Labeling of foods derived from GM animals

Alison Van Eenennaam, Ph.D.
Cooperative Extension Specialist
Animal Biotechnology and Genomics
Department of Animal Science
University of California, Davis, USA
http://animalscience.ucdavis.edu/animalbiotech/

- Bachelor of Agricultural Science; University of Melbourne, Australia
- M.S. & Ph.D. Genetics; University of CA, Davis, USA
- Wife, mother, grocery shopper, and U.S. consumer

Overview

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

Background

The principles of food labeling in the U.S. 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

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

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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)

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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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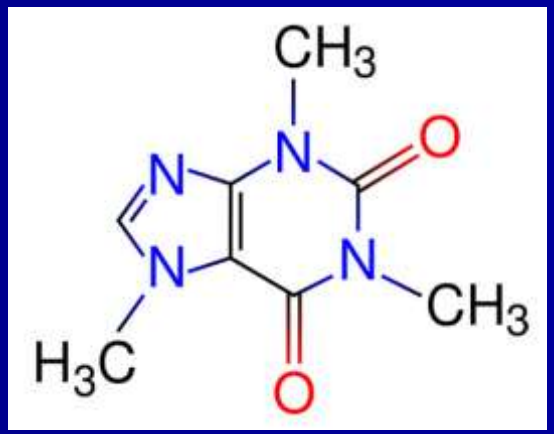
Voluntary labeling is allowed if it is not false or misleading

Non-misleading

"Cholesterol-free oil"

– Such claims are forbiden in the USA because they imply other vegetable oils have cholesterol, when in fact, none do.

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



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

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

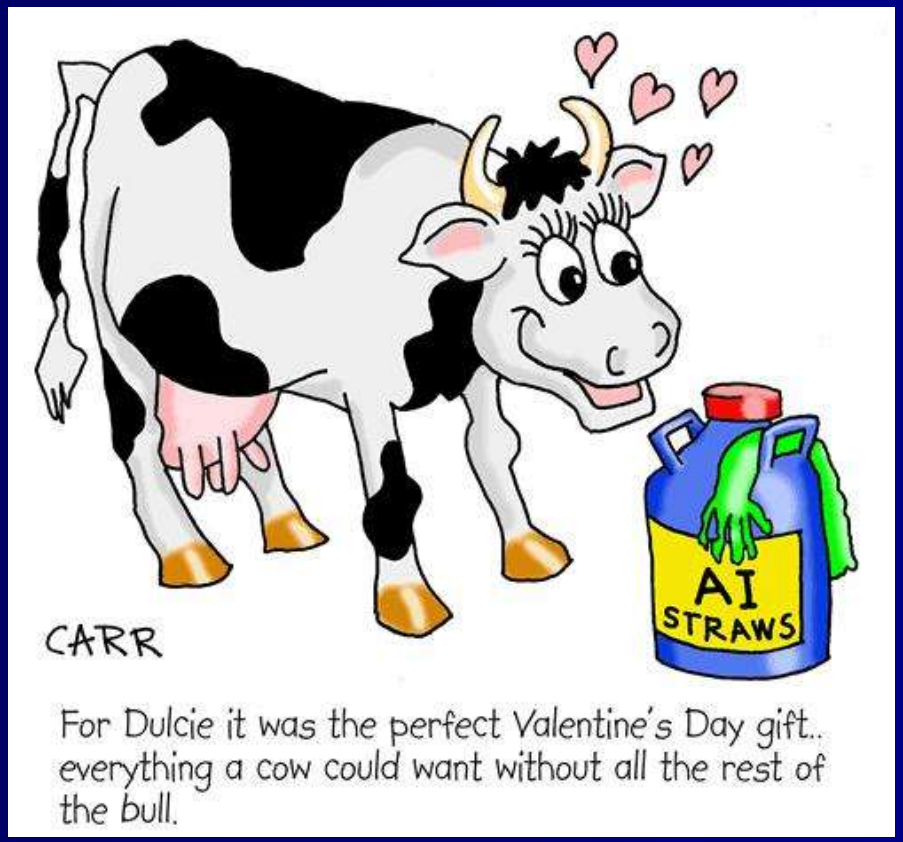
OUR COWS ARE NOT TREATED WITH THE GROWTH HORMONE rBST

GMO

DEMETER CERTIFIED BIODYNAMIC®

CERTIFIED NATURALLY GROWN

What if other production methods that do not "materially" affect the product are targeted for labeling?

