FAP 2207

H. Environmental Assessment

1. DATE APR 9 1987

2. NAME OF APPLICANT/PETITIONER

Phillips Petroleum Company

On behalf of their subsidiary, Provesta Corporation

3. ADDRESS: All communication regarding the petition should be directed to:

C. J. Miller

Phillips Petroleum Company

13 A4 Phillips Building

Bartlesville, OK 74004

(918) 661-9070

4. DESCRIPTION OF PROPOSED ACTION

a. Requested approval - Petitioner requests the promulgation of a regulation allowing for the use of Pichia pastoris dried yeast as a component of animal food.

b. Location where product will be produced - All production of P. pastoris dried yeast is done at Provesta's Dried Yeast Plant

located at Building 94H Phillips Research Center near Bartlesville, Oklahoma.

c. Locations where product will be used - P. pastoris dried yeast will be used at locations throughout the United States as an ingredient in animal food.

d. Location where product can be disposed of - Under normal circumstances, P. pastoris dried yeast will be consumed by animals and will not require disposal in the environment. If a container of P. pastoris is found to be off-specification or contaminated, it can be disposed of in a sanitary landfill in accordance with local, state and federal regulations.

e. Type of environment adjacent to locations b, c and d above - The Dried Yeast Plant is adjacent to the other research and pilot plant facilities located in the Phillips Research Center (PRC). PRC is located just outside the city limits of Bartlesville, Oklahoma.

It is not possible to accurately predict all environments which may be adjacent to locations (c) and (d) because use and/or disposal of P. pastoris will often occur once the product leaves Provesta's responsibility.

5. IDENTIFICATION OF CHEMICAL SUBSTANCE THAT IS THE SUBJECT OF THE PROPOSED ACTION:

a. Complete Nomenclature - Pichia pastoris

b. CAS Registry No. - Not Applicable

c. Molecular Weight - Not Applicable

d. Structural formula - Not Applicable

e. Physical description - White to cream colored powder.

f. Additives - None

g. Impurities - P. pastoris dried yeast is a pure product, however, product runs are routinely analyzed for the possible presence of the following impurities:

1. Heavy Metals

Element	Recommended Limits[3]
Arsenic	< 2 ppm
Lead	< 5 ppm
Mercury	< 0.1 ppm

2. Microbiological

	Recommended Limits[3]
Std. Aerobic Plate Count	< 100,000/g
Clostridium perfringens	< 100/g
Staphylococcus aureus	< 1/g
Salmonella	< 1/50 g
Mold Count	< 100/g
Yeast Count	< 100/g
Streptococcus	< 10,000/g
Coliform	< 10/g

3. Trace Components

Component	Recommended Limits[3]
Methanol	< 20 ppm
Formaldehyde	< 20 ppm

6. INTRODUCTION OF THE SUBSTANCES INTO THE ENVIRONMENT (21 CFR 25.312(b)(5)(i)):

The following emissions are estimated to take place from the production of Pichia pastoris dried yeast at the Dried Yeast Plant at PRC:

. Wastewater

Wastewater is generated from the cleaning of the fermentor, pasturizers, and spray drier. Cleaning takes place approximately every ten days from the yeast production facilities and each cleaning procedure generates approximately 1150 gallons of wastewater. An estimated composition of the wastewater is presented in the following table.

PICHIA PASTORIS YEAST PRODUCTION WASTEWATER

Parameter	Concentration, mg/L
Biochemical Oxygen Demand	2498
Suspended Solids	500
Total Dissolved Solids	1000
Total Phosphorus	335

The wastewater is discharged to the PRC process sewer which in turn discharges to four on-site oxidation/settling ponds (two of which are aerated) along with other PRC wastewaters. After

pre-treatment in the oxidation/settling ponds, the effluent is pumped to the City of Bartlesville Chickasaw Wastewater Treatment Plant for secondary treatment prior to discharge. Discharge to the city sewer takes place in compliance with the Industrial Wastewater Discharge Permit (No. 84-001) issued to Phillips Petroleum Company by the City of Bartlesville. The City of Bartlesville's pretreatment program has been approved by the U. S. Environmental Protection Agency (EPA).

