USDA Regulatory Update for Partially Defatted, Finely Textured and Mechanically Separated Red Meat Products

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The question of which components of animal carcasses can and cannot be recovered and labeled as "meat" (or, more specifically, by the name of a specific species such as "beef" or "turkey") is of critical concern to virtually everyone in the meat and livestock sector. Logic would suggest that our industry would share a common understanding of such matters so that all of its members can go on about their business. To my knowledge, for example, there is not much confusion on the assembly lines in Detroit or Yokohama as to what is and is not an automobile, nor do I suspect that there are conferences of food scientists who will gather to debate what is and is not a cauliflower or watermelon.

In the meat industry, however, we have just such a problem as we find ourselves at a confusing, but potentially promising juncture - at the end of two decades of confusion and indecision over the parameters of the definition of our basic product. My objective today is to provide you with some historical background on the roots of this confusion, and discuss a possible framework for its resolution.

I would hasten to emphasize the obvious - that I am not a scientist. As such, my ability to fully discuss and evaluate the purely technical dimension of this issue is limited. I would also add, however, in deference to my friends in the scientific community, that in most respects, confusion over the definition of meat has never been and nor is today primarily a scientific issue. To the contrary, it has been engulfed in the mysteries of law and politics, and in the often mundane detail of the administrative decision-making process. Without doubt, we all would all be better off if the bulk of this issue could be extracted from this context and resolved and on something closer to a purely scientific basis. For this to occur, however, a proper foundation for both understanding and working within the current regulatory system must be laid.

Definition of Meat

We would do well to start at the beginning and examine USDA's core statutory responsibility in this area. Meat and poultry products are regulated by USDA in accordance with the requirements of the Federal Inspection Act[1] and the Poultry Products Inspection Act[2]. Parallel language in these statutes provides the Department with the ability to take action in various ways against the product which is adulterated under the terms of these Acts or, more significantly for the purposes of today's discussion, "misbranded." Product is misbranded if, among other things, its labeling is false and misleading in any particular.[3]

In addition, the Department is provided with the authority to prescribe definitions and standards of identity for various meat and poultry products when it concludes that this would be in the public interest.[4] Finally, USDA maintains a highly specific system of control over product formulation and labeling through continuous inspection itself,[5] and also, through its maintenance of a prior label approval program. This is in contrast to marketers of FDA-regulated foods, who reach their own conclusions about compliance with FDA labeling and other requirements, implement their own decisions and, if incorrect, assume some level of enforcement risk. The marketer of a USDA-regulated meat and poultry product is required by regulation to provide detailed formulation and processing information to the agency on a product-by-product basis, supply proposed labeling and abide by the agency's decision to approve or disapprove the label in question.[6]

Any processor who is attempting to determine whether his product is in fact meat and can be labeled as such will start with a reference to the general definition of this term, supplied by the meat inspection regulations. This definition provides, in relevant part that "meat" is:

> The part of the muscle of any cattle, sheep, swine, or goats, which is skeletal or which is found in the tongue, in the diaphragm, in the heart, or in the esophagus, with or without accompanying and overlying fat, and the portions of bone, skin, sinew, nerve and blood vessels which normally accompany the muscle tissue and which are not separated from it in the process of dressing. This does not include the muscle found in the lips, snout or ears.[7]

While this language may provide definitive guidance to the disappointed purveyor of pig lips, it does not take a law degree to see that this definition perhaps leaves more questions unanswered than answered. What more specifically are the

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Reciprocal Meat Conference Proceedings, Volume 46, 1993.

[1] 21 U.S.C. 601 *et. seq.*
[2] 21 U.S.C. 451 *et. seq.*
[3] 21 U.S.C. 610, 601(n) (1), 21 U.S.C. 458, 453 (h) (1).
[4] 21 U.S.C. 607(c), 457(b).
[5] 21 U.S.C. 604, 605, 606, 21 U.S.C. 455.
[6] 9 CFR 317.4, 381.132.
[7] 9 CFR 301.2(rr).

portions of bone, skin and sinew which "normally accompany" muscle tissue during dressing? What of product is separated by non-traditional techniques such as mechanically deboning or low-temperature rendering? This regulation and, up until the mid 1970's, the rest of the meat inspection regulations, were silent on these points.

