

Brian Schweitzer
Governor

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Nancy K. Peterson
Director

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February 11, 2005

The Honorable Rick Ripley, Chair
Natural Resources and Commerce
Appropriations Subcommittee
PO Box 200400
Helena MT 59620-0400

Dear Chairman Ripley:

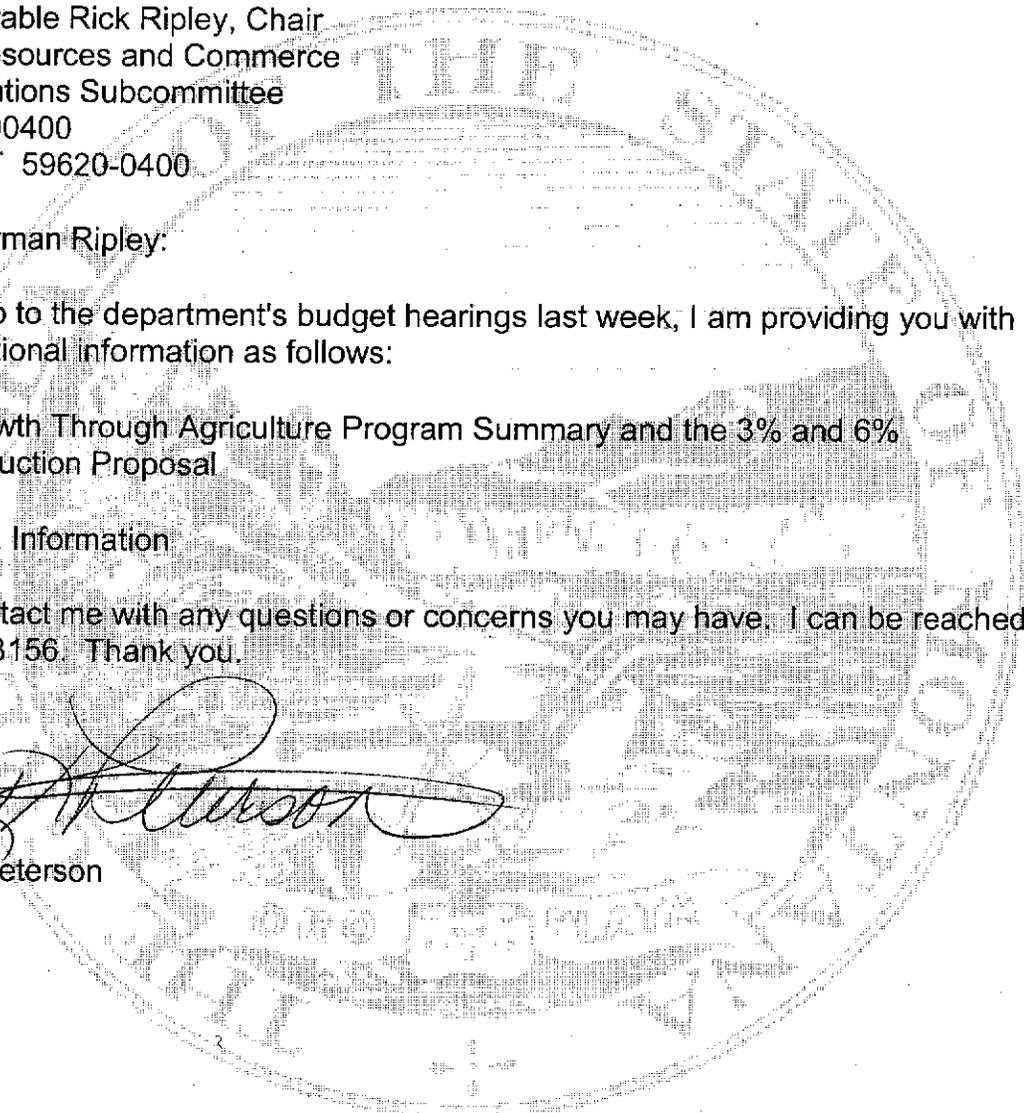
In follow up to the department's budget hearings last week, I am providing you with some additional information as follows:

- Growth Through Agriculture Program Summary and the 3% and 6% Reduction Proposal
- BSE Information

Please contact me with any questions or concerns you may have. I can be reached at (406) 444-3156. Thank you.

