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I. Introduction.

Tyson Foods, Inc. is pleased to have the opportunity to respond to the Agency's public notice prompted by the petition filed by Hormel Foods. Our comments propose a re-definition of "natural" to meld current growing/processing techniques with good science and consumer perception; and suggest that definitions for "naturally raised" or "naturally processed" not be made a part of the current discussion and proposal.

Our position is a product of several considerations, each of which and *in toto* we believe represent principles upon which all can agree: since regulatory proposals are designed to codify public health matters for the greatest good, they must be based upon protecting public health through "good" science first and "public perception" second. Further, it is necessary that regulatory standards based upon public health concerns not be so restrictive or so phrased that the public negatively perceives and avoids otherwise good quality, healthy, and safe food products which do not qualify for the subject definition.

There can be no doubt that Policy Memo 055 (the "Policy") has functioned admirably to bring a sense of order to "natural" claims for the past twenty years – particularly since the Food and Drug Administration and the Federal Trade Commission were unable to reach a consensus even with significant stakeholder input. In our view, the Policy was appropriately premised, twenty years ago, on "Grandma's kitchen". At that time it seemed accurate to use the basic concept that if Grandma didn't know about it, if it wasn't intuitive, then it wasn't *natural*. However, our nostalgia for a simpler time – the good old days when Grandma used only what was commonly available – does not meet today's growing/processing and product distribution needs.

The Policy provided the basic "level playing field" which could be modified by a case-by-case, pre-market, prior approval process of labels. Exceptions and refinements to the basic definition have created anomalies that disallow a "natural"

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claim because an ingredient considered "natural" for flavoring was deemed "unnatural" if used to add color ("artificially") to the product. Case-by-case analyses and rulings have created uncertainty and inequality, and have progressively led us to the point that we have surely, albeit unintentionally, left our bedrock definition of "natural" behind us in our thinking and in practice.

We agree with the Agency that it is time to re-visit "natural". Over time there have been exponential improvements in processing techniques and analytical detection methods; general improvement in the ingredients, nutritional quality, and wholesomeness of foods; and growing consumer attention to and awareness of processing methodology and technology. However, we believe that unless a firm foundation for "natural" is laid down, in words and concepts clear to all, case-by-case analysis will creep back into the system and we will, within another few years, be here again discussing how to re-define "natural."

II. Policy Memo 055 was intended to keep pace with advancing thought and technology, but has not kept up with changes in processing, product safety, or consumer perception.

a. The times they are a-changin'

There may be no more compelling comment calling for reconsideration of the current definition of "natural" than the comment made by a presenter in Washington last December 12, that "producers supplying . . . cattle raised to protocols we have developed far exceed the current definition of natural." How is that possible? More natural than *natural*?[1] The overarching and critical concept in the quest for "natural" must be safety of the product through good science and a definition that the public understands. In Section IV below, this comment discusses the results of a significant consumer survey project undertaken to assess the current perceptions and understanding of "natural" in the marketplace.

It was the original intent of policy memos that they be periodically announced in the Federal Register, otherwise the process would remain forever subject to case-by-case rulings that make uniformity difficult to achieve and foreclose the opportunity for notice and comment among experts and stakeholders. Time and technology compel us in 2007 to re-visit the concept while also challenging us to not again offer a definition that contains the seeds of its own destruction. ("Those who do not learn from history are doomed to repeat it." George Santayana)

Focusing on a two-part definition, the Policy is a snapshot in time that did not consider all the options available then or predict those available now. Because there was no proposal and comment period, there is no history to explain why certain definitions were initially accepted and others rejected, or even whether they were considered. And by allowing a case-by-case analysis, the Policy has allowed a mutation of the underlying concept over time, again without an effective means of public or expert comment and even more critically, without communicating decisions and rationales to persons other than the label submitter and the expediter as to why a

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[1] *"Naturally Raised Livestock and Meat Marketing Claim Listening Session"*, December 11, 2006, page 35.

new ingredient or process (and recently, even previously approved ingredients) are or are not permitted under the Policy. The language of the Policy has remained unchanged while changes in the practical application of the Policy and definition of "natural" have occurred without an official approval or notification process.

b. <u>The voluntary claims conundrum</u>

Marketers and producers cannot be criticized for voluntary claims calling out the absence of those ingredients or residues the public perceives negatively; however, the result is a growing public demand for promoting exclusion – tell us what is not included or not permitted. Products which do not make the desired exclusion claim are perceived negatively, driving the use of claims in a fashion which creates confusion and a sense of false uniqueness or consumer safety, i.e., "no hormones" claims are called out on the labels of products which are precluded, by regulation, from using hormones and then the claim is qualified as prohibited in fine print as a footnote.[2]

