FROM CONCEPT TO EQUIVALENCY: THE 503 REGULATIONS AND THE PATHOGEN EQUIVALENCY COMMITTEE

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Since its creation in 1985, the Pathogen Equivalency Committee (PEC) has been reviewing innovative and alternative sludge disinfection technologies with regards to their abilities to protect human health and the environment. The PEC is charged to make recommendations on whether these novel technologies provide equivalent protection to those technologies already included in 40 CFR Part 503, Standards for the Use and Disposal of Sewage Sludge. This paper provides an overview of the Part 503D regulations and the process through which the PEC makes equivalency recommendations. Since the promulgation of Part 503, few composting type processes have been recommended as equivalent through the PEC. Currently, the use of worms to compost sewage sludge (vermicomposting) is under investigation along with other disinfection technologies including the use of chemicals such as chlorine dioxide, lime, and a fumigant. Updates on composting processes will be given. In addition to reviewing applications for equivalency, the PEC provides advice on project design and testing of new sludge disinfection technologies and expertise on all issues related to pathogens and the protection of human health, including concerns with emerging pathogens. Information on emerging pathogens of concern will also be shared.

Part 503D and the Regulation of Composting Sewage Sludge

The U.S. Environmental Protection Agency began regulating the use and disposal of sewage sludge in 1979 under Title 40 of the Code of Federal Regulation (CFR), Part 257. Part 257 classified sewage sludge as a solid waste under the Resource Conservation and Recovery Act (RCRA). In 1993 the regulations were updated and re-issued under the joint authority of RCRA and the Clean Water Act under 40 CFR, Part 503; The Standards for the Use or Disposal of Sewage Sludge. The new Part 503 regulations transferred authority over sewage sludge from Part 257, except in cases where sewage sludge is commingled with industrial waste. Subpart D of the Part 503 regulations was designed to limit human exposure to disease causing organisms, or pathogens. The regulation accomplishes this through two sets of requirements which are designed to lower the number of pathogens in sewage sludge before it is applied to land (pathogen reduction) and reduce the introduction of new pathogen sources to, and the transmission of those pathogens that remain from the application site (vector attraction reduction). To apply composted sewage sludge to land or use the compost in some other beneficial manner, both pathogen reduction and vector attraction reduction requirements must be met. The information for the remainder of this section is summarized from Environmental Regulations and Technology: Control of pathogens and vector attraction in sewer sludge (U.S. EPA 2003).

Pathogen Reduction Requirements

Part 503D splits pathogen reduction requirements into two different categories, Class A and Class B. Sewage sludge can meet pathogen reduction requirements through composting in several different ways under either category. There are six alternative methods to meet Class A pathogen reduction. Alternative 1, thermal treatment using defined time and temperature regimes, and Alternative 2, alkaline treatment using high pH in combination with high temperatures, are plausible but not practical for composting, as they are likely cost prohibitive compared to other alternatives. Alternatives 3 and 4, treatment with other or unknown processes, were originally developed to deal with orphaned piles or lagoons, but have more recently been expanded to cover situations where the treatment process can not be well defined. Instead of following technology based requirements, as in the other 4 options, Alternatives 3 and 4 rely on microbiological monitoring of three classes of organisms, bacteria (either fecal coliform or *Salmonella* sp.), viruses (enteric), and parasites (viable Helminth ova). This can be cost prohibitive because a greater sampling frequency is required to assure that the results are representative of the material being utilized. Still Alternatives 3 and 4 are used for composting in some instances where time and temperature requirements cannot be guaranteed. The use of Alternatives 3 and 4 is highly discouraged. Without a defined treatment, the absence of specific organisms can not be used to infer the numbers of other potentially pathogenic organisms in the biosolids. Nor can the absence of these organisms be guaranteed over time sans the barrier a treatment technology provides.