Sincerely,

Nancy K. Peterson
Director



Montana Department of Agriculture

Growth Through Agriculture Program Summary

Dollar for Dollar Matching Contributions:

To date, the Montana Growth Through Agriculture Program has invested approximately \$8.84 million in 273 projects, with initial dollar for dollar matching contributions from applicants amounting to roughly \$43.77 million.

Economic Return:

The economic return of projects receiving Growth Through Agriculture Program funding is reported to be \$101.3 million dollars, according to mandatory quarterly reporting requirements and voluntary award recipient surveys. This equates to roughly \$11.45 returned to the community for each dollar of Growth Through Agriculture funding initially invested and has also led to the creation or preservation of approximately 533 FTE.

Return on Investment:

Since the May 2000 Special Legislative Session, the Growth Through Agriculture Program has invested funds in roughly 97 private sector businesses and ag-entrepreneurs' projects, where 43 of the awards were made with a repayment provision, and 54 were made without a repayment provision. That equates to 45% of the investments made by the Ag-Development Council having repayment provisions and 55% of the awards (primarily for initial feasibility studies, business planning, market analysis, etc) made as grants.

The GTA Program currently has 68 projects in "active status" – which means they are not yet completed or are in repayment status. Thirty of those projects do not have a repayment provision associated with them. The remaining 38 projects have a repayment provision associated with them – with 28 projects currently in repayment status and 10 projects that are still in a deferral period. These repayment revenues are in addition to the economic returns and matching contributions made by successful GTA program applicants.

Funding Utilization & Funding Reductions:

Growth Through Agriculture Program funding reductions are proposed to be made in the Grants/Transfers expenditure category, which will reduce the amount of funding available for awards to successful program applicants, where Coal Tax Shared Revenue account funds have been fully utilized in previous years.

GTA Program - Coal Tax Trust Shared Revenue Account Funding Reductions:

2007 Biennium:

1st level Budget	Exec. Budget	3% Reduction	6% Reduction
Personal Services	\$158,218	\$158,218	\$158,218
Operations	\$64,912	\$64,912	\$64,912
<u>Grants/Transfers</u>	<u>\$731,527</u>	<u>\$702,887</u>	<u>\$674,247</u>
Total	\$954,657	\$926,017	\$897,377

Natural Resources & Commerce Appropriations Subcommittee - Coal Tax Trust Shared Revenue Account Adjustments:

1. Based on Committee executive action taken on 2/3/05, and request for input from the agencies receiving funds from the Coal Tax Shared Revenue Account on how the agencies propose to reduce their approved budget requests by 6%, the Department of Agriculture offers the following:
2. The Department calculates a 6% reduction to be \$28,639 for FY06, \$28,640 for FY07, for a total of \$57,279 over the biennium.
3. The Department would propose to reduce funding in the Grants Expenditure Category to meet the 6% reduction requirement.

Executive Request GTA Program - Coal Tax Trust Shared Revenue Account		Executive Request less 6% Reduction GTA - Coal Tax Trust Shared Revenue Account	
Expense Category	FY06 Std Bdg	FY07 Std Bdg	Biennium Total
Salaries	61,327.00	61,092.00	122,419.00
Per Diem	0.00	0.00	0.00
Benefits	10,148.00	10,164.00	20,312.00
Health	11,040.00	11,040.00	22,080.00
Vacancy Save	-3,301.00	-3,292.00	-6,593.00
	79,214.00	79,004.00	158,218.00
Other Services	10,091.00	10,108.00	20,199.00
Supplies & Materials	802.00	802.00	1,604.00
Communications	2,897.00	2,897.00	5,794.00
Travel	6,906.00	6,910.00	13,816.00
Rent	8,447.00	8,484.00	16,931.00
Utilities	0.00	0.00	0.00
Repair & Maintenance	393.00	393.00	786.00
Other Expenses	2,891.00	2,891.00	5,782.00
	32,427.00	32,485.00	64,912.00
Grants	275,764.00	275,763.00	551,527.00
Transfers	90,000.00	90,000.00	180,000.00
Total	477,405.00	477,252.00	954,657.00

Regulatory Oversight for Livestock Feed Safety related to BSE in Montana

Montana Department of Agriculture's (MDA) Role is to ensure safe and effective feeds in Montana through inspections and sampling activities.

