

Department of Environmental Protection

Jeb Bush
Governor

Twin Towers Office Building
2600 Blair Stone Road
Tallahassee, Florida 32399-2400

Colleen M. Castille
Secretary

July 17, 2006

Mr. Christopher W. Young
Biotech Restorations, LLC
137 Cross Center Road, #143
Denver, North Carolina 28037

Re: **Factor Remediation Formula**

Dear Mr. Young:

The Bureau of Petroleum Storage Systems hereby accepts Factor Remediation Formula (FRF) for the remediation of petroleum contamination. This letter supersedes that of April 30, 2003, issued to Resource Technologies Environmental LLC of Pendleton, South Carolina for Gene Expression Factor. Aside from changes to the name and address of your firm, and the name of the product itself, the only other changes indicated by Biotech Restorations LLC (BTR) are those associated with the manufacturing process and the protein structures of the formulation. These changes do not raise any new environmental concerns on the part of the Bureau.

Our original acceptance of this product was only for the ex situ treatment of contaminated soil and sediment, but this superseding acceptance extends to in situ treatment as well, for both soil and groundwater. Additionally, in this superseding acceptance, we have not carried forward a discussion on how Source Removal rules and restrictions set forth in Section 62-770.300, Florida Administrative Code (F.A.C.), apply. In its place, we have substituted a discussion about the requirements of Section 62-770.700, F.A.C., for site-specific Remedial Action, since case study narratives of projects undertaken suggest that most FRF applications have been of the site-specific, Remedial Action phase type.

As BTR has indicated, FRF is not genetic engineering but rather a protein complex that enables specific repressed genes of indigenous, aerobic and anaerobic microorganisms to produce the reductive enzymes needed for the destruction of persistent contaminants in the environment. It is our understanding that the contaminants themselves can chemically cause such gene repression. The treatment process involves the mixing of a small amount of FRF into the contaminated media, along with macro-nutrients, micro-nutrients, water, and oxygen in the case of aerobic degradations. In cases where indigenous microorganisms are not sufficiently present, suitable non-pathogenic microorganisms from an external source can be added.

This acceptance of FRF is for applications within the jurisdiction of the Bureau of Petroleum Storage Systems, which is primarily the cleanup of petroleum in soil and groundwater pursuant to Chapter 62-770, F.A.C. Other bureaus within the Department of Environmental Protection, or other state agencies may recognize this acceptance if their needs are similar, but this Bureau is not responsible for applications beyond its jurisdiction. Some of those applications are the reclamation of agricultural land, and treatment of other organic pollutants such as pesticides, solvents, polychlorinated biphenyls and dioxin.

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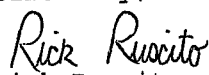
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We recommend placing a copy of this letter in the appendix of site-specific Remedial Action Plans proposing FRF. In this way, technical reviewers throughout the state will be informed that the Bureau of Petroleum Storage Systems has considered the application of FRF from a regulatory standpoint. Enclosure 1. provides additional information, and identifies some applicable regulations that need to be taken into account when using FRF.

While the Bureau of Petroleum Storage Systems does not endorse specific or brand name remediation products or processes, it does recognize the need to determine their acceptability from an environmental standpoint with respect to applicable rules and regulations, and the interests of public health and safety. After an acceptance is issued, vendors must then market a product or process on its own merits regarding performance, cost and safety in comparison to competing alternatives in the marketplace. In no way, however, shall this regulatory acceptance be construed as certification of product performance. Additionally, the Department emphasizes a distinction between its regulatory "acceptance" and an approval. Products and processes are accepted but they are not approved. Furthermore, it is not a requirement that an acceptance letter be issued for a product or process in order for it to be proposed in a site-specific Remedial Action Plan, provided all applicable and appropriate rules and regulations are addressed.

