In the future, a verified production control program regulation may determine under what circumstances animal production claims may be made on a label. The Agency is currently studying the advisability of rulemaking on Verified Production Control, but a federal regulation has yet to be proposed.

Summary

Descriptive terms which convey information about the nutritional value or quality of a food product are useful to consumers when making product choices in the market place. This information is most accessible when displayed on the immediate food container (i.e., label). In order to avoid confusion, descriptive terms must be accompanied by definitions which adequately explain the terms. In the case of nutrition-related claims, analytical sampling offers a means of assuring the accuracy of stated claims, while natural claims can be verified by means of ingredient statements and processing procedures. Obviously, space availability on a product's label is severely limited. Therefore, the development of concise, yet informative definitions for popular labeling terms is vital to our efforts when approving labeling claims which are both truthful and not misleading.

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Discussion

P. Lewis: What do you do about labeling when the reference standards change – like the new Handbook 8 for beef products? Does the manufacturer, if he is still going to claim a 25% reduction, have to show a 25% reduction under the new standards?

K. Leddy: When you talk about standards, don't get them confused with regulatory standards. If you are talking about data in Handbook 8, there has only been one revision since 1963, in 1986 for beef products. When that came out, we no longer accepted data that was published in 1963. They have to compare to data published in a recent, recognized reference source.

Lewis: In handling animals, what about a person who wants to say no antibiotics were used? What do you do about animals that were treated for disease with antibiotics?

Leddy: If they state on the label that no antibiotics had been administered, that means that the claim must be true for the entire life of the animal, including therapeutic and subtherapeutic uses. This has to be stated in the testimonial or producer protocol that we require.

Lewis: You would have a pretty hard time proving this, wouldn't you?

Leddy: Yes, this is a difficult area. We are looking forward to verified production control, and perhaps that will help.

J. Wise: You said producer testimonials, but your example showed Litvak who is a packer. Does he get the producer testimonials or is it his testimonial?

Leddy: The label is always issued to the establishment but the producer would have to go to a Federally-inspected establishment and have it apply for the label on their behalf.

W. Henning: You mentioned vertical integration, and a year or so ago that was part of the standard for Verified Production Control claims. Is it still or has it been removed?

Leddy: I really can't answer that. I know before the program was formalized it was a requirement. For those who don't know, vertical integration means there is either direct ownership between the producer and the slaughter facility or some sort of limited partnership. This would tie the producer into the claims and give the Agency some recourse. What the new regulation will require, I don't know. I have not seen the proposed regulation. It has not been published in the *Federal Register* yet.

D. Kropf: When talking about natural, you said minimally processed. What are examples of exceeding minimally processed?

Leddy: Something like bleaching or organic solvent extraction. Things that will fundamentally alter the product from its natural state. If the product is a multi-ingredient product, something like white flour would be enough to eliminate it from the natural definition.

Kropf: That doesn't include tumbling, massaging or other manipulations?

Leddy: Yes. If tumbling fundamentally alters the product by letting the product absorb more water than it would naturally have, then we would probably turn that down on the basis that the product is no longer in its natural state.

D. Huffman: You indicated that lean or extra lean was less than 22.5% for ground beef, but earlier you said that lean was less than 10% and extra lean was less than 5%. Philosophically, isn't there a little contradiction here that we are permitting less than 22.5% to be labeled "lean" or "light." It seems that this is a lot of fat to be calling it "lite" or "lean."

Leddy: Those are special exceptions for ground beef and hamburger. They represent a 25% reduction from the regulatory standard, which we consider a significant reduction from the standard.

Huffman: Do you think this will be in place through the foreseeable future?

Leddy: Yes, but you never know. I don't see any indication that it won't be.

Kropf: This is a follow-up. If someone were creating a (ground beef) product with 5% or 10% fat, that would have the same name unless you create new categories. What are we going to do with the new super-low fat ground beef products? I think they are coming.

Leddy: They would have the fat and lean disclosed on the label, so the purchaser would have that information if they wanted it.

