NOSB NATIONAL LIST
FILE CHECKLIST

LIVESTOCK

MATERIAL NAME: **#14 Probiotics**

✓ **NOSB Database Form**

✓ **References**

____ **MSDS (or equivalent)**

✓ **TAP Reviews from:** **Lynn Brown, William Zimmer, and Marta Engel**

NOSB/NATIONAL LIST
COMMENT FORM
LIVESTOCK

Material Name: #14 Probiotics

Please use this page to write down comments, questions, and your anticipated vote(s).

COMMENTS/QUESTIONS:

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1. In my opinion, this material is:
_____ Synthetic _____ Non-synthetic.

2. This material should be placed on the proposed National List as:
_____Prohibited Natural _____Allowed Synthetic.

TAP REVIEWER COMMENT FORM for USDA/NOSB

Use this page or an equivalent to write down comments and summarize your evaluation regarding the data presented in the file of this potential National List material. Complete both sides of page. Attach additional sheets if you wish.

This file is due back to us by: Sept 19, 1995

Name of Material: Probiotics

Reviewer Name: MARTA W. ENGEL, D.V.M.

Is this substance Synthetic or non-synthetic? Explain (if appropriate)

Non-Synthetic

If synthetic, how is the material made? (please answer here if our database form is blank)

This material should be added to the National List as:

___ **Synthetic Allowed** **Prohibited Natural**

or, ✓ **Non-synthetic (This material does not belong on National List)**

Marta W Engel D.V.M.

Are there any use restrictions or limitations that should be placed on this material on the National List?

Please comment on the accuracy of the information in the file:

Any additional comments? (attachments welcomed)

These products by and large are safe and non-toxic. They can also be ineffective if not used properly.

Do you have a commercial interest in this material? ___ **Yes;** ___ **No**

Signature Marta W. Engel DVM **Date** 9/21/95

Please address the 7 criteria in the Organic Foods Production Act:
(comment in those areas you feel are applicable)

(1) the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;

(2) the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment;

(3) the probability of environmental contamination during manufacture, use, misuse or disposal of such substance;

(4) the effect of the substance on human health;

(5) the effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock;

(6) the alternatives to using the substance in terms of practices or other available materials; and Good management is always very important.

(7) its compatibility with a system of sustainable agriculture.
I don't see any problems with probiotics in sustainable ag/organic farming systems.

TAP REVIEWER COMMENT FORM for USDA/NOSB

Use this page or an equivalent to write down comments and summarize your evaluation regarding the data presented in the file of this potential National List material. Complete both sides of page. Attach additional sheets if you wish.

This file is due back to us by: Sept. 19, 1995

Name of Material: Probiotics

Reviewer Name: Lynn Brown

Is this substance Synthetic or non-synthetic? Explain (if appropriate)

Synthetic

If synthetic, how is the material made? (please answer here if our database form is blank)

This material should be added to the National List as:

X Synthetic Allowed ___ Prohibited Natural

or, ___ Non-synthetic (This material does not belong on National List)

Are there any use restrictions or limitations that should be placed on this material on the National List?

Should be allowed as a supplement to good management. Cannot replace good management.

Please comment on the accuracy of the information in the file:

Information is accurate.

Any additional comments? (attachments welcomed)

Do you have a commercial interest in this material? ___ Yes; X No

Signature Lynn R Brown **Date** 9/14/95

Please address the 7 criteria in the Organic Foods Production Act:
(comment in those areas you feel are applicable)

(1) the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;

No Problem

(2) the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment;

No problem

(3) the probability of environmental contamination during manufacture, use, misuse or disposal of such substance;

No problem

(4) the effect of the substance on human health;

May be benificial in some situations.

(5) the effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock;

No problem

(6) the alternatives to using the substance in terms of practices or other available materials; and Good husbandry practices are always helpful, however, probiotics can supplement the natural organisms in the digestive tract and improve animal performance.

(7) its compatibility with a system of sustainable agriculture.

Probiotics are compatible with sustainable agriculture

TAP REVIEWER COMMENT FORM for USDA/NOSB

Use this page or an equivalent to write down comments and summarize your evaluation regarding the data presented in the file of this potential National List material. Complete both sides of page. Attach additional sheets if you wish.

This file is due back to us by: Sept. 19, 1995

Name of Material: Probiotics

Reviewer Name: William Zimmer D.V.M.

Is this substance Synthetic or non-synthetic? Explain (if appropriate)

Non Synthetic

If synthetic, how is the material made? (please answer here if our database form is blank)

This material should be added to the National List as:

____ **Synthetic Allowed** ____ **Prohibited Natural**

or, ✓ **Non-synthetic (This material does not belong on National List)**

Currently listed as "prohibited Natural", but does not meet criteria for prohibition under Section 2118 (c)(2)

Are there any use restrictions or limitations that should be placed on this material on the National List?

If included on the list, Yes. Any preparations used for intra mammary applications should carry a 24 hour milk withholding to minimize bacteria counts in milk. Naturally occurring organisms only. rDNA not allowed!

Please comment on the accuracy of the information in the file:

Incomplete! Additional microorganisms, properties including enzyme and vitamin metabolism, and applications including silage inoculation. Legally must carry statement "Live, Viable, Naturally occurring microorganisms!!!