Food and Drug Administration's (FDA) Role is to prevent the occurrence and establishment of BSE through inspection and sampling activities of animal feeds entering and within the US and associated with their overall charge of protecting the US food supply.

U.S. Department of Agriculture's (USDA) Role is to enforce tissue restrictions in animals and animal feeds imported into the US.

The Montana Department of Agriculture continues to work with FDA and USDA in a collaborative effort to prevent the occurrence and establishment of BSE in the US and Montana. The department works closely with FDA, both on the national level and the district level, to coordinate sampling and inspection activities.

The Montana Department of Agriculture has contacted other Montana state agencies (DFWP, DPHHS, Department of Livestock) that perform PCR/DNA and they have stated they cannot conduct PCR/DNA analysis on feed products for the Department of Agriculture. (*see attached letter from Marc Bridges dated February 9, 2005*) Useful life of PCR equipment is 6 to 8 years.

A few other state's departments of agriculture are pursuing PCR/DNA analysis, but are not currently available to perform PCR animal speciation analysis on a contract basis.

Livestock Feed Samples related to BSE

Montana Department of Agriculture:

- 75 firms annually distribute 222,000 tons of feed intended for ruminants in or into Montana;
- 10 Canadian firms distributed 12,000 tons of livestock feeds into Montana in 2004.

Samples collected from June 2003 – January 2005:

- 44 samples from **8 of the 10 Canadian firms** importing feed into Montana were collected;
- 35 samples from **17 of the 44 Montana firms** manufacturing feed in Montana were collected;
- 17 samples from **7 of the 21 out-of-state firms** shipping feed into Montana were collected;
- 96 samples have been collected from 32 companies, representing 43% of the companies manufacturing or shipping ruminant feeds in and into Montana.

For your information: The department is currently increasing livestock feed sampling at the Canadian border at the request of the Governor.

FDA / Seattle District Office:

Samples collected in FY 04:

- approximately 6 domestic samples are collected by FDA within Montana during BSE inspections;
- approximately 30 samples were collected of Canadian feed destined for Montana;
- approximately 30 samples were collected of Canadian feed entering the US passing through Montana.

	Feed Inspections						BSE Related Feed Samples					
	FY 04		FY 05		FY 06		FY 04		FY 05		FY 06	
	Feed facility	BSE	Feed facility	BSE	Feed facility	BSE	domestic	imports	domestic	imports	domestic	imports
Department	164	45	184	45	184	50	28	44	30	50	40	60
FDA in MT (approximately)	6	6	6	6	6	6	6	30	6	*30	not available	
FDA in US (approximately)	26,000 nation-wide including state inspections conducted under contract w/ FDA over a 7 year period (www.fda.gov/cvm/index/updates/BSE0206up.htm)						700	700	*900	*900	not available	

* See attached email from Charles M. Breen, Seattle District Director, Food and Drug Administration, which indicates 147 samples at Washington, Idaho and Montana border crossings. We have estimated 60 samples will be taken at Montana border crossings. Approximately 30 samples will be Canadian feed destined for Montana; the remaining 30 samples will be Canadian feed entering the US passing through Montana.

As email further states, the FY05 work plan also calls for collection of 900 domestic animal feed samples to be examined for the presence of undeclared animal protein.

Nancy Peterson
WE

DEPARTMENT OF LIVESTOCK



BRIAN SCHWEITZER, GOVERNOR

PO BOX 202001

STATE OF MONTANA

BOARD OF LIVESTOCK (406) 444-7323
BRANDS ENFORCEMENT DIVISION (406) 444-2045
ANIMAL HEALTH DIVISION (406) 444-2043
CENTRALIZED SERVICES DIVISION (406) 444-9040
MEAT & POULTRY INSPECTION BUREAU (406) 444-5202
MILK & EGG BUREAU (406) 444-9761

HELENA, MONTANA 59620-2001

February 9, 2005

To: Chairman Representative Rick Ripley
Appropriations & Finance Joint Sub Committee
Natural Resources

From: *W/All
TSP* Marc Bridges
Executive Officer
Department of Livestock

Re: Feed testing of mammalian tissue at Department of
Livestock Veterinary Diagnostic Laboratory by use
of PCR (Polymerase Chain Reaction)

Mr. Chairman and Members of the Committee:

On February 3, I was requested to look into the Department of Livestock VDL's ability to test feed for mammalian tissue on behalf of or for the Montana Department of Agriculture with the DOL, VDL PCR.

