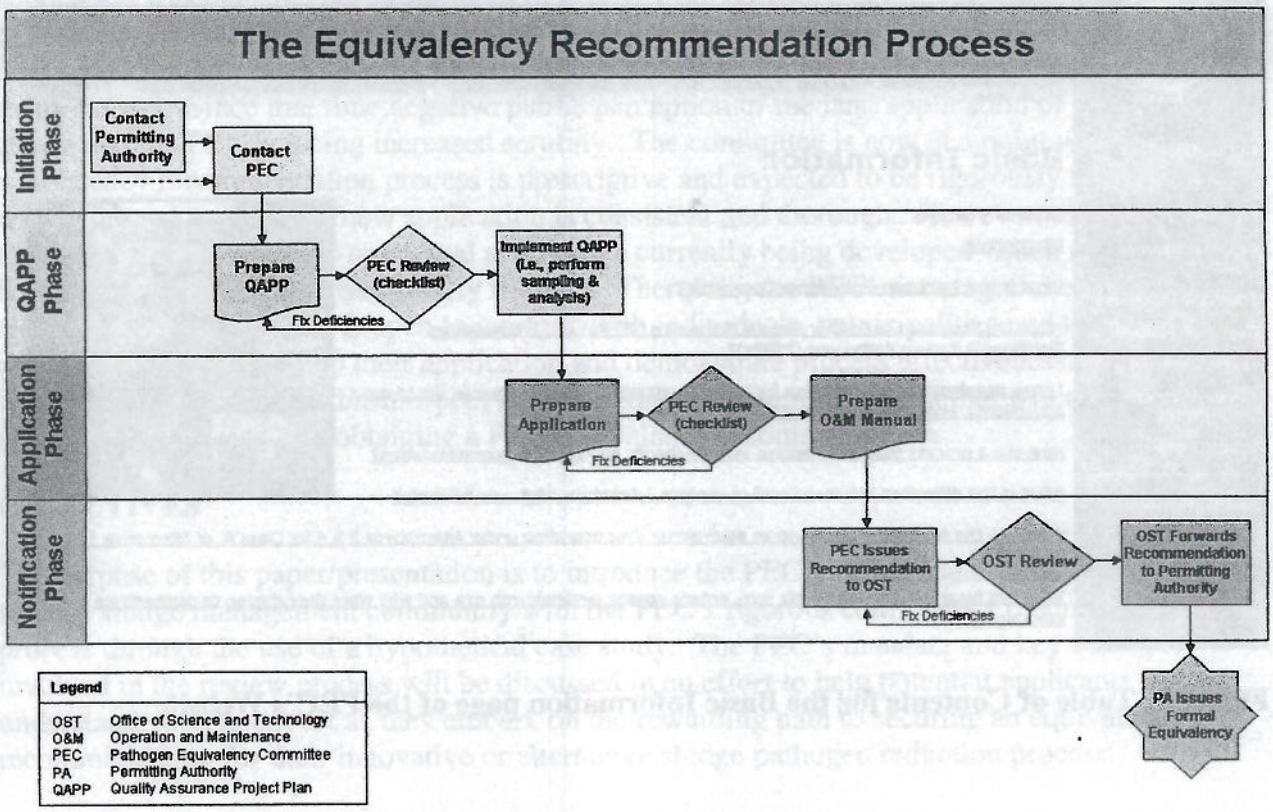

Figure 2: The eleven steps of the equivalency recommendation process can be broken down into 4 phases.

INITIATION PHASE

Website contents relevant to this stage. As described on the *How to Apply* page, to begin the application process it is preferred that a new applicant first contact their permitting authority (either state or EPA regional biosolids coordinator). It will be the permitting authority's call on whether or not to involve the PEC. Contact information for all biosolids coordinators can be found through the Coordinator Locator page. In certain cases, where no treatment plant or specific location is involved, the PEC can be contacted directly through their general e-mail address, pec@epa.gov, as indicated on the website.

QAPP PHASE

Website contents relevant to this stage. A quality assurance project plan (QAPP) is now required as an integral part to the equivalency application. A QAPP is a written document that describes the experimental design, sampling and analytical procedures, quality assurance procedures, quality control specifications, data analysis, and other technical activities that must be implemented to ensure that the results of the project will meet project objectives. Data in support of an equivalency application must be collected in accordance with the QAPP so that the desired quality in sample collection, laboratory analysis, data validation, reporting,

documentation, and recordkeeping are of a known quality. Prior agreement between the applicant and the PEC on what, where, when, and how data is collected will save money and effort in the long run.

The information contained on the *Quality Assurance Project Plan* page is provided to guide applicants in the preparation of a clear and complete QAPP. In addition to the discussion of some of the key concepts in QAPP development, this page also contains links to annotated guidelines, example QAPPs, a completeness checklist used by the PEC to review QAPPs and applications, and more.

Almost as important to this phase as the QAPP page is the *Equivalency Criteria* page. This page provides the goals of equivalency testing and the QAPP objectives.

There are four criteria to be met to receive an equivalency recommendation:

1. Identification of Critical Process Parameters
2. Verification of Pathogen Reduction
3. Demonstration of Successful Scale-up
4. Appropriate Documentation of Field and Laboratory Procedures.