Any additional comments? (attachments welcomed)

These products should be allowed, are safe as outlined by AAFCO and FDA - See attached excerpts from AAFCO and FDA "Generally Recognized as Safe"

Do you have a commercial interest in this material? ✓ **Yes;** ____ **No**

Signature William A. Zimmer DVM **Date** 9-7-95

Please address the 7 criteria in the Organic Foods Production Act:
(comment in those areas you feel are applicable)

(1) the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;

None

(2) the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment;

non toxic, naturally occurring biological substances

(3) the probability of environmental contamination during manufacture, use, misuse or disposal of such substance;

None

(4) the effect of the substance on human health;

Numerous positive effects as described in medical journals regarding yogurt cultures, enteropathogenic interactions, etc.

(5) the effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock;

Not Applicable to soils under current definition. Aids in crop storage and animal/livestock health and production under common modern livestock rearing conditions including housing, feeding of stored feeds and timed feeding and milking practices. Positive effects on stressed animals.

(6) the alternatives to using the substance in terms of practices or other available materials; and

Stress management should be treated seperately, as stress is not a disease but rather a dynamic set of living conditions which can cause an animal to manifest symptoms of disease.

(7) its compatibility with a system of sustainable agriculture.

Compatible. The sustainability of agriculture hinges on the biologically active component of soils, etc. How we utilize and understand the natural systems will determine our long term survival.

Dear Zea,

Sept. 15, 1995

I wish to add a few more comments regarding the section on "Probiotics" you have sent me.

First, "Probiotics" is a large, inclusive heading. The information which followed in the section was very narrow. It focused on primarily only one subsection of "probiotic" known as Lactic Acid Producing bacteria (e.g. Lactobacillus). At the broadest disscussion the section covers direct fed microorganisms. Several other entities are lumped under the term "probiotic".

By the way, "probiotic" is a laymans generic term. It was coined by Dr. Parker, formerly of Pioneer International HyBrids (I believe).

Please refer to the AAFCO text I have included. Section 36 covers fermentation products. Many fermentation products are included under "probiotics". These include Direct Fed Microorganisms (that is live, viable microorganisms), fermentation products which are not viable, extracts of fermentations which include enzymes, vitamins or other metabolites, yeast culture which has its own definition in AAFCO, etc.

I also take exception to the statements regarding probiotics covering up for "underlying conditions

causing the stress". This statement sounds exactly like statements issued by FDA. FDA wishes to control "probiotics" as drugs. They define "stress" as a disease. Stress is not a disease, (and I have never seen a medical or veterinary reference label it as such) but rather a set of conditions which can predispose animals to existing diseases. If stress was a disease, we would all be sick.

Stress is a condition which must be adressed as a seperate issue. It includes numerous uncontrollable components such as weather, growing conditions, seasonal changes, animal husbandry practices, etc.

In fact, nearly all of the animal husbandry practices employed in agriculture today contribute to stress on animals. Confinement, grouping, shipping, handling, milking, genetic improvement, ration formulating are just a few of the "good animal husbandry" practices which stress animals. Stress is condition of agriculture.

How we choose to handle and control stress is a critical issue, but don't lump it with probiotics, nutrition or any other item on the National List.

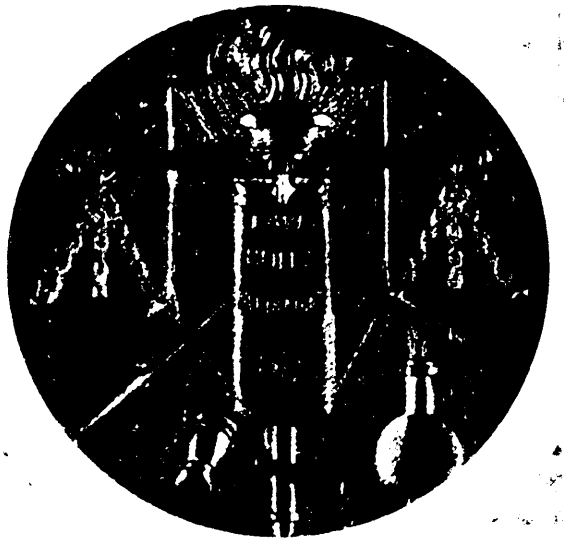
Sincerely,

W. H. Ramsey DVM

OFFICIAL PUBLICATION

- See Section 36
- especially Note
Section 36.14

1995



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33.6 **Corn Endosperm Oil** is obtained by the extraction of oil from corn gluten. It consists predominantly of free fatty acids and glycerides, and must contain not less than 85% total fatty acids, not more than 14% unsaponifiable matter, and not more than 1% insoluble matter. If an antioxidant(s) is used, the common name or names must be indicated followed by the word "preservative(s)". (Proposed 1963, Adopted 1968.) Reg. 8.322

IFN 4-02-852 Maize endosperm oil

33.7 **Vegetable Oil Refinery Lipid, Feed Grade** is obtained in the alkaline refining of a vegetable oil for edible use. It consists predominantly of the salts of fatty acids, glycerides, and phosphates. It may contain water and not more than 22% ash on a water-free basis. It is to be neutralized with acid before use in commercial feed. (Proposed 1964, Adopted 1968, Amended 1980, Adopted 1981.)

IFN 4-05-078 Vegetable oil refinery lipid

33.8 **Corn Syrup Refinery Insolubles, Feed Grade** is obtained in the refining of a corn syrup. It consists predominantly of the fatty fraction of corn starch together with protein and residual carbohydrate. It may contain water and not more than 7% ash nor less than 50% fat on a water-free basis. (Proposed 1964, Adopted 1968.)