Dr. Layton, the Administrator and chief pathologist, informed me that there are various different types of PCR machines, and the DOL, VDL PCR is not approved to perform the testing.

The Department of Livestock, Veterinary Diagnostic Laboratory PCR is a "real time" PCR and not approved by the FDA to perform feed testing. The type of PCR approved by the FDA to do feed testing is a "conventional PCR".

Another issue that Dr. Layton brought to my attention is the issue of cross contamination in our lab. The Department of Livestock VDL is continually testing mammalian tissue, blood, etc. in our PCR for various types of diseases.

The Department of Agriculture wishes to test feed for mammalian tissue. The risk greatly increases for the possibility of cross contamination resulting in false positives, and the potential for greater liability.

Dr. Layton also stated that the DOL, VDL would have to be certified by the FDA to perform the tests, if we had the ability to perform the tests, which we do not have.

I have also enclosed an article for you information. If you have any further questions please feel free to contact me at 444-0528.

cc: Nancy Peterson, Director
Montana Department of Agriculture

~~~~ What The Heck is PCR? ~~~~

Polymerase chain reaction (PCR) is a technique which is used to amplify the number of copies of a specific region of DNA, in order to produce enough DNA to be adequately tested. This technique can be used to identify with a very high-probability, disease-causing viruses and/or bacteria, a deceased person, or a criminal suspect.

In order to use PCR, one must already know the exact sequences which flank (lie on either side of) both ends of a given region of interest in DNA (may be a gene or any sequence). One need *not* know the DNA sequence in-between. The building-block sequences (nucleotide sequences) of many of the genes and flanking regions of genes of many different organisms are known. We also know that *the DNA of different organisms is different* (while some genes may be the same, or very similar among organisms, there will *always* be genes whose DNA sequences differ among different organisms - otherwise, would be the *same* organism (e.g., same virus, same bacterium, an identical twin; therefore, **by identifying the genes which are different, and therefore unique**, one can use this information to identify an organism).

A gene's building-block sequence is the *precise* order of appearance, one after the other, of 4 different components (deoxyribonucleotides) within a stretch of DNA (deoxyribonucleic acid). The 4 components are: Adenine, Thymidine, Cytosine and Guanine, abbreviated as: A, T, C and G, respectively (a 4-letter alphabet). The arrangement of the letters (one after the other) of this 4-letter alphabet generates a "sentence" (a gene sequence). The number of letters in the sentence may be relatively few, or relatively many, depending on the gene. If the sentence is 1000 letters-long, the sequence would be said to be 1 kilobase (1000 bases).

As an example:

ATATCGGGTTAACCCCGGTATGTACGCTA would represent part of one gene. DNA is double-stranded (except in some viruses), and the two strands pair with one another in a very precise way. **EACH** letter in a strand will pair with only one kind of letter across from it in the opposing strand: **A ALWAYS** pairs with **T**; and, **C ALWAYS** pairs with **G** across the two strands.

So:

TTAACGGGGCCCTTAAA.....TTTAAACCCGGGTTT

Would pair with:

AATTGCCCCGGGAAATT.....AAATTTGGGCCCAA

Now, let's say that the above sequences "flank" (are on either end of..) the gene, which includes a long stretch of letters designated as:

These are known, absolutely identified to be, the sequence of letters which **ONLY** flank a particular region of a particular organism's DNA, and **NO OTHER ORGANISM'S** DNA. This region would be a target sequence for PCR.

The first step for PCR would be to synthesize "primers" of about 20 letters-long, using each of the 4 letters, and a machine which can link the letters together in the order desired - this step is easily done, by adding one letter-at-a-time to the machine (DNA synthesizer). In this example, the primers we wish to make will be exactly the same as the flanking sequences shown above. We make **ONE** primer exactly like the lower left-hand sequence, and **ONE** primer exactly like the upper right-hand sequence, to generate:

```
TTAACGGGGCCCTTTAAA.....TTTAAACCCGGGTTT
AATTGCCCGGGAAATTT.....>
and:
<.....TTTAAACCCGGGTTT
AATTGCCCGGGAAATTT.....AAATTTGGGCCCAAA
```

Now, the may be a very long set of letters in-between; doesn't matter. If you look at this arrangement, you can see that if the lower left-hand primer sequence (*italics*) paired to the upper strand could be extended to the right in the direction of the arrow, and the upper right-hand sequence paired to the lower strand could be extended to the left in the direction of the arrow (remembering that the also represent letters, and opposite pairing will ALWAYS be A to T and C to G), one could successfully exactly duplicate the original gene's **entire sequence**. Now there would be four strands, where originally there were only two. If one leaves everything in there, and repeats the procedure, now there will be eight strands, do again - now 16, etc.. therefore, about 20 cycles will theoretically produce approximately one-million copies of the original sequences (2 raised to the 20th power).

Thus, with this amplification potential, **there is enough DNA in one-tenth of one-millionth of a liter (0.1 microliter) of human saliva (contains a small number of shed epithelial cells), to use the PCR system to identify a genetic sequence as having come from a human being!** Consequently, only a very tiny amount of an organism's DNA need be available originally. Enough DNA is present in an insect trapped within 80 million year-old amber (fossilized pine resin) to amplify by this technique! Scientists have used primers which represent present-day insect's DNA, to do these amplifications.

Here is how PCR is performed:

First step: unknown DNA is heated, which causes the paired strands to separate (single strands now accessible to primers):

Second step: add large excess of primers relative to the amount of DNA being amplified, and cool the reaction mixture to allow double-strands to form again (because of the large excess of primers, the two strands will always bind to the primers, instead of with each other).

Third step: to a mixture of all 4 individual letters (deoxyribonucleotides), add an enzyme which can "read" the opposing strand's "sentence" and extend the primer's "sentence" by "hooking" letters together in the order in which they pair across from one another - A:T and C:G. This particular enzyme is called a DNA polymerase (because makes DNA polymers). One such enzyme used in PCR is called *Taq* polymerase (originally isolated from a bacterium that can live in hot springs - therefore, can withstand the high temperature necessary for DNA-strand separation, and can be left in the reaction). Now, we have the enzyme synthesizing new DNA in opposite directions - **BUT ONLY THIS PARTICULAR REGION OF DNA.**

After one cycle, add more primers, add 4-letter mixture, and repeat the cycle. The primers will bind to the "old" sequences as well as to the newly-synthesized sequences. The enzyme will again extend primer sentences ... Finally, there will be PLENTY of DNA - and ALL OF IT will be copies of just this particular region. Therefore, by using different primers which represent flanking regions of different genes of various organisms in SEPARATE experiments, one can determine if in fact, any DNA has been amplified. If it has not, then the primers did not bind to the DNA of the sample, and it is therefore highly unlikely that the DNA of an organism which a given set of primers represents, is present. On the other hand, appearance of DNA by PCR will allow precise identification of the source of the amplified material.

Evers, Lesa

From: Gray, Andy
Sent: Friday, February 11, 2005 7:57 AM
To: Evers, Lesa
Cc: Ames, Greg; Rise, Donna
Subject: FW: Feed sample work plan from FDA

FYI -

-----Original Message-----

From: Breen, Charles M [mailto:CHARLES.BREEN@fda.gov]
Sent: Friday, February 04, 2005 4:24 PM
To: Taylor, David
Cc: Burbach, Miriam R; Corcoran, Celeste M; Gray, Andy
Subject: Feed sample work plan

Dave,

Got your voice mail message.

The FY05 work plan is for FDA to collect 900 samples of imported animal feed and examine for the presence of undeclared animal protein. The Seattle District portion of the plan is to collect 147 samples, mostly of feed coming south across the borders of Washington, Idaho, and Montana.

The FY05 workplan also calls for collection of 900 domestic animal feed samples to be examined for the presence of undeclared animal protein.

These are planned numbers, not a promise.

Charles

Charles M. Breen
Seattle District Director