The Bureau of Petroleum Storage Systems reserves the right to revoke its acceptance of a product or process if it has been falsely represented. Additionally, Bureau acceptance of any product or process does not imply it has been deemed applicable for all cleanup situations, or that it is preferred over other treatment or cleanup techniques in any particular case. A site-specific evaluation of applicability and cost-effectiveness must be considered for any product or process, whether conventional or innovative, and adequate site-specific design details must be provided in a Remedial Action Plan. You may contact me at (850) 877-1133, extension 3722 if there are any questions.

Sincerely,


Rick Ruscito, P.E.
Ecology and Environment, Inc.
Bureau of Petroleum Storage Systems
Petroleum Cleanup Section 6


Rebecca S. Lockenbach
FDEP Section Leader
Bureau of Petroleum Storage Systems
Petroleum Cleanup Section 6

Enclosures: (1) Additional Information
(2) Proposed Injection Well(s) for In Situ Aquifer
Remediation at a Petroleum Remedial Action Site

c: Tom Conrardy - FDEP/Tallahassee

History:

ppl #216
inn_105.doc
4/30/03

ppl #301
inn_105a.doc
7/17/06

ENCLOSURE 1

ADDITIONAL INFORMATION

1. Description: Factor Remediation Formula (FRF) is for the remediation of some of the most degradation-resistant chemical contaminants in the environment. It involves the mixing of a small amount of a protein complex into the contaminated media, along with macro-nutrients, micro-nutrients, water, and oxygen in the case of aerobic degradations. FRF can also be used to stimulate anaerobic microorganisms, so that they too may produce the reductive enzymes needed to degrade persistent contaminants such as pesticides and PCBs.
2. Regulations: Chapters of the Florida Administrative Code cited below are currently available at web page www.dep.state.fl.us. They can be accessed from this web page by selecting the tab labeled "Site Map", and then selecting "Rules", which is listed under the heading of "Legal Information".
3. Responsibilities: The onus is on the manufacturers and users of remediation products and processes to meet all applicable and appropriate regulations. The Bureau of Petroleum Storage Systems can help by pointing out the regulations that apply, but the responsibility to comply rests ultimately with the manufacturer and the user.
4. Permits: No permit is necessary for the onsite cleanup of petroleum-contaminated soil using FRF if the cleanup is in accordance with an approved site-specific Remedial Action Plan pursuant to Section 62-770.700, Florida Administrative Code (F.A.C.). As for the use of the FRF process as a commercial, stationary or mobile soil treatment facility, a permit is required.
5. Addition of microorganisms: As indicated by Biotech Remediations LLC (BTR) microorganisms from an external source can be added in cases where indigenous microorganisms are not sufficiently present in the contaminated media to be treated. Such microorganisms can be either aerobic or anaerobic. Additionally, in order to comply with Florida's minimum groundwater criteria, such microorganisms must be non-pathogenic.
6. Cleanup Target Levels for contaminants of concern: The current groundwater cleanup target levels (GWCTL) for petroleum and other contaminants of concern at a remediation site, for an unconditional declaration of No Further Action, are set forth in Table I of the April 17, 2005 issue of Chapter 62-777, F.A.C.

The current soil cleanup target levels (SCTL) for petroleum and other contaminants of concern at a remediation site, for an unconditional declaration of No Further Action, are the Direct Residential Exposure and Leachability levels of Table II in the April 17, 2005 issue of Chapter 62-777, F.A.C. The lower of the two levels shall be met. For example, the current direct residential exposure soil cleanup level for benzene is 1.2 milligrams per kilogram (mg/Kg), and its soil cleanup level for leachability, based on groundwater cleanup criteria, is .007 mg/Kg. Therefore, the lower of the two goals to be met in the case of benzene is the leachability goal of .007 mg/Kg.

7. FRF and its nutrient additives: By the time a cleanup project is completed, any residuals in the groundwater and soil, due to FRF and its macro- and micro-nutrient additives, must meet their respective cleanup target levels set forth in Tables I and II of Chapter 62-777, F.A.C.

In regard to the FRF protein itself, the Bureau does not have any major environmental or toxicological concerns. It is known that proteins occur in all living matter and that they are essential for the growth and repair of animal tissue. They are large organic molecules consisting of carbon, hydrogen, oxygen, and nitrogen atoms, arranged to contain a large number of amino acids.