IFN 4-02-893 Maize syrup process residue

33.14 **Calcium Salts of Long-Chain Fatty Acids** are the reaction products between calcium and long-chain fatty acids of vegetable and/or animal origin. They shall contain a maximum of 20% lipid not bound in the calcium salt form and the percent total fat shall be indicated. The unsaponifiable matter (exclusive of calcium salts) shall not exceed 4% and moisture shall not exceed 5%. If an antioxidant(s) is used, its common name(s) must be indicated on the label. Prior to conducting an assay for total fats, hydrolysis of the calcium salts should be performed to liberate the lipid fraction. (Adopted 1993)

33.15 **Hydrolyzed _____Sucrose Polyesters, Feed Grade** is the product resulting from the acid hydrolysis of sucrose polyesters, such as olestra, to make them digestible. It shall consist predominantly of fatty acids and contain, and be guaranteed for, not less than 85% total fatty acids, not more than 2% Sucrose Polyesters (hex ester and above), not more than 2% unsaponifiable matter, and not more than 2% insoluble impurities. Maximum moisture must also be guaranteed. Its source must be stated in the product name; i.e., "Hydrolyzed animal sucrose polyesters," "Hydrolyzed vegetable sucrose polyesters," or "Hydrolyzed animal and vegetable sucrose polyesters." If an antioxidant(s) is used, the common name or names must be indicated, followed by the words "used as a preservative." (Proposed 1993, Adopted 1994)

36. FERMENTATION PRODUCTS

Investigator and Section Editor–Darrel Sharpe, MO

Official

36.1 **Condensed, Extracted Glutamic Acid Fermentation Product** is a concentrated mixture of the liquor remaining from the extraction of glutamic acid, combined with the cells of Corynebacterium lilium used to produce the glutamic acid. (Proposed 1964, Adopted 1965.) Reg. 573.500

IFN 5-01-595 Glutamic acid fermentation residue condensed

36.2 **Extracted _____Presscake** is the filtered and dried mycelium obtained from _____ fermentation. (For label identification the source must be indicated as penicillium, streptomyces, citric acid, etc.) (Adopted 1951.)

IFN 5-07-154 Penicillium fermentation presscake dehydrated

IFN 5-07-155 Streptomyces fermentation presscake dehydrated
IFN 5-07-156 Citric acid fermentation presscake dehydrated

36.3 **Extracted _____ Meal** is the ground _____ presscake. (For label identification the source must be indicated as penicillium, streptomyces, citric acid, etc.) (Adopted 1951.)

IFN 5-06-163 Penicillium fermentation presscake meal extracted
IFN 5-06-164 Streptomyces fermentation presscake meal extracted
IFN 5-06-162 Citric acid fermentation presscake meal extracted

36.4 **Dried Extracted _____Fermentation Solubles** is the dried extracted broth obtained from _____ fermentation. (For label identification the source must be indicated as penicillium, streptomyces, citric acid, etc.) (Adopted 1951.)

IFN 5-06-166 Penicillium fermentation solubles extracted dehydrated
IFN 5-06-167 Streptomyces fermentation solubles extracted dehydrated
IFN 5-06-165 Citric acid fermentation solubles extracted dehydrated

36.6 **Dried _____Fermentation Extract** is the dried product resulting from extracting and precipitating by means of non-aqueous solvents or other suitable means, the water soluble materials from a fermentation conducted for maximum production of enzymes using a non-pathogenic strain of the microorganisms _____ in accordance with good manufacturing practices. (For label indentification the source must be indicated as **B subtilis, A.oryzae, A. Niger,** etc.) (Proposed 1960, Adopted 1962.)

IFN 5-06-147 Bacillus subtilis fermentation extract dehydrated
IFN 5-06-148 Aspergillus niger fermentation extract dehydrated
IFN 5-06-149 Aspergillus oryzae fermentation extract dehydrated

36.7 **Dried _____ Fermentation Solubles** is the dried material resulting from drying the water soluble materials after separation of suspended solids from a fermentation conducted for maximum production of enzymes using a nonpathogenic strain of the microorganism _____ in accordance with good manufacturing practices. (For label identification the source must be indicated as **B. subtilis, A. oryzae, A. niger,** etc.) Proposed 1960, Adopted 1962.)

IFN 5-29-779 Bacilus subtilis fermentation solubles dehydrated
IFN 5-29-781 Aspergillus niger fermentation solubles dehydrated
IFN 5-29-780 Aspergillus oryzae fermentation solubles dehydrated

36.9 **Undried Extracted _____ Solids and Fermentation Solubles** is undried mycelium and extracted broth or the extracted and undried mycelium and broth obtained from _____ fermentation. (For label identification the source must be indicated as penicillium, streptymyces, citric acid, etc.) (Proposed 1969, Adopted 1970.)

IFN 5-06-171 Citric and fermentation solids with solubles liquid
IFN 5-06-172 Penicillium fermentation solids with solubles liquid
IFN 5-06-173 Streptomyces fermentation solids with solubles liquid

36.10 **Condensed _____ Fermentation Solubles** is the product resulting from the removal of a considerable portion of the liquid by-product resulting from the action of the ferment on the basic medium of grain, molasses, whey, or other media. (For label identification, the source must be indicated as "Condensed (Whey, Grain, or Molasses) Fermentation Solubles." (Adopted 1958, Amended 1951, 1980.)