The failure to deal adequately with voluntary claims in labeling has also contributed to the blurring of the line between label claims related to product safety/quality and those which attempt to codify evolving consumer perception - a perception that may not always be based correctly on safety issues, or worse, may lead to mistaken safety concerns for product that is truly safe. Unfortunately, through the use of negative labeling claims or labeling schemes which often originate merely to placate the concerns of a limited interest group, FSIS has allowed alternative production practices and techniques to be perceived in the negative or as unsafe or unhealthy. These concerns cannot be dealt with fully by a re-definition of "natural" but must be dealt with in a subsequent AMS review of "processing" and "naturally raised" claims.

c. <u>Accentuate the positive, eliminate the negative</u>

Because voluntary claims such as those describing livestock care and handling practices are indeed voluntary – they have prompted and even encouraged the use of "negative" labeling claims for support. Negative both in terms of "no ..." but also negative in the implication that other products are not as healthy or not as safe for consumers. A consumer perception has thus been allowed, by neglect, to evolve into a safer, healthier, "better for you" implication.

USDA/FSIS should be very careful that its black letter rulemaking not stake out an official government position on issues of public perception where reasonable minds can differ. Otherwise, the labeling branch will establish and further a "negative" perception for which there is no basis in good science. It is clearly not the role of a regulator to reinforce unsubstantiated and negative concerns about health and safety. *In doing so, the USDA/FSIS runs the risk of undermining the public's sense of confidence in the Agency's ability to make decisions based upon and backed up by*

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[2] Study respondents who identified themselves as users of fresh chicken and pork were asked whether federal regulations allowed the use of added hormones and steroids. 60% pf the chicken users and 59% of the pork users didn't know, and an additional 34% of the chicken users and 35% of the pork users answered "yes" incorrectly, indicating a 94% lack of accurate knowledge.

good science. When drafting regulations to establish required or permitted label claims, regulators must examine the possible interpretations and implications of the approved claims so that product safety-related claims remain consumer perception neutral. Regulators should not create a claim important to health and safety which implies a health, safety, or emotional negative. In addition, as will be discussed in greater detail below, recent court cases caution any regulatory agency that its definitional authority in the areas it regulates can be held to go too far if it does not allow for appropriate qualifiers.[3]

III. Focus of a new "natural" definition must be to codify a general understanding of the term; regulators have historically not performed well in educating consumers to the meaning of terms.

The Nutrition Labeling and Education Act (the "Act") made dramatic changes in food labels, taking certain words out of the general lexicon and giving them specific meanings intended to increase information and the utility of information. Noting that the "E" in NLEA stands for education, legislative history clearly indicates that successful implementation of the Act would require educational programs from FDA and the industry to teach consumers the definition of now precisely defined terms: *fewer, reduced, high, low, free, zero* and others. Consumers were also to be educated as to how best to use these descriptors to make informed choices about a healthy diet regimen. There may be no adequate way to assess whether or not the government and industry working together have met their education obligation, but the Center for Science in the Public Interest (CSPI) has been vocal in its criticism of the effort.[4]

A study by Balasubramanian and Cole, "Consumers' Search and Use of Nutrition Information: The Challenge and Promise of the Nutrition Labeling and Education Act", reported in the Journal of Marketing (July 2002, pp. 112-127) suggests that NLEA has had mixed results; increasing awareness of negatives while lessening attention to health attributes. But most significantly for this discussion and in line with the view of the CSPI, consumers evaluate claims heuristically, i.e., in a common sense manner, and are far less likely to read the facts panel for in-depth information than claims. The study lends support to the CSPI's call for more concise, easily understood, front-of-the- package information.

This further suggests that regulators should be very careful when seeking to express the meaning of a term beyond the consumer everyday meaning – most consumers just aren't going to understand usage outside the common parlance. This reality argues for definition of a well-thought-out, functional, popularly acceptable meaning sufficient to convey the regulatory message. An attempt to create a new, broader definition requiring consumer education or USDA public service announcements is not going to be successful. Consumers don't access or don't understand the message. *And in the intervening time, concepts of negativism may*

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[3] See *Pearson v. Shalala* and *Whitaker v. Thompson*, discussed in Section VI.c below.

[4] See: The Center for Science in the Public Interest ("CSPI") *"Petition for Advance Notice of Proposed Rulemaking . . ."* to propose a rule *". . . on the Use of Symbols on the Principal Display Panel to Communicate the Healthfulness of Foods"* (11-30-06)(no docket number assigned).

creep into the public definitions causing otherwise good product attributes to be turned into negatives once again.