Kropf: I think I would still question that the name that catches the consumer first is the same for all of these. I'm not sure all consumers are going to follow up as well as I would like them to do and look for the fat percent.

Leddy: Well, it would be prominently displayed.

Wise: I think that is one of the benefits of the Policy Memos. It does allow them to change a little more rapidly if something does occur overnight, say in the area of low-fat ground beef.

Leddy: If we see a real trend in the industry, we do, through our policy memos, have the ability to change relatively quickly.

G. Davis: I agree with Dale on that. Is there any way that the decision on the 22.5% will ever be reversed, and what would it take to get it reversed? I really think it is misleading. It should be at the 5% and 10% level. I have seen some data of Brad Berry's that compared various lean or lite ground beef products with less than 10% fat and, surprisingly, the letter I received indicated the palatability was acceptable; and I think it was a surprise to Brad. I think Don was implying this also. I think there is probably other data that indicates this will work and here we are with 22.5%. I'm wondering, isn't the 22.5% misleading on the other side?

Leddy: You can always petition the Agency with that kind of information and I am sure it will be considered.

R. Epley: I am puzzled by the difference in philosophy regarding the use of the words "organic" and "natural." I know organic is not permitted because, at least in the memo I've seen, it said it means too many things to too many people. Why can't we have a definition for organic if we can have a definition for natural?

Leddy: Have I talked to you on the phone about this? (Laughter)

Epley: I think so but I am still asking the question. My students asked the question.

Leddy: Call me Monday, OK? Seriously, we are seeing a lot of interest in the term "organic." There are several states that now have laws regarding the use of the term "organic." I think that we might develop a definition, but we are not at that point just yet. Again, you run into how are we going to verify it, what does it mean, and what if it is linked into the growing conditions of the crops fed to the animals, etc. There are a lot of extension people in this room. Are you willing to go out and help with the verification? That is part of the big dilemma we face.

Epley: So, basically, it is easier to define and enforce minimally processed than it is organic.

Leddy: Yes. You can look at product formulations and ingredients and say, "Yes, this is or it isn't." Most of the time it is pretty clear cut. But when you start talking about things that go back to the live animal, and in the case of organic, back to the crops fed to those animals, and the soil for those crops, you are talking about a lot of verification and enforcement.

Epley: This is my last remark regarding organic. You said several states have rules and regulations regarding that. Are they designated states? If they are a designated state or if they have federal inspection, and you don't allow organic but the state does, can they produce it?

Leddy: I think some of them are designated states, but I don't know if all of them are. A product wouldn't be able to bear a label that used the term "organic" out of a Federally-inspected establishment.

J. Kemp: Why do you use the terms "lean" and "extra lean" interchangeably? It seems that is confusing.

Leddy: That is just for ground beef and hamburger.

Kemp: I know that; but it is still confusing to the consumer if one calls it lean and the other extra lean and it means the same thing officially.

Leddy: Well, we do have the percent lean and fat disclosed on the label but I don't have a real good answer for that.

Wise: I'm not sure I know the answer, but I don't think Kathy was there when they came up with the policy, which is part of the problem. However, I would guess that they went back and they found pretty much interchangeable usage at retail. We may get it clarified one of these days.

R. Henrickson: My question relates to cooked ham. We see hams labeled 25% added ingredients, 32% added, etc. Hams coming from out of the country just say "cooked in its own juices." Do these terms apply to imported hams as well as hams produced in the states?

Leddy: I think anything coming in has to meet the specifications or all of the requirements as rigidly as what we apply to our domestic products. I am really probably not the person you need to talk to about that kind of question, but I will be happy to get you to the right person. You might want to talk to someone in Foreign Programs.

Henrickson: What does it mean – "cooked in its own juice" – all of them are cooked in their own juice?

Leddy: Most of the ones I see are either with "natural juices" or "with water added," one or the other. I am not real familiar with what you are talking about but I am sure someone could help you with that.