IFN 5-06-300 Cattle whey fermentation solubles condensed
IFN 4-07-153 Cereals grain fermentation solubles condensed
IFN 5-25-399 Sugarcane molasses fermentation solubles condensed

36.11 **Dried _____ Fermentation Product** is the product derived by culturing _____on appropriate nutrient media for the production of one or more of the following: enzymes, fermentation substances, or other microbial metabolites, and dried in accordance with approved methods and good manufacturing practices. Protein, fat, fiber, cell count, enzyme activity or nutrient metabolite level shall be guaranteed where applicable. (For label identification the source must be indicated as B. subtilis, A. oryzae, A. niger, Lactobacilus acidophilus, Lacatobacilus bulgaricus or Streptococcus faecium). (Proposed 1976, Adopted 1983.)

IFN 5-06-150 Bacillus subtilis fermentation product dehydrated
IFN 5-06-151 Aspergillus niger fermentation product dehydrated
IFN 5-06-152 Aspergillus oryzae fermentation product dehydrated
IFN 5-06-153 Lactobacillus acidophilus fermentation product dehydrated
IFN 5-06-154 Lactobacillus bulgaricus fermentation product dehydrated
IFN 5-06-155 Streptococcus faecium fermentation product dehydrated

36.12 **Liquid _____ Fermentation Product** is the liquid product derived by culturing or fermenting _____ on appropriate liquid nutrient media for the production of one or more of the following: enzymes, fermentation substances, or other microbial metabolites, and stabilized by approved methods in accordance with good manufacturing practices. Percent solids, cell count, enzyme activity or nutrient metabolite level shall be guaranteed where applicable. (For label identification the source must be indicated as B. subtilis, A. oryzae, A. niger, Lactobacillus acidophilus, Lactobacillus bulgaricus or Streptococcus faecium.) (Proposed 1976, Amended 1979, Adopted 1983.)

IFN 5-06-156 Bacillus subtilis fermentation product liquid
IFN 5-06-157 Aspergillus niger fermentation product liquid
IFN 5-06-158 Aspergillus oryzae fermentation product liquid
IFN 5-06-159 Lactobacillus acidophilus fermentation product liquid
IFN 5-06-160 Lactobacillus bulgaricus fermentation product liquid
IFN 5-06-161 Streptococcus faecium fermentation product liquid

Note: Dried Cultured Skimmed Milk--refer to 54.5 Milk Products Section. Condensed Cultured Skimmed Milk--refer to 54.6 Milk Products Section.

36.14 **Direct-Fed Microorganisms**-- The following microorganisms were reviewed by the Food and Drug Administration, Center for Veterinary Medicine and found to present no safety concerns when used in direct-fed microbial products:

Aspergillus niger
Aspergillus oryzae
Bacillus coagulans
Bacillus lentus
Bacillus licheniformis
Bacillus pumilus
Bacillus subtilis
Bacteroides amylophilus
Bacteroides capillosus
Bacteroides ruminocola
Bacteroides suis
Bifidobacterium adolescentis
Bifidobacterium animalis
Bifidobacterium bifidum
Bifidobacterium infantis
Bifidobacterium longum
Lactobacillus curvatus
Lactobacillus delbruekii
Lactobacillus fermentum
Lactobacillus helveticus
Lactobacillus lactis
Lactobacillus plantarum
Lactobacillus euterii
Leuconostoc mesenteroides
Pediococcus acidilacticii
Pediococcus cerevisiae (damnosus)
Pediococcus pentosaceus
Propionibacterium freudenreichii
Propionibacterium shermanii
Saccharomyces cerevisiae
Streptococcus cremoris
Streptococcus diacetylactis

Bifidobacterium thermephilum
Lactobacillus acidolphilus
Lactobaccilus brevis
Lactobacillus bulgaricus
Lactobacillus casei
Lactobacillus cellobiosus
Streptococcus faecium
Streptococcus intermedius
Streptococcus lactis
Streptococcus thermophilus
Yeast (as defined elsewhere)
(Proposed 1991, Adopted 1993)

Tentative

T36.4 **Dried Extracted _____ Fermentation Solubles** is the dried extracted broth obtained from _____ fermentation. (For label identification the source must be indicated as penicillin, streptomyces, or citric acid or as permitted by FDA.) (Proposed 1988, Amended 1992)

IFN 5-06-166 Penicillium fermentation solubles extracted dehydrated
IFN 5-06-176 Streptomyces fermentation solubles extracted dehydrated
IFN 5-06-165 Citric acid fermentation solubles extracted dehydrated

T36.6 **Dried _____Fermentation Extract** is the dried product resulting from extracting and precipitating by means of non-aqueous solvents or other suitable means, the water soluble materials from a fermentation conducted for maximum production of enzymes using a non-pathogenic strain of the microorganism _____ in accordance with good manufacturing practices. (For label identification the source must be indicated as B subtilis, A. oryzae, A. Niger or as permitted by FDA.) (Proposed 1988, Amended 1992)

IFN 5-06-147 Bacillus subtilis fermentation extract dehydrated
IFN 5-06-148 Aspergillus niger fermentation extract dehydrated
IFN 5-06-149 Aspergillus oryzae fermentation extract dehydrated

T36.7 **Dried _____Fermentation Solubles** is the dried material resulting from drying the water soluble materials after separation of suspended solids from a fermentation conducted for maximum production of enzymes using a non-pathogenic strain of the microorganism _____ in accordance with good manufacturing practices. (For label identification the source must be indicated as B. subtilis, A. oryzae, A. niger or as permitted by FDA.) (Proposed 1988, Amended 1992)