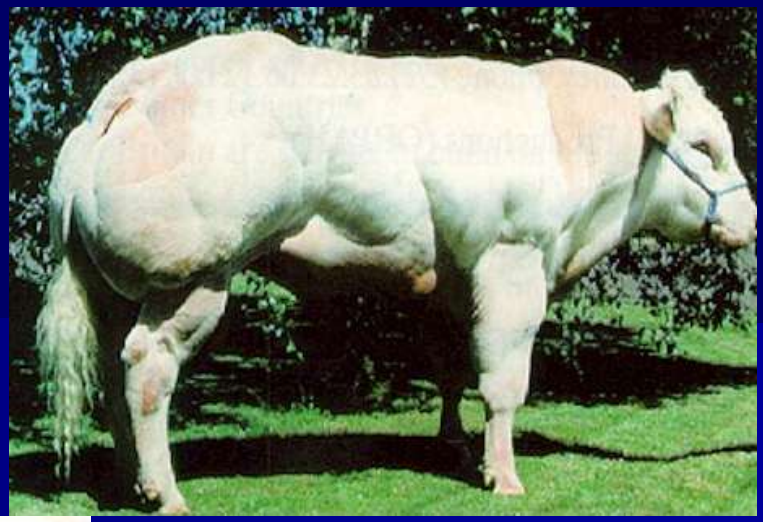


"In order to force the animals to continue giving milk, factory farm operators typically impregnate them using artificial insemination every year"

http://www.peta.org/issues/animals-used-for-food/dairy-industry.aspx

Should the consumer who objects to artificial insemination have a right to know about its use on the label ?

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



CERTIFIED*
MYOSTATIN
EXPRESSER
RAISED & HANDLED

Arguments for mandatory labeling

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

"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 GE labeling, but other surveys show that consumers rarely put forward GE labeling unless they are prompted.

The results depend on how the questions are worded.

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

Please indicate whether you strongly agree, somewhat agree, somewhat disagree or strongly disagree (n=1,001)

- Food products made from genetically engineered animals should be labeled as such