John Carpenter: The term, "minimally processed," if you take a processed meat product and process it to 150°F, is that minimally processed? What about the one that is cooked

to 155? Is one natural and the other not?

Leddy: Cooking would be something that we would consider not more than minimally processed. The temperature doesn't matter. Minimal processing, things that are done to render a product safe or edible, are considered less than minimally processed and they would qualify for natural. Temperature wouldn't have any bearing on it. We are talking about things that would alter the product.

Carpenter: I don't think your definition tracks with the words that you are using. You are using minimally processed; that to me means processing at the lowest temperature, for example, that you could use. How do you keep one meat processing firm from saying my product is minimally processed because I only take it to 150°F and my neighbor can't call his natural because he takes his to 155°F.

Leddy: We wouldn't tell him that he couldn't use "natural" based on that. There wouldn't be any conflict between those two processors based solely on that information.

Carpenter: I guess my point is the term minimally processed, as you have defined it, is so broad that it doesn't really mean much.

R. Waldman: When we have to resort to going to a market-basket survey, how do you determine how much data is needed, and what kind of data?

Leddy: You have to go through one of the companies that does survey work and that is why it gets to be so expensive. That is why most companies prefer to get the data from a regulatory standard or a reference like Handbook 8 if they can. You have to find out who is holding at least 75% of the market and go out and collect samples and compare your product against those. We have to see the results from the survey company to insure that you have collected samples that represent 75% of the nation-wide market. I think some exceptions have been made when they can show they are only selling the product in a very close regional area.

R. Rogers: I would like for you to explain the part about dilution with water. I contest that with most cured products, the fat content is at least partially due to being diluted with water.

Leddy: When we get a label that has a lean or extra lean claim on it, we look at just the meat portion of the product formulation to determine whether or not the fat met the requirements before the addition of water.

Rogers: You mean it is not based on final product?

Leddy: No, not for water-added products. We carefully look at that. It would be the same for water-added emulsion type products.

W. Jones: In your animal production claims and producer testimonials, is this testimonial taken all the way back to the origin of birth of these calves? For example, if a feeder in West Texas is making these claims, do we get producer testimonials for the origin of the calves in Alabama?

Leddy: If the claim does not make any statement about, for example, "no antibiotics were used during the last 100 days in the feedlot," it means the claim has to be true for the entire life of the animal. If the feeder has multiple producers supplying him, he has to give us production protocols signed by each of those producers. They would have to substantiate that they are not using those drugs at all during the animal's life and if they purchased the calves, they would have to have information from that person as well.

C. Calkins: I'm afraid I got confused with your definition of minimally processed. It sounds as though items that we would traditionally classify as processed meats can still be defined as minimally processed. We talked about cooking, adding water, etc. So does the definition of minimally processed mean minimally processed beyond what the standard for that product normally is?

Leddy: Minimal processing includes those processes such as cooking, roasting, grinding, anything that would be used to render the product edible or safe for human consumption. Fermentation would be included. Processed meats run into trouble more with the "no artificial ingredients" part of the natural definition.

Calkins: For example, is ground beef considered minimally processed?:

Leddy: Yes.

Calkins: Can we make an emulsified product and label it "natural" and say that it has been minimally processed?

Leddy: Right. There are some natural hot dogs, for example, that do not contain nitrite. We would look at the ingredient statement and it will qualify for the natural label because it is "no more than minimally processed" and "contains no artificial ingredients."

Huffman: You mentioned claims for percent fat and percent lean on the label. How do you determine percent lean? Is it by difference?

Leddy: Yes, it would be by difference.

G. Hargus: Back to this other issue. It seems to me like along the way they were talking about traditional techniques and processes. Was that lost somewhere?

Leddy: With the natural? I think it has been expanded considerably since 1982.

Kropf: Would you venture to tell us with the addition of dietary fiber ingredients to meat products, what label complications there would be and what you see is going to happen in this area? Let's say we are adding formacellulose, regardless of the source, to bologna or ground beef.