Most Class A composting facilities meet the pathogen reduction requirements using Alternative 5, use of a process to further reduce pathogens (PFRP). Composting is one of six listed PFRPs. Three composting methods, within-vessel, aerated static pile, and windrow are acceptable for Class A. The conditions defined in Part 503D for these methods are listed in Table 1. Specifying a minimum number of turnings for windrow composting was meant to ensure oxygen was supplied to the composting pile to avoid anaerobic conditions. The final Class A alternative, Alternative 6 is to use a process that has been granted equivalency to a PFRP by the permitting authority involved. All Class A facilities are required to perform periodic microbiological testing on their final product. To maintain a Class A designation, either fecal coliform densities must be less than 1,000 MPN per gram total solids (dry weight) or *Salmonella* sp. must be less than 3 per 4 gram total solids (dry weight).

Table 1. Pathogen Reduction Requirements for Composting of Sewage Sludge

Class	Method	Temperature (°C)	Minimum Number of Consecutive Days	Additional Requirements
A	Within-Vessel or Static Aerated Pile	55	3	none
	Windrow	55	15	Minimum of 5 turnings
B	Within-Vessel, Static Aerated Pile, or Windrow	40	5	Minimum of 4 hours within 5-day period temperature must exceed 55°C

Class B pathogen reduction requirements are less restrictive than Class A. They can be met using any one of three alternatives along with defined site restrictions based on the intended use of the land to which the treated sludge is to be applied. Alternative 1, similar to Alternatives 3 and 4

for Class A, relies on routine monitoring; the differences being that only one organism must be monitored for Class B (fecal coliform) and because of the site restrictions the acceptable level of organisms is higher. Alternative 2 is the use of a process to significantly reduce pathogens (PSRP). Part 503D lists five PSRPs, one of which is composting. Although Class A composting is more common, most Class B composting facilities will use Alternative 2 by following the operational requirements laid out in the composting PSRP. Again all three composting methods are acceptable; however, for PSRP composting there is no difference in operational parameters as listed in Table 1. Alternative 3 is the Class B equivalent to Class A, Alternative 6, use of a process that has been granted equivalency to a PSRP by the permitting authority involved. The typical process for using this Alternative is the same as Class A Alternative 6, but the Class B's less restrictive pathogen indicator limits are the measure against which the new process is compared. With the exception of Alternative 1, Class B facilities are not required to perform microbiological testing. Still, it is felt that the treatment technologies employed through Class B Alternatives 2 and 3 provide better and more consistent protective value from a human health standpoint than microbial testing in the absence of treatment.

Vector Attraction Reduction Requirements

In addition to reducing pathogens, vector attraction must also be reduced before composted sewage sludge can be applied to land. If sludges are not adequately composted, animals such as mice and birds, as well as, insects such as mosquitoes and flies, will be attracted by the available food source. As the animals and insects move on and off the compost, they may carry pathogens to locations where humans could come into contact with them thereby acting as vectors of disease. To reduce this risk, the available food source must be lowered to levels that will not attract such vectors. Part 503D provides 12 options for meeting vector attraction reduction (VAR) requirements, although only two of the options are appropriate for the composting methods described in the regulation, options 5 and 10. There is no class distinction with VAR requirements. Either option can be used for Class A or B processing.

Option 5 is aerobic treatment of sewage sludge for at least 14 days at temperatures above 40°C with an average temperature greater than 45°C. These conditions must be met either concurrent with or following the pathogen reduction requirements for Class A compost, to minimize the potential for bacterial regrowth. Obtaining VAR for composted sludge through option 5 is generally believed to be easily attained. Composting times for Class B (any method) or Class A (within-vessel or static aerated pile methods) simply need to be extended for an additional 9 or 11 days, respectively while meeting the given temperature requirements. The extended composting time is intended to allow surviving microbes to further decompose remaining substrate to below acceptable levels. VAR requirements for Class A using the windrow method are met automatically when the pathogen reduction requirements are followed successfully.

Option 10 is the incorporation of sewage sludge into the soil. Under this option, composted material must be incorporated within the top six inches of soil. Incorporation must occur within six hours of application for Class B composted sludge, or within eight hours of application for Class A compost. Incorporation of the compost dilutes the food source and provides some physical barrier between the food source and the vectors.