Discharges from the Chickasaw Wastewater Treatment Plant are regulated by National Pollutant Discharge Elimination System (NPDES) permit number OK 0030333 issued by the EPA.

Total discharges of wastewater from PRC average approximately 300,000 gallons per day, while total wastewater discharges from the Chickasaw Wastewater Treatment Plant average approximately seven million gallons per day.

Due to the small flow and biodegradable nature of the wastewater generated by Pichia pastoris production, this wastewater will not significantly impact either the PRC discharges or the wastewater discharged from the Chickasaw Wastewater Treatment Plant. Both discharges will remain in compliance with their respective discharge permits.

Solid Waste

Very little solid waste is expected to be generated by the production of Pichia pastoris dried yeast. The only anticipated source will be off-specification yeast that cannot be sold as a lower grade product. It is estimated that a maximum of 300 to 400 pounds of this waste will be generated in a year. The material will be placed in fiberpacks and disposed of at the City of Bartlesville Landfill, which has been permitted by the Oklahoma State Department of Health (Permit No. 3557025M). Due to the very small quantity and non-hazardous nature of the off-specification yeast, the disposal of this material at the Bartlesville Landfill should have no significant impacts on landfill operations or regulatory compliance.

Air Emissions

During the production of Pichia pastoris dried yeast by fermentation, gases are released into the atmosphere from the fermentors and the drier. The gases are composed of carbon dioxide, oxygen, nitrogen and water vapor. All the gases are non-polluting and are not subject to EPA, state or local air regulations.

Particulate matter is removed from the vent gases by scrubbing or filtering. The amount of particulate matter released to the

atmosphere would be in compliance with federal, state and local regulations and ambient standards.

7. FATE OF EMITTED SUBSTANCES IN THE ENVIRONMENT (21 CFR 25.31a (b)(5)(ii)):

P. pastoris dried yeast is intended only as a replacement for similar protein supplements already in use, therefore, the volume of dried yeast in the environment is not intended to increase.

No change in the concentration or distribution of the metabolites of P. pastoris are expected because this product will be used basically as a source of protein in the animal's diet and will be digested by the animal in the same manner as any other proteinaceous substance.

Under normal storage conditions, P. pastoris does not readily degrade. If disposal of the product in a landfill is required, P. pastoris dried yeast will be degraded as any other organic substance.

The only occasions in which this yeast would be broken down into its constituent parts would be those cited above - digestion by animals or environmental degradation.

Therefore, the use of P. pastoris dried yeast cannot reasonably be expected to significantly alter the concentration and distribution of the product, its metabolite, degradation products or its constituent parts in the environment.

8. ENVIRONMENTAL EFFECTS OF RELEASED SUBSTANCES (21 CFR 25.31 a(b)(5)(iii)):

No environmental effects are expected as the result of the use of P. pastoris dried yeast as an animal food additive.

As explained in Item 6 above, the only production waste streams emitted into the environment from the yeast manufacturing facility are the vent gases and wash water. Both of these streams are adequately treated before their release into the environment.

The dried yeast product itself is consumed and digested by animals. In the event that the yeast product is off-spec or becomes contaminated, it is disposed of in a sanitary landfill and will undergo normal decay processes.

9. USE OF RESOURCES AND ENERGY

The following energy and natural resource requirements were estimated for the production of P. pastoris at the Dried Yeast Plant:

Energy Requirements

Electricity - 6.9 kwh/lb product

Steam- 3.3 lb steam/lb product

Natural gas- 24,000 btu/lb product

Natural Resources Requirements

	lb/lb product
Water-	3.51
Potassium hydroxide-	2.57×10^{-4}
Potassium sulfate-	4.24×10^{-2}
Calcium sulfate dihydrate-	2.64×10^{-3}
Magnesium sulfate heptahydrate-	3.47×10^{-2}
Zinc sulfate heptahydrate-	4.80×10^{-4}
Ferrous sulfate heptahydrate-	1.56×10^{-3}
Cupric sulfate pentahydrate-	1.45×10^{-4}
Manganous sulfate monohydrate-	9.85×10^{-7}
Sulfuric acid-	2.27×10^{-4}
Phosphoric acid (75%)-	0.11
Ammonia-	0.12
Methanol-	2.50
Air @ 65 psig-	36.49