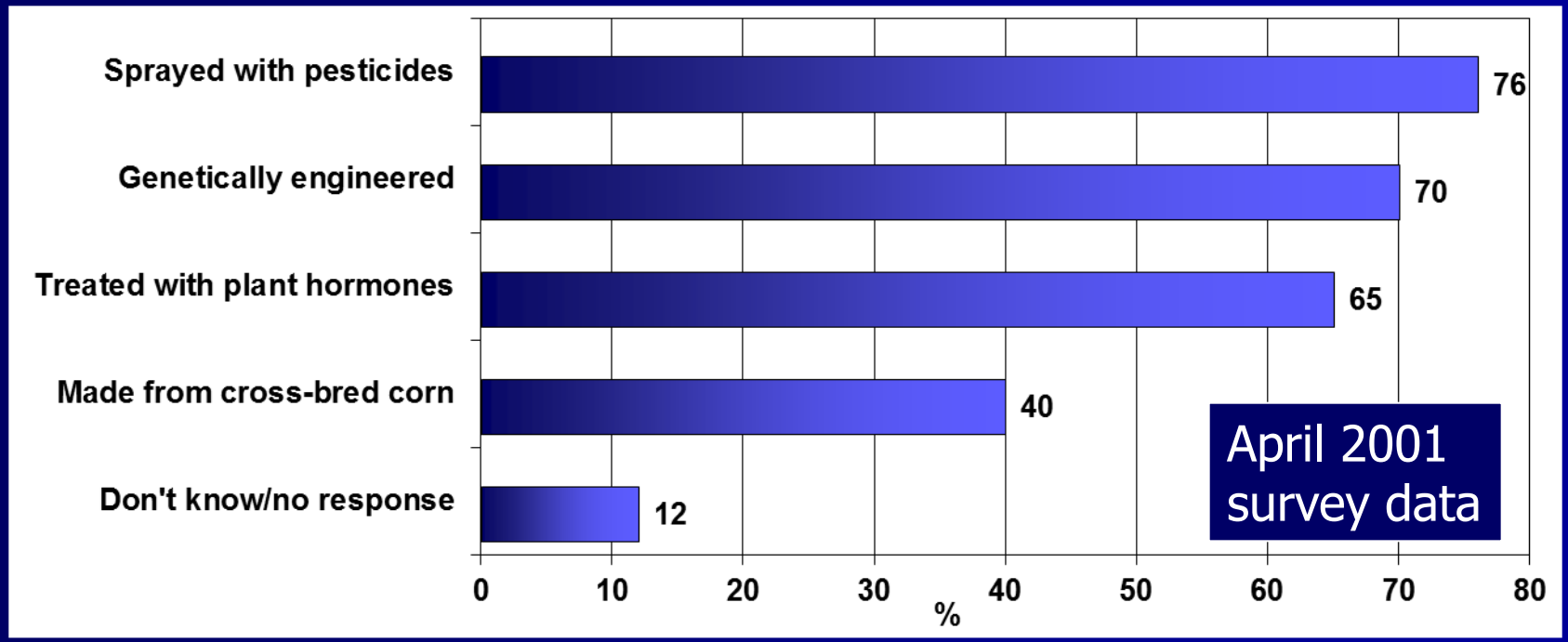
  95 percent agreed or strongly agreed

Over 90% agreed with **all** of the labeling questions asked

- Processed or packaged foods should be labeled by country of origin
- Meat treated with carbon monoxide should be labeled as such
- Meat and dairy products from cloned animals should be labeled as such
- Meat that contains any irradiated components should be labeled as such
- Specialty meat/fish stores should label their products by country of origin
- Country-of-origin labeling for products should always be available at point of purchase