Part 503D Shortcomings and Possible Upcoming Changes

The U.S. EPA recognizes that the current Part 503D regulation has its shortcomings. Under the current rule, the U.S. EPA is required to perform a biennial review. Following this review, it is anticipated that at least some of these shortcoming will be addressed either by modification of the rule itself, or by issuing new guidance. With regards to composting, these shortcomings include poor process descriptions, the inability of VAR requirements to produce sufficiently stable materials with regard to odors, outdated microbiological methods, and the lack of risk based pathogen standards.

Currently, the process descriptions for the three methods of composting in Part 503D lack the detail needed to carry these processes out with consistency between applications. All three of the composting methods in use today (within-vessel, aerated static pile, and windrow) were originally approved under Part 257 in1979 and have not been significantly updated since. The state of the practice has evolved and this new knowledge should be incorporated into the regulation. In particular, updated and more detailed operational considerations need to be incorporated on how to successfully meet the required temperature conditions given the heterogeneous temperature regimes that develop in composting piles. Cooperation with and a willingness to learn from groups such as the U.S. Composting Council which have a wide breath of experience in composting is necessary to improve the sewage sludge composting regulations with a mutually beneficial outcome.

It is recognized that the current option 5 VAR requirements do not require sufficient curing time to control odors in all cases. This is an indication that the VAR requirements may not be strict enough to produce a stable product. Furthermore, odor problems are most often behind complaints of illness by the public. Although the current literature is split on whether or not malodors are a potential cause of concern for human health with support for (Schiffman *et al.* 2000) and against (Cain *et al.* 2004) the issue, the need to address this nuisance in some fashion is acknowledged.

The microbiological testing methods currently mandated and referenced in Part 503 are deficient in that they do not specifically address handling of complex matrices such as compost. Guidance to help bridge the gap between the referenced standard methods and complex matrices has been included in the so-called White House Document (U.S. EPA 2003) since its original printing in 1992. New bacterial methods for fecal coliform and *Salmonella* sp. have been developed, standardized and validated since the promulgation of Part 503 that include sample handling and pre-treatment procedures tailored to biosolids. Verbiage regarding how to deal with bulking materials has been specified in the new methods which will make application of these methods to composted sludges more uniform. The public comment period on these methods recently closed and they are expected to be added to Part 136 (U.S. EPA approved methods) in the near future. However, for the new methods to be accepted for regulatory compliance, the Part 503D regulation must also be amended to allow for the Part 136 methods to be used. This will not happen overnight, but it is on the drawing board. Since Class A composting facilities must comply with routine microbiological monitoring, these facilities will be affected by this rule change if and when it goes into effect, as will Class B composting facilities operating under Alterative 1 (microbial monitoring). The new methods are currently available online at http://epa.gov/waterscience/methods. Research on *Ascaris* sp. and enteric virus methods is ongoing. If the proposed modification to Part 503D is put in place, any updates or improvements to these methods will officially recognized as soon as they are added to Part 136.

When the 503D regulations were written in the early nineties, the state of the science of microbial risk assessment was not developed enough to support risk-based pathogen standards for biosolids (U.S. EPA 1995). Since then the body of knowledge on this subject, including the availability of scientifically-sound exposure data has grown and some people believe that regulatory

questions may now be answered using microbial risk assessments. More advanced models can incorporate realistic considerations of infectious disease, like immunity and secondary infection (Eisenberg *et al.* 2004). The current pathogen reduction standards are largely technology-based. Following a microbial risk assessment, the pathogen standards may be supported or need adjustment, either outcome would be positive. Although such a comprehensive undertaking is not currently underway, and is unlikely to be performed before the close of the next review period, it is a necessary step that should be anticipated for the future.

