# "Safety of food from GE animals. The evidence to date, and a scientific evaluation of the need for mandatory process-based labeling"


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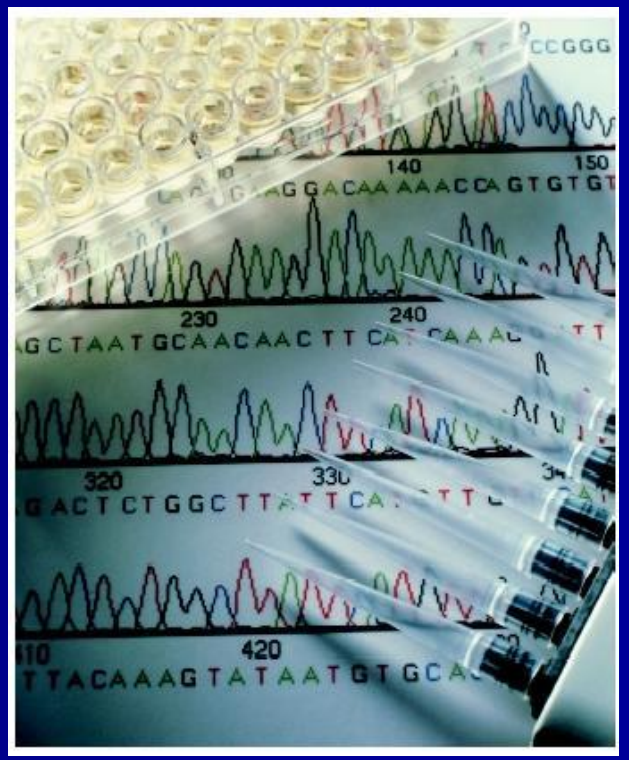
***"The mission of the animal genomics and biotechnology extension program is to provide broad, science-based extension programming on the uses of animal biotechnologies in livestock production systems."***




http://animalscience.ucdavis.edu/animalbiotech

# Overview

- Principles of U.S. food labeling
- Mandatory versus voluntary
- Case study: AquAdvantage salmon
- Arguments for mandatory labeling
    1. Public opinion
    2. Consumer choice
    3. Right to know



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# Background

The principles of food labeling are the same, whether or not the food is made from a GE source (plant or animal).

1. Labels cannot be false
2. Labels cannot be misleading
3. Label must describe basic nature of the food (e.g. fish)
4. FDA cannot require labels include information about production methods if there is no material difference in the products due solely to the production process
5. Voluntary labeling is allowed if not false or misleading

Source: http://www.fda.gov/Food/LabelingNutrition/FoodLabelingGuidanceRegulatoryInformation/Topic-SpecificLabelingInformation/ucm222608.htm



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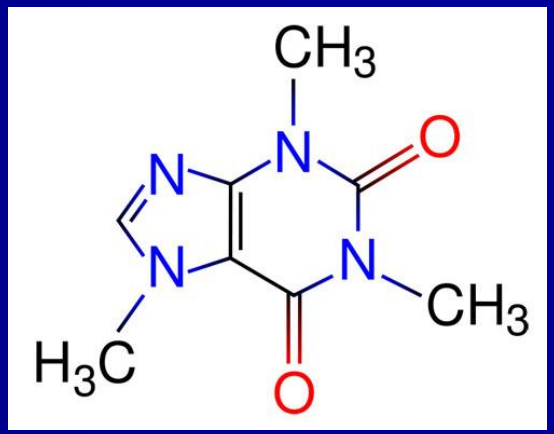
# Although some labels do exist that are both false and misleading!!


CAFFEINE!!!

# FDA cannot **mandate** that labels include information about production methods if there is no material difference in the products

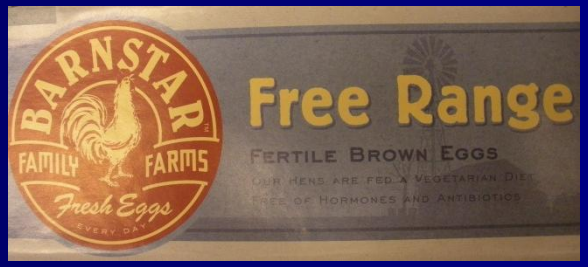
FDA cannot require additional labeling about production methods unless it is necessary to ensure that the labeling is not false or misleading. Another way of stating this point is that FDA cannot require labeling based solely on differences in the production process if the resulting products are not materially different due solely to the production process.

http://www.fda.gov/Food/LabelingNutrition/FoodLabelingGuidanceRegulatoryInformation/Topic-SpecificLabelingInformation/ucm222608.htm#Background

# Voluntary production method labeling











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# rBST Labeling: Voluntary labeling stating the milk is from cows not treated with r-BST must also have a disclaimer of similar font next to it stating the FDA has found no significant difference between milk from treated and untreated cows.



# Legal opinion regarding mandatory production method labeling

The Second U.S. Circuit Court of Appeals ruled that a labeling mandate grounded in consumer perception, rather than in a product's measurable characteristics, raises serious constitutional concerns – namely, that it violates commercial free speech. The court held that food labeling cannot be mandated merely because some people would like to have the information, and ruled mandatory rBST labeling unconstitutional because they forced producers to make involuntary statements contrary to their views when there was no material reason to do so.

Source: International Dairy Foods Association vs. Amestoy 92 F.3d 67 (1996)
http://www.public.iastate.edu/~jwcwolf/Papers/IDFA_Amestoy.pdf

# Voluntary labels have provided the US consumer with a wide range of production method choices - including GE free

USDA ORGANIC

CERTIFIED HUMANE RAISED & HANDLED

NO rBST

OUR COWS ARE NOT TREATED WITH THE GROWTH HORMONE rBST

GMO

DEMETER CERTIFIED BIODYNAMIC®

CERTIFIED NATURALLY GROWN



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# What is a "material" difference?

Definition(s) of material (adjective)

- Of substantial import; **of much consequence**, important
- Directly relevant to a matter (especially a law case)

# What differences *of much consequence* exist between foods from GE animals and "conventional" animals

- What do we know about foods from genetically engineered animals?
  AND
- What do we know about foods from "conventional" animals?