IV. A new definition of "natural" must be developed which codifies good science, public health and safety, consumer perception and accepts the reality that "processing techniques" are better described by label qualifiers than pre-market regulatory absolutes.

a. The need for a principled definition

The General Principles for Food Standards (*70 Federal Register 29214 (5/20/05)*) describes four guiding principles for a "food standard petition." While the agencies may not have had the issue of "natural" and FSIS in mind at the time, the principles nevertheless apply. Food standard petitions must: (1) protect the public; (2) describe the basic nature of the food; (3) incorporate the essential characteristics of the food; and (4) not make the food appear greater or less than comparable foods, or foods with similar ingredients (emphasis added). Unfortunately, over time "natural" has become a term of "better than" when foods which are not entitled to carry the "natural" claim are just as "safe" (or even safer) and of as high a quality as food which qualifies to carry the term. In its re-definition of "natural", FSIS must present a definition that is health and safety neutral and based upon good science.

b. A refined definition of "natural" must focus on what consumers understand

Tyson Foods, Inc. recently sponsored a Monadic Quantitative Internet Study fielded by Marketing Research Services, Inc. (MRSI), an independent research organization, using a large national survey population (3,601 total respondents; assessing all respondents on some queries as well as individual cells of 600 respondents each), the Tyson Foods Natural Labeling Study ("TFNLS"). A description of the study protocol and significant findings and learning follows.

TYSON FOODS, INC. NATURAL LABELING STUDY
Study Methodology and Respondent Criteria

This study was designed as a single-cell definition evaluation, conducted via the internet in February 2007. A nationally representative sample of consumers was first screened for qualifications. To participate in this research, respondents were required to meet the following qualifications:

- Female (75%) / Male (25%)
- 21-64 years of age
- Purchased a form of chicken, beef, or pork at least once every two to three months
- Not food company employed (a company that is involved in the manufacturing, processing or distribution of food products) or industry employed (USDA or FDA)

Upon qualification, consumers were exposed to only one labeling concept (both a written definition and a representation of the packaging using fresh chicken as an example) and asked to evaluate it by responding to a set of questions. Each concept was tested among 600 consumers. In addition, some of the questions were asked to a broader sample of consumers (3,601) and if applicable, this has been noted in the research findings.

Learning Relevant to the Current USDA Natural Definition

Respondents were provided the current USDA-based definition of natural and were probed as to their understanding of this definition:

> Chicken, beef, or pork products that have no artificial flavoring, coloring, chemical preservative, or any other artificial or synthetic ingredient. Product may be minimally processed and contain added ingredients, enhancements and marinades, provided that they are also deemed natural. (For example, fresh chicken may have a natural lemon herb seasoning.)

- Only 22% responded that the current definition fit "extremely well" with how consumers want natural to be defined.

- When asked about which words or phrases in the definition they did not understand, 28% of the 600 consumers questioned said they did not understand at least part of this definition.

- There is little consumer understanding around the term "minimally processed", supported by the fact that 79% of consumers demonstrated they do not know the meaning of minimally processed.

- When made aware of the current USDA definition of "minimally processed", 60% of consumers stated that it either would not affect or would negatively affect their decision to buy a natural chicken, beef, or pork product. Thus, even if made aware of the existing definition, the majority is not impacted or is impacted negatively.

Learning Relevant to a Proposed Definition of Natural

Respondents were asked to consider a proposed definition of "natural" and were probed as to their understanding of this definition:

> Chicken, beef, or pork that has only a single ingredient – chicken, beef, or pork, or chicken, beef, or pork products that contain all natural ingredients. (For example, fresh chicken may have a natural lemon herb seasoning.) If the product includes all natural ingredients, those added ingredients would be listed on the package. Product has no artificial ingredients and no preservatives.

- 96% of consumers reported "understanding all or most" of the proposed natural definition.

- 91% of consumers found this proposed definition to be "completely or somewhat acceptable" for a natural definition for chicken, beef, or pork products. 3% of consumers found this definition to be "somewhat or completely unacceptable."

- 78% of consumers said this proposed definition "fits extremely well or fits well" with how they would want natural to be defined.

- 32% of consumers said this proposed definition fit "extremely well" with how they want natural to be defined compared to only 22% of consumers who responded that the current definition fit "extremely well" with how they want natural to be defined – a statistically significant difference at the 90% confidence level.

- 61% of consumers stated that the proposed definition would make shopping either "much easier or somewhat easier." Less than 2% of consumers said it would make shopping "somewhat harder or much harder."

Respondents were asked about the acceptability of products labeled as "natural" that contain natural ingredients and natural preservatives.