The Pathogen Equivalency Committee and New Composting Methods

The Pathogen Equivalency Committee (PEC) was created in 1985 by the U.S. EPA to provide technical expertise to permitting authorities in the event that a facility under their jurisdiction wishes to operate under Class A, Alternative 6 (a process equivalent to a PFRP) or Class B, Alternative 3 (a process equivalent to a PSRP). Under the invitation of the permitting authority, the PEC is tasked to review the appropriate process information and analytical data included in the application package from the entity seeking process equivalency, and make a recommendation to the permitting authority as to whether or not pathogen reduction equivalency to a PFRP/PSRP has been sufficiently supported. Currently, the PEC consists of 11 members with expertise in microbiology, virology, parasitology, medical and veterinary science, environmental engineering, wastewater treatment, statistics, and sludge regulations. It is a multi-agency group with representatives from U.S. EPA's Office of Research and Development, Office of Water, and Regional Offices, as well as from the Center for Disease Control. The main charge for the PEC is to uphold the protection of human health. Their mission in reviewing an equivalency application is to ensure that new processes employed for sewage sludge disinfection are robust and effective in pathogen reduction (PSRP) or pasteurization (PFRP). Thus, they provide the benefit of more alternatives for disinfecting sludges to utilities while assuring the public that the new alternatives are safe. The PEC members also provide guidance to permitting authorities and members of the regulated community on issues related to pathogen reduction and vector attraction reduction requirements and the use of proper analytical methods for Part 503D compliance.

PEC Recommended Composting Methods

Thus far there are only two methods of composting that have gained a recommendation of equivalency through the PEC, the Scarborough Sanitation District and International Process Systems, Inc. Both methods were found equivalent to a PFRP. Both of these methods are variations on the approved methods in the regulation and, therefore, seeking a recommendation from the PEC was appropriate. The Scarborough Sanitation District in Maine approached the PEC with a unique pseudo-composting process in which fly ash was used as the bulking agent. After mixing the dewatered solids with the bulking agent, the sludge was composted in static aerated piles. Data provided in their application package demonstrated that temperatures of 60 to 70°C were reached within 24 hours and maintained for up to 14 days, thus exceeding the time and temperature requirements for Class A static aerated piles (Smith *et al.* 2003). Since Scarborough's pseudo-composting process generates heat (at least in part) through chemical reaction with the fly ash and not through biological reactions as would a typically composting process, the PEC was consulted. Equivalency was recommended on the basis that the elevated temperatures were adequately

maintained throughout the pile and that regardless of how the elevated temperatures were achieved they will still provide the necessary pathogen destruction.

International Process Systems, Inc. (ISP) out of Glastonbury, CT, developed a unique reactor in which to perform within-vessel composting. In ISP's process a composting mass of sludge moves through five zones in a unique reactor at a controlled rate. One zone in the reactor evenly heats the composting sludge to a temperature of at least 55°C and the compost remains in this zone for a minimum of three days. Thus, the time and temperature requirements for the within-vessel composting PFRP were met within ISP's reactor and the PEC recommended the process for equivalency on these grounds.

Additional Composting Methods under PEC Evaluation

A different type of composting utilizes worms. Some individuals may argue that this process should not even be labeled composting. In any event, the process has long been used for kitchen and yard scraps, but more recently two companies have independently engineered vermicomposting into a method for treating wastewater sludges. Vermitech Ltd. out of Australia and Oregon Soil have both approached the PEC about obtaining PFRP equivalency for their vermicomposting processes. These companies believe that the worms can produce a compost-like material and of necessity do it at a lower temperature and shorter time than traditional composting. Some lab scale studies have shown that vermicomposting can reduce the number of viruses and viable Helminth ova faster than natural die-off. Unfortunately these studies were not carried out long enough to support PFRP equivalency (see below). The actual method of disinfection provided by the worms is unknown. It has been suggested that the as solids move through the worm's digestive tract, they are pulverized and interact with bactericidal and virucidal secretions.