Leddy: We do not permit the addition of fortification ingredients to the product. We permit ingredients to be used that are fortified, but we do not permit the direct application of things like fiber, calcium, to the product. The Agency has held the policy that meat and poultry products don't need additional fortification.

Kropf: I see a problem here because I think on the horizon there is a lot of interest in adding this.

Leddy: Right. There have been some suggestions made that the regulatory agencies should move toward making it easier for these kinds of products to come out of the industry. That may happen in the future, but the other has been the Agency policy. You can always propose something.

Kropf: How complicated will it be to fight that through or talk to you people until it might be changed?

Leddy: It's not hard to talk to us.

Wise: It's just hard to win.

Henning: I have a question on animal production claims. Are ionophores still going to be allowed under the new regulations?

Leddy: Under verified production control? I have no idea what is going to happen with that. But, I have had a ruling from FDA's Center for Veterinary Medicine that ionophores are antibiotics. So they would not be permitted under any

kind of "no antibiotic" claims.

Henning: Last year, the ruling was that they were not considered antibiotics because they only work inside the intestinal system. That was also from Royce Harr (FSIS, Science).

Leddy: I asked the Center for Veterinary Medicine for a decision and it was their ruling that ionophores are antibiotics.

Epley: I have one more question about natural. Are the artificial ingredients listed somewhere and those that are not artificial?

Leddy: Yes, there are some examples given in the Policy Memo. Any synthetic ingredient, vitamin and mineral enrichments, certainly any chemical preservative would be considered artificial.

Epley: Let me address that. Nitrite is an artificial ingredient but salt is not?

Leddy: Uniodized salt would be permitted.

Rogers: How about saltpeter? It is a naturally-occurring nitrite.

Leddy: I have never seen a request for that. If it was in the ingredients statement, we would turn it down.

V. Montalvo: I have a question on analysis. In order to get label approval for a "lite" label or something, you require three analyses for verification. Right? But then the product cannot leave because it does not have a label and the industry usually makes batches of 600 or 800 pounds. We have to make three consecutive lots but we cannot move the product until the label approval comes back to us. Is there another way this can be done?

Leddy: You have to have the minimum of three analyses, not necessarily on consecutive lots for the initial label approval. When you get into nutrition labeling verification, that is when you get into the 12 consecutive lots that have to be sampled. There are some situations where special approval might be given based on one analysis for pilot project product based upon the requirement that you come forth with more data for the final label approval. A temporary approval might also be given for a very short time period to make sure that the labeling claim is accurate. On a case-by-case basis, we sometimes get these types of requests.

Davis: Many of us in this room received a book from the National Academy of Sciences called "Designing Foods." I think on pages 104 and 105 they discussed natural, lean and lite. In the section on lite, they indicated that it was based on the carcass. In working with this, I only know of, I think, one company that was approved for about two months with the carcass. Would you clarify that, and if so, did you get to see the copy and how is USDA going to respond?

Leddy: I don't know where the author of that particular chapter got the information. It was surprising that some of the information they had was very up to date and right on target, but there were a couple of things, and that was one example, where they were totally out of line. We rescinded that kind of approval in August or September, 1986. We no longer will approve "carcass lite" or "carcass lean" designations. It goes for primals and retail cuts only. That was a mistake; and as far as I know, they did not ask any of us in labeling to review the chapter for our comments.

Carpenter: If I make a product out of red meat and fish protein, how can I label that?

Leddy: I'll have to put you in touch with someone on that. There is a lot of interest in this area, but it is not one I am working in.

V. Johnson: Are flavorings added to sausage considered natural?

Leddy: It depends on how they are identified. If they are just listed as flavorings, we ask to get more information. If they turn out to be something recognized as a natural ingredient, we would permit it.

J. Hodges: USDA and FDA have certain rules that differ in all of these label claims. If you were to make a general statement as to whether USDA or FDA is more restrictive, which would you choose?

