PROJECT XL PROPOSAL

HIGH-TEMPERATURE CATALYTIC OXIDATION PROCESS FOR MIXED WASTE IN A PHARMACEUTICAL RESEARCH LABORATORY

Proposed By:

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INTRODUCTION

Ortho-McNeil Pharmaceutical (OMP) and the R.W. Johnson Pharmaceutical Research Institute (PRI), divisions of Johnson & Johnson, are pleased to present the following proposal for consideration as a Project XL initiative with the U.S. Environmental Protection Agency's Office of Reinvention. It is PRI's understanding that Project XL ventures are real world endeavors to achieve exceptional environmental results through the implementation of innovative strategies. In order to introduce a viable Project XL initiative, the project must develop alternative environmental management strategies that: (1) produce superior environmental performance, (2) produce benefits such as cost savings, paperwork reductions, and/or regulatory flexibility, and (3) are supported by stakeholders. To demonstrate whether an XL project will achieve superior environmental performance, companies must consider both quantitative and qualitative measures to determine if the expected environmental performance will produce environmental benefits superior to current accepted practices. PRI believes it can obtain superior environmental benefits through the use of an on-site bench-top high temperature catalytic oxidation process for the treatment of mixed waste generated in a laboratory environment as opposed to the current methods of acceptable mixed waste management and disposal practices. In order to achieve these benefits, PRI would like a regulatory exemption to utilize this technology without the regulatory burden of a waste treatment permit.

BACKGROUND

PRI develops and utilizes radiolabeled compounds for the research and development of pharmaceuticals / drugs. This process and the procedures being followed are closely regulated by the Nuclear Regulatory Commission (NRC) and the Food and Drug Administration (FDA). Under normal operating conditions, the research process yields a desired radiolabeled compound and a solution which contains radiolabeled material having no further use to PRI. PRI's production of a radiolabeled compound utilizes an isotopically-labeled organic compound and a solvent. The solvents used vary and may undergo a chemical reaction during production of the radiolabeled compound. The solvent used are mixed with the radioisotope to produce the radiolabeled compound. As a result, the waste mixture will contain both radioactive material and an organic compound. The organic compound will always be a hazardous substance and, thus, the waste will always be considered a "mixed waste."

Currently, "mixed waste" is regulated under the base RCRA program. As such, it must be managed as a hazardous waste and be shipped off-site within 90 days of being generated. However, there are very few licensed and approved treatment facilities that can accept mixed waste in the United States. The millions of dollars spent shipping mixed waste throughout the U.S. for off-site treatment and disposal may have a greater negative impact to the environment than is necessary.

PRI has developed a unique treatment process, which oxidizes the mixed waste and thereby destroys its hazardous component completely. Once the oxidation destroys the hazardous component of the mixed waste, water and CO2 are produced. Carbon-14 labeled compounds generate radioactive CO2 and Tritium (H-3) labeled compounds generate radioactive water. After further processing, these materials are disposed as low-level radioactive waste. Low-level radioactive wastes are easily stabilized and disposed at various facilities throughout the country.

However, after a thorough review of the regulations, OMP and PRI have determined that the oxidation process requires a TSDF permit under RCRA. This determination was based on the following:

PRI generates more than 1000 kg of hazardous waste per month and is considered a large quantity generator and thus does not qualify for certain RCRA exemptions

The oxidation process undoubtedly meets the definition of "treatment" insofar as the oxidation is performed to destroy the components of the Solution which are hazardous . The EPA (and PA DEP) allows the treatment of hazardous waste within 90 days of generation as long as treatment occurs on-site in a totally-enclosed treatment facility. EPA's regulatory interpretation of the term "totally-enclosed treatment facility" has indicated that the treatment facility must:
(a) be completely contained on all side,
(b) pose negligible potential for the escape of constituents to the environment, and
(c) be connected directly to the process which generates the waste.
PRI's oxidation process fails to meet the interpretation of "totally-enclosed" because it does not meet items (b) and (c) above.
PRI cannot claim exemption from the "mixture" nor "derived from" rules therefore, anytime a listed hazardous waste is oxidized it will remain a hazardous waste and thus a "mixed waste."

PRI is currently operating the oxidation process under a Treatability Study approved by the Pennsylvania Department of Environmental Protection (PA DEP). The treatability study is being conducted to evaluate the potential of the catalytic process to destroy the organic components of the mixed waste so it may be reclassified and disposed as low-level radioactive waste. To date, the study has generated extremely positive results and has shown that the oxidation process is capable of meeting our hypothesis. However, the treatability study is not an approval to allow “treatment” of hazardous waste and therefore, a more permanent solution is needed.

