













Biotechnology: Extending the Green Revolution

American Salmon

New Ag Breakthrough: Mutagenesis

"Scientists have discovered that by bombarding seeds such as wheat and rice with intense bursts of radiation, they can mutate the genes of these plants, and by careful selection, pick out the mutants that grow faster, are hardier and survive better. These scientists claim the resulting plants do not need to be tested for safety"

Review of Agriculture Technology, No 16-42

Questions:

Would you eat wheat or rice chosen this way? Should these products be tested? How? By Whom? Should they be labeled?

What is Genetic Engineering of Agricultural Animals?

- Deliberate modification of the animal genome, in contrast to spontaneous mutation.
 - It's been going on for centuries
- Transgenesis, is a new method that moves a gene expressing a desirable trait from the same species or another species into the genome of an agricultural animal, who will then express that desirable trait.
 - It is more efficient and more powerful than the traditional methods
- GE is being studied with animals traditionally used for food (agricultural animals) as well as companion animals

It is not the same as cloning which is equivalent to creating identical twins



What's in Your Barnyard?

Cattle:

- reduction: of lactose; mastitis; allergens;
- increased resistance to BSE;
- increased protein production;
- reduced fat;
- Better feed conversion
- improved meat quality

• Sheep:

- Increased wool growth
- Increased meat production;
- Parasite/viral resistance

Pigs

- Reduced environmental waste
- Reduced fat

What's the Tide Bringing In?

- Salmon, Trout, Carp, Tilapia, Pike, Shrimp,
 Oysters, Abalone, ...
 - Better growth & production factors
 - Smaller environmental footprint
 - More Omega 3
 - Better feed conversion
 - Able to use plant feed more readily



What's the Tide Bringing In?

Fishes:

Zebrafish Medaka **Grass carp** Common carp Goldfish Wuchang fish Giant loach Northern pike Rainbow trout Coho salmon Atlantic salmon Arctic charr Mummichog Striped bass Largemouth bass Walleye

Tilapia



Crustaceans:

Crayfish
White shrimp
Brine Shrimp
Giant prawn





Mollusks:

Pacific oyster
Eastern oyster
Blue mussel
Dwarf surfclam
Red abalone
Japanese abalone

Traits:

- Growth
- •Disease Resistance
- •More omega 3
- •Better food conversion

The "Old" Science of Biotechnology

- Selective Breeding
 - Corn
 - Peaches
 - Watermelon
 - Water Buffalo
 - Turkey
 - Tilapia

- Hybridization
 - Wheat
 - Tomatoes
 - Grapefruit
 - Mules
 - Farm-Raised StripedBass

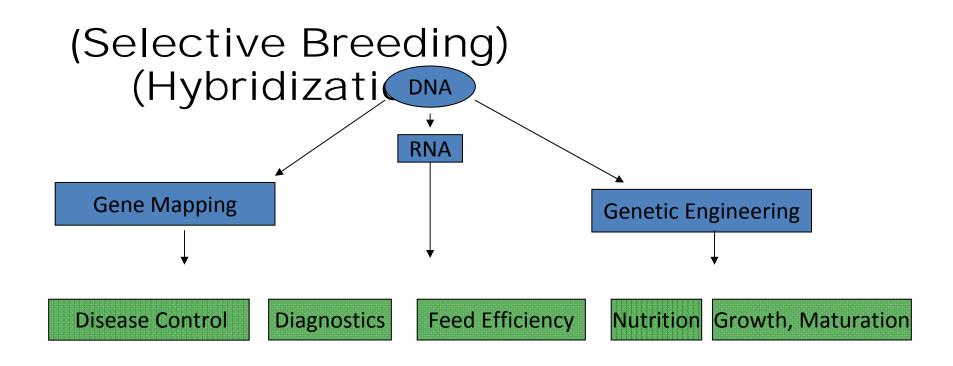
Trial and error; slow and steady, but effective over time – A very long time.

Then came the discovery of DNA.





The New Science of Biotechnology





Disease Control: Not your father's vaccine

- Enhancing the immune system through gene change
 - Increase lysozyme; major histocompatibility complex (MHC); cecropins
- siRNA: blocking the expression of virus proteins
- Receptor blockers: stop the entrance of pathogens into cells
- DNA vaccines
- Oral Delivery: change the acid balance in the digestive tract

Feed Efficiency

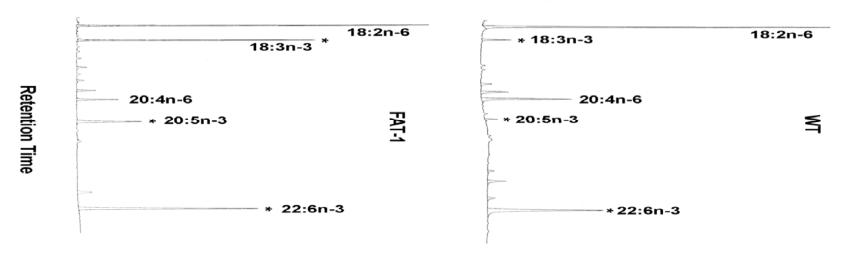
- New plant feeds substitute for fishmeal in animal feeds
- New digestive pathways, faster growth rates
 - Increasing Sustainability