Although both Oregon Soil and Vermitech are pursuing PFRP equivalency for vermicomposting, Vermitech has an operating demonstration of its process in Granville, PA which has been operating as a Class A facility since late 2004 under Alternative 4 (testing of an unknown process). In the Granville operation the worms are housed in steel cages which are raised off the ground. Dewatered sludge is fed daily to the top of the cage and their product, BioVerm, is harvested out the bottom. Vermitech is in the planning stages of conducting additional studies, both in the lab and at this full scale operation.

The PEC's Equivalency Recommendation Process

A unique sludge disinfection process that does not conform to any of the defined processes or process alternatives (PFRPs and Alternatives 1 and 2 for Class A or PSRPs for Class B) must either comply with exhaustive microbiological testing during each monitoring event (Class A, Alternatives 3 and 4, or Class B, Alternative 1) or apply for equivalency to a PFRP/PSRP (Class A, Alternative 6/Class B, Alternative 3). From a utility's perspective, the exhaustive microbiological monitoring requirements may be cost prohibitive. From a proprietor's prospective, receiving an equivalency recommendation is very valuable. It not only provides strong support for the process's efficiency and reliability, it also allows the proprietor to market their process more easily without the hindrance of additional monitoring requirements. Given these benefits, several new entities enter the PEC's equivalency recommendation process each year.

It should be noted upfront that a new process to significantly or further reduce pathogens can

be granted equivalency only by the permitting authority. However, the PEC nearly always is consulted by the permitting authority for an equivalency recommendation prior to the permitting authority granting equivalency. There are two scopes to an equivalency, site-specific and national. Due to their potentially wider influence, applications for national equivalencies require additional work. The following four phases of the PEC's equivalency recommendation process are geared toward site-specific equivalencies. The considerations for national equivalencies are included as an optional fifth phase.

Recently the PEC held an intensive retreat where experts in the field were brought in to assist the committee members in reviewing the equivalency recommendation process. Some changes to the process have already occurred as a result of this retreat and will be reflected in the description below. However, additional changes are still under review. The parts of the equivalency process that are subject to change will be identified. The PEC is currently developing a website to assist potential applicants through the equivalency recommendation process. All final changes in the equivalency process will be reflected in the PEC's website. The official launch of this website is expected to be in mid 2006. Interested individuals are encouraged to monitor the U.S. EPA's website (www.epa.gov) for the launch of the PEC's website around this timeframe. The following is the first published detailed description of the evolving equivalency recommendation process and overrides earlier descriptions (Smith *et al.* 2003;U.S. EPA 2003).

Process Initiation Phase

In general, inquires about applying for process equivalency should be directed to the appropriate permitting authority. If there is any question as to whom the appropriate permitting authority is for a given case, the PEC can be contacted directly via a newly designated e-mail box: pec@epa.gov. In most cases the permitting authority will be the regional biosolids coordinator. The state biosolids coordinator is the permitting authority in states which have been authorized to issue their own permits in accordance with the 40 CFR Part 503 regulations. Currently only seven states (Arizona, Ohio, Oklahoma, South Dakota, Texas, Utah, and Wisconsin) are authorized. A list of the regional and state biosolids coordinators currently is available on-line at http://www.epa.gov/owm/mtb/biosolids/biocords.pdf. If the permitting authority determines that applying for equivalency is appropriate for the situation, they will generally begin consultation with the PEC.

Quality Assurance Project Plan Phase

This phase includes the planning and testing of the proposed equivalent process. In the past, applicants were encouraged, but not required, to prepare a Quality Assurance Project Plan (QAPP) to provide a framework for testing their process. Now a QAPP will be a necessary first step in the equivalency recommendation process. 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. A QAPP must be developed before beginning testing so that the desired quality in sample collection, laboratory analysis, data validation and reporting, and documentation and recordkeeping are achieved and maintained.