Leddy: We are more restrictive in the area of natural because, as far as I know, FDA has no definition for natural. For lite, I think their requirement is one-third less fat which would be more restrictive. I believe on sodium we are pretty much the same. The thing that bothers me the most is that a lot of people go to FDA for all the information and they get FDA's regulations for things and forget that meat and poultry is regulated by USDA. So a lot of times there is misinformation in the media.

Hodges: I think you have hit the point that I was driving at. I think there ought to be some compatibility between FDA and USDA. We run into this all the time and I would hope that over the course of the next few years we would be better at that.

Naumann: Are oleoresins considered natural?

Leddy: No. They would exceed the minimally processed definition for natural. Only whole or ground spices, not oleoresins or extracts, would be permitted.

Wise: For comparisons with Handbook 8, can they pretty much pick and choose the comparisons they want to make? For example, could it be on either a raw or cooked basis.

Leddy: Comparisons must be made based on how the product is sold. If they are selling a raw product, the comparisons must be with raw product, unless they provide cooking methodology along with nutritional data derived from their cooked product.

G. Findley: For standards for lite, what happens if USDA Handbook 8 and a market-basket survey are in conflict? As an example, Texas A&M just recently completed its market-basket survey that shows that beef in the market today is about 25% to 27% leaner than it is according to Handbook 8. How would you resolve that conflict and what do people use in making their claims?

Leddy: At the present time, we are permitting the comparison to Handbook 8. Fortunately or unfortunately, there have been some big changes since that data was collected. It is something that we are aware of and looking into, but no decision has been made as to what we are going to do about it.

Fenniman: Do you know when you might be looking into this?

Leddy: In the very near future.

R. Terrell: In response to that, I don't see anything wrong with the approach of having the producer going out and define the market-basket survey group just like we do in industry.

Leddy: Right, that can always be done but it is a very expensive way of getting this information.

Terrell: They have a very expensive product to sell. They

can afford it. For those of you who don't remember, let me point out one thing. You need to understand that in the original inspection act of 1906, there was a clause that charged the USDA with prevention of misbranding and adulteration of food products, and that is essentialy how FSIS got in the labeling business. We are the only industry in the U.S. that is required to submit pre-market labels for approval before we market a product. The FDA does not operate that way. So, it is a little unique to the meat food industry that we operate that way. On behalf of your group (SLD), I would like to say that once you learn the system and work with the people, it is not frustrating at all. The problem is that most of you want to cheat. Most of you want that exclusive, non-competitive advantage.

Unknown: Would you define exactly what a market-basket survey is?

Leddy: There are companies that collect survey information. That is the real expensive part of this, acquiring that information, because the companies wanting label approval have to get data for all products that constitute up to 70% or 75% of the market. Once they have that information, they have to go out and collect the products, conduct the analyses, and of course analyze their own products for comparison. If there is any data in a reference source or a regulatory standard they can compare to, that is certainly what the companies would rather do. They must submit the market-basket information from the survey company to us at the time the label comes in for approval as well as the data from the analyses on the products.

D. Schafer: I have been aware of at least one instance, there may be others, where there was no identifiable other product in the market and there was a possibility of their establishing a standard and then, I guess, making another product that was 25% less than the standard. Is that possible?

Leddy: We are only permitting that now for sodium claims. I think it was permitted for other types of claims such as fat and caloric claims, but when Policy Memo 71 was issued in 1986, that comparison was rescinded although sodium comparisons were still permitted.

M. Dikeman: You indicated that in the future you plan to implement a verified production program.

Leddy: The regulation will be proposed in the *Federal Register*.

Dikeman: I am just thinking of examples like if someone wanted to claim that a product is pesticide free, herbicide free, residue free, etc. How far do you anticipate going with that kind of label?