http://www.consumersunion.org/pub/core_food_safety/006298.html

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

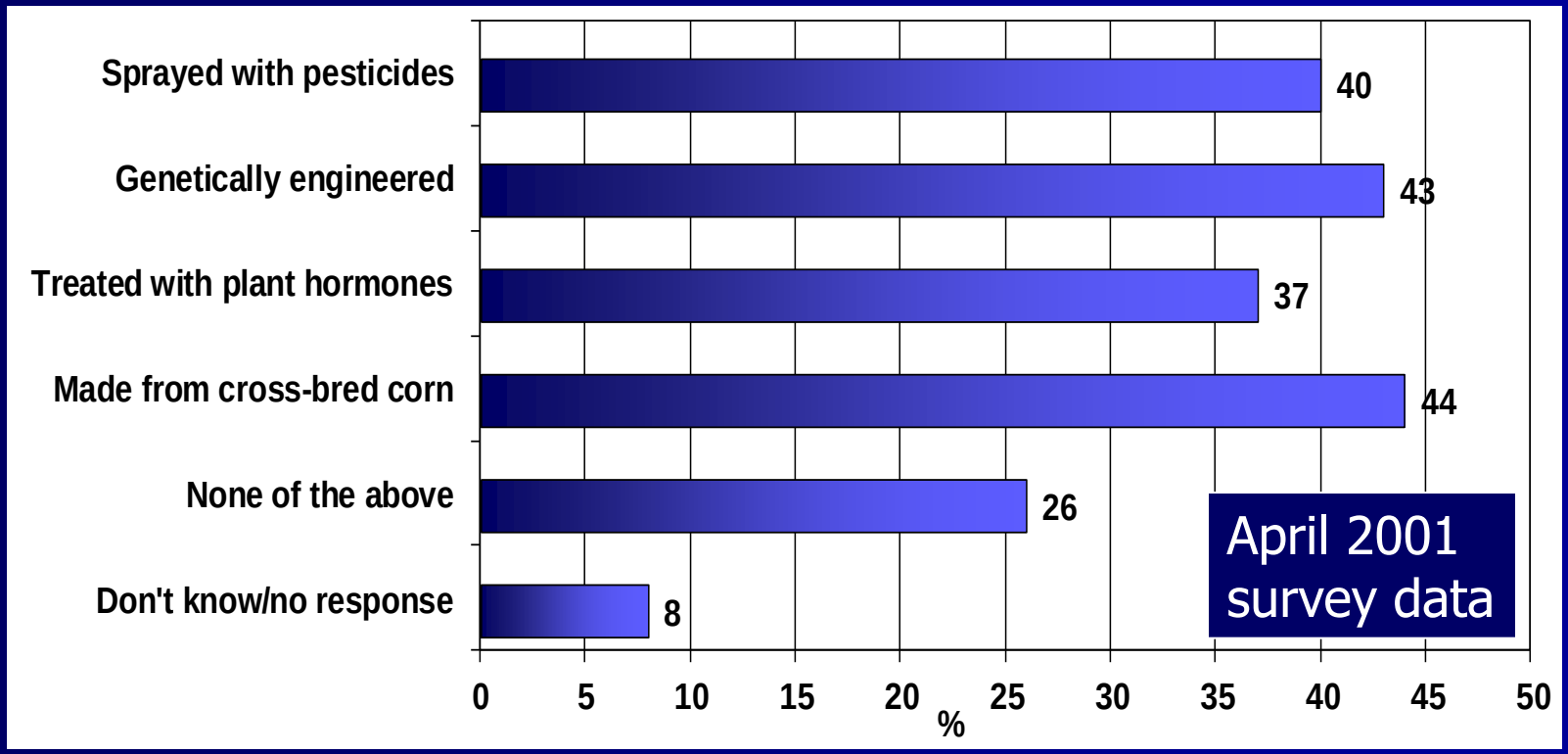
n = 1,017

Would you buy meat or milk products from genetically engineered animals if they were available? (n=1,001 2008)

29% would; 71% would not

http://www.consumersunion.org/pub/core_food_safety/006298.html

Would you buy fruits or vegetables that were labeled as being 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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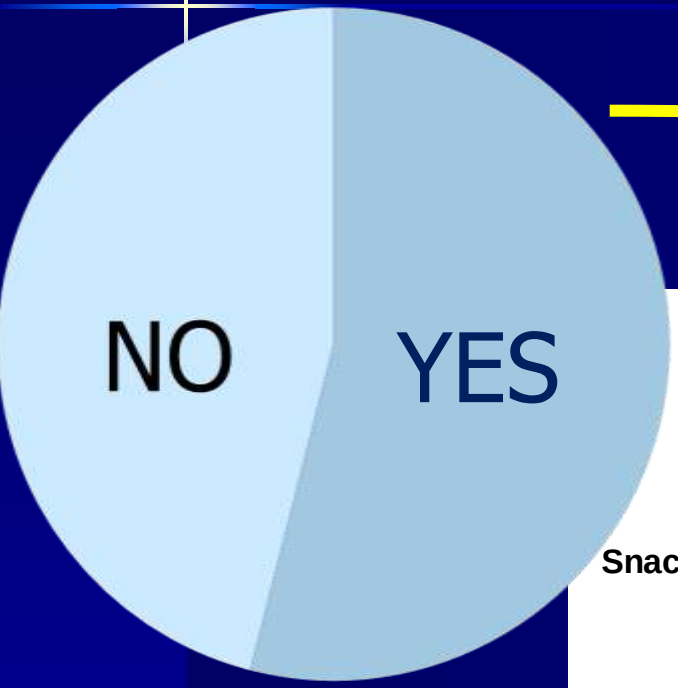
Does the experience in the U.S. show consumers avoiding GE?