Within the FDA system, the manufacturer or food processor would be left at this point with a decision to make. He would hold his product up against the regulations, consult with any technical, legal or other experts as he deemed appropriate, and come to his own conclusion as to compliance. If, at some later date, FDA believed that he had come to a wrong decision, and was marketing misbranded product, the agency could inform him that his product was considered to be misbranded. He, in turn, would have the option of agreeing and adjusting to accommodate FDA, or alternatively, challenging the agency and requiring it to establish that his product was, in fact, labeled in a manner which is contrary to law.

Prior Label Approval

The USDA processor travels a different route. On such questions, the prior approval system requires him to square the issue with the USDA. One can reasonably debate the relative merits of this system. Arguably it entangles the agency in a good deal of administrative trivia and absolves the industry of a basic compliance responsibility. Arguably, it also does a better job of assuring consistency and protecting the consumer. Under any circumstances, one advantage of the program to the manufacturer or proponent of a new or innovative product is the ability to ultimately get USDA to make a clear ruling, generally within a reasonable time frame, and if not eliminate, at least substantially lessen, any future enforcement risks. It is difficult, to say the least, for USDA to determine that a product's formulation and labeling are acceptable, and then turn around at a later date and determine that it is misbranded.

Both the pluses and minus of this system were confronted by the processors and equipment manufacturers who began to experiment with mechanical meat deboning techniques in the late 1960's and early 1970's. Unlike their counterparts in the fish processing business, for example, they could not simply experiment with the technology, settle upon terminology such as "minced fish" ("minced meat"?) and go on about their business. A more direct process with USDA was required and was in fact undertaken and during this period, there was considerable discussion with USDA, review of equipment and presentation of data. This was all geared toward persuading the agency that the mechanically deboned product in question was, in fact, legitimately classified as meat, and should be labeled by a species name such as "beef" and "pork." This burden was carried, label approvals were issued, and, by 1975 a healthy, growing trade in this new product was established. This trade was anchored in the commitment from USDA that in the agency's best judgment, the product was properly labeled.

Under normal circumstances, this might be the end of the story. And in fact, for thousands and thousands upon thousands of meat and poultry products, this is the end of the story. Unfortunately, for mechanically deboned meat, and, as we shall see, for the broader universe of other meat products prepared with alternative technologies, this was not to be.

Regulation of Classes of Meat

Problems originally arose in the context of a well-intentioned effort by USDA, initiated in 1975, to establish a comprehensive framework for a wide variety of new, non-traditional meat products. USDA began work on its so-called "classes of meat" regulation which in effect, attempted to update and elaborate upon the broad, all-purpose definition of meat cited above. It was not simply designed to address mechanically deboned products but also attempted to comprehensively resolve questions surrounding analogous products such as low-temperature rendered items and various by-products. The goal was not to simply classify all such items as meat, but to make distinctions through mechanisms such as composition and specific product standards limitations, to provide a system for appropriately pigeon-holing this entire spectrum of products. Its details aside, it was a worthwhile effort and, had it succeeded, might well have provided a valid framework for future issues of this nature.

It did not succeed. The regulation that was proposed in 1976 was never finalized. Its fate became tied with a more specific mechanically-deboned meat issue, ultimately to everyone's detriment. At the time the regulation was originally being developed, it came under review, as all such regulations do, within USDA's Office of General Counsel. As is normally the case, questions and concerns arise within such reviews and are discussed and debated between lawyer and client. One of the issues which surfaced during this particular review was the current status of mechanically deboned meat. When it learned that current agency policy was to permit the use of such product, the General Counsel expressed concern that the agency was prejudging the issue. How it asked, could the agency possibly be proposing regulation of mechanically deboned meat in a certain fashion, subject to public comment and possible revision if it had already committed to a course of approvals through its label approval process? To remedy this problem, the General Counsel recommended, and the agency adopted, the plan of publishing, contemporaneous with the overall proposal on classes of meat, a so-called "interim final rule" advising the public that the agency had determined that current usage of mechanically deboned product and its labeling as meat was acceptable, but making such approval subject to change based upon future public comment.