- ***Acceptability of the presence of natural ingredients***:
  The majority of consumers found it "acceptable" for some natural ingredients to be added to products and still be labeled /called natural. Specifically, these include broth, water, natural flavors, natural coloring and malted barley, with consumers scoring individual acceptability as high as 76%.

- ***Acceptability of the presence of natural preservatives***:
  The majority of consumers found it "acceptable" for the following ingredients functioning as preservatives to be added to products and still be labeled/called natural: salt, sea salt, concentrated celery juice, concentrated lemon juice, sugar and vinegar, with consumers scoring individual acceptability as high as 64%.

Respondents were asked about requiring a standardized list of natural ingredients.

- 88% of consumers responded that the government should publish a list of ingredients that it considers natural and are approved for chicken, beef, or pork processors/producers to use. Clearly, consumers are looking for an authoritative source – an indicator of consumer interest in "natural" labeling.

V. Natural Ingredients.

As discussed above and documented by the TFNLS, there is a demonstrated need for a clearly defined, standardized list of "natural ingredients." Growers, producers, manufacturers and consumers need consistency and this is the perfect opportunity for the industry and regulators to step back and create just such a list, which this commentator proposes as **GRAN (Generally Recognized As Natural)**. After a petition is filed and a safety and suitability review conducted (as used for GRAS petitions),[5] substances would be approved as "natural ingredients" by FDA and FSIS with the advice of a commission modeled on the NACMCF (National Advisory Committee on Microbiological Criteria for Foods) and the NACMPI (National Advisory Committee on Meat and Poultry Inspection). *The new NACGRAN would bring the perspectives of academics, scientists, producers, manufacturers, growers and consumers to the approval process and provide balance and transparency to the final decisions.*

A GRAN substance would not be subject to the possible "sometimes is, sometimes isn't" categorization that exists today. Once approved and entered on the GRAN list, the approved substance would be acceptable as "natural" for all uses. This standardization will allow a focus on innovation that has been inhibited by the industry being unable to reliably predict label approval of an ingredient, whether new or previously approved.

The GRAN process would also serve to eliminate confusion and frustration as to why evaporated seawater salt is "natural" but salt mined from the ground is not "natural". Or why either lemon juice or vinegar is "natural" unless it functions in whole or in part as an antimicrobial. Given that food safety is a primary concern and goal of the Agency, and lemon juice and vinegar can be used to inhibit deleterious organisms, why perpetuate an unnecessary and even dangerous distinction? Wouldn't those who prefer "natural" also prefer a "natural" microbial rather than a synthetic one? The current definition penalizes food safety needlessly.

VI. Concepts of "minimal processing" or "naturally raised" should not be part of a definition of "natural."

a. The current definition of "natural" includes a concept of "minimal processing." Perhaps more than any other concept, this is the part of the definition which causes the most difficulty. In the TFNLS, fully 79% of respondents demonstrated that they did not have an understanding of the term "minimally processed".

The TFNLS probed consumer awareness of "minimally processed". When made aware of the current USDA definition of minimally processed, 60% of consumers stated that it either would not affect or would negatively affect their decision to buy a natural chicken, beef, or pork product. Thus, even if made aware of the existing definition, the majority is not impacted or is impacted negatively.

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[5] See: http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/7120.1_Amend_8.pdf.

From a technological standpoint, attempting to identify acceptable natural or minimal processing techniques is one of those unwanted seeds of destruction we all wish to avoid here. Processors and manufacturers cannot predict the technology changes the future will bring, and cannot devalue investments made in developing new, improved or unique processes by making them public in the rulemaking process. However, if we adhere to a consumer-driven standard, the common sense definition, then the processing or growing standards the consumer finds acceptable will control and the regulators can remain hands-off the technology. Experience shows that consumers will not accept irradiated, unlimited shelf-life product as "natural" – it is quite simply a market issue, not a regulatory issue. The TFNLS showed that the purchase decisions of 60% of respondents were not affected by issues of "minimal processing." *Clearly then, "processing" claims and label schemes which are not related to product safety must be driven by the market and not controlled by regulation.*

b. Consumer research, as well as history, shows us that attempts to define "naturally raised" and "minimal", et al. (as growing or processing terms) do not fit with this "natural" rulemaking. The companion study to the TFNLS found that "naturally raised" has no standard meaning for fresh chicken, beef, or pork in the mind of consumers. When asked to define the term in an open-ended question format, there was no single definition/claim cited by a majority of consumers.[6]

Because both "naturally raised" and "minimal" fail the common understanding test, they are not properly considered here. "Naturally raised" may be subsumed by "certified" protocols and processing should be controlled by the marketplace. In any event, both should be examined separately and later.