The primary objective of every QAPP written as part of an equivalency application is essentially the same; statistically significant data supporting the process's ability to achieve a

specified log reduction in pathogens or pathogen indicators. Currently, the actual pathogens/indicators used, as well as the required log reduction which must be achieved in the demonstration of a new process is based on the historical information used in the development of the original sewage sludge regulations (40 CFR 257). For a PSRP equivalency, a new process must show that it can reliably achieve a 2-log reduction in fecal coliform (per gram dry weight) under specified operating conditions. For a PFRP equivalency, a new process must show both a 3-log reduction in enteric viruses (per 4 grams dry weight) and a 2-log reduction in viable Helminth (specifically, *Ascaris*) ova (per 4 grams dry weight). A portion of the experimental approach may take place at a bench scale, but it is imperative that successful scale-up (at least to pilot scale) be demonstrated to receive an equivalency recommendation. Applications based solely on laboratory or bench scale data will only gain a laboratory scale equivalency. These requirements are the heart of every equivalency application and as such they were given serious consideration at the recent PEC retreat. Negotiations on possible changes to these requirements are ongoing and are discussed separately below (see Possible Upcoming Changes to the Equivalency Recommendation Process).

The recent decision to make the QAPP a formal part of the equivalency recommendation process was, in part, a consequence of the current public concerns surrounding the beneficial use of biosolids. When followed, a well developed QAPP will ensure that the results submitted in support of a process are statistically significant and were acquired under appropriate quality assurance and quality control measures, thereby reassuring the agency and the public of the safety of the new process. The importance of a QAPP cannot be underestimated. It is an extremely beneficial undertaking for the applicant. In the past, the PEC has received applications in which the data was either collected or handled improperly or the analytical procedures could not be well defined by the applicant. The data could not be validated in these cases and the applicant was required to retest their process adding additional expense to the undertaking. Preparation and pre-approval of a project plan will eliminate such unfortunate occurrences. Also, the information required in the application for an equivalency recommendation is largely drawn from the QAPP requirements. For this reason, careful preparation of a QAPP will serve as a good head start on the application itself, and therefore, should not be thought of as a wasted effort.

After the QAPP has been developed, the PEC will review and approved the plan or suggest appropriate changes. Once the QAPP has been agreed upon the applicant must carry out their testing in accordance with the plan. In some cases, the PEC may conduct on-site reviews to ensure that the QAPP is indeed being followed. The upcoming PEC website will contain several tools to assist applicants in developing a successful QAPP. These tools include guidelines in a detailed outline format and two example QAPPs. A checklist which is used by the PEC in review of QAPPs will also be available. This checklist will clearly show the type of information the PEC will be looking for in a QAPP. It can be used as a self-check before submittal.

Application Phase

After testing has been completed, applicants should prepare an application. Detailed guidelines for such an application will be provided on the PEC website. A general outline for an application is shown in Figure 1. The summary fact sheet is a ready-made, fill-in form which also will be provided on the website. It contains space for the applicant to provide information on key process parameters, sludge characteristics for which the process is applicable along with any process limitations, and contact information for the applicants. Copies of the application should be submitted concurrently to the appropriate permitting authority and the PEC.

Review and Notification Phase

Obtaining a recommendation of equivalency requires a thorough examination of the process descriptive information and analytical data by the PEC which can be lengthy (3 or more months from the time the PEC receives a completed application). A completeness checklist very similar to the checklist used to evaluate the QAPP will be used to evaluate the application as well. The checklist should ensure that the review is not only complete but uniform between applications. There are four outcomes of an equivalency application, full equivalency, conditional equivalency, not equivalent, or more information necessary. In the event that an equivalency application is found to be not equivalent or needing more information, the reasoning behind such a decision or a description of the additional information necessary will be provided. If the PEC finds the process to be equivalent, the PEC will make a recommendation of full or conditional equivalency with specified operational parameters. A conditional equivalency will outline additional conditions and/or constraints under which the process must be run. A request for an operation and maintenance (O&M) manual will be made. The applicant must produce an O&M manual for the process that dictates how to remain within the specified operating parameters and additional conditions, if applicable. The request for an O&M manual has been made in the past, but this publication is the first document to call it out as a formal step in the equivalency recommendation process. Once the O&M manual is received the equivalency recommendation is passed on to (and reviewed and approved by) the U.S. EPA's Office of Science and Technology (OST). OST is responsible for sending the Agency's official letter of recommendation to the permitting authority along with the O&M manual. Again, it should be noted here that although the PEC's recommendations are typically followed, they are not formal binding agency decisions, as the permitting authority ultimately makes the final decision on equivalency.