In retrospect, this was advice that neither should have been offered nor accepted. To the contrary, the Department could have, and should have stood its ground on the validity of the case-by-case decision-making which is inherent in the prior approval process. The agency should have said that it had made these judgments as it always did, based upon the best available data as supplied by the labeling applicants, but that it was now interested in elevating these decisions into regulations and seeking broader public input. By publishing the so-called interim final rule, however, a perfectly legitimate piece of agency judgment was turned into the very thing which USDA was attempting to avoid - a prejudged regulation. By publishing the interim final rule, the agency hung the equivalent of a "kick me" sign on its previous approvals for mechanically deboned product.

Litigation, Regulation, Litigation, Regulation....

Consumer interests obliged by kicking. They brought suit in 1976 in the United States District Court for the District of Columbia alleging that, through publication of the interim final rule, the agency had inappropriately prejudged the issue. The Court agreed with this line of reasoning, enjoining continued production of this product unless and until the agency completed rule making necessary to properly evaluate the use of the product.[8] This opinion is often mischaracterized by various individuals, including USDA representatives, as a definitive legal finding that the product was not "meat." This is incorrect. What the court said was no more and no less than that USDA had not engaged in the procedures necessary to make a reasoned evaluation of this question.

After convening an expert panel to evaluate the product, the agency proceeded with its regulatory process. Significantly. the 1976 election returns had intervened and some of the same individuals who had led the challenge to the previous mechanically deboned regulation were now occupying policy-making positions in the Department. The result was the initial publication of a proposal in 1977, which would have required industry to characterize the ingredient as "tissue from ground bone" and include, on the labeling of any products in which the product was used, a specification of the product's powdered bone statement contiguous to the product name. Industry resistance was as strong as it was predictable, and the Department was persuaded that, at least, the "tissue from ground bone" ingredient designation was excessive, settling on the more prosaic "mechanically separated (species) product." Despite this adjustment, all of the additional paraphernalia surrounding the regulation was sufficient to effectively eliminate domestic trade in the product.

By 1980, another election had taken place and the Reagan-Bush era of deregulation was upon us. Changing the restrictions on mechanically deboned product was near the top of the list, and in fact was identified as a priority item in a deregulatory task force by then Vice President George Bush. The result was the publication of a new regulation in 1982[9] which moderated regulation of the product by eliminating the product qualifier requirement and eliminating the term "product" from the designation of the ingredient. As a result, at the end of the proceeding, a manufacturer who produced mechanically separated pork in accordance with the parameters of the standard was required to do no more and no less than state the term in the ingredient statement of a finished product.

Another legal challenge unfolded, this time from the consumer side, but the regulation was ultimately validated in the courts. It should be noted however, that this support was less than overwhelming. In his opinion on appeal, Judge (now Supreme Court Justice) Antonin Scalia characterized the labeling scheme as "minimally informative" and observed that the case allowed the rare opportunity to observe both sides of Bismarck's famous aphorism that one should not observe the making of either laws or sausages.[10]

For whatever reason, the meat industry has, with few exceptions, refused to take USDA up on this renewed offer. Despite considerable investment in the product and in its supporting technology, USDA's essential conclusion that the product, if properly labeled, is perfectly safe, and, ironically, despite the government's characterization of the 1983 effort as a successful piece of deregulation, the production and marketing of what is now to be called "mechanically separated meat" is still virtually non-existent.

Discrepancies In Meat and Poultry Regulation

Without question, a major factor behind industry reluctance to embrace this ingredient is the disparate treatment afforded to its poultry counterpart. Product which is known in the trade (and the trade alone) as "mechanically deboned poultry" has been marketed successfully with virtually no regulation and with little direct controversy by the poultry industry for decades. The only applicable regulatory restriction is upon the total bones solids limit of one percent in product to be labeled and classified as "boneless poultry."[11] This hospitable definition permits virtually all mechanically deboned product to be labeled with a species name such as "chicken" or "turkey."