IFN Number 5-29-779IFN Name Bacillus subtilis fermentation solubles dehydrated
IFN 5-29-781 Aspergillus niger fermentation solubles dehydrated
IFN 5-29-780 Aspergillus oryzae fermentation solubles dehydrated

T36.9 **Undried Extracted _____ Solids and Fermentation Solubles** is undried mycelium and extracted broth or the extracted and undried mycelium and broth obtained from _____ fermentation. (For label identification the source must be indicated as penicillium, streptomyces, citric acid or as permitted by FDA.) (Proposed 1988)

IFN 5-06-171 Citric acid fermentation solids with solubles liquid
IFN 5-06-172 Penicillium fermentation solids with solubles liquid
IFN 5-06-173 Streptomyces fermentation solids with solubles liquid

T36.13 **Extracted _____ _____** is the filtered and dried mycelium obtained from _____fermentation. (For label identification the source must be indicated as penicillium, streptomyces, or citric acid and must be stated as that in the second word of the name. The third word of the name is for the form of the ingredient, i.e. presscake, meal, or pellets.) (Proposed 1988)

IFN 5-07-154 Penicillium fermentation presscake dehydrated
IFN 5-07-155 Streptomyces fermentation presscake dehydrated
IFN 5-07-156 Citric acid fermentation presscake dehydrated

'Invisible bugs' earn better rep with researchers

By Robert S. Boyd
News-Tribune Washington Bureau

Science:
Uses for bacteria

WASHINGTON — The time has come to put in a good word for bacteria, which have been getting a bad press lately.

These invisible bugs — the oldest and simplest living creatures — get blamed, properly, for everything from children's ear infections to leprosy and the plague.

But now, thanks to the increasing pace of discoveries in biology and genetics, scientists are finding lots of useful jobs for bacteria to do.

So small that 3 million of them could line up along a yardstick, micro-organisms are being put to work mining gold, cleaning up toxic wastes, protecting crops, removing stains, and manufacturing drugs, fuels and biodegradable diapers.

"Bacteria are wonderful," said Rona Hirschberg, a biologist at the University of Missouri who

Please see Bacteria, Page 6A

Bacteria: Have bad reputation, but do us a lot of good

From Page 1A

studies them.

Without bacteria in their stomachs, cows couldn't change grass into milk and steak.

Without bacteria, there would be no oil or gas, no cheese or yogurt, no pickles or sauerkraut.

Without bacteria to recycle dead animals and plants, scientists say life on Earth would cease within a few weeks.

"For most of us, the name 'bacteria' raises specters of plague, cholera, tuberculosis, leprosy, diphtheria and other dreaded ills," a Nobel Prize-winning biologist, Christian de Duve, wrote in a new book on the origin of life.

"However, disease-causing microbes are only a small minority among a wide diversity of harmless or useful forms, which occupy almost every possible kind of habitat, from the balmy shelter of the human gut to the brine of drying seas and the boiling waters of volcanic springs."

Bacteria consist of bits of DNA and protoplasm encased in a rubbery shell. The complete DNA, or genetic code, of a single bacterium — one that causes ear infections — was deciphered for the first time this summer.

Here are some of the helpful tasks bacteria are already performing:

Cleanup crew

Waste-gobbling bacteria feed happily on chemicals polluting the soil or water. They break down toxic compounds, like pesticides and PCBs, leaving water, carbon dioxide and other harmless products.

They make possible flushless toilets for vacation homes and campsites. They turn Palm Beach County's smelly sewage into odorless compost. They wiped oil off Alaskan beaches after the Exxon Valdez disaster. They scrubbed the bilges of the Queen Mary in Long Beach harbor.

Bioremediation — as this process is called — is cleaning up abandoned tire plants in Akron and auto plants in Detroit.

Factory workers

Mixed with chemicals in huge vats, bacteria help manufacture biodegradable plastic cups, shampoo bottles and diaper liners. They turn wood fibers into threads thinner and stronger than spider silk. They make thin films out of cellulose to cover burns.

They are getting into the energy business — producing ethanol from corn and trees, removing sulfur from coal and crude oil, splitting water into hydrogen and oxygen.

Assistant Energy Secretary Christine Ervin told Congress that "bio-processing" can provide "an environmentally benign, renewable production method" for clean-burning fuels.

For most of this century, farmers have been adding bacteria known as rhizobia to fields of legumes — like peas, beans, alfalfa and clover — because of the microbes' ability to take nitrogen out of the air and "fix" it to the roots of the plants.

Bacteria that fix nitrogen increase crop yields and replace environmentally harmful fertilizers.

Now scientists are using genetic engineering to develop improved strains of rhizobia with even higher yields.

Other bacteria fight diseases that afflict tomatoes, onions and other crops. Some breeds produce a substance that protects cotton from weevils and corn from worms.

Miniature miners

They don't wear hard hats, but some kinds of bacteria are busy mining gold, uranium and copper. These microbes feast on sulfur and iron compounds that prevent the recovery of precious minerals from low-grade ores.

The ore is crushed, a bacterial soup is added, and eventually the gold is extracted.

Peter Philip, president of Newmont Gold Co. in Denver, said its patented "bio-leaching" process will make it possible to take an additional million ounces of gold from its Nevada mines.

Health workers

As well as causing disease, microbes are major suppliers of drugs to treat sickness.

E. coli bacteria are notorious for their role in sometimes fatal intestinal infections. But E. coli also serve as factories to make insulin, a life-saving medicine for diabetics.