Improving Nutrition: The FAT-1 Gene

More Omega 3's in Fish* and Farm Animals

Relative Intensity



- Omega 3 Acids (DHA, ALA, EPA) increase 10X
- •Omega 6 Acids (AA, LA) decrease
- •6:3 Balance close to the ideal of 1:1

*Zebra Fish, MGH Labs 2005



Improving Feed Efficiency Plant Source of Long-Chain Omega 3





Soybeans that produce Omega-3's normally available in quantity from fish meal (and algae!)

20% of Soy oil SDA – today it is 0%

Focus on human food applications

SDA soybeans can replace a high percentage of fish oil and meal for feed

Taste and Stability improvements over fish oil

-A Monsanto Product-



Growth & Productivity: the AquAdvantage

Broodstock Program

What is it?

- Egg to Harvest in half the time
- Salmon, trout, and tilapia

How does it work?

A change in one gene

to allow the fish to produce its

own growth proteins year round, not seasonally & use it more efficiently

No foreign proteins or hormones, no increase in hormone levels in the fish





The Benefits of Aquabiotechnology

For Industry: Increased Productivity

- Lower mortality from disease
- Better growth rates
- Improved FCRs

For the Environment: A smaller footprint

- Improved economics facilitates land-based farming
- Faster growth means more food from fewer ocean pens
- Sterile fish avoids genetic impact on the wild stock
- Better FCR: less feed, more food
- Plant substitutes for fish meal and fish oil

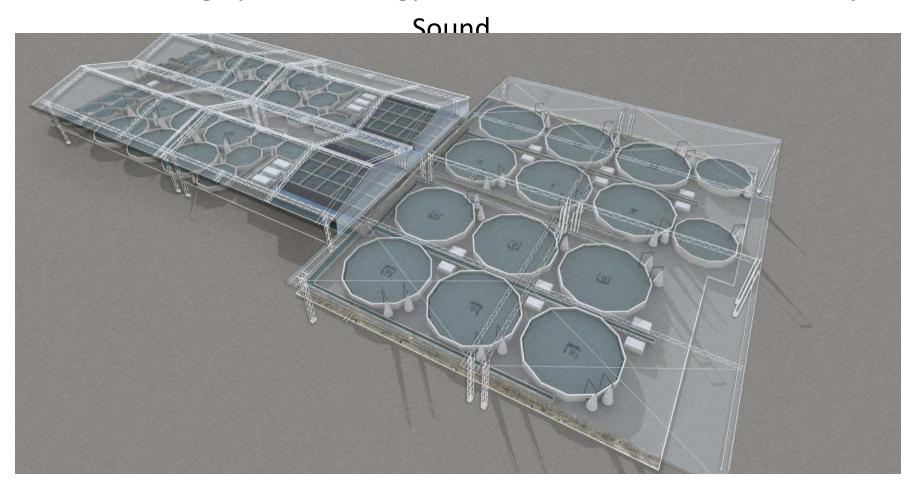
For Consumers: Lower Prices, Increased Health

- Lower prices, Increased availability
- Better nutritional profile of the product
- Fewer (no?) antibiotics

The Result: Economics that make the transition to enclosed systems more likely

Hi-Tech Salmon Farming

Recirculating Systems: Energy Efficient, Indoors, Environmentally





Projected Financials: 2000 Ton Unit

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	TOTALS
Revenue							
Sales, kg (gutted)		1,490,074	1,986,765	1,986,765	1,986,765	1,986,765	
Price per kg	6.25	6.35	6.40	6.40	6.45	6.50	
Gross		9,461,970	12,715,298	12,715,298	12,814,636	12,913,975	\$ 60,621,177
Discort Consta	1 622 454	F 122 210	F 260 271	F 402 464	F F40 022	F 600 776	¢ 20 CFC 107
Direct Costs	1,622,454	5,122,219	5,260,271	5,402,464	5,548,923	5,699,776	\$ 28,656,107
Indirect Costs	1,540,475	1,873,834	1,979,759	1,988,333	2,000,145	2,012 ,223	\$ 11,394,768
Add-back: Interest	464,246	451,417	433,651	418,534	402,564	385,694	\$ 2,556,106
Add-back: Depreciation	600,830	600,830	600,830	600,830	600,830	600,830	\$ 3,604,978
EBITDA	\$ (2,097,853)	\$ 3,518,163	\$ 6,509,749	\$ 6,343,864	\$ 6,268,962	\$ 6,188,500	\$ 26,731,385