National Equivalency Phase (Optional)

For a recommendation of national equivalency, the process must consistently produce the required pathogen/indicator reductions under the variety of conditions that may be encountered at different locations across the country. A recommendation of national equivalency is usually preferred because it enables the treatment processes to be marketed, sold, or used at different locations in the United States. To receive a national equivalency the process must be tested at pilot and/or full scale under a variety of conditions and using a variety of sewage sludges. Typically, sludge characteristics and climatic and operational conditions do not vary significantly at a single location. In most situations the PEC requires that the process be tested in more than one location before granting a national equivalency recommendation. Thus, the process, starting from the QAPP phase will need to be repeated at least two times at other locations. Processes affected by local climatic conditions or that use materials that may vary significantly from one part of the country to another are unlikely to be recommended as equivalent on a national basis. Again, the PEC's recommendation for national equivalency is just that, a recommendation. A formal binding national process equivalency will require the approval of more than one permitting authority. And even then, some jurisdictions, in particular the delegated states, may have stricter requirements under which the national equivalency may not hold. In general, however, once approved by two or more permitting authorities, a formal letter of national equivalency issued by OST will be transferable across the

country.

Possible Upcoming Changes to the Equivalency Recommendation Process

Some changes to the PEC's equivalency recommendation process were easily incorporated. These changes were largely included to help formalize and streamline the process in order to get equivalency applications reviewed in a timelier manner. These changes were discussed above. They include the more formal routing of potential applicants through a permitting authority before correspondence with the PEC is initiated, the required development and pre-approval of a quality assurance project plan before any testing is conducted, more detailed guidelines for the QAPP and the application, the PEC's use of a completeness checklist in their review of both QAPPs and applications, the required submittal of an O&M manual, and finally the required approval of more than one permitting authority in order to receive official national equivalency status. However, the heart of the equivalency process, the required data necessary to support the statement that a process is equivalent to a process to further reduce pathogens, requires a much more thoughtful appraisal. The following discussion is directed towards PFRP equivalencies only.

In recent years, the scale-up requirement has lead to a great deal of difficulty for the PFRP equivalencies. As shown in Table 2, the concentrations of naturally occurring enteric viruses and viable Helminth ova in raw sludge have dropped well below the levels necessary to demonstrate the required log reductions for PFRP equivalency. While this is good news from a public health standpoint, it has been problematic for entities applying for PFRP equivalency. Seeding sludges with pathogenic microbes has become needed at the pilot or full scale which is costly and difficult to coordinate at best. In many cases, it may even be outright forbidden due to the potential health risks of an accidental release of pathogens. Also, the specified organisms of concern were identified some 25 or so years ago, when the information supporting the 1979 Part 257 sludge regulations was collected. Since then 26 new agents of infectious disease have been identified (WHO 2003). The PEC recognizes these concerns. One of the main purposes for the recent PEC retreat was to review the indicator organisms required for PFRP equivalency in light of emerging pathogens and scale-up problems.

Table 2: Average Microbial Concentrations*

Organism	Past (1940 - 1980)	Present (1994 - 2005)
Fecal coliform (count/gdw)	2.0×10^7	2.0×10^7
Salmonella (count/gdw)	4.1×10^2	5.7×10^1
Enteric viruses (pfu/gdw)	4.0×10^2	1.0×10^0
Helminth ova (count/gdw)	< 1 to 50	≤ 1

*Re-created from (Millner 2005)