c. "Process" claims can be made appropriately on a label using generally understood qualifiers and disclaimers. Where there is significant agreement for claims, FDA has established the meaning of claims or has promulgated the means by which significant agreement can be obtained. One need look no further than the worthwhile progress made since the enactment of the NLEA or the DSHEA (Dietary Supplement Health Education Act). When there is not significant agreement, the series of cases begun with *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999) and *Whitaker v. Thompson*, 248 F. Supp. 2d 1 (D.D.C. 2002) make it clear that qualifying language, disclaimers and the like can be introduced on labels to explain, qualify, or limit a claim that otherwise would be misleading standing alone.

The same rationale is easily applied to "process" claims which are not safety related but express consumer preferences and perceptions. FSIS cannot place itself in the position of establishing a singular definition of "processing" or "process" where additional language, qualifiers, or even disclaimers can be used to avoid or cure any potential consumer confusion. FSIS has gone on record in earlier proceedings which discuss label claims that it does not object to factual statements on the labeling of

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[6] Concurrent with the Tyson Foods Natural Labeling Study, your commenter sponsored a companion study to assess issues surrounding consumers' understanding of "naturally raised" and similar claims. The results of that survey will be included in subsequent comments to the AMS.

meat and poultry products.[7] Producers will have a choice of using the definition of "natural" developed and promulgated as a result of this rulemaking plus any "processing" claim with appropriate descriptors or qualifiers that will pass the test of market acceptance and regulatory review.

Because process claims are easily the matter of label copy, subject to review by regulatory agencies under existing authority and by consumers, they are not appropriate for a notice and comment rulemaking by FSIS as to their effectiveness or utility. Certification procedures are also available to those who wish to avail themselves of that labeling protocol. But if the claim is made, producers should be required to place the basis or certification of the claim on the label. Process claims are a perfect arena for competitors to innovate and express their product improvements. Consumers are free to hear the claim, assess the basis of the claim, and make a personal decision whether or not to purchase. Process claims do not require governmental review and approval in advance. By way of further example, where product claims are not safety or health related, as in structure/function claims, FDA has not intervened to define or review claims in advance, opting for appropriate cautionary language that the claims have not been evaluated or approved by FDA. *Similar government non-involvement is appropriate where the basis of the claim is stated, no safety concerns are raised, and consumers can make their own informed choices.*

VII. Conclusion.

Based upon the foregoing, we propose to the FSIS a two-part definitional rulemaking as follows:

NATURAL:

Chicken, beef, and/or pork with no added ingredients

OR

Chicken, beef, and/or pork products that contain only **all natural ingredients**

- Product may be manufactured utilizing "processing aids" as defined under FDA. (Processing aids are substances which have a momentary technical effect and not a lasting effect on the treated food.)[8]
- Natural ingredients which also have processing aid effect would be permitted so that "natural" product remains safe through handling.
- Only ingredients qualifying as GRAN would be permitted.

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[7] "Food Safety and Inspection Service (FSIS) Statement of Interim Policy Guidance", United States Department of Agriculture, October 14, 2005.

[8] See: http://www.cfsan.fda.gov/~lrd/CF101100.HTML.

ALL NATURAL INGREDIENTS:

- Non-protein substances which qualify as "natural" by the GRAN process.
- Examples of natural ingredients are salt, sugar, distilled vinegar, concentrated lemon juice, chicken broth, etc.
- "**No Artificial Ingredients**" would describe a product of all natural ingredients which would not otherwise qualify as "natural" with no added ingredients.
- Any additional moisture which is retained as the result of post-evisceration processing in excess of naturally occurring moisture must be prominently declared on the label as is currently required; however, would still qualify under the "All Natural Ingredients" definition.[9]
- Products with artificial ingredients (not GRAN), including artificial preservatives, cannot be labeled "natural". Natural preservatives would fall under the "No Artificial Ingredients" statement and would require no further call out.

Tyson Foods, Inc. encourages the Food Safety and Inspection Service and the US Department of Agriculture to re-define their regulatory definition of "natural" and "natural ingredients" as outlined above. We believe the language and concepts are scientifically sound and consumer friendly (as supported by the TFNLS consumer data). These proposals would continue to insure a wide range of safe, wholesome meat products labeled to encourage informed consumer choice and market appeal while maintaining a level playing field of vigorous competition among producers to satisfy an ever-changing consumer demand.

Respectfully submitted,

TYSON FOODS, INC.

Richard L. Bond
President & Chief Executive Officer

[9] See: http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/6700-1.pdf.