In the absence of information about variability that exists in the later, it is not possible to evaluate whether any differences observed in food derived from GE animals are "material"



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# Genetically Engineered Food Right-to-Know Act

Boxer (D-CA) and DeFazio (D-OR)

"fish created to grow at twice their normal rate are materially different, novel, patentable foods"…and therefore should be labeled

# 1957 vs. 2001 chickens

# The basic risk question for the consumption of food derived from GE animals is "What is the risk of *direct* or *indirect* effects associated with consumption of edible products derived from the GE animal?"

**Table 12. Characterization of Potential Direct and Indirect Effects**

| Direct Effects | Indirect Effects |
|---|---|
| - Alterations from Gene Expression Product (Chinook salmon growth hormone) including<br>  - Alterations in Levels of Hormones Associated with the Somatotropic Axis, including IGF1<br>- Allergenicity of the Gene Expression Product | - Alterations in the Composition of Edible Tissues<br>- Alterations in the Endogenous Allergenicity of Edible Tissues |

Page 63, AquAdvantage Briefing packet. http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM224762.pdf

# Compositional analysis

- A total of 73 market sized Atlantic salmon were analyzed for carbohydrate, ash, moisture, protein, total fat, vitamins, minerals, amino acids, and fatty acids and levels were not statistically different for all analytes with the exception of Vitamin B6.
- Levels of vitamin B6 were statistically elevated (7.67 vs. 7.2 µg/g) in the transgenic salmon; levels were 49 fold less than the maximum allowable consumption level according to a margin of exposure estimate

Pages 77-97, AquAdvantage Briefing packet. http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM224762.pdf

# Direct effects

- Isoelectric focusing and 2-dimensional gels of protein extracts revealed no differences in patterns between the AquAdvantage salmon and control Atlantic salmon
- Analysis of 10 farmed control, 33 sponsor control and 30 genetically engineered salmon revealed no statistically significant difference in the muscle/skin levels of growth hormone, insulin growth factor 1 (IGF1), estradiol, testosterone, triiodothytonine (T3), thyroxine (T4), or 11-keto testosterone
- Mean IGF1 levels (ng IGF1/g): 10.26 ± 4.97 GE (n=6) versus 7.34 ± 2.82 control (n=11).

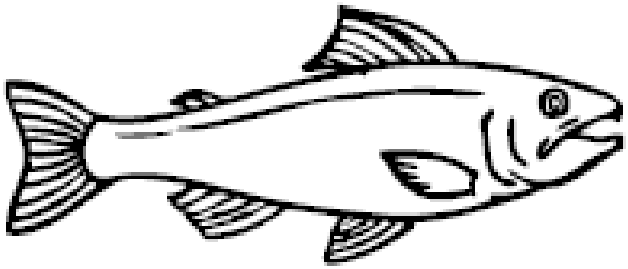
Pages 62-75, http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM224762.pdf

**What if you knew that the FDA had studies—from AquaBounty, the company that wants to commercialize GMO salmon— that showed that GMO salmon is:**

**MORE ALLERGENIC:** GMO salmon have mean allergenic potencies that are 20% and 52% higher than normal salmon.

**MORE CARCINOGENIC:** GMO salmon has 40% more IGF1, a hormone linked to prostate, breast and colon cancers in humans.

**LESS NUTRITIOUS:** GMO salmon has the lowest omega-3 to omega-6 ratio of any salmon.



**LIKELY TO CHANGE THE BACTERIA OF YOUR GUT:** Horizontal gene transfer, where the bacteria of the human gut takes up modified DNA from GMO foods during digestion, has been shown occur with soy and is likely to happen with GMO salmon, too.

**ALL MESSED UP:** GMO salmon has increased frequency of skeletal malformations like "humpback" spinal compression, increased prevalence of jaw erosions or "screamer disease," and multisystemic, focal inflammation in its tissues.

**NOT GOING TO SAVE WILD SALMON:** The main justification for GMO salmon is that it could reduce the pressure on wild fish stocks, but consumption isn't the primary pressure on wild Alaskan salmon, destruction of their habitat is.

**LEARN MORE & TAKE ACTION: ORGANICCONSUMERS.ORG/FISH/**



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# IGF level (ng/g) in tissues from GE AquAdvantage salmon and contemporary controls

| Group | N | N (>3.27 IGF1 ng/g) | Mean | std | Min | max |
|---|---|---|---|---|---|---|
| GE | 30 | 6 | 10.26 | 4.971 | 3.97 | 18.43 |
| Control | 33 | 11 | 7.34 | 2.818 | 3.56 | 12.24 |

**Table 18. IGF1 levels in Various Foods**

| Species | Source (tissue) | units | Range | Mean |
|---|---|---|---|---|
| Chinook salmon[1] | Plasma | ng/ml | 5-35 | - |
| Coho salmon[2] | Plasma | ng/ml | 7-13 | - |
| Coho salmon[3] | Plasma | ng/ml | 10-15 | - |
| Gilthead Bream[4] | Plasma | µg/L | 36-100[5] | - |

Page 69 & 71, AquAdvantage Briefing packet. http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM224762.pdf

# Potential allergenicity of the Gene Expression Product

- Homology searches were conducted to evaluate the potential cross-reactivity of the Chinook salmon growth hormone with known allergen protein sequences. There were no amino acid sequence identities of greater than 35% in segments of 80 amino acids with any entries in allergen databases.
- The pepsin resistance assay was not performed for the native Chinook salmon growth hormone that is expressed in ABT salmon, based on the premise that "*there is no scientific rationale to suggest an altered resistance to pepsin when the protein is expressed in Atlantic salmon rather than in Chinook salmon*."

Pages 75-77, AquAdvantage Briefing packet. http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM224762.pdf



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# Endogenous allergens in fish

- The major allergens responsible for cross-reactivity among distinct species of fish and amphibians are parvalbumins. These proteins control calcium flow in the muscular sarcoplasm of the white meat and have a molecular weight of approximately 12 kD[1].
- Parvalbumins are resistant to thermal and enzymatic degradation.
- Parvalbumin (Sal s l) is the major allergen in the white muscle of Atlantic salmon[2]
- The Chinook salmon GH protein has no structural similarity to known allergens


1. Wild LG, and S.B Lehrer. 2005. Fish and shellfish allergy. Current allergy and asthma reports. 5:74-49.
2. Lindstrom CD, van Do T, Hordvik I, *et al.* 1996. Cloning of two distinct cDNAs encoding parvalbumin, the major allergen of Atlantic salmon (Salmo salar). *Scand J Immunol* 44:335–344.

