

allergens do so.

The industry leaders have been developing and sharing this information with others for years. Unfortunately, we now know that some companies prefer to do nothing until it is regulated rather than doing the right thing for their customers. Further, food allergen control measures should be part of the HACCP plan for all companies who use allergens, not just the few industry leaders who get it.

And, finally, let's keep in mind that consumers cannot possibly manage their food allergies alone. They must have accurate information on the label and proper food allergen management at the plant in order to avoid a reaction.

Thank you for your time.

[Applause.]

MS. MUNOZ-FURLONG: Any questions from the panel?

[No response.]

MS. MUNOZ-FURLONG: Thank you.

DR. ZINK: Our next commenter is Mark Nelson from Grocery Manufacturers--it has here "Grocery Manufacturers Association." Is it that or "Grocery Manufacturers of America"? Okay, Grocery Manufacturers of America.

MR. NELSON: Good morning. As Don indicated, my name is Mark Nelson. I'm the vice president for scientific and regulatory policy with the Grocery Manufacturers of America. GMA is the world's largest association of food, beverage, and consumer product companies. Our members have U.S. sales of over \$500 billion and employ 2.5 million people in the 50 states.

We apply legal, scientific, and technical expertise from member companies to specific food, nutrition, and public policy issues affecting the industry.

GMA is led by a board of 41 CEOs, and we speak for the food and consumer product manufacturers and sales agencies at the state, the federal, and international levels on legislative and regulatory issues. We also lead efforts to

improve productivity, efficiency, and growth in the food, beverage, and consumer products industry.

Now, with that preamble, I'd like to jump to the topic and indicate that I'm pleased to be here at the first public meeting convened by the Food and Drug Administration to deal with this important project of food safety and good manufacturing practices.

Good manufacturing practices are employed by the food industry, as we've seen in Part 110 of FDA's regulations. So let me begin again by thanking FDA for including the food industry and other members of the public at this very early stage in the decisionmaking process.

GMA agrees that food safety and food GMPs warrant the A List priority status given it by the agency, and we thank you for the opportunity to share our very preliminary views with you today.

In response to your recent Federal Register notice, GMA's members and staff are reviewing this matter in considerable detail through our technical committees, and we plan to

submit detailed written comments later this year.

But without preempting the detailed comments and the detailed review, what I'd like to offer today is a top-line view of the general principles that we believe need to guide FDA's review of its food good manufacturing practice regulations.

The first principle is food safety. As FDA has already articulated, this review needs to focus on the important role the food GMP regulations play in ensuring food safety and public health. For over a quarter of a century, the food GMPs have served as the foundation for food safety in our nation's food manufacturing facilities, and that role is appropriate and needs to continue, adhering to the concept that GMPs provide effective, broad-based, prerequisite programs for ensuring food safety.

Moreover, effective food safety programs must always start with the science. GMA supports FDA's current evaluation of the food GMPs so long as that review stays tied to scientifically

supported steps to ensuring food safety.

Principle number two is flexibility. Because the food GMPs are umbrella regulations covering all food products, flexibility is a necessity. GMA urges FDA to take into account the wide variations that exist across the food industry, including the size of establishments, the types of food produced, the food processing technologies that are available, and the level and types of risks presented.

In this regard, GMA would recommend that FDA look closely at the Codex food hygiene standard, amended as recently as 1999, that addresses general principles for food hygiene. By focusing on general principles, Codex recognized the critical nature of incorporating flexibility into a GMP approach in order to allow, indeed to encourage different industries to apply those general principles in a way that is most appropriate to their circumstances.

As an example, whereas the current food GMP regulations require 45 degrees as the standard

for refrigeration, and which over time has come to conflict with the food code and other regulatory standards for food categories, the Codex standard calls for refrigeration at a temperature that is adequate for ensuring the safety and suitability of the particular food at issue. It also includes requirements for monitoring, measuring, and some of the other topics we've heard about today. This flexibility allows industry to achieve food safety in a science-based way in a manner most suitable for particular situations.

Principle number three is effectiveness. Food safety measures need to be well focused and effective for their intended purpose. Any new measures that FDA considers need, A, to be based on real problem; B, to be closely tailored to meet these problems; C, have a clear scientific underpinning; and, D, are practical and cost-effective to implement. It is here where industry input can perhaps be of greatest assistance to the agency. Any new proposed measure should be developed only in close consultation with

the food industry to be certain that they make sense in the real-world context of food processing, manufacture, and distribution.

It is also important that any revisions to the food GMPs be effective for the clear purpose the GMPs are intended to serve, that is, as foundational prerequisite controls for food safety. We all recognize that in some settings GMPs alone are not sufficient, and companies need to go beyond GMPs and implement a HACCP plan, sometimes mandatory, sometimes voluntary, depending on the food category.