The emerging pathogen issue has to be inspected from two directions. First, such pathogens must be evaluated to asses their risk of transmission through sewage sludge being utilized on land. Second, if such a route of transmission is possible, then the pathogen must be further evaluated to ensure that its rate of die-off is equal to or greater than the pathogen indicators currently used to assess disinfection process effectiveness (i.e., *Ascaris* ova and enteric viruses). Since 1979, the microorganisms responsible for some devastating diseases have been discovered. The information in Table 3 provides some well known examples. In addition to new pathogens, the re-emergence of known pathogens can also be problematic and should not be ignored. For example, increases in the

Table 3: Some Well-known Emerging Pathogens since 1979*

Year	Organism	Disease
1982	*Borrelia burgdorferi*	Lyme disease
1983	HIV-1, HIV-2	Acquired immunodeficiency syndrome
1983	*Escherichia coli* O157:H7	Hemorrhagic colitis; hemolytic uremic syndrome
1989	Hepatitis C virus	Paternally transmitted hepatitis
1992	Vibrio Chlerae O139:H7	New strain of cholera
1996	Prion (BSE)	Meningitis, encephalitis
1997	Influenza A Virus H5N1	New variant of Creutzfeldt-Jacob disease
1999	West Nile Virus	Encephalitis, fever
2000	SARS coronavirus	Severe acute respiratory syndrome
2004	Influenza A virus HPAI, H7N7, and H7N3	Avian influenza

* Information taken from (WHO 2003) and (Millner 2005)

number of immune compromised individuals due to increases in successful organ transplants, new cancer treatments, and the emergence of AIDS, have lead to a re-emergence of concerns with *Cryptosporidium* and microsporidia (WHO 2003). The PEC is currently investigating emerging and re-emerging pathogens for possible inclusion in or replacement of the required organisms of concern. However, for the time-being the committee feels confident that evaluation of the current suite of indicator organisms in their deliberations is protective of human health when considered along side the stressors they are subjected to.

Concern over process evaluation and demonstration of process effectiveness under pilot and full scale compels the PEC to be open to the use of surrogate organisms. Because the committee does feel strongly about the protective value of the current required organisms, it is unlikely that *Ascaris* ova or enteric viruses will be replaced for the purposes of determining a process's efficiency. What is likely is the requirement for the testing of one or more additional organisms during the bench scale testing. Such information would be used to discern the relationship between the survival curves of such organisms and that of *Ascaris* ova and enteric viruses. The additional organisms will be chosen for their naturally-occurring prevalence in the sludge of concern and their potential to survive treatment. Then in scale-up, the reduction of the surrogate organism can be used along with the established relationships to *Ascaris* ova and enteric viruses to support equivalency. Discussions on how the PEC will handle these scale-up complications are underway.

Summary

The 40 CFR 503D regulations contain defined conditions for the composting of wastewater sludges prior to beneficial use in the way of time and temperature requirements. Composting can be and is used to meet the pathogen reduction requirements for both Class B and the more stringent Class A biosolids, while at the same time meeting vector attraction reduction requirements. However, the process descriptions in Part 503D, especially the lack of curing time, are not sufficient to consistently produce a stable, non-odiferous product in all cases. Alternative methods of composting are allowable under Part 503D as long as they are evaluated and found to achieve an equivalent level of protection of human health to the defined process conditions in the regulation. The pathogen equivalency committee was established in 1985 by the U.S. EPA to perform such process evaluations and make equivalency recommendations. Since then, only two unique composting methods have been recommended for equivalency and one new method of composting is currently under evaluation.

In light of changes in the public's perception of the beneficial use of biosolids, changes in the microbial population in untreated sewage sludge, and the recognition of emerging and re-emerging pathogens; the pathogen equivalency committee is currently updating and formalizing its equivalency recommendation process. A detailed description of the current process including some of the more easily adaptable improvements is presented. Some of the more involved possible improvements are still under debate within the committee. These possible changes will affect the number and actual pathogens/indicators used to demonstrate equivalency and scale-up of a new process. Concurrent to these discussions, a website is being developed for the PEC that will eventually make steps of the equivalency recommendation process accessible to all interested parties.

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