Leddy: First, we do not anticipate ever approving any kind of claim that indicates that a product is free of some sort of potential problem such as residues. Although it may not have detectable levels or it may have safe levels of something, there is nothing to say that although it is undetectable, there isn't any there. Verified production control, I wish I could be real specific answering questions, but I have not seen the proposed regulation. I think it is with our office of General Counsel. In earlier drafts, it was a program designed to control the exposure of animals to residues and residue-producing chemicals. It does not necessarily mean that they can't use approved drugs in the rearing of the animal. There will be minimums that will have to be met, but producers may wish to go further. However, it will depend upon how the final regulation is written.

N. Webb: Can you give us the history of the 25% minimum rule? How did we come to have 25 rather than 27, 30 or 18?

Leddy: I believe they just determined that anything less than 25% would not be a significant reduction. It wouldn't be worth mentioning. You could say lower fat and it would be 5% less, and it just isn't worthy of drawing attention on the label for the consumer.

Webb: I know some people who don't agree with that.

Terrell: Part of that was the original Food and Drug ruling. USDA may have followed that.

Webb: They set plus or minus 20% as a variance, but they set a 25% minimum. Was this statistically done, or judgmentally or arbitrarily?

Leddy: I can't answer that.

Webb: I had one more question and that is what I would call a moving target. Someone gets a label approved on beef products that says it is 33% less fat, calories, whatever they want to claim, and they base it on the Handbook prior to 1986. Then a person comes along after 1986 and the level is not the same, and they cannot make the 25% claim. What is being done about the first person who got approval? For example, Choice beef is entirely different in the 1986 edition than the 1963 edition.

Leddy: When a Policy Memo comes out, it effectively negates everything that came before that. We no longer permit them to compare to the older handbook. They will be given a period of time to come into compliance. There is usually a statement in every Policy Memo that labels not in compliance will have a period of time to come into compliance or the label is rescinded.

T. Mann: What do you do to establish a certain method of measurement? For example, on a lite breading claim, would this be measured as percent pickup when it is still in the raw state or would you take the final cooked product and attempt to scrape it off? Do you determine the method?

Leddy: We don't really determine the method but it has to be conducted on the product as it is sold to the consumer. That would be the product as you are finished with it. The methodology, all we say about that, that in the case such as fat, it must be approved, such as A.O.A.C. or FSIS-approved methods, for fat determination. Although it is allowed, I have not personally seen a lite claim come in for breading.

R. Kelly: In the supernatural type products, you say that the producer has to establish the claims, there has to be carcass segregation, etc. Is live identification of the animal required?

Leddy: Yes, there has to be some method. It is usually included in their producer protocol that they submit to us about animal identification. If they also raise other animals that are not produced under the same conditions, they must somehow identify the animals and keep them segregated.

Kelly: What would happen if they insisted that they had just the one form of production? That is, they would only produce supernatural.

Leddy: They would have to state in writing that they do not have any other type of production. I don't want to mislead anyone and have you think that "supernatural" is an approved claim – that was a joke. We do not have any labels that say "supernatural," but we do have negative animal

production claims.

Kelly: I have one other question about this word lite spelled "l-i-t-e." Is that a word or is that an ad word for a beer-buzz commercial?

Leddy: I think it is an acceptable term for light to indicate that the product is comparatively low in one of those components, and we accept it if it's spelled lite, light, lightly, anything that resembles the word "light."

T. Flaherty: So I understand the procedure, let's take the example of the Swift Lite program. They are making the claims of 33% less calories or 25% less fat. Now the nutritional analysis was done on an uncooked product or, as you said, as sold at retail. If the market-basket for trimmed pork loins is a quarter-inch fat trim, they must take the loins and trim them closer than the industry standard, say to one-eighth inch, in order to make their nutritional claims. Is that correct?

Leddy: If that is how they are selling their product to the consumer. We don't care if they have to trim to arrive at those levels and then compare it to the data in the Handbook. We have no objection to trimming fat in order to reach their reduction as long as it is the way they sell their product. They can't just trim for purposes of label approval and then sell half-inch trim to the consumer. That is when the nutrition labeling verification procedure is used. The inspector in the plant would verify that they are following the procedures that had been approved through the regional office.