In regard to ammonia, the Bureau believes, at worst, that a small amount of ammonia could be amongst the by-products when the FRF protein decomposes, due to the amino acids. But given the low concentration of protein that is used (measured in micrograms) the Bureau believes it is more likely that the major contribution to residual ammonia nitrogen, if any, would be the ammonium fertilizer-like macro-nutrient. The groundwater cleanup target level for residual ammonia is 2.8 milligrams per liter, per Chapter 62-777, F.A.C., and its soil cleanup target level per that same chapter is determined on a site-specific basis using the Synthetic Precipitation Leachate Procedure (SPLP) or the Toxic Characteristic Leachate Procedure (TCLP).

As for the residual concentrations of ingredients in the fertilizer-like macro- and micro-nutrients, the onus shall be on BTR, users of FRF, and those who prepare Remedial Action Plans to identify the complete chemical composition of the remediation fluid to be applied, and to identify those ingredients that are regulated by the State of Florida as contaminants.

For injection-type, aquifer remediation projects, should any of the ingredients not meet a groundwater standard in the remediation fluid to be injected, then the ingredient shall be identified, and the requirements of Rule 62-522.300(2)(c), F.A.C., shall be met in order to obtain permission by rule for a temporary injection zone of discharge. In order to comply with the rule, a site-specific Remedial Action Plan must (a) identify the chemical species in the remediation fluid to be injected that do not meet their groundwater standard; (b) specify the size of the zone of discharge that is needed (usually as a radius of influence for each injection point); (c) specify the length of time that a temporary injection zone of discharge is needed; and (d) propose groundwater monitoring of the chemical species in the remediation fluid that do not meet their groundwater standard. The Remedial Action Plan must also contain the information that will be needed by the reviewer, who upon its approval, will complete and submit the injection notification memorandum of Enclosure 2 to the Underground Injection Control Section of the Department's Division of Water Resource Management.

8. Disposition of ex situ treated soil: The residual concentrations of the contaminants of concern, and the residual concentrations of FRF and its macro- and micro-nutrients must be such that their leachate does not negatively impact the underlying groundwater (or a nearby surface water body) when soil that has been treated ex situ is returned to its excavation pit of origin or used elsewhere. In order to avoid unwanted, excessive leaching, the residual concentrations of the contaminants of concern, and the FRF and its macro- and micro-nutrient chemical species,

must meet their default leachability-based Soil Cleanup Target Levels set forth in Table II of Chapter 62-777, F.A.C., or they must pass a Synthetic Precipitation Leachate Procedure (SPLP) test.

9. Disposal of spent process water for ex situ treatment applications: As BTR has indicated, the FRF treatment uses large amounts of process water, and that contaminated groundwater from the remediation site itself can be used for this purpose. When it is time to dispose of the spent process water, however, users of the FRF process should first ensure that its quality is commensurate with the method of disposal. For example, spent process water that is allowed to percolate back into the water table will have to be of higher quality than that which is discharged to a sanitary sewer or trucked away to a commercial industrial water treatment facility. For spent FRF process water that is disposed at the site via percolation, its quality should meet the groundwater cleanup target levels of Chapter 62-777, F.A.C., for both the contaminants of concern that were being remediated at the site, and any FRF ingredients and additives that are listed in Chapter 62-777, F.A.C.
10. Dosage: For ex situ soil treatments, BTR has indicated that twenty (20) pounds of FRF is used per ton of soil that is treated, and the amount of protein incorporated into every pound of finished product is approximately 100 micrograms. The Bureau provides the 20 pounds per ton dosage for information only, and recommends that potential users of FRF contact BTR for assistance in determining a dosage based on site-specific conditions, likewise for in situ treatments.

Memorandum

Florida Department of Environmental Protection

TO: Richard Deuerling, Mail Station 3530
Division of Water Resource Management
Underground Injection Control Section
Florida Department of Environmental Protection
2600 Blair Stone Road, Tallahassee, FL 32399-2400

FROM: _____ [see Note 1.]