# Important Variations in Parvalbumin Content in Common Fish Species: A Factor Possibly Contributing to Variable Allergenicity A. Kuehn, T. Scheuermann, C. Hilger, F. Hentges· 2010. *Int Arch Allergy Immunol* 2010;153:359-366 (DOI: 10.1159/000316346)

**Table 1.** Parvalbumin contents in raw fish, and commercially processed and cooked fish samples by quantitative ELISA

| | Fish sample | Fish n | Extracts n | Parvalbumin mg/g | Parvalbumin %[1] |
|---|---|---|---|---|---|
| Herring | raw | 2 | 12 | 3.8–5.7 | 3.3 |
| | pickled | 2 | 6 | 1.2–2.8 | 5.6 |
| | cooked | 2 | 12 | 3.0–4.4 | 16 |
| Carp | raw | 2 | 12 | 2.5–5.0 | 3.0 |
| | cooked | 2 | 12 | 2.1–4.0 | 15 |
| Redfish | raw | 3 | 18 | 2.0–3.0 | 2.2 |
| | cooked | 2 | 12 | 1.7–2.3 | 14 |
| Trout | raw | 6 | 36 | 2.0–2.5 | 1.3 |
| | smoked | 2 | 6 | 0.9–1.1 | 9.2 |
| | cooked | 2 | 12 | 1.7–2.0 | 11 |
| Salmon | raw | 2 | 12 | 1.9–2.5 | 1.2 |
| | smoked | 2 | 6 | 0.7–1.0 | 8.9 |
| | cooked | 2 | 12 | 1.5–1.9 | 9.5 |
| Cod | raw | 4 | 24 | 1.5–2.5 | 1.7 |
| | cured | 2 | 6 | 1.0–1.3 | 1.3 |
| | cooked | 2 | 12 | 1.3–1.9 | 7.2 |
| Mackerel | raw | 3 | 18 | 0.3–0.7 | 0.1 |
| | smoked | 2 | 6 | 0.08–0.15 | 2.3 |
| | cooked | 2 | 12 | 0.2–0.5 | 5.3 |
| Tuna, white | raw | 6 | 36 | 0.01–0.05 | 0.03 |
| | cooked | 2 | 12 | 0.01–0.03 | 0.2 |
| Tuna, dark | raw | 2 | 12 | ND | – |
| Tuna | canned | 2 | 6 | ND | – |

Two tissue samples were taken from each raw fish at different longitudinal body positions. ND = Not detected.
[1] Percentage per total soluble protein.

"The parvalbumin content of most commonly consumed fish species varies considerably. Differences range from several fold to one hundredfold. In raw fish, parvalbumin levels decreased significantly in the following order: herring > carp > redfish > salmon/trout > cod > mackerel > tuna. Differences in herring and tuna Parvalbumin levels were found to vary by a factor of 100".



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# "What level of change in endogenous allergens would be (un)acceptable?"

*"There is no consensus in the scientific and medical communities regarding the magnitude of the increase in endogenous allergens in an allergenic food that would present an additional risk to public health (Goodman et al., 2008), especially given that individuals that are allergic to a particular food would likely avoid that food"*

Was GE salmon more allergenic than its non-GE comparator? "The allergenicity potential of GE triploid salmon was not significantly different from sponsor control"

Page 97, AquAdvantage Briefing packet. http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM224762.pdf

# Food/Feed Safety: Does food or feed from the GE animal pose any risk to humans or animals consuming edible products from GE animals compared with the appropriate non-transgenic comparators?

FDA conclusion of food/feed safely evaluations:

"*We therefore conclude the food from AquAdvantage Salmon (the **triploid** ABT salmon) that is the subject of this application is as safe as food from conventional Atlantic salmon, and that there is a reasonably certainty of no harm from the consumption of food from this animal. No animal feed consumption concerns were identified*".

Page 62, AquAdvantage Briefing packet. http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM224762.pdf

# THIS IS NOT A FOOD SAFTY ISSUE

The World Health Organization, the National Academy of Sciences, AMA and more than 300 independent medical studies on the health and safety of genetically modified foods have reached the same determination that foods made using GM ingredients are safe, and in fact are substantially equivalent to conventional alternatives.

**June 2012. The American Medical Association (AMA) adopted a formal statement explicitly opposing the mandatory labeling of genetically modified foods.**

"*there is no scientific justification for special labeling of genetically modified bioengineered foods, as a class, and that voluntary labeling is without value unless it is accompanied by focused consumer education*."

# "Opinion polls show an overwhelming majority of people support mandatory labeling of GM foods"

- It all depends on how the question is asked

Environmental groups and critics of biotechnology claim that >95% of consumers responding to surveys indicate that they want GM labeling, but other surveys show that consumers rarely put forward GM labeling unless they are prompted.

**The results depend on how the questions are worded.**

http://www.flickr.com/photos/azrainman/1004637156

# Three main arguments for mandatory GM labeling

1. **Public opinion**: Polls show an overwhelming majority of people support mandatory labeling of GM foods
2. **Consumer choice**: People should have a choice in what types of products they purchase and consume
3. **Right to know**: People have the right to know what is in their food



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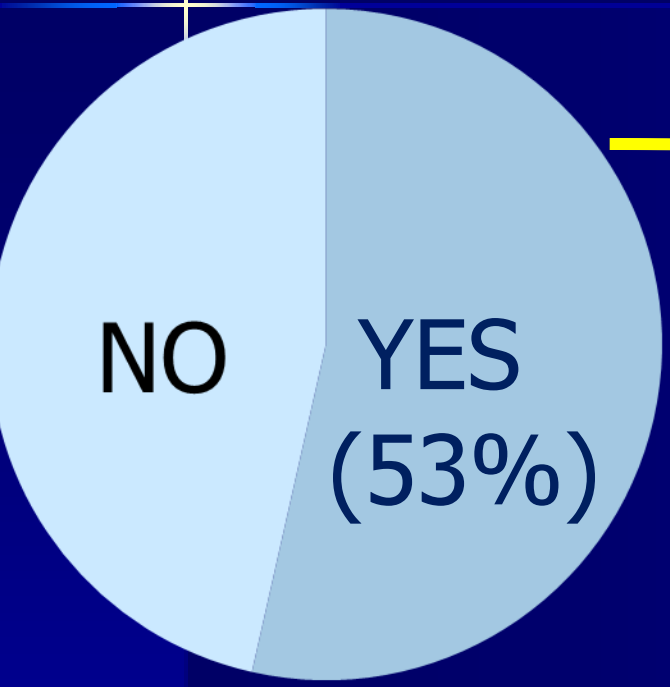
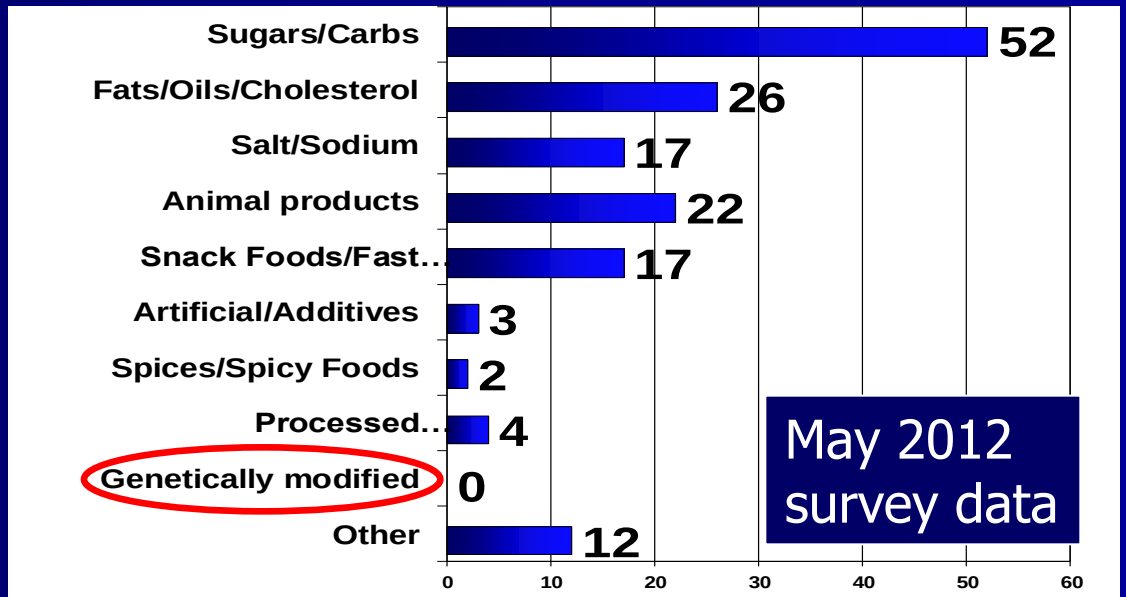
# Thinking about your diet over the past few months, are there any foods or ingredients that you have avoided or eaten less of?? (n=750)




What foods or ingredients have you avoided? [OPEN ENDED]




International Food Information Council Foundation

http://www.foodinsight.org/Content/5519/IFIC%202012%20Food%20Technology%20Survey-US%20Topline%20Summary.pdf



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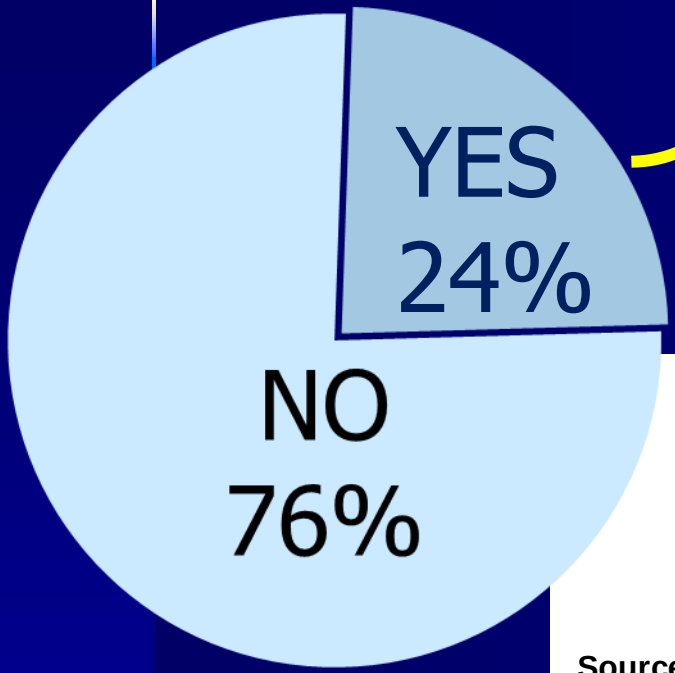
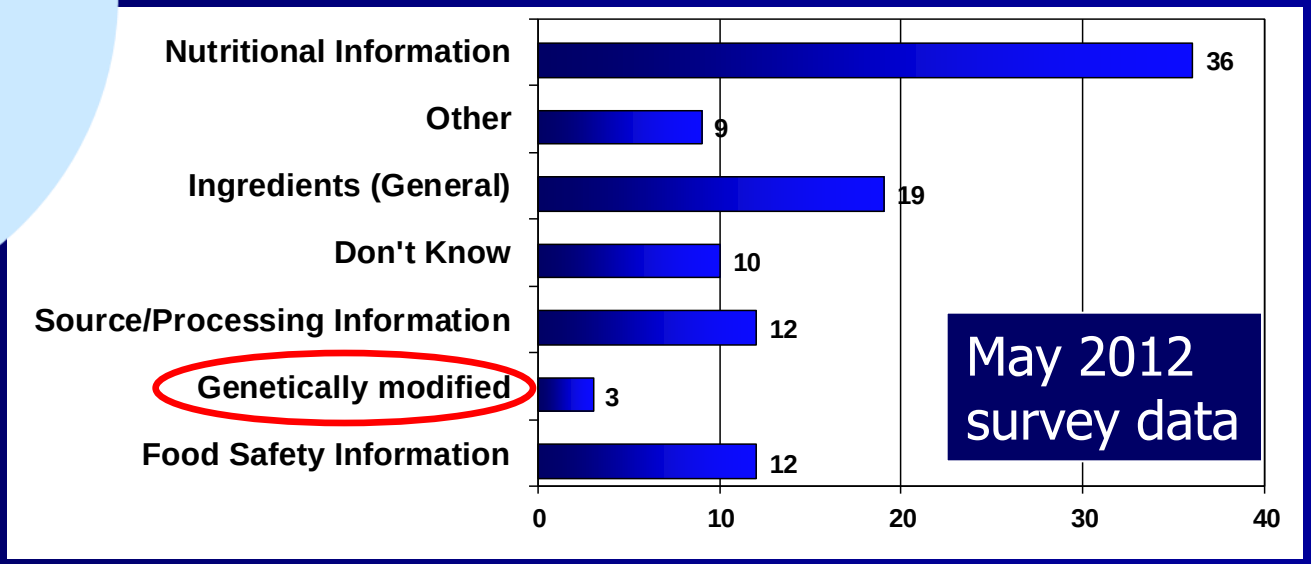
# Can you think of any information that is not currently included on food labels that you would like to see on food labels? (n=750)




What types of information would that be? [OPEN ENDED]




IFIC International Food Information Council Foundation

http://www.foodinsight.org/Content/5519/IFIC%202012%20Food%20Technology%20Survey-US%20Topline%20Summary.pdf



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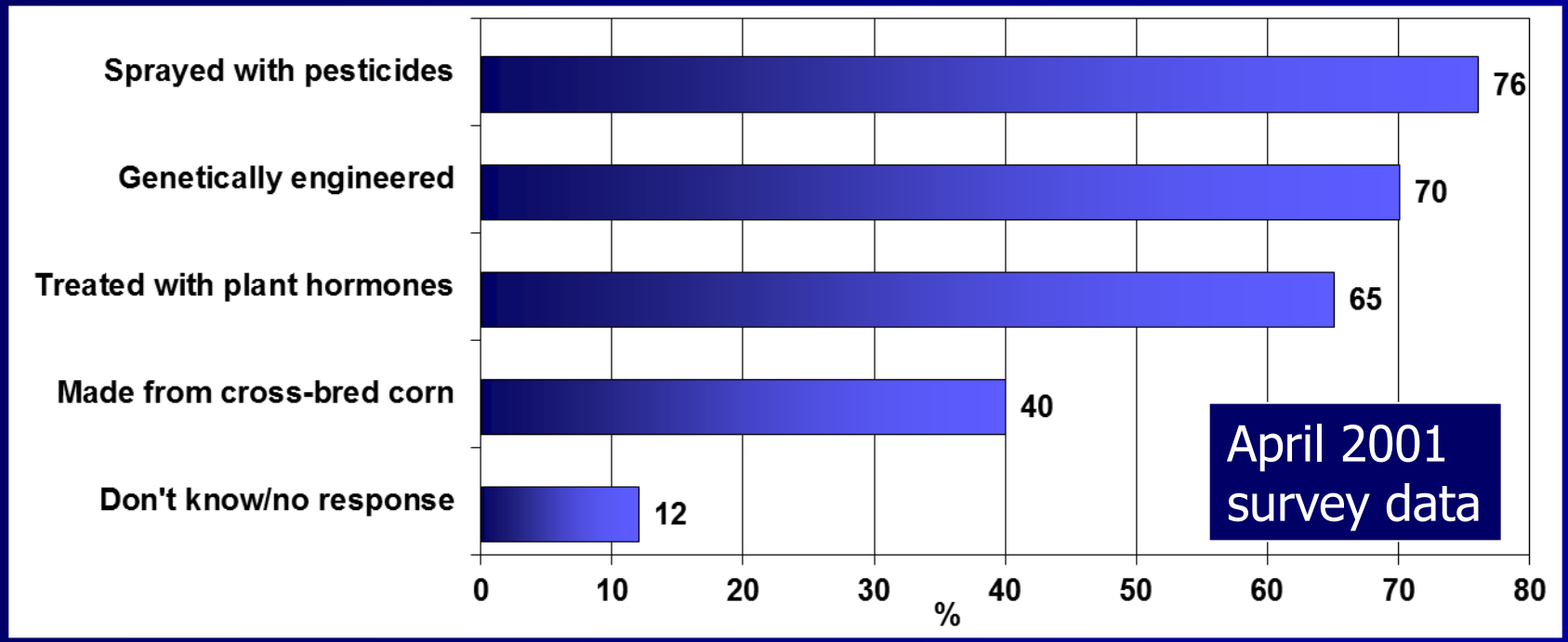
# Modern agriculture uses many technologies to increase productivity. Do you think the words *(item below)* should appear on the label of a food product where one or more ingredients were from crops which were...




CENTER FOR Science IN THE Public Interest
*The nonprofit publisher of Nutrition Action Healthletter*

http://www.cspinet.org/new/labeling_gefoods.html
n = 1,017

# Labeling about genetically engineered ingredients could increase the cost of food. Would you be willing to pay for such labeling if labeling increased the cost of your family's food by…

- Over $250 a year 7%
- $250 per year 5%
- $50 per year 16%
- $10 per year 17%
- Nothing 44%
- Don't know 11%

http://www.cspinet.org/new/labeling_gefoods.html



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# Does the experience in the U.S. show consumers avoiding GE?

- In experimental and real world market tests in North America, the presence of GE-food has not had a significant impact on actual purchase decisions
- If 90% plus of North American consumers wanted products free of GE, then organic food and food labeled as GE-free would be a much larger share of US market

Smyth, S. and P.W.B. Phillips. 2003.Labeling to manage marketing of GM foods. *Trends in Biotechnology*, 21: 389-393.

# 1. Public opinion pros and cons

- **Pro**: Polls show an overwhelming majority of people support mandatory labeling of GM foods
- **Con:** Majority (99%) of consumers don't ask for mandatory labeling of GM (unless specifically prompted by the question)
- Imposes substantial economic costs along the entire food supply chain and puts costs of labeling onto all consumers – including majority who are not concerned about GM

# Arguments for mandatory labeling

1. **Public opinion**: Polls show an overwhelming majority of people support mandatory labeling of GM foods
2. **Consumer choice**: People should have a choice in what types of products they purchase and consume
3. **Right to know**: People have the right to know what is in their food



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# Does mandatory labeling provide choice?

- Experience with mandatory labeling in the European Union, Japan, and New Zealand has not resulted in consumer choice. Rather, retailers have eliminated GM products from their shelves to avoid being targeted by NGOs
- "A real concern is that mandatory labeling could force GM foods out of the market. Mandatory labeling in Europe virtually eliminated any ability to choose GM foods, because there were fewer than 10 acknowledged GM products."

Gary E. Marchant, Guy Cardineau, and Thomas Redick. 2010. Thwarting Consumer Choice: The Case Against Mandatory Labeling for Genetically Modified Foods. Rowman and Littlefield Publishing Group.



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# Is labeling being sought to provide consumer choice?

**"Following the launch of the European labeling requirement, Greenpeace announced it would summon thousands of volunteers across Europe to police grocery stores and ensure they were not stocking food with GM labels"**

Gary E. Marchant, Guy Cardineau, and Thomas Redick. 2010. Thwarting Consumer Choice: The Case Against Mandatory Labeling for Genetically Modified Foods.

**"Proponents of mandatory GM labeling make no secret that mandatory labeling is not their final goal."**

Klintman, M. (2002), 'The Genetically Modified (GM) Food Labelling Controversy: Ideological and Epistemic Crossovers', Social Studies of Science, Vol.32, No.1, pp.71–91.

**"Personally, I believe GM foods must be banned entirely, but labeling is the most efficient way to achieve this. Since 85 percent of the public will refuse to buy foods they know to be genetically modified, this will effectively eliminate them from the market just the way it was done in Europe."**

Dr. Mercola, http://vtdigger.org/2012/04/17/wanzek-genetically-modified-food-is-perfectly-healthy/

# What about when the GE product is materially-different? e.g. Labels for Golden Rice

- Method-based label
  - "This product has been genetically modified"
- Product-based label
  - "This product contains high levels of vitamin A"
- Which label enables consumers to make an informed choice?

# 2. Consumer choice pros and cons

- **Pro**: People should have a choice in what types of products they purchase and consume
- **Con**: Implementation of mandatory labeling has not resulted in consumer choice. In fact it has been used as a weapon to demonize GE food and prevent the availability of that option to consumers
- What information does labeling as "Contains GMO" provide to enable informed choice – GE for WHAT and how does the product differ?

# Arguments for mandatory labeling

1. **Public opinion**: Polls show an overwhelming majority of people support mandatory labeling of GM foods
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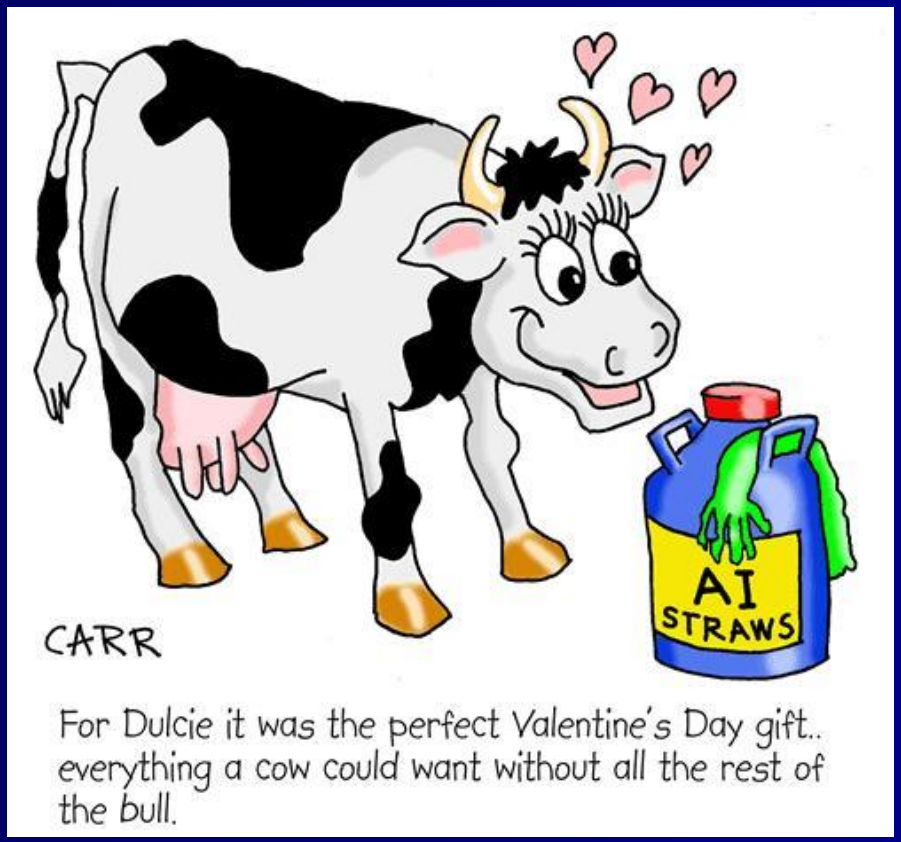
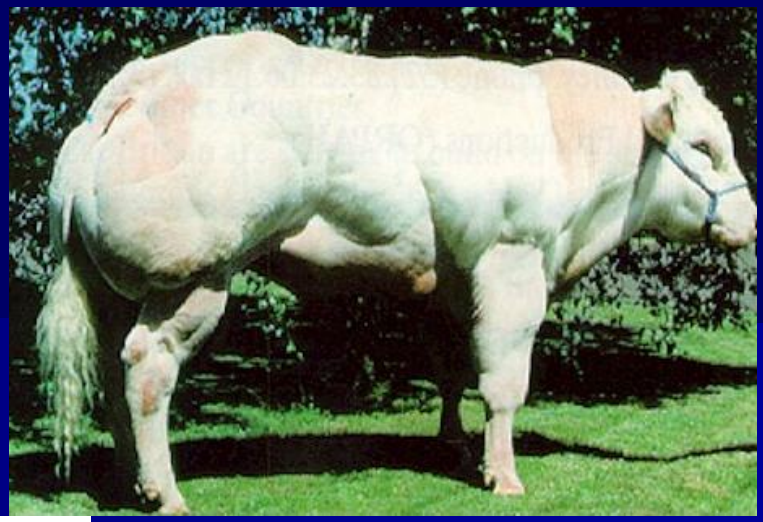
# Do other production methods that do not "materially" affect the product qualify for right to know?




***"When artificial insemination (AI) was first introduced into cattle breeding there were concerns that AI was not natural, and would lead to abnormal outcomes"***

Foote, R.H. (2002). The history of artificial insemination. *Journal of Animal Science* 80, 1-10.

# Or label for people who object to double-muscled cattle breeds….



CERTIFIED*
MYOSTATIN
EXPRESSER
RAISED & HANDLED



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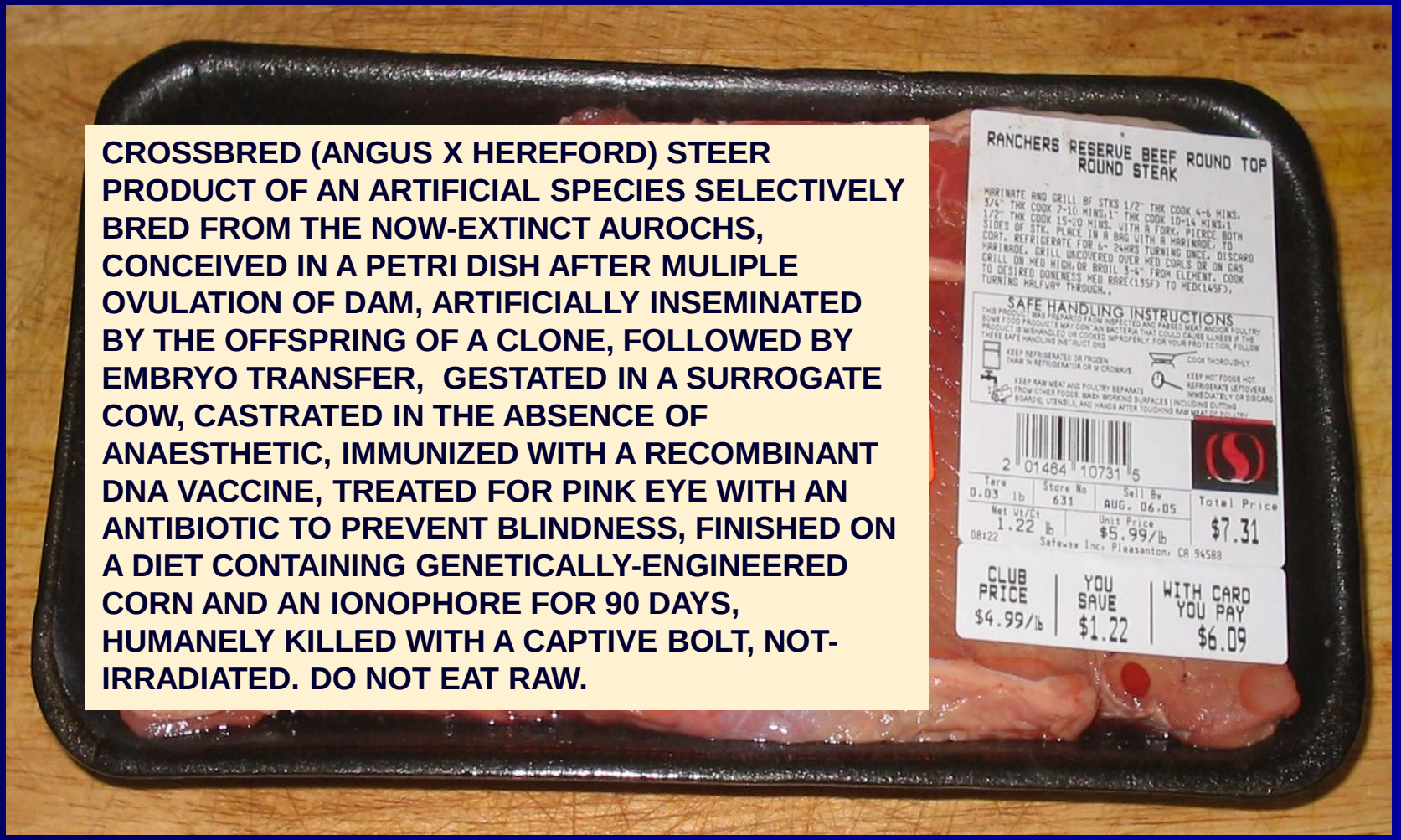
# Should there be mandatory "right to know" labeling about all aspects of the food production process?




CROSSBRED (ANGUS X HEREFORD) STEER PRODUCT OF AN ARTIFICIAL SPECIES SELECTIVELY BRED FROM THE NOW-EXTINCT AUROCHS, CONCEIVED IN A PETRI DISH AFTER MULIPLE OVULATION OF DAM, ARTIFICIALLY INSEMINATED BY THE OFFSPRING OF A CLONE, FOLLOWED BY EMBRYO TRANSFER, GESTATED IN A SURROGATE COW, CASTRATED IN THE ABSENCE OF ANAESTHETIC, IMMUNIZED WITH A RECOMBINANT DNA VACCINE, TREATED FOR PINK EYE WITH AN ANTIBIOTIC TO PREVENT BLINDNESS, FINISHED ON A DIET CONTAINING GENETICALLY-ENGINEERED CORN AND AN IONOPHORE FOR 90 DAYS, HUMANELY KILLED WITH A CAPTIVE BOLT, NOT-IRRADIATED. DO NOT EAT RAW.



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# Bill to require labeling of food that contains or is produced using genetically engineered material

House Bill 2175- 77th Oregon legislative assembly--2013 Regular Session
http://www.leg.state.or.us/13reg/measpdf/hb2100.dir/hb2175.intro.pdf

**Labeling required for food from organisms which have been injected or otherwise treated with a GE material, or which have been fed GE materials**

- Recombinant DNA vaccines
- GE feed – how often? Never ever?
- rBST
- 90% of North American cheese made with GE fermentation-produced chymosin (FPC)



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# There is a lot of literature available on GE and its use in animal agriculture

## Recombinant DNA vaccines

Council for Agricultural Science and Technology. 2008. **Vaccine Development Using Recombinant DNA Technology.** Issue Paper 38. CAST, Ames, IA.

## GE feed

Council for Agricultural Science and Technology. 2006. **Safety of Meat, Milk, and Eggs from Animals Fed Crops Derived from Modern Biotechnology**. Issue Paper 34. CAST, Ames, IA.

## GE animals

Council for Agricultural Science and Technology (CAST). 2011. **The Science and Regulation of Food from Genetically Engineered Animals.** CAST Commentary QTA2011-2. CAST, Ames, Iowa.

# 3. Right to know pros and cons

- **Pro**: People have the right to know what is in their food
- **Con**: Singles out GM technology for right to know, not other production methods. "*There is no prima facie case that consumers have a right to know everything through mandated labels or at any cost.*"

Kalaitzandonakes, N., 2004. "Another look at Biotech Regulation" Regulation. 27(1):44-50.

# FDA Public Hearing on the Labeling of Food Made from the AquAdvantage Salmon, September 21st, 2010




Alison Van Eenennaam, Ph.D., UC Davis

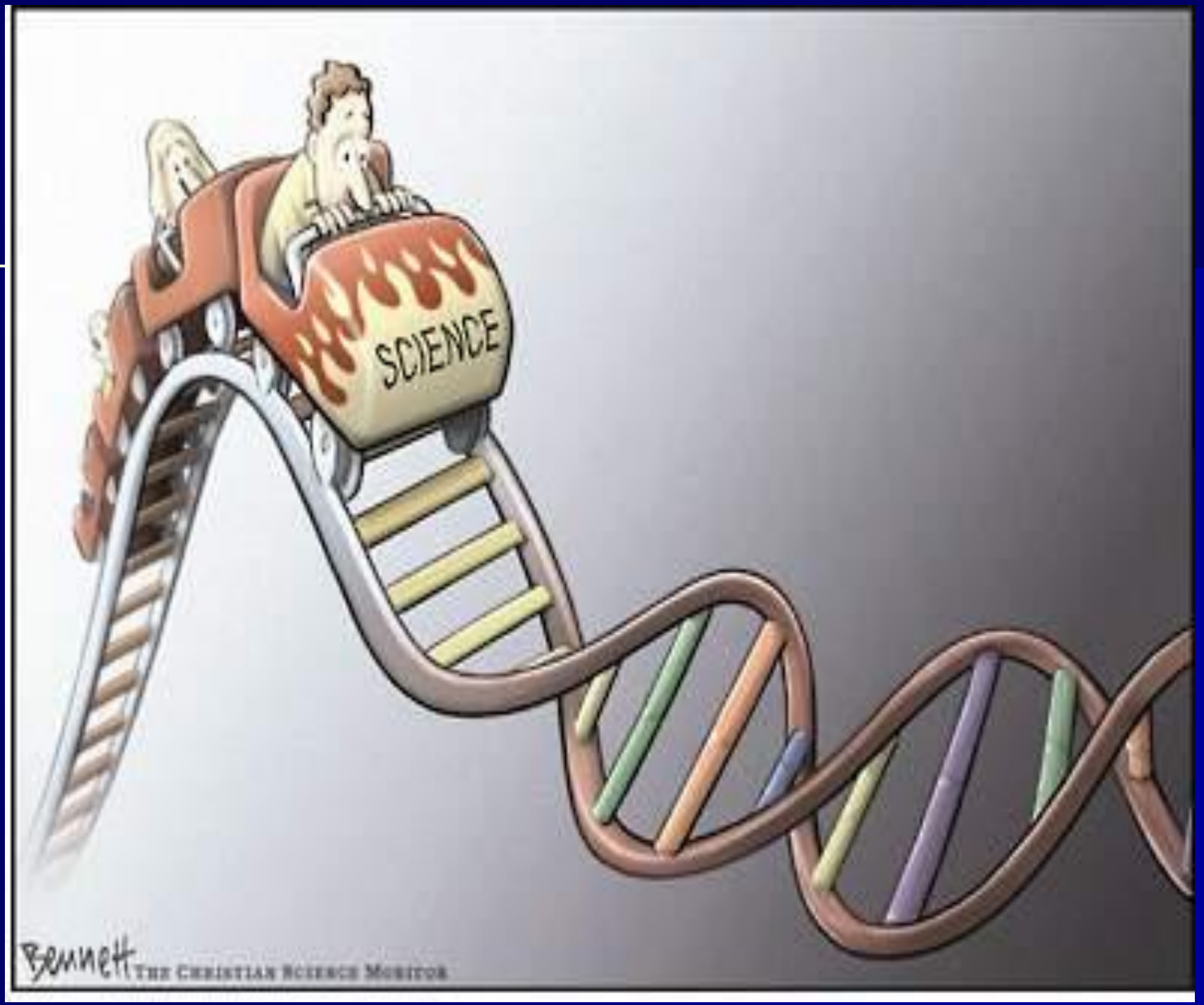
# Public testimony from Center for Science in the Public Interest

"There are many production methods for food products and many production methods for salmon. Identifying this production method without requiring all the other production methods to be identified would needlessly discriminate against genetic engineering and not provide the consumer with information about the "material" differences in this particular salmon… Providing information without education about what that information means is not particularly helpful to the consumer."

Greg Jaffe, Center for Science in the Public Interest, Washington, D.C.
http://cspinet.org/new/pdf/salmon_labeling_presentation.pdf

# Conclusions

- Mandatory labeling is not a simple matter of putting some additional ink on a package
- There are several reasons put forward for mandatory labeling which can be argued either way
    1. Public opinion/depends on question
    2. Consumer choice/lack of choice
    3. Right to know/scope of methods to include
- Labeling GE is not a food safety issue and developers are understandably wary of the additional costs of supply chain segregation – and having their brand targeted by opponents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Bennett
The Christian Science Monitor