T. Bidner: How do you verify that the company is using the labels correctly? How does that process work?

Leddy: The inspector in the plant has control over the labels and they have the nutrion labeling verification procedure and they have to be following those procedures. The inspector won't permit the label to be used on the product or the product will be retained if the label is not being used correctly or if the label is going on other products that the company might produce. That is one of the reasons the inspector is there.

Bidner: If the product is retained, what happens to it?

Leddy: We get a lot of phone calls.

Terrell: I can help you out on that. If the product is retained for mislabeling, if you want to sell it at that price, you relabel it the right way. The best way to prevent mislabeling of product is to have your quality control organization in your plant believing that they ought to do the damn business right to begin with. And that is why you see fewer and fewer people in the meat business, quite frankly. Twenty years from now, you are going to see half the people you see in this room, probably.

D. Kinsman: In this same vein of thought, is the monitoring strictly visual or is there some backup chemical analysis, if you will?

Leddy: For these kind of claims? Yes, we require for any kind of fat claim that they have analyses and submit them at the time of approval to demonstrate that it did meet the reduction.

Kinsman: Do you survey this over a period of time?

Leddy: That is part of the nutrition labeling verification procedure. During the first year, the companies have to sample four times, a composite of 12 units. That is Level One. Then after a year of successfully meeting their labeling claims, the company can switch into Level Two which is annual sampling to verify the accuracy. The data is submitted through the inspector and eventually gets through channels to us, but we are mainly involved with the initial label approval and after that, monitoring really falls on the inspection people.

Schafer: The inspector is randomly sampling the products during that first year?

Leddy: The company is but they have to notify the inspector when they are pulling the samples. The company is totally responsible for this.

Schafer: Do you respond to complaints then, when someone out there might be thinking that this doesn't really meet the standard?

Leddy: Yes, we follow up on inquiries and complaints.

Nancy Webb: My comment was that you do prescribe the chemical analyses. The company may be responsible for having it done, but you tell them when it has to be done and how often to do the sampling. It is not something they have the freedom to do or not to do. I just want to be sure that everyone understands.

Flaherty: We have been talking about labels and nomenclature that are used in a Federally-inspected plant. What about at store level? There are a lot of labels that say lite, lean, etc., that are affixed on packages of product, maybe it is fresh, maybe it is processed, at store level. Do you have jurisdiction or compliance rules there?

Leddy: We do have compliance officers but the retail stores really fall under the state and local governments who have primary responsibility. What you are talking about, as far as we are concerned, falls under point-of-purchase materials and the kind of dilemmas that we are facing now with people bypassing label approval by going with point-of-purchase materials that may be affixed to the packaging. If it is point-of-purchase material, it is still labeling even though it hasn't come to us for prior approval. It does fall under all the provisions of the Meat Inspection Act, but it doesn't have to come to us for prior approval if it doesn't originate from a federally-inspected establishment.

Neil Webb: I understand that you have no jurisdiction unless the inspection legend is on the label, is that correct?

Leddy: I think we always have the authority if it is misused. Maybe Jim can help me out.

Wise: I think inspection is a little bit like grading, it is kind of a hope and a prayer half the time. If it is misleading or misuse of the term, we do have some authority, at least on the grade side under P.L. 272. They don't have to use grade terms, but if they are used, they must be used correctly on only graded product. I think it is a little bit the same for some other claims, but it is a real tough area when you think of all the retail stores in the country. You can probably walk into one in any part of the country and you are going to find something misused somewhere along the line.

Webb: This is an important point. We have researched it pretty thoroughly with FSIS and our interpretation was, that was given back to us, now this may not be right, if the inspection legend wasn't on the label there was not a thing they would do about it. It is up to the local people.

Leddy: It is up to the local people, but just because it doesn't have an inspection legend on it, doesn't mean that it isn't labeling. It just hasn't come to us for prior approval.

Wise: What Neil is saying is, on retail product, you have no authority if it is not carrying the inspection legend on the label

at the local level. Fresh product is where you really get into problems. I'm afraid Neil is probably right.