DATE: _____

SUBJ: **Proposed Injection Well(s) for In Situ Aquifer
Remediation at a Petroleum Remedial Action Site**

Pursuant to paragraph 62-528.630(2)(c), F.A.C., inventory information is hereby provided regarding the proposed construction of temporary injection well(s) for the purpose of in situ aquifer remediation at a petroleum-contaminated site.

Site name: _____
Site address: _____
City/County: _____
Latitude/Longitude: _____
FDEP Facility Number: _____

Site owner's name: _____
Site owner's address: _____

Well contractor's name: _____ [see Note 2.]
Well contractor's address: _____

Brief description of the in situ injection-type aquifer remediation project:

Summary of major design considerations and features of the project:

Areal extent of contamination (square feet): _____
Number of injection wells: _____

Richard Deuerling

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Date: _____

Site name: _____

FDEP Facility No.: _____

Composition of injected fluid [see Note 3.]

(ingredient, wt. %): _____

Injection volume per well (gallons): _____

Single or multiple injection events: _____

Injection volume total (all wells, all events): _____

A site map showing the areal extent of the groundwater contamination plume, and the location and spacing of injection wells and associated monitoring wells is attached.

The following is a summary description of the affected aquifer:

Name of aquifer: _____

Depth to groundwater (feet): _____

Aquifer thickness (feet): _____

The injection well(s) features are summarized below, and/or a schematic of the injection well(s) is attached.

Direct-push or HSA/Mud rotary (*circle the appropriate well type*)

Diameter of well(s) (i.e., riser pipe & screen) (inches): _____

Total depth of well(s) (feet): _____

Screened interval: _____ to _____ feet below land surface

Grouted interval: _____ to _____ feet below land surface

Casing diameter, if applicable (inches): _____

Cased depth, if applicable: _____ to _____ feet below land surface

Casing material, if applicable: _____

The in situ injection-type aquifer remediation plan for this petroleum contaminated site is intended to meet the groundwater petroleum cleanup criteria set forth in Chapter 62-770, F.A.C. Additionally, all other groundwater standards will be met at the time of project completion for any residuals associated with the ingredients of the injected remediation products, and any by-products or intermediates produced as a result of the chemical or biochemical transformation of those ingredients or the contaminating petroleum during their use. Applicable primary and secondary drinking water standards are set forth in Chapter 62-550, F.A.C., and additional groundwater quality criteria are set forth in Chapters 62-520 and 62-777, F.A.C.

The remediation plan estimates that site remediation will take _____ months. We will notify you if there are any modifications to the remediation strategy which will affect the injection well design or the chemical composition and volume of the injected remediation product(s).

Richard Deuerling

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Date: _____

Site name: _____

FDEP Facility No.: _____

The proposed remediation plan was approved on _____ by an enforceable approval order. A copy is attached. The remediation system installation is expected to commence within 60 days. Please call me at _____ if you require additional information.

Note 1. Local programs are not authorized to approve underground injections into aquifers. Reason: Per agreement with the USEPA, the FDEP cannot delegate this authority. Local programs, after reviewing a Remedial Action Plan or an injection proposal document, should prepare the Approval Order and route it to Tallahassee for Bureau Chief's signature, and then complete this form. This form is primarily for use by state and local program technical reviewers, but petroleum remediation contractors may fill in all blanks except those labeled "FROM" and "DATE" on page 1, and the approval date and telephone number blanks in the last paragraph. Those blanks should be completed only by a state or local program reviewer.

Note 2. If an injection well installation contractor has not yet been selected, then indicate the name and address of the project's general remediation contractor/consultant.

Note 3. Complete chemical analysis of injected fluid is required by Chapter 62-528, F.A.C. Proprietary formulations shall make confidential disclosure. Injected fluids must meet drinking water standards of Chapter 62-550, F.A.C., unless an exemption or variance has been granted.