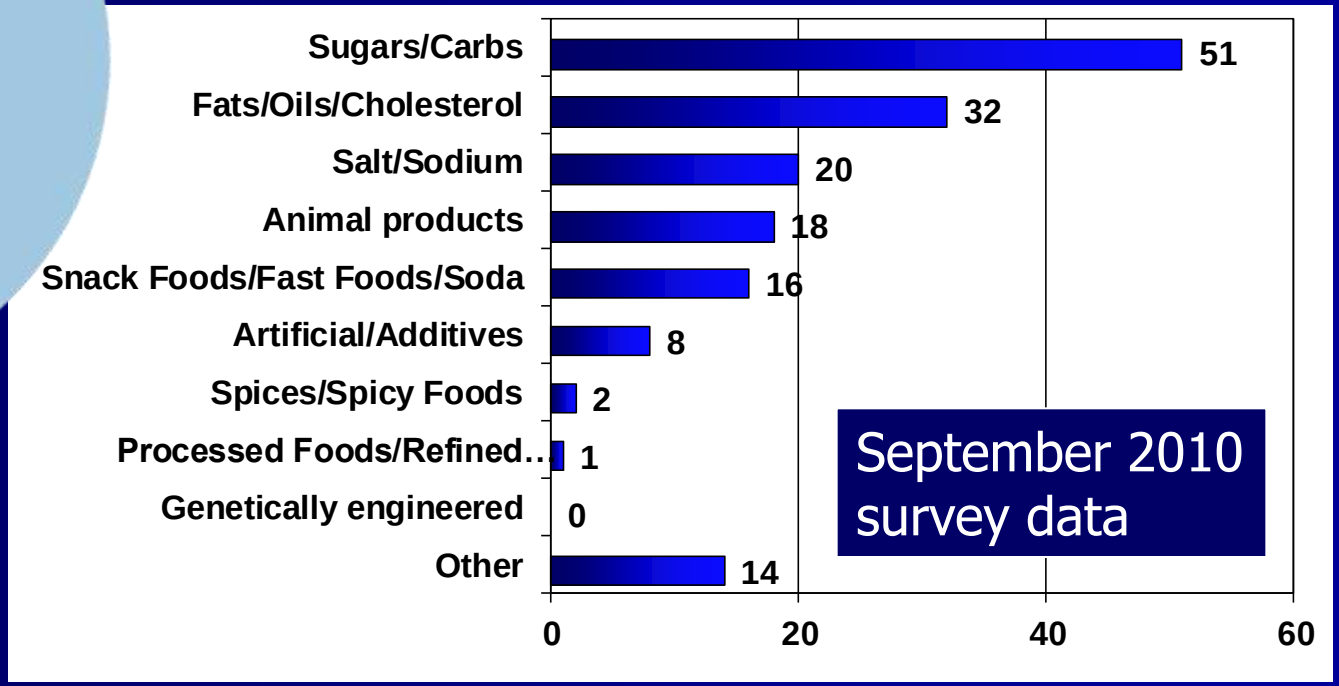
- In experimental and real world market tests in North America, the presence of GE-food has not had a significant impact on actual purchase decisions
- If 90% plus of North American consumers wanted products free of GE, then organic food and food labeled as GE-free would be a much larger share of US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

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

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/3843/Final%20Draft_2010%20ES%20TOPLINE%20DATA_5-26-10.pdf