In addition, the conditional exemption for on-site treatment of mixed low-level radioactive wastes from Subtitle C regulations, proposed by the EPA’s Office of Solid Waste in the Federal Register on March 1, 1999, may not apply to this treatment process because it utilizes a thermal process. Additionally, this proposed exemption may not go into effect until June 2001 at the earliest.

BASIS FOR THE PROPOSAL

Ortho-McNeil, on behalf of PRI, would like to propose the high temperature catalytic oxidation treatment process for mixed wastes generated in a laboratory environment as a candidate for Project XL. This proposal is based on the following:

There are very limited commercially available disposal facilities for "mixed waste"
The oxidation process is an extremely economical approach to the treatment of "mixed waste" (OMP has saved over $1.5 million is disposal costs to date through the use of this technology in the treatability study)
The process transforms a hazardous, toxic waste into a relatively innocuous low-level radioactive waste
The technology is readily transferable and could be used by various companies and organizations throughout the country who generate similar wastes
The TSDF permitting process is extremely complicated, very costly, very time consuming (averaging 3 to 5 years) and applies to the entire facility not just the oxidation treatment process.

Ortho-McNeil would like to request that the EPA, through Project XL, provide one of three solutions to this problem:

Exempt the bench-scale treatment of mixed wastes from permitting requirements,
Provide permit-by-rule exemptions for the bench-scale treatment of mixed wastes, or
De-list post-oxidation wastes pursuant to 40 CFR Section 260.20 and 260.22 to allow the treatment of listed hazardous waste.

QUALITATIVE ANALYSIS

Currently accepted practices for the management and disposal of mixed wastes containing high levels of tritium (3H) and carbon-14 (14C) radionuclides generated in biomedical research laboratories include any of three options: (1) off-site treatment and disposal, (2) evaporation in laboratory hoods (which is prohibited in most facilities), or (3) storage of short-lived nuclides for decay. Each of these options involves practices detrimental to the environment and behaviors with a moderate to high degree of risk to the environment, employees, and surrounding communities. The largest and most readily available off-site commercial treatment and disposal option consists of fuels blending / thermal destruction at Diversified Scientific Services, Incorporated (DSSI) in Kingston, Tennessee. The thermal destruction treatment process results in the release of a large percentage of radioactivity directly into the atmosphere. In addition, this option involves a high degree of risk to employees in handling, cross-country transportation, and on-site and off-site storage of large volumes of mixed waste and high levels of radioactivity. These practices greatly increase the risk of a release to the environment through spills or accidents. Additionally, this option

is prohibitively expensive (up to $35,000 per curie). Uncontrolled evaporation of wastes in fume hoods is a common practice in laboratory settings that has the obvious harmful effect of direct air releases of radioactivity and hazardous chemicals into the atmosphere. Storage for decay of short-lived radionuclides involves the long-term storage of high volumes of mixed wastes, containing high levels of radioactivity, with the potential risk of a release to the environment through leaks, spills or accidents. In addition, this practice violates the 90-day limit for accumulating hazardous wastes on-site in 40 CFR §262.34 under the Resource Conservation and Recovery Act (RCRA) which currently regulates the management of mixed wastes. Storing rather than promptly treating these wastes increases the potential for an unnecessary impact to employees and the environment.

PRI's alternative proposal, bench-top treatment of mixed waste utilizing high temperature catalytic oxidation at the point of generation, yields many environmental benefits superior the detrimental environmental effects associated with the current accepted practices for the management and disposal of mixed wastes. High temperature catalytic oxidation achieves a 99.999% or greater destruction efficiency for the organic component of the mixed waste and completely captures all radioactivity in the form of low-level radioactive water. The resulting radioactive water can then be shipped to a commercial facility for tritium recovery or vitrified (in a glass matrix) for ultimate disposal. This alternative results in no release of radioactivity or hazardous chemicals to the environment. In addition, this method can be performed in a safe, highly controlled laboratory setting with well-trained and experienced personnel. Treatment at the point of generation reduces the volume of waste and levels of radioactivity
handled, thereby greatly minimizing the risk of an accidental release to the environment through handling, storage, processing, or transportation activities.

QUANTITATIVE ANALYSIS

Compiling a clear and accurate understanding of the magnitude and extent of the mixed waste disposal dilemma facing pharmaceutical companies and other research institutions is very difficult. The International Isotope Society conducted a survey in 1996 to try to determine the amount of mixed waste that was generated domestically in 1995. The Society sent out 100 surveys to various pharmaceutical companies, universities and commercial service organizations. Based on the responses received (50 out of 100 surveys were returned), approximately 7,500 curies of tritium mixed waste and 390 curies of carbon-14 mixed waste were generated by the respondents to the survey. Projecting these results yields a very conservative estimate of almost 16,000 curies of radioactive mixed waste being generated during 1995. This is an extremely conservative estimate in the fact that it only covers the 100 organizations who were chosen to participate in the survey. In addition, as radioactive materials become more widely used,
the amount of mixed waste generated is sure to increase.