In looking to modernize Part 110, FDA should keep its focus on those prerequisite controls which, if implemented well, can minimize the number of potential hazards that would need to be addressed by a HACCP.

Principle number four is efficiency. The effectiveness of any GMP needs to be tied closely to efficiency. One such example of efficiency is that whenever new measures are warranted, FDA needs to assess whether such measures require changes in

regulation or whether such measures are more appropriate and more efficient to implement through added guidance or interpretation of existing regulations.

For example, advances in guarding against cross-contamination of food allergens may well be a subject that is more properly and effectively and efficiently addressed in guidance rather than in regulations. A second example can be found again in the Codex food hygiene standard, where the standard is more specific than FDA's food GMPs in calling for the use of potable water and then defining potable water by referring to the latest edition of WHO guidelines for drinking water quality.

The point here is that Codex recognized that as science changes, it is easier to change guidelines and regulatory standards, and FDA should incorporate the same philosophy. By supplementing the food GMP regulations with more specific guidance documents, FDA can create a more efficient and practical mechanism for the rapid incorporation

of advances in science, food safety knowledge, and food processing.

Indeed, the fact that the current good manufacturing practices modernization effort is based on regulations that are 25 years old underscores the value of using a more efficient mechanism.

Before concluding, let me add a few additional thoughts. It should go without saying that the scope of the food GMP regulations needs to stay clearly within the agency's statutory authority as derived from the insanitary conditions provision of the law. Moreover, FDA needs to base any proposed implementation schedule on a timetable that is reasonable and provides added time for small businesses to comply.

Finally, given the importance of this initiative and given the fact that the comment period falls within the summer months, GMA urges that the deadline for written comments be extended an additional 30 days, until October 10th, so that the industry can provide the kind of detailed

comments this subject so clearly warrants. And I think we heard comments this morning about the review studies that will not be available until the end of September, and it would be very useful to have those available to inform any comments that we intend to make. GMA will be filing a formal request for an extension with the agency.

In conclusion, GMA appreciates the opportunity to provide oral comments to the FDA at today's public meeting. GMA supports a thoughtful evaluation to modernize the food GMPs under the principles of adhering to food safety goals, ensuring flexibility in application and food safety, and incorporating effectiveness and efficiency in any resulting changes. The food GMPs have served the public well for the past quarter of a century, and through this modernization process, which incorporates close industry involvement, they will serve the public even better in the future.

Thank you very much.

[Applause.]

MS. LOSIKOFF: I was just curious. Are

those Codex documents final that you were referring to?

MR. NELSON: The food hygiene code, the general principles of food hygiene, yes, are final. They're on the Codex website. If I remember correctly, they were amended in '92, then redone in '99. And if you give me your e-mail address, I can send you a copy.

DR. ZINK: The next statement, if Bill Pearce representing Pacific Rim Crab would come to the microphone.

MR. PEARCE: I'll make this real short. I have already made a partial statement, but I wanted to elaborate on it.

One of our concerns, we've just received information from the NFI, National Fisheries Institute, that 83 percent of all of the seafood consumed in the United States now is imported. So that means we know 83 percent is not inspected at the source. That's a gimme. Now we've got 17 percent in the United States that can actually be sold in the back of a pick-up truck with no

inspection at all whatsoever. So I want to make a statement on behalf of the seafood industry.

We agree totally--and I have worked in factories where we had our HACCP plan, we had everything that we needed to make it work, and we made it work and we felt comfortable with the product that went out.

Here we have the fastest-growing protein in the United States that's not inspected as though it was beef or poultry. So my point is that we need to look not as much at the money spent on this and not as much at the money spent on all these people in this building. It's like having a police department with 700 chiefs and two policemen. It doesn't work unless you enforce it, and we are not getting the enforcement in the field nor overseas, and we need to look at some system that we can control what comes into this country, and not just a random container check, one out of 10 or 15, that are plugged and done sanitary, because the rest of it you're eating and there's nothing inspected, nothing at all.

Any questions from the panel?

[No response.]

[Applause.]

DR. ZINK: I'd like to invite Scott Pete--I hope I've got those names in the right order--Scott Pete from Export Incorporated to come make a statement. Is Scott with us?

[No response.]

DR. ZINK: No. Okay. Jenny Scott, National Food Processors Association.

MS. SCOTT: Thank you for the opportunity to provide comments on FDA's current good manufacturing practice regulations for foods and the possible need to modernize them.

FDA's GMP regulations set forth basic principles of good sanitation and hygiene practices for food processing plants