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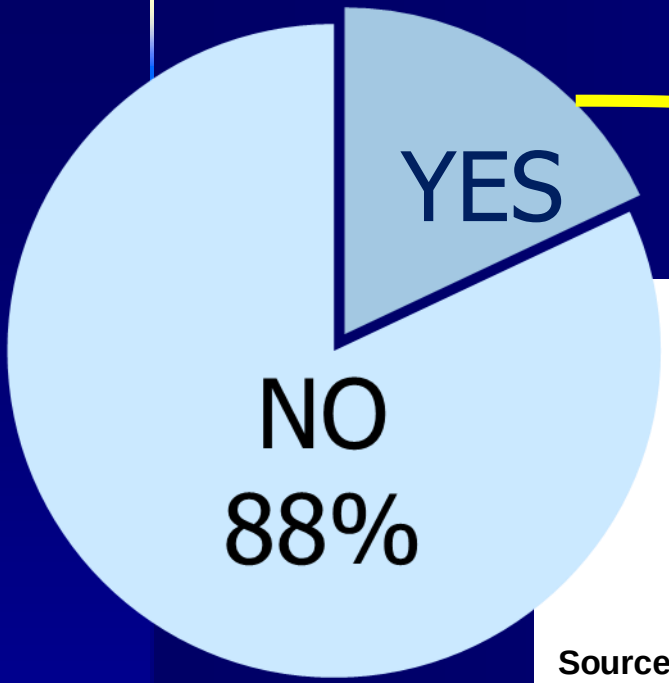
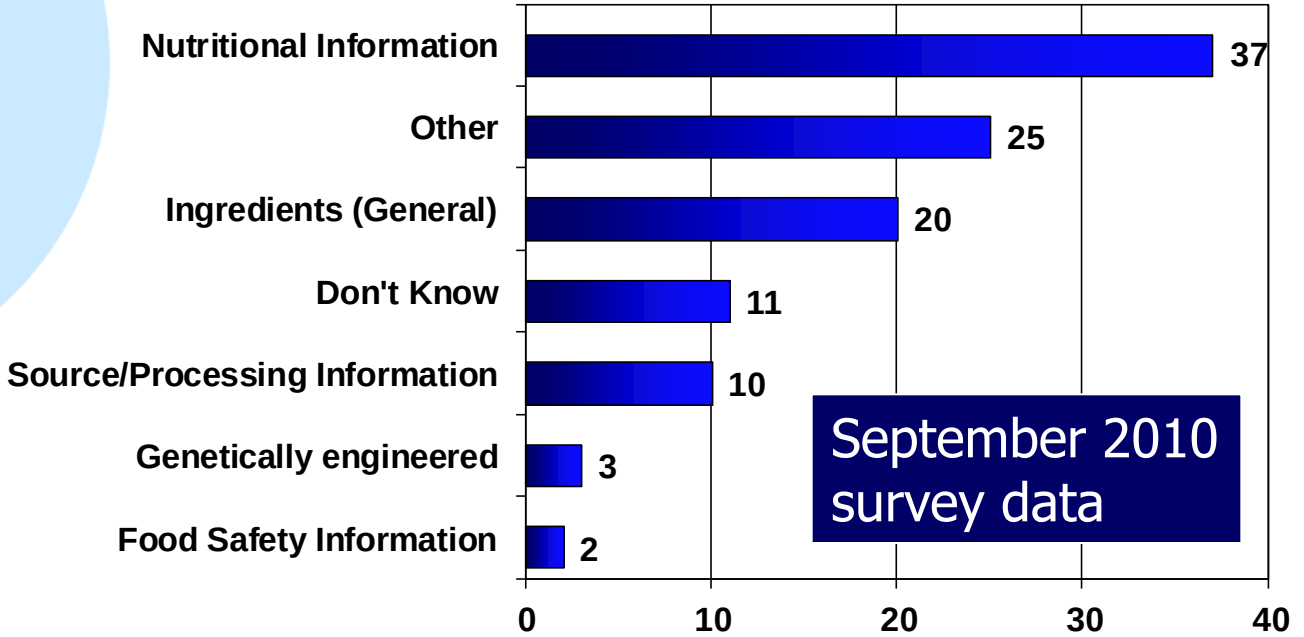
Can you think of any information that is not currently included on food labels that you would like to see on food labels? (n=750)



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



International Food Information Council Foundation

http://www.foodinsight.org/Content/3843/Final%20Draft_2010%20ES%20TOPLINE%20DATA_5-26-10.pdf

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Public opinion argument

- **Pro**: Polls show an overwhelming majority of people support mandatory labeling of GM foods
- **Con:** Majority of consumers don't suggest mandatory labeling of GM unless prompted
- Imposes substantial economic costs along the entire food supply chain and puts costs of labeling onto all consumers – including those who are not concerned about GE

Arguments for mandatory labeling

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

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 GE products from their shelves to avoid being targeted by NGOs
- "A real concern is that mandatory labeling could force GE foods out of the market. Mandatory labeling in Europe virtually eliminated any ability to choose GE foods, because there were fewer than 10 acknowledged GE 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.