Currently, there are two commercially available mixed waste treatment facilities in the United States. The primary mixed waste treatment facility in the U.S. is Diversified Scientific Services, Incorporated (DSSI) in Kingston, Tennessee. DSSI's current rate structure for mixed waste treatment ranges from $20,000 to

$35,000 per curie of waste treated, depending on the radioactivity and the volume of the waste, with an average cost of $30,000 per curie. The current treatment technology employed by DSSI utilizes fuels blending / thermal destruction with a large fraction of the treated radioactivity being released directly into the atmosphere. DSSI is permitted to release up to 50,000 curies of radioactivity per year. In addition, DSSI's current license limit only allows them to accept and store, on-site, up to 5,000 curies at any one time. If all of the mixed waste generated by the 100 organizations included in the International Isotopes Society's survey was treated at this commercial waste treatment facility, approximately 16,000 curies of radioactivity would be released directly into the environment and the waste disposal costs, when utilizing this "outdated" treatment technology, would approach a half a billion dollars.

PRI's innovative waste management strategy, if utilized by these 100 organizations and others around the country, could result in the elimination of the release of up to 16,000 curies of radioactivity. In addition, the half a billion dollars in disposal cost savings could re-directed into research and the development of new medicines and new advancements in science.

At the present, Johnson & Johnson generates up to 10 curies of radioactive mixed waste per year. However, if synthesis research was not severely restricted by waste disposal options and the prohibitive environmental risks and costs associated with these options, this figure could approach 50 curies per year. By employing the bench-top high temperature catalytic oxidation process to treat this mixed waste on-site, J&J may currently eliminate the release of up to 10 curies of radioactivity per year and realize a cost avoidance of up to $300,000 annually. And, with unrestricted research activities, these figures could potentially increase to 50 curies and $1.5 million annually.

Regardless of the actual numbers, PRI's innovative approach would greatly reduce the amount of radioactivity being directly released into the atmosphere by the outdated "polluting" technology utilized by the primary commercial mixed waste treatment facility in the United States.

OTHER BENEFITS

An exemption to allow bench-top catalytic oxidation of mixed wastes without a permit will result in many other benefits as well. In addition to the superior environmental performance discussed above, these benefits include: (1) opportunities to develop technologies to recycle/reuse radioactivity and other technological advances, (2) cost savings, (3) creating a competitive advantage for domestic companies and research organizations, (4) support from stakeholders, and (5) transferability of technology.

(1) Opportunities to Develop Radioactivity Recycling / Reuse and Other Technologies - The principle advantage of providing an exemption for on-site treatment utilizing the catalytic oxidation process for the biomedical research community is the potential for generating a uniform waste stream that is amenable to recycling and reuse while completely eliminating the release of radioactivity and hazardous materials into the environment. There has been great interest from outside parties who would like to utilize and improve

on the technology developed by PRI. One company is interested in recovering tritium from the radioactive water generated by the catalytic oxidation process. This process would recycle the radioactivity and completely eliminate its release into the environment. The technology currently exists to recover and reuse tritium and there is notable interest in developing the market utilizing this approach. Another company would like to manufacture a standard bench-top system, based on PRI's unit, that can be sold off-the-shelf to research institutions so they could perform on-site treatment in a laboratory setting. This would produce a uniform radioactive water waste stream that is receptive to recycling and which would further develop the market for radioactive recycling. Still another company is interested in scaling-up the catalytic oxidation process to create a viable, environmentally-sound, cost-effective, commercially available waste management option for mixed waste.

(2) Cost Savings - Currently, many research institutions are not permitted to generate mixed waste due to the limited disposal options and prohibitive disposal costs associated with these wastes. PRI's alternative environmental management strategy would result in a tremendous cost savings opportunity for PRI, Johnson & Johnson, and all R&D institutions. Current commercially available TSDF's may charge between $20,000 to $40,000 per curie of activity to treat mixed wastes. Based on the survey of 100 domestic pharmaceutical companies, universities, commercial facilities and other organizations, conducted by the International Isotope Society in 1996, domestic institutions generate approximately 16,000 curies of tritium and carbon-14 mixed waste annually. At an average disposal cost of $30,000 per curie, disposal of mixed wastes is costing domestic companies, conservatively, up to $480 million per year. For PRI, disposal costs may range from $250,000 to $300,000 per year for mixed waste. For Johnson & Johnson, these disposal costs may exceed $1.5 million per year. These costs must be passed on to our customers in higher costs for prescriptions and other pharmaceutical products. In addition, the costs stated above only apply to disposal costs and do not include the costs for waste analysis and transportation, which could be preclusive as well.