Bacteria are producing "a whole new class of anti-fungicides, anti-insecticides and human pharmaceuticals," said Robert Uffen, a biochemist at the National Science Foundation.

ACID-PRODUCING BACTERIA MAY HALT INTESTINAL DISEASES

Researchers at the Johns Hopkins Children's Center have proven a decades-old theory about the role of "good" bacteria and intestinal disease. The first controlled study proved that *Bifodbacteri bifidum*, commonly detected in human breast-milk, and *Streptococcus thermophilus*, found in cultured milk-products like yogurt, reduce the risk of developing diarrhea in youngsters by almost 80 percent. In addition, these specific bacteria may prevent the excretion of dangerous agents known to spread the disease from child to child.

"These results tell us that simple dietary supplementation with these bacteria could have major national and international health effects," says Robert Yolken, Johns Hopkins Children's Center.

Inexpensive, easily available and harmless enough for children to ingest every day, these bacteria could one day be incorporated into daily nutritional regimens to prevent diarrheal disease. "We might be able to put them into milk delivered to schools and day-care centers," says Yolken. However, researchers still don't know who should take it, how much they should take, when or in what form.

NOSB Materials Database

Identification

Common Name **Probiotics** **Chemical Name**

Other Names Direct-fed Microbial Products

Code #: CAS **Code #: Other**

N. L. Category Prohibited Natural **MSDS** no

Chemistry

Family

Composition Beneficial microorganisms, such as *Lactobacillus* strains and *Streptococcus faecium*. May also contain vitamins, minerals and other additives.

Properties produce lactic acid which helps restore normal balance to animals digestive tract.

How Made

Probiotics are "made" in the same way as cultures for dairy products, through either a Daily Propagated Culture in liquid or freeze dried form, using frozen cultures or concentrates which are thawed as needed, or using Direct Vat Inoculation cultures. The initial microorganisms are obtained from animals' guts or from plants. Most manufacturers have a room where the starters are incubated and then provided for inoculation. Each type of product has specific requirements for single strain or blend of culture species, time and conditions of inoculation.

Use/Action

Type of Use Livestock

Use(s) As gels, boluses and dry mixes for a variety of conditions. Digestive aid. Disease preventative. Growth promoter. Primarily used for pigs and poultry; not as effective for ruminants.

Action In general, bacteria in cultures repopulate the animals' gut with beneficial microorganisms and aid the animals own bioflora by utilization of carbohydrate in conversion to lactic acid. Effective as a preventative measure but not when disease has taken a firm hold. Also have direct suppression effect on pathogenic microflora.

Combinations should not be used in combination with antibiotics.

Status

OFPA

N. L. Restriction Category 1

EPA, FDA, etc May be regulated as new animal drugs, food additives, or foods, depending on claims and content.

Safety Guidelines

Directions

Registration under CPG 7126.41 **State Differences**

Historical status

Internationl status

OFPA Criteria

2119(m)1: chemical interactions

Claims made for probitoics include reducing early mortality, increasing market weight, improve feed conversion, improve egg quality and reducing treatment costs. It is unclear how most of these are acheived in practice, but it must have something to do with the microbiological balance in the animals digestive tract.

2119(m)2: toxicity & persistence

non-toxic and break down biologically in the environment.

2119(m)3: manufacture & disposal consequences

2119(m)4: effect on human health

Some evidence that probiotic use can exclude human enteropathogens from poultry.

2119(m)5: agroecosystem biology

May be used in situations where high stress exists in animals, thus covering up the underlying conditions causing the stress (such as high confinement) which should be addressed themselves. May also be used to aid digestibility of carbohydrate sources that would not ordinarily be used as feed.

2119(m)6: alternatives to substance

Good animal husbandry in general to avoid stress, high quality feed.

2119(m)7: Is it compatible?

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See also attached.

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AB: Pure strains of Lactobacillus ssp. isolated from a commercial probiotic consortium were checked in a double layer solid medium for their inhibition activities against selected pathogenic bacteria including serotypes of Listeria monocytogenes, Escherichia coli and Salmonella. The antagonistic properties of the Lactobacillus strains may be related to the production of bacteriocin-like compounds. All the pathogens tested were inhibited by one or a few strains of Lactobacillus, the best inhibition was observed against L. monocytogenes but the inhibition was also satisfactory against E. coli, Salm. typhimurium and Salm. enteritidis.

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SO: J-Dairy-Sci. Champaign, Ill. : American Dairy Science Association. June 1992. v. 75 (6) p. 1415-1422.
CN: DNAL 44.8-J822
AB: Probiotic ice cream was made by fermenting a standard ice cream mix with Lactobacillus acidophilus and Bifidobacterium bifidum cultures and then freezing the mix in a batch freezer. Survival of the L. acidophilus and B. bifidum, as well as beta-galactosidase activity, was monitored during 17 wk of frozen storage at -29 degrees C. Probiotic ice cream was prepared at pH 5.0, 5.5, and 6.0 to determine consumer preferences and was compared with standard Utah State University "Aggie" ice cream. All samples were strawberry-flavored and were evaluated by 88 judges. The preferred pH of probiotic ice cream, based on overall acceptance, was pH 5.5. We demonstrated that probiotic ice cream is a suitable vehicle for delivering beneficial microorganisms such as L. acidophilus and B. bifidum to consumers. The bacteria can be grown to high numbers in ice cream mix and remain viable during frozen storage.