Projected Cash Flow											
	2009	2010	2011	2012	2013	2014	2015	2016			
Cash Flow from Operations											
HQ Management Operations	(262,069)	(375,000)	(347,000)	(309,500)	(322,625)	(336,406)	(350,877)	(361,403)			
Net Income from Production Ops			(3,162,929)	2,465,917	5,475,269	5,324,501	5,265,568	5,201,976			
Add back: depreciation			600,830	600,830	600,830	600,830	600,830	600,830			
Working capital				(246,592)	-	(9,934)	(9,934)				
Cash Flow	(262,069)	(375,000)	(2,909,099)	2,510,655	5,753,473	5,578,990	5,505,587	5,441,403			
Cash Flow from Financing											
Grants and Loans		8,500,000									
Equity Investments	360,000	7,500,000									
Capital Expense		(12,016,592)									
Cumulative Cash Flow \$		\$	\$	\$	\$	\$	\$	\$			
	97,931	3,608,408	699,309	3,209,963	8,963,437	14,542,427	20,048,014	25,489,417			

Restarting a domestic industry

The Result? AquAdvantage salmon can be grown domestically indoors for less than the cost of imports.

Economic and Safety Benefits:

- Improved balance of payments
- Local production = jobs
- Industry will be land-based: reducing the environmental footprint dramatically
- Energy Savings: eliminate international jet transport
- Improved food safety and traceability
 - Local production in indoor facilities eliminates exposure to most environmental pathogens

So Who's Watching the Shop?

Do we have proper regulatory control?

- Worldwide, the Codex Alimentarius Commission In concert with other multinational organizations is developing approaches
- In the US, it's the FDA:
 - New Animal Drug Regulations: "The Gold Standard"
- In Canada its
 - CFIA, DFO, Environment Canada, Health Canada: do they talk to each other?



FDA Regulatory Process

New Animal Drug Approval (NADA)

- Science-based, rigorous, 'gold standard'
- Pre-market approval process; includes post-market monitoring
- Mandatory
- Covers all GE animals traditionally used for food and companion animals

All Studies required for a "food" approval are also required for a "drug" approval: plus more

The FDA Process in Practice: AquAdvantage Salmon

- 15 years
- Multiple Studies
- Political Delays
- Unprecedented Transparency
 - Release of all "drug" data to the public and the VMAC
- Public Hearings
 - The Veterinary Medical Advisory Hearing ("VMAC")
 - Labeling Hearing

The FDA Conclusion

 "Aqua Bounty salmon meets the standard of identity for Atlantic salmon as established by FDA's Reference Fish Encyclopedia. All other assessments of composition have determined that there are no material differences in food from ABT salmon and other Atlantic salmon."

Question: Why did this take so long and does the public believe it?

What About a Mandatory Label?

- Labels must be accurate, informative and not misleading, as mandated by the Food Drug and Cosmetic Act and are limited to providing measurable data that meet these objectives:
 - Safety data, nutritional information, any special use restrictions

This is summed up as the policy to label "product, not process".

Once we agree to label process, is there a limit? Every interest group can demand a label of their choice. How far did this product travel? Does this milk come from an artificially inseminated cow? What is the size of the farm?

Demands by opponents to biotechnology to require labels identifying foods as containing "GMOs" is an example of an interest group attempting to use the government to forward a particular point of view at the expense of the general public. It is false advertising in that it implies a nutritional or safety difference when none exists.

The demand for a GMO label is not to encourage choice, it is to delegitimize a technology



What About the Environment?

- AA Salmon are sterile and will be grown inland
- Far less impact on the environment than current practice
- What if they escape?
 - "Much safer than when domestic salmon escape; they will have limited, local impact, and disappear quickly. They are not suited to the environment; they do not have a Trojan Gene"
 - Dr. William Muir, author of the Trojan Gene Hypothesis

The Fall Out: After the Hearing

[The VMAC] was an opportunity for some special interest groups to hijack the process for their own agenda – all in the name of transparency.

This fast growing salmon has had a decade-long regulatory adventure...

While the VMAC was dutifully evaluating the data some special interest groups were cherry picking out snippets of data that supported menacing soundbites about cancer and allergies, ignoring the overwhelming body of data that suggested these salmon were in fact just fast-growing Atlantic salmon.

Alison Van Eenennaam, PhD VMAC Member



Eat Like a Man

In Defense of Frankenfish

Something's fishy in the FDA

The Washington Post

Labels may not be necessary on genetically altered foods

Thursday, September 23, 2010

IF A GENETICALLY engineered salmon is cleared for America's supermarkets, it will be because of convincing evidence the fish is safe to eat and not harmful to the environment.

Why Biotech Foods Are Kosher

Los Angeles Times

Something could be fishy

The environmental risks need further study before AquaBounty Technologies is allowed to market its super-salmon.