If the treatment process has not been previously optimized, this should be done at this stage. By the end of the QAPP phase, all critical process parameters such as treatment time, temperature, chemical dosing, etc., must be clearly identified and their expected levels noted. Verification of pathogen reduction must be central in the QAPP. The required criteria for demonstrating pathogen reduction are presented on the website in a table as seen here (Table 2). Notable changes from what was previously required include optional but highly recommended organisms which may be measured in place of or in addition to fecal coliform, a log reduction requirement for fecal coliform (or other optional organism) for a PFRP equivalency, and the requirement that the end product must meet the process compliance parameters from 40 CFR 503.

Table 2: CRITERIA FOR DEMONSTRATING PATHOGEN REDUCTION
Mandatory Minimum Requirements

	PSRP Equivalency	**PFRP Equivalency**
Process Efficiency Parameters:	≥ 2 log reduction of fecal coliform bacteria **and/or** ≥ 2 log reduction of *E. coli* bacteria **and/or** ≥ 2 log reduction of *Enterococcus* spp. bacteria	**1)** ≥ 3 log reduction of total enteric viruses, **and** **2)** ≥ 2 log reduction of viable helminth (*Ascaris*) ova, **and** **3)** ≥ 3 log reduction of fecal coliform bacteria **and/or** ≥ 3 log reduction of *E. coli* bacteria **and/or** ≥ 3 log reduction of *Enterococcus* spp. bacteria **and/or** ≥ 3 log reduction of *Salmonella* spp. bacteria
Process Compliance Parameters (The 40CFR503 Requirements):	≤ 2,000,000 MPN or CFU/ g total solids (TS) of fecal coliform in the treated sludge	Organism densities in the treated sludge of: **1)** ≤ 1 pfu/4 g TS of total enteric viruses, **and** **2)** ≤ 1 viable helminth (*Ascaris*) ova/4 g TS, **and** **3)** ≤ 1,000 MPN fecal coliform / g TS **or** ≤ 3 MPN *Salmonella* spp./4 g TS (applicant's choice)

The verification may be performed at laboratory, pilot, or full scale. Some issues regarding the potential need for spiking or surrogate organisms are discussed on the *Equivalency Criteria* page. If full scale is not used for the verification studies, successful scale-up of the process must be operationally demonstrated. Depending on the complexity of the QAPP to this point, it may be advisable to develop the test plan for the scale-up requirement in a separate QAPP. The fourth criterion is the formal notification of the requirement for a QAPP.

APPLICATION PHASE

Website contents relevant to this stage. The *Equivalency Recommendation Process* page, a sub-page to the *How to Apply* page, describes the steps involved in this phase. The guidelines for application itself are provided in an annotated outline form similar to that for the QAPP guidelines. Applicants should find that the majority of the information required in the application can be directly copied from the QAPP. Any deviations from the agreed upon QAPP need to be clearly identified.

In the past applicants were asked to provide a summary fact sheet with their applications. The Pathogen Reduction Equivalency Application Package formalizes and replaces the summary fact sheet. The package includes a ready-made fill-in form for applicants to provide summary information regarding their process. Summary information consists of such key things as the formal process name and description, operating conditions, performance, and reliability. Following the form is a list of attachments necessary to complete the application package. These attachments include the full application, the final QAPP with deviations identified in an addendum, raw data, and references. Included at the end of the form are line by line instructions in addition to information on where to get help with the form or its components, a list of prerequisites to the form, and where and how to submit you completed application package.

As described on the website, once the application is reviewed and accepted by the PEC, the applicant will be asked to provide an operation and maintenance manual for their process. The application will not be formally approved until this manual is received.

NOTIFICATION PHASE

Website contents relevant to this stage. This phase is more of a formality. The steps of this phase are listed on the *Equivalency Recommendation Process* page for informational purposes only. The applicant is not required to do anything during this phase but continue to work on their O&M manual if one was not yet submitted. During this phase the U.S. EPA will issue a letter recommending or not recommending equivalency depending on the results of the testing. This recommendation is then considered by the permitting authority wherever the new process is proposed for use. Although the permitting authority does reserve the right to disagree with the recommendation for equivalency, this has never occurred in the PEC's 25 year history.

SUMMARY

The option to use an innovative sludge treatment process and still operate within the confines of the regulations is important for the growth and evolution of the sewage sludge management industry. However, as science in the area of human health also progresses and the general public's proximity to land application sites grows due to urban sprawl, the PEC must update their

process to evaluate these innovative sludge treatment processes to ensure the public's health is being sufficiently protected. The information presented here and in greater detail on the PEC's website (www.epa.gov/nrmrl/pec) describes the rigorous equivalency evaluation process and provides assistance to possible applicants so that progress in our field can continue smoothly and safely.

Notice

The U.S. Environmental Protection Agency, through its Office of Research and Development, funded and managed, or partially funded and collaborated in, the research described herein. It has been subjected to the Agency's peer and administrative review and has been approved for external publication. Any opinions expressed in this paper are those of the author (s) and do not necessarily reflect the views of the Agency, therefore, no official endorsement should be inferred. Any mention of trade names or commercial products does not constitute endorsement or recommendation for use.

REFERECE

U.S. Environmental Protection Agency Pathogen Equivalency Committee website, www.epa.gov/nrmrl/pec. 2008.