This product was and remains an essential building block of the further processed poultry industry which exploded in the 1970's and 1980's. It constitutes virtually 100% of the meat portion of such products as chicken and turkey franks. As a practical matter, the availability of this alternative, inexpensive unregulated product had provided an attractive alternative to manufacturers of comminuted product and has, in no small measure, helped to facilitate the continuing integration of the meat and poultry processing industries. On the other hand, for those wedded by reasons of tradition, economics or simple choice to red meat products only have found it difficult, if not impossible, to absorb a regulatory burden which is not confronted by so many of their competitors.

This competitive frustration took a specific form in 1986 when a group of whole-hog sausage makers brought suit yet again in Federal District Court in Washington, D.C. to challenge the disparate treatment of mechanically separated meat and poultry. Reduced to its essence, their complaint was, and remains today, simple and straight forward: Comparable meat and poultry products are being treated inequitably. Under these circumstances, meat should be deregulated but, under any circumstances, the discrepancy in treatment should not continue.

USDA's response to this challenge, if it can be called that, represents perhaps the least attractive chapter in this saga. The 1986 litigation was resolved with a commitment by the Department to do no more and no less than entertain a petition to be submitted by these original litigants, in support of some sort of regulatory change. The petition was promptly filed, leaving the Department with the task of selecting one of the three basic options it has always faced when confronted with this question — either (1) deregulate the treatment of the meat product to make it more similar, if not identical, to the treatment of poultry, (2) further regulate poultry along the lines now established for meat, or (3) develop a rationale to support a continuation of the difference. Seven years later, one can be either appalled or impressed by the Department's abil-

[8] *Community Nutrition Institute v. Butz*, 420 F.Supp. 751 (D.D.C. 1976).
[9] 9 CFR 319.5; 47 *Fed. Reg.* 28214.
[10] *Community Nutrition Institute v. Block*, 747 F.2d 50 (D.C. Cir. 1984).
[11] 9 CFR 381.118(d).

ity to continue to avoid giving an answer to this question. Without delving into all of the procedural details, it recently took the filing of a second lawsuit by these same litigants to get an order directing the Department to take some minimal action in this direction by August of 1993.

The Department's considerable skills at playing cat and mouse may not yet be exhausted, but it is reasonable to speculate that we may finally be at a point where some serious effort can be made to reconcile this issue on the public record.

Problems With Current Regulation

Under these circumstances, it makes sense to pause and take a more careful look at the mechanically separated meat regulation itself and examine why it is the source of so much continuing unresolved controversy. It is, after all, one of the most comprehensive regulatory exercises that has engaged USDA over the past 20 years, incorporates a great deal of public comment and scientific input and has received support, albeit reluctant, in the courts. What is wrong, therefore, with this picture?

In my opinion, the regulation is flawed in two fundamental ways. First, it offers a general definition of the product which encompasses any finely comminuted product prepared by mechanical separation.[12] This regulatory language is offered in a casual, common-sense sort of way, but it perpetuates a false premise and serves to frustrate future innovation. The Department should not be concerning itself with the means of production itself, nor should it be tying product label to such a variable. To do so establishes a precedent which imposes an unmanageable label upon virtually any new processing technique. No one cares, for example, whether milk is derived from a cow by hand versus by machine. As long as what winds up in the pail has the organoleptic characteristics associated with the term "milk," there is no basis for additional regulatory concern or interference.

In making this point, one does not necessarily have to take issue with the Department's premise within the regulation that the introduction of a somewhat higher level of a component such as calcium through the mechanical deboning processes might differentiate the product and dictate the need for different labeling. To the extent that this is a legitimate concern, however, it is one best addressed by a stipulation of finished product characteristics rather than focusing upon methods of processing.

The second basic problem with the regulation is that while it establishes a detailed definition of mechanically separated product, focusing upon variables such as protein quality, bone particle size and the like,[13] the processor is provided with a fairly detailed definition of what in this case is *not* meat, without being offered any new guidance as to what it is. The consequence, to those in the industry of an innovative bent, has been to create a process where one first attempts to avoid the fatal trap of the mechanically separated meat regulation. Once this is accomplished, however, one enters into a fog. What are the minimum PER's for other types of non-traditional product? What alternative forms of separation, non-mechanical or otherwise, do not generate special labeling? No such guidance is provided by the mechanically separated meat regulation, the general definition of meat regulation or any other official document. As a result, the processor faces the dilemma of a reader not unlike the reader of a map of the United States in which the only state which is clearly identified and delineated is Nebraska. The traveler's first task is to determine whether or not he is in that particular state. If, however, he is trying to figure out whether he has made his way to Texas, the map offers no assistance.