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A Belly Full Of Bacteria

It may be just the thing to help control livestock diseases safely and cheaply

MIKE BRUSKO

Remember those robust, 100-year-old European peasants who appeared in TV commercials for a famous yogurt manufacturer a few years ago? While their long, healthy lives may not have been totally due to eating yogurt, scientists say it just could be possible that certain bacteria in cultured milk products help control diseases naturally.

And when relatives of those bacteria are fed to stressed livestock, the result can be improved disease-resistance and feed digestion, and a nearly 50-percent reduction in health-care costs per head, by some estimates. "It's a totally different approach to animal production," says Roger Crum, vice president of marketing for Pioneer Hi-Bred International's Microbial Genetics Division. "Our products are based on naturally occurring organisms. They're used to get (animals) back on feed . . . and help them provide their own defense system."

That's not to say that livestock farmers should throw out their Bovatec and Rumensin and stock up on La Yogurt, Crum quickly points out. "If an animal is sick, it's going to have to be treated with something." But if the health problems caused by today's intensive, confinement livestock operations can be largely *prevented*, Crum and others feel that the need for antibiotics and drugs will be reduced. And that's exactly what probiotics, a new generation of microbial products named for their beneficial effect on microorganisms, are designed to do.

200 Ways To Cut Drug Use

Today, there are some 200 probiotic products available to American farmers as gels, boluses and dry mixes for blending or topdressing. Some can be bought from seed and feed stores, while others are sold only to veterinarians or feed manufacturers.

Photo courtesy of Pioneer Hi-Bred International Inc

Scientists are constantly evaluating new strains of beneficial bacteria to improve weight gain, digestion and disease-resistance in livestock.

Many, like Pioneer's Probios and Probiocin lines, contain genetic relatives of the *Lactobacillus* bacteria found in yogurt, sauerkraut, sausage and pickles. "We use the same basic culture in all of our products," says Crum. "We get them either from animals' guts or from plants. They're non-disease-causing, lactic acid-producing organisms."

Unlike antibiotics, these microbial materials do not "sterilize" the gut of an animal. In fact, they do just the opposite. They repopulate the animal's small intestine with beneficial organisms that, under normal conditions, grow there naturally. Why do that? Because most modern livestock operations offer an animal anything but normal conditions, says Crum.

Long-distance travel and crowded living quarters place today's livestock under enormous stress, he explains. That can lead to a poor appetite and a decline in the number of beneficial bacteria in its gut. "When an animal is under stress, its natural immunity goes on hold. What we try and do is provide a new source of (beneficial) bacteria that can help the animal defend itself . . . get it back on feed quickly, and keep it there."

Crum says that even though antibiotics initially wipe out all forms of intestinal microlife, sick animals treated with drugs can eventually rebuild their own defense systems. But in the time it takes to do so, the illness often causes a profit-robbing weight loss. "A feeder calf, if it gets sick, could lose 20 or 30 pounds before it gets well," he says. "You've got to put that weight back on just to break even."

Since probiotics are not drugs, they won't be effective against a disease that has already overwhelmed an animal, notes Crum. Nor will they have much effect on an animal whose gut already contains an adequate number of beneficial bacteria.

But they can be a cost-effective way of helping livestock rebuild their immune systems when they're most susceptible to disease, Crum asserts. For example, say a cattleman buys 20 calves from a distant source. Statistics show that four or five of them are sure to contract some kind of illness. Com-

bining the cost of antibiotics (about $15 per head) with the total weight loss (about $35 per head) means that the illness cost the farmer from $200 to $250, says Crum.

"Our tests show that we can reduce the number of animals that will get sick by half," he adds. According to Pioneer's research, had the farmer treated *all 20 calves* with beneficial bacteria, as few as two calves would become ill. At $1.50 per head, the total cost of the probiotic treatment comes to $30. Add in the $35-per-head cost of the weight loss in the two sick animals, and the farmer would save up to $140—more than 50 percent.

Theory 'Sound'

One thing probiotics do have in common with antibiotics is that no one fully understands why and how they work. "I think it's theoretically possible," says Dr. Dwayne Savage, a University of Illinois microbiologist who works with many of the bacteria used in probiotics. "They tend to help cattle grow on less feed . . . to improve feed efficiency, and perhaps, in some cases, help them resist disease."

Agrees Lou Sudoma, product marketing manager for Christian Hansen's Laboratory in Milwaukee, Wis.: "From a theory standpoint, it's very sound. But from a technology standpoint, the probiotic industry is still in its infancy."

Christian Hansen's manufactures two different lines of probiotics for sale exclusively to feed manufacturers. Biomate FG Concentrate is a blend of *Lactobacillus acidophilus* (which is also found in Pioneer's products), and *Bacillus subtilus*, a different bacteria that Sudoma says is more capable of withstanding the high temperatures to which pelleted feeds are subjected.

While this product also helps naturally fortify animals' defense systems, Sudoma is not permitted to say so in advertisements. "It's obvious that these products are generally recommended as safe," Sudoma points out. "There are no withdrawal periods, and that's according to the FDA." But beyond that, the promotional claims that he and other probiotic manufacturers can make are severely restricted by FDA regulations. "You can state the product's name. You can say what organisms it contains and a guaranteed viability (number of live organisms). And if you've done some university studies, you *may* be able to show the raw data,

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but not make any direct claims for it. That's kind of a gray area."