Terrell: The USDA General Counsel clearly stated that USDA has no specific jurisdiction over retail stores. The grading people do. If it is a misuse of the grade label, they can intervene. If it is a misuse of something that relates to FSIS, the General Counsel says no, you can't actively go in and do a thing, but you can go through your network to the state network or the health authority, etc., and pick it up.

Dikeman: Have you had any requests for other kinds of nutritional labeling, such as lower in cholesterol, higher in fiber, or lower in certain fatty acids, etc.?

Leddy: We do permit fatty acids to be declared as long as they follow FDA's proposed reg that is out on cholesterol labeling. We are following that as a format. Lower cholesterol would be a comparative claim. If they can compare to a product in Handbook 8, and meet a 25% reduction, they can make the claim. However, cholesterol claims cannot stand alone. They would have to put on all of the nutritional labeling I mentioned – calories, protein, carbohydrates, fat and cholesterol. They would not necessarily have to include the percent of the RDA's but they would have to have that much to support it. I think FDA is expected to come out with a final reg which may tie cholesterol labeling into some other required things, such as saturated or polyunsaturated fatty acids.

S. Shackelford: In reference to natural claims, how will we enforce these standards or claims at the producer level that people are making, such as no use of growth stimulants?

Leddy: Now it is verified by means of producer testimonials. How verified production control programs will work when it is published as a regulation, I really don't know. I think the answers will be there but I really don't know until I see the regulation.

Kinsman: From a philosophical standpoint, how far can we go with labeling? One, does it raise the seed of doubt in the minds of many, and therefore is damaging to merchandising? Secondly, do we have a knowledgeable enough consuming public to utilize this information?

Leddy: Do you mean how much information can we put on a label before we've gone too far?

Kinsman: Yes, from a practical standpoint.

Leddy: There are no restrictions if they can fit it on a label and it's not interfering with any required feature of the label.

Kinsman: That is not the sense of the question. How much information does the consumer have background knowledge to utilize in making a realistic selection? Secondly, when we say it is such and such in cholesterol, does this then raise the specter of doubt? Maybe they hadn't even thought of cholesterol until it was drawn to their attention.

Wise: Let me take the first half. I think we have people out there who are not knowledgeable enough to use all the claims, but we also have people who are knowledgeable enough and want the claims. I think we have to try and cover the whole spectrum. The second point, though, I think is a concern a lot of people have, particularly on the natural. By allowing natural on one, does it reflect badly on a large portion of the production that does not qualify for that particular label? Or, in fact, if they wanted to, they could put it on a large part of the production but it means very little.

Leddy: I really don't know how to answer that as far as going too far with the consumer. I think it is really hard to read the consumer and there is a need to find out what consumers really think about this. I know there is some concern among certain segments of the industry that something labeled "no antibiotics were administered to these animals" might make the product next to it, that isn't so labeled, appear unsafe. However, the Agency has maintained that these labeling claims should be permitted if they can verify that they are true.

Kelly: There are a number of people operating who are offering natural meat that is probably being sold through a custom slaughtering and processing person. It doesn't really come under inspection because it is custom exempt, and they are making claims such as "no antibiotics," etc., and you know that the animals are just being picked up at the livestock market and they don't know the background at all. There is no way of controlling that. Not only that, but they are charging a tremendous premium and people are really being misled just because of a sales promotion.

Leddy: If it doesn't come to us for prior approval, we have no way of knowing that it is there until we receive a complaint. If we do get a complaint, then we will follow up on it.

Schafer: In fermented sausage, I would assume sugar would be added. Would that be interpreted as non-natural?

Leddy: Yes, it would be prohibited because it is not considered a natural ingredient. The Policy Memo reads that neither the product nor any ingredient in the product can be more than minimally processed. It is a fairly restrictive definition for multi-ingredient products. Honey or raw sugar would be permitted. Salt is permitted because it is used in so many products as long as it is not iodized.