To abuse this metaphor a bit further, the next resort of the traveler is probably going to be to stop and ask someone for directions. For the proponent of an innovative new meat recovery process, this takes him back to the prior label approval system where, at least in theory, he still has the right to ask for such directions and to receive some sort of definitive answer.

This very process has in fact been taking place over the last several years, with mixed results. Various proponents of the meat recovery systems, some involving new forms of low-temperature rendering, others entailing new systems of mechanically-based recovery, have come before the Department maintaining that their product has the essential characteristics of "beef" and "pork" and is distinct from the hyper-regulated products such as mechanically separated meat, and have sought corresponding label approvals. Those enterprises with a sufficient amount of resources, persistence and scientific support have had some success in obtaining such approvals. Almost invariably, however, they have been granted on the most tentative and hesitant basis. They are invariably couched as "temporary approvals," pilot programs, and the like. The subtext of such quasi-approvals is that the Department feels that it is on thin ice, is doing the company a favor, and that one should not expect to count on such continued generosity for the indefinite future.

This process reflects another unfortunate consequence of the mechanically-separated meat debate, but one which exists outside the four corners of the regulation. As these actions suggest, controversy surrounding this ingredient has helped to erode the Department's confidence in its own case-by-case prior approval system. Despite the fact that such decisions can be legally, logically and politically justified if they are based upon adequate data, today's USDA seems either unwilling or unable to make the type of clear decision on such an issue which a company can put in the bank and use as a basis for long-term product development and marketing programs.

Framework for the Future

This is not a viable way to proceed, either for the government or industry. Everyone needs to be able to understand the ground rules, work within them, and have some confidence that once a decision is made. it is both permanent and defensible.

What is now needed, and after some 20 years of the regulatory confusion spawned by mechanically-separated meat, is for such a new framework to be established. In doing so, the following principles might be worth keeping in mind:

1. Mechanically separated meat needs to be recognized for what it is, something of a regulatory dead-

[12] 9 CFR 319.5(a).
[13] 9 CFR 319.5(a), (e).

end. The industry should not spend another 10 years beating its head against a legal, political and scientific wall in some effort to pursue limited changes in such a regulation. The problem is broader and needs to be addressed on a comprehensive level.

2. Correspondingly, new, comprehensive definitions for "meat" and "poultry" must be established. There are those who would argue that such an effort is too complex and potentially controversial. That might be the case if the status quo were acceptable, but it is not.
3. Such definitions should focus upon finished product characteristics only, as opposed to methods of processing. Such notions are fully compatible with the movement towards a more analytically based inspection program, guided by principles such as the Hazard Analysis Critical Control Point system.
4. There is compelling need for scientific involvement in the establishment of such global definitions, and the identification of appropriate criteria. The two most obvious which come to the mind of a lay person are protein quality and bone particle size, but there may well be others. The more scientific horsepower that can be brought into this exercise, the better its chances of permanent value.
5. Issues of global harmonization are obviously relevant. The United States cannot afford to perpetuate a system of regulation which is so idiosyncratic and confusing that it will not mesh within the emerging international market place.

Arguably this is a tall order, but certainly not one beyond the capacities of the talent assembled in this room. Meat processors, scientists and regulators ought to be working together to evaluate innovations in meat recovery in a sensible, even-handed manner, in an environment where such products can rise and fall based upon their quality of scientific support, and their ultimate acceptability to the consumer. Unfortunately, the procedural and political morass I have described today permits no such thing. Hopefully, by charting a course in this new direction, we can begin moving towards a point where you will have less of a need to be talking with lawyers about contradictory regulatory procedures and more of an opportunity to be talking with your customers about innovative new products.