PMC-EF2a

(2,04,02)

U.S. DEPARTMENT OF ENERGY EERE PROJECT MANAGEMENT CENTER NEPA DETERMINATION



RECIPIENT: Novozymes, Inc.

STATE: CA

PROJECT TITLE:

SynTec-Synthetic Biology for Tailored Enzyme Cocktails

Funding Opportunity Announcement Number DE-FOA-0000719 Procurement Instrument Number
DE-EE0006110

NEPA Control Number CID Number GFO-0006110-001 EE

Based on my review of the information concerning the proposed action, as NEPA Compliance Officer (authorized under DOE Order 451.1A), I have made the following determination:

CX, EA, EIS APPENDIX AND NUMBER:

Description:

A9 Information gathering, analysis, and dissemination

Information gathering (including, but not limited to, literature surveys, inventories, site visits, and audits), data analysis (including, but not limited to, computer modeling), document preparation (including, but not limited to, conceptual design, feasibility studies, and analytical energy supply and demand studies), and information dissemination (including, but not limited to, document publication and distribution, and classroom training and informational programs), but not including site characterization or environmental monitoring. (See also B3.1 of appendix B to this subpart.)

B3.6 Small-scale research and development, laboratory operations, and pilot projects

Siting, construction, modification, operation, and decommissioning of facilities for smallscale research and development projects; conventional laboratory operations (such as preparation of chemical standards and sample analysis); and small-scale pilot projects (generally less than 2 years) frequently conducted to verify a concept before demonstration actions, provided that construction or modification would be within or contiguous to a previously disturbed or developed area (where active utilities and currently used roads are readily accessible). Not included in this category are demonstration actions, meaning actions that are undertaken at a scale to show whether a technology would be viable on a larger scale and suitable for commercial deployment.

Rational for determination:

The goal of the project is to develop a synthetic screening tool that enables rapid assessment of unexplored natural diversity to deliver cost effective enzyme solutions tailored to specific industrial biorefineries. Funding from DOE would be used to support all phases of the project, from construction of the novel screening system, to its use in tailoring a specific cocktail for hydrolysis of AFEX™ pretreated corn stover (AFEX™ PCS), and also for the purposes of benchmarking the performance of initial and final enzyme cocktails in a defined assay.

Project tasks include:

- Task 1. Establish SynTec (Synthetic Biology for Tailored Enzyme Cocktails) platform
- Task 2. SynTec Proof of concept: identify effective hemicellulases for AFEX-PCS.
- Task 3. SynTec Proof of concept: identify cellulases for AFEX-PCS.
- Task 4. Technoeconomic modeling of accomplishments

All project work is considered bench laboratory scale and would be completed within laboratories at the following three sites: Novozymes, Inc located in Davis CA, Novozymes North America (NZNA) located in Franklinton NC, and Michigan Biotechnology Institute (MBI) located in Lansing MI. These laboritories have rigorous safety guidelines in place and would observe all applicable federal regulations, including regulations promulgated by OSHA, EPA, the North Carolina Department of Labor, and North Carolina Department of Environment and Natural Resources. NZNA is also subject to regulation as a food and ingredient manufacturer, which falls under the purview of the USDA/FDA. NZNA also conducts a Zero Enzyme Allergies program for enzyme handling, use and storage, tailored towards enzyme safety and designed to prevent workers from developing enzyme allergies. The MBI portion of this project may involve the use of genetically altered materials that are not classified by APHIS. The work with these materials is done under the supervision of MBI's Institutional Biosafety Committee, which is registered with the National Institutes of Health (NIH) and is in compliance with all NIH guidelines regarding rDNA research.

Novozymes would be utilizing and developing genetically modified bacteria (Bacillus subtilis and Aspergillus oryzae) strains. The strains would be maintained in a laboratory setting (i.e. the strains developed would not be used for commercial production of enzymes). Novozymes, Inc. is a Biosafety Level 1 (BL1) research facility. BL1 lab practices are used with all recombinant DNA work, even if the work is considered exempt from NIH Guidelines. All research involving recombinant DNA would be treated as prescribed by the most recent edition of NIH's Guidelines for Research Involving Recombinant DNA Molecules and as prescribed by law. All cultures, stocks, and other regulated wastes would be decontaminated before disposal by an approved decontamination method such as autoclaving.

Shipment and receiving of all living recombinant and regulated cultures and stocks would be completed in compliance with the policies of the US Department of Agriculture and the US Customs Department and all items are traceable via a Novozymes database.

Based on review of the project information, DOE has determined that the proposed project activities would not have a significant individual or cumulative impact to human health and/or environment. DOE has determined that these activities are consistent with actions contained in DOE categorical exclusions A9 "Information gathering, analysis, and dissemination," and B3.6 "Small-scale research and development, laboratory operations, and pilot projects," and is categorically excluded from further NEPA review.

NEPA PROVISION

DOE has made a final NEPA determination for this award

Insert the following language in the award:

If you intend to make changes to the scope or objective of your project you are required to contact the Project Officer identified in Block 11 of the Notice of Financial Assistance Award before proceeding. You must receive notification of approval from the DOE Contracting Officer prior to commencing with work beyond that currently approved.

Note to Specialist:

Casey Strickland 6/13/2013

SIC	GNATURE OF THIS MEMORANDUM CONSTITUTES, A RECORD OF THIS DECISION.
NE	PA Compliance Officer Signature: Date:
FIE	ELD OFFICE MANAGER DETERMINATION
	Field Office Manager review required
NC	O REQUESTS THE FIELD OFFICE MANAGER REVIEW FOR THE FOLLOWING REASON:
	Proposed action fits within a categorical exclusion but involves a high profile or controversial issue that warrants Field Office Manager's attention.
	Proposed action falls within an EA or EIS category and therefore requires Field Office Manager's review and determination.
BA	SED ON MY REVIEW I CONCUR WITH THE DETERMINATION OF THE NCO :
Fiel	ld Office Manager's Signature: Date:
	Field Office Manager