10. MITIGATION MEASURES

No adverse environment impacts are associated with the production, use or disposal of P. pastoris dried yeast, therefore, no measures to mitigate such effects are required.

11. ALTERNATIVES TO PROPOSED ACTION

No potential adverse environmental effects have been identified with the production, use or disposal of P. pastoris dried yeast as an animal food additive.

12. LIST OF PREPARERS:

J. P. Stevenson, P.E.
Environmental Engineer
Phillips Petroleum Company
M.S. Civil Engineering, Purdue University - 1977
B.S. Environmental Engineering, Purdue University - 1976

F. W. Mulloy
Environmental Engineer
Phillips Petroleum Company
B.S. Chemical Engineering, New Mexico State University - 1960

G. E. Fink
Environmental Engineer
Phillips Petroleum Company
B. S. Environmental Engineering, Montana College of Mineral Science and Technology - 1981

H. R. Hunt

Senior Research Engineer

B.S. Chemical Engineering

C. J. Miller

Consumer Protection Scientist

Masters in Natural Science

B.S. - Biology/Education

13. CERTIFICATION:

The undersigned official certifies that the information presented is true, accurate and complete to the best of the knowledge of the persons responsible for preparation of the environmental assessment.

DATE April 9, 1987

C J Miller

Signature of Responsible Official

Consumer Protection Scientist

Title

[1]Lodder, J. L., editor; The Yeast; North Holland Publishing Co., Amsterdam; pg 511-513.

[2]Phaff, H. J. and C. W. Price; "Strengths and Weaknesses of Traditional Criteria in the Systematics of Yeasts as Revealed by Nuclear Genome Comparison"; Single Cell Protein - Safety for Animal and Human Feeding; Editors - Silvio Garattini, Silvio Paglialunga and Nevin S. Scrimshaw; pg 1-12; © 1979.

[3]Hoogerheide, J. C.; Yamada, K.; Littlehailes, S. D.; and Ohno, K.; Guidelines for Testing Single Cell Protein Destined as a Protein Source for Animal Feed II; International Union of Pure and Applied Chemistry, Pure and Applied Chemistry, Vol. 51, pp. 2537-2560.

[4]Ness, W. R. and M. L. McKean; Biochemistry of Steroids and Other Isopentenoids; Chemistry Park Press, Baltimore; pg. 386-387.

[5]Swartz and Cooney, 1981, Appl. Environ. Microbiol, 41, pp. 1206-1213.

[6]Litchfield, J. H.; Single Cell Proteins; Science, Vol. 219, Feb. 1983; pp. 740-746.

[7]Food Tech., May 1974.

[8]R. L. Vetter, Correspondence to D. W. Dreisker, November 27, 1982. (See Appendix III (A).

[9]Fujimaki, M.; "Research on the Development of Assessment Method for Safety of SCP (Single Cell Protein) for Animal Feeding in Japan"; Dept. of Food Nutr.; Ochanomizu Univ., Tokyo, Japan; Colloq. Int. Proteines. Org. Unicell, (Conference Proceedings), 1983.

[10]Garanttini, Silvio; Silvio Paghalunga and Nevin S. Schrimshaw (editors); Single-Cell Protein - Safety for Animal and Human Feeding; Proceedings of the Protein-Calorie Advisory Group of the United Nations System Symposium" Investigations on Single-Cell Protein"; March 31 - April 1, 1977; @ 1979.

[11]Senez, J. C.; "Conclusions"; International Symposium on Single Cell Protein; Paris, France; January 28-30, 1981; pages 345-347.

CJM:gb-13