At first glance, laws governing the use of antibiotics appear more lenient. "As long as the manufacturer has data to show (safety, effectiveness and withdrawal times), we can approve the product," says Dr. Max Crandall of FDA's Center for Veterinary Medicine in Rockville, Md. But in the early '70s, FDA added a new requirement that is just beginning to have a major impact on the meat industry: The makers of antibiotics must prove that bacterial resistance to their products will not be transferred to antibiotics used in human health care.

Many of the $270 million worth of antibacterials used by the livestock industry conform to this regulation. But penicillin and tetracyclines don't have to, because they were already on the market when the new law went into effect. "Once a product is on the market, *we* have to show that it is harmful . . . before we can get it off the market," Crandall explains.

Low, "sub-therapeutic" levels of penicillin and tetracyclines have been fed to livestock for growth promotion and disease control since the 1950s. The same products are also widely used in human medicine. And recent studies strongly suggest that antibiotic-resistance among disease-causing organisms in animals can be transferred to human beings who consume meat from those animals. The result: "super bacteria" that no amount of drug can kill. "Any time you're using antibiotics, you're going to have resistant organisms," says Crandall. "The question is: How much does the feeding of subtherapeutic doses contribute to this?"

Digestive Aids Boost Growth

If a ban on the low-level feeding of antibiotics is forthcoming, such products could, and most likely would, still be used therapeutically to fight disease outbreaks in animals. In that case, administering probiotics to a herd—like the mythical farmer in Crum's example—could keep drug costs to a minimum.

But would farmers be without the growth-promoting effects of the products they're using now? Not at all, say Crum and Sudoma. Many of the bacteria in probiotics serve as digestive aids. For example, the *B. subtilus* in Christian Hansen's Biomate FG Concentrate and Biomate 2B "breaks down protein into the readily absorbable amino acids," says Sudoma. "It takes some of the pressure off the animal and aids in the digestive process." Ultimately, that leads to improved feed conversion, he says, quickly adding that nobody is sure why this happens.

Some companies specialize in prod-

Where To Get Probiotics

Probiotics first appeared on the market in the late '60s and early '70s, and manufacturers are constantly evaluating new strains of bacteria for various uses, and for their compatibility with modern livestock drugs. Below is just a sampling of the kinds of products available, and their uses. Be sure and ask what form the product comes in (gels, bolus, dry granular), and whether it can be purchased retail.

Company	Product	Uses
Pioneer Hi-Bred International Inc. Microbial Genetics Div. 6800 Pioneer Parkway Box 258 Johnston, Iowa 50131 (515) ~~270-3599~~ 270-4111	Bovine One	Cattle
	Porcine One	Hogs
	Probios 180R	All livestock
	Probios Plus Bolus	All livestock
	Probios 180D	All livestock
	Equine One	Horses
Christian Hansen's Laboratory Inc. 9015 W. Maple Street Milwaukee, Wis. 53214 (414) ~~259-1132~~ 476-3630	Biomate FG Concentrate *(added to feed)*	All livestock
	Biomate 2B *(added to feed)*	All livestock
Diamond V Mills Box 4408 Cedar Rapids, Iowa 52407 (319) 366-0745	Diamond V Yeast Culture *(added to feed)*	All livestock
G. A. Jeffreys & Co. Inc. P.O. Box 709 Salem, Va. 24153 (703) 389-8220	Enzymes *(added to feed)*	All livestock
The Fertrell Co. Box 215 Bainbridge, Pa. 17502 (717) 367-1566	Nutri-Hay *(hay inoculant)*	All livestock
	Nutri-Sil *(silage inoculant)*	All livestock
	Rumi-Cult 40	Ruminants

ucts designed solely to "predigest" high-fiber feeds into sugars and starches, much like those which break down lactose in milk for humans who can't tolerate this complex sugar. "We manufacture generic enzyme products for many, many feed companies," says Jim Tobey, vice president and director of research for G.A. Jeffreys & Co. Inc. of Salem, Va. "I know that many of them use them in feed, and many formulate them in silage fermentation aids."

G.A. Jeffreys' products are not probiotics by definition, Tobey points out. "What we're talking about here are feed items. They're really used more as processing aids than for growth promotion."

Diamond V Mills of Cedar Rapids, Iowa, produces a dry yeast mixture that farmers can blend with dry feed or a silage-grain ration. Says Dr. Charles Stone, the company's director of technical service and nutrition: "It does a lot of different things. In dairy cows, it stimulates the number of fiber-digesting bacteria. It also provides unidentified growth factors. Most of our research indicates that it stimulates bacteria to improve digestion."

Currently, only a small percentage of feeds are treated with enzymes or yeasts to improve digestion, says Tobey. That's because the sugars and starches in corn and soybeans are more easily metabolized than those in high-fiber materials like oats and barley.

In the long run, though, Tobey feels such products can help the livestock industry—and agriculture in general—become less dependent on corn and soybeans. "We can make our food chain more efficient by feeding the high-fiber feeds to the ruminants that can digest them, and leaving the more readily available foods for humans (and other non-ruminants)," he explains.

Whether it's for disease-prevention, growth-promotion, or both, livestock experts agree that benign microbial products are here to stay. "There's a lot of interest out there, and I think that interest is going to increase," predicts Sudoma of Christian Hansen's Laboratory. "There's always going to be a place for antibiotics, but I do think there's going to be a ban on the broad-spectrum products (like penicillin and tetracyclines)."

University of Illinois' Savage takes an even broader view: "In the end, what it boils down to is that neither antibiotics nor probiotics are going to be substitutes for good animal husbandry." □