(3) Competitive Advantage - The availability of commercially available mixed waste disposal facilities, excessive disposal costs, the lack of adequate storage facilities and current regulatory restriction on treatment options and accumulation times have severely restricted most research activities that generate mixed wastes. This has caused a major disadvantage for domestic pharmaceutical research institutions, which must utilize radioactive materials in the highly competitive commercial arena. Excessive disposal costs have severely limited research activities that generate mixed wastes and have effectively locked out small research institutions and universities from participating in this research. Many companies are contracting out research to foreign companies who manage wastes in the cost friendly, environmentally detrimental manner of incineration that releases large quantities of radioactivity directly into the atmosphere. For pharmaceutical companies who choose to participate in this arena of research and who diligently manage mixed waste in accordance with current regulations, the excessive waste management costs must be passed on to the consumer. Furthermore, the costs currently being incurred by waste disposal could be re-directed and better utilized in the research and development of new medicines and new advancements in science.

(4) Stakeholder Interest - The success of high temperature catalytic oxidation in the treatment of mixed wastes at PRI has generated great interest among many stakeholders including government agencies, the National Tritium Lab, the National Institute of Health, domestic and international pharmaceutical research companies, commercial manufacturers, raw material suppliers and mixed waste treatment facilities. In addition, three stakeholders have shown great interest in this technology that is very exciting (see item #1 above). Additional stakeholder interest comes from the local communities in which facilities that generate mixed waste are located. These communities would be more comfortable with the knowledge that the mixed waste is being treated in a highly controlled environment, with no release to the atmosphere, as opposed to current methods of evaporating mixed waste into the atmosphere, or storing large quantities of mixed waste on-site, or transporting mixed waste through the communities for off-site disposal.

(5) Technology Transfer - The technology developed by PRI for bench-top catalytic oxidation of mixed waste is transferable to any organization that generates or treats mixed wastes. This includes the electric power industry, pharmaceutical companies, research institutions, and colleges and universities among others. The technology has been proven to achieve an over 99.999% destruction efficiency for virtually any organic compound containing tritium or carbon-14. PRI has hosted over 100 companies, organizations and individuals who have shown interest in utilizing this technology.

SUMMARY

In summary, PRI believes we can obtain superior environmental performance, in addition to the other benefits mentioned above, through the use of on-site bench-top catalytic oxidation for the treatment of mixed waste as opposed to the current methods of mixed waste management practices in the following areas:

(1) No Release to the Environment

Catalytic oxidation of mixed wastes results in a 99.999% destruction of the organic component and complete capture of the radioactive component, with the potential for recovery and recycling, resulting in no release of hazardous chemicals or radioactive materials into the environment.

Reduced Risk

On-site bench-top treatment of mixed wastes in a highly controlled environment, greatly reduces or eliminates the risk of the potential release of radioactivity or hazardous materials into the environment as a result of a leak, spill or accident during handling, storage, and transportation of waste.

PRI started this proactive initiative in an effort to address the problems and the risks associated with the management of mixed low-level radioactive wastes. PRI has been developing and testing the catalytic oxidation technology for over seven years. They have readily available data that demonstrates destruction

removal efficiencies between 99.999 and 99.99999% for an extensive list of organic materials. PRI has shared this technology with Ontario Hydro, a large energy service provider in Ontario, Canada who provides electricity to 305 municipalities and almost 3 million customers. This benefaction included helping Ontario Hydro set up a system, at our expense, in an effort to create a cost effective, commercially available treatment and recycling alternative. PRI's ultimate goal is to establish a worldwide standard for an environmentally safe treatment process that completely destroys the organic component and recovers and recycles the radioactive component of all mixed wastes. We believe this Projec
t XL initiative is the first step in achieving our goal.

STATEMENT OF BELIEFS

The Johnson & Johnson Family of Companies and all of its employees adhere to Our Credo, a system of values and a statement of principles and beliefs which guide our business in all that we do. Our Credo makes commitments to being a responsible corporate citizen to the communities in which we live and work and to the world community as well, to protecting the environment and natural resources, to developing innovative programs, and to providing high quality products and services for our patients at a reasonable cost. In pursuing this Project XL initiative, we feel we are upholding the Johnson & Johnson Credo pledge to our customers, employees, communities and stockholders.