NGO take on EU labeling laws

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 GE 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.

What about when GE the 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?

Consumer choice argument

- **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
- Labeling as "GE" does not enable informed choice – GE for WHAT and how does the product differ?

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Morality and approval of traditional cross-breeding (n=600)

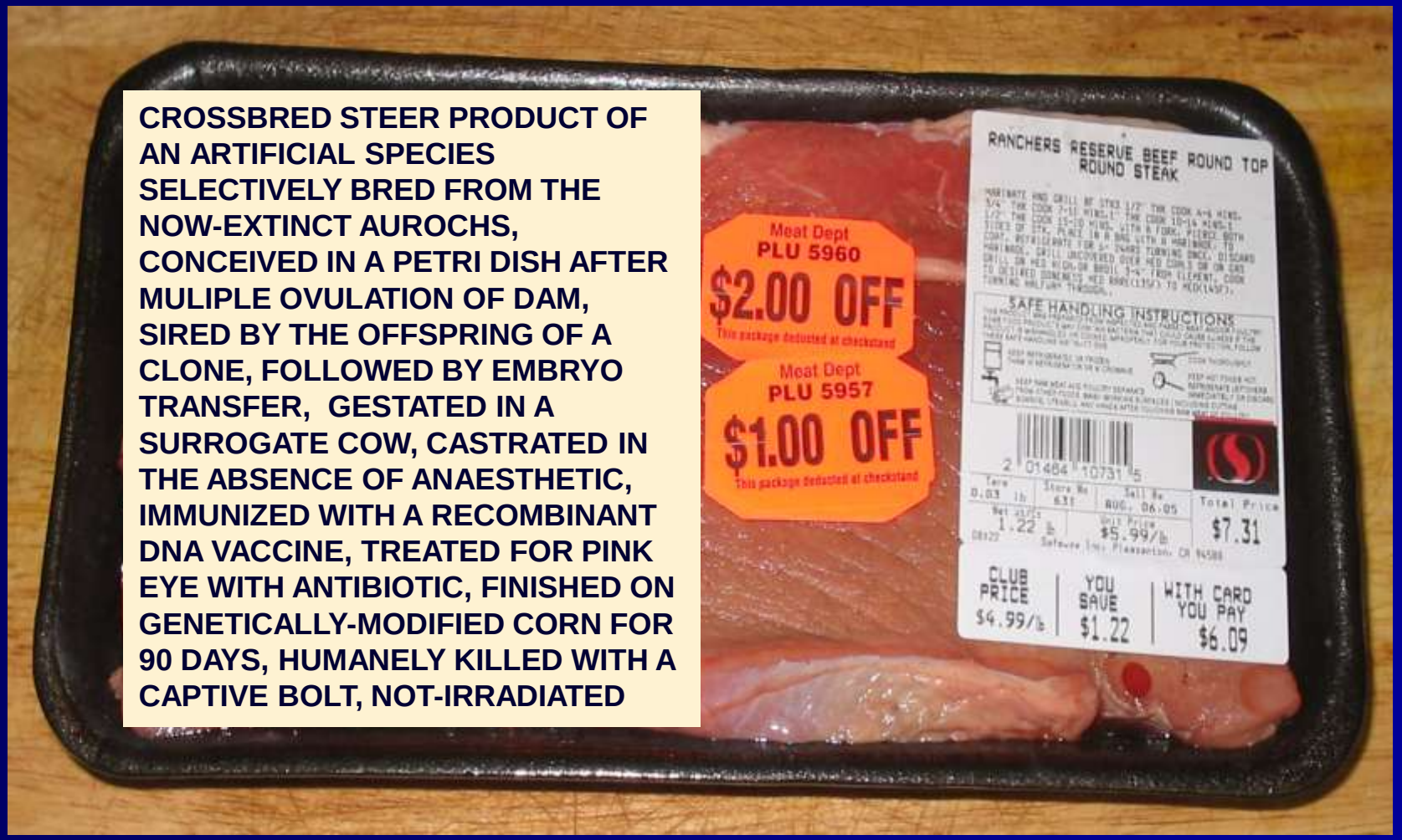
Most of New Jersey's citizens (59%) approve of producing hybrid plants by using traditional cross-fertilization techniques. **However, one-in-five people (20%) believes that it is morally wrong to produce new plants in this way.**

Producing hybrid animals through cross-breeding is viewed even more negatively. Most people (62%) in New Jersey disapprove of producing hybrid animals using this method and half (50%) believe that it is morally wrong

Braford = Brahman x Hereford

Biotechnology attitudes survey - New Jersey, 1993. Rutgers
http://ageconsearch.umn.edu/bitstream/18170/1/pa94ha01.pdf

If process-based labels become mandatory were would the line be drawn as to relevant information…



Ethical argument

- **Pro**: People have the right to know what is in their food
- **Con**: Singles out GE 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

Background about the FDA Public Hearing on the Labeling of Food Made from the AquAdvantage Salmon, September, 2010

- Which facts about the AquAdvantage Salmon seem most pertinent for FDA's consideration of whether there are any "material" differences between foods from this salmon and foods from other Atlantic salmon?
- IF FDA determined there are "material" differences, how would that difference be described on a food label in a way that is truthful and nonmisleading?

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

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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

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.

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

Does the transgene increase the level of endogenous fish allergens?

- 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]

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".

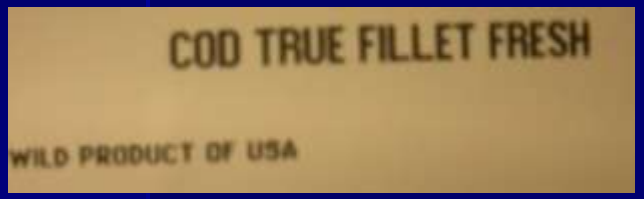
"What level of change in endogenous allergens would be (un)acceptable?"

"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"

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

Fish case at my local supermarket

Country of Origin Labeling (COOL) is a labeling law that requires retailers to notify their customers with information regarding the source of certain foods – including fish and shellfish.



COOL label would be quite distinct for a farmed Atlantic salmon grown in Panama

Public testimony from Food and Water Watch

"We are not willing to settle for making other labels do double duty. We're not going to settle for country of origin labeling being used as code for how we're somehow supposed to educate people which countries are producing genetically engineered salmon this year. That is not acceptable. That's not a label that discloses what we need".

Patricia Lovera , Food and Water Watch, Washington, D.C.
http://stopgefish.files.wordpress.com/2011/02/transcript-of-labeling-hearing-fda-2010-n-0385-0339.pdf

Public testimony from Food and Water Watch

Question from FDA panel: I would like for you, if you could, to elaborate a little more on really what the messaging is in terms of how to use the food, what specific attributes may be changed in the food if the food says genetically engineered. I mean, through your presentation you mentioned things like allergens. … But if the food simply says, genetically engineered, how does that convey that to a consumer?

MS. LOVERA: "Well, we've heard a lot about education, and I assume that the industry is going to be trying to educate or market this product in a way"

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

"Frankenfish" Labeling Bill Introduced

California legislature 2011/12 session ASSEMBLY BILL No. 88

"Concerns about genetically altered salmon include, but are not limited to human health risks, including, but not limited to, potential allergenicity".

Conclusions

- Labeling is not a simple topic
- There are several arguments for mandatory labeling which can be argued either way
  - Public opinion/depends on question
  - Consumer choice/lack of choice
  - Right to know/scope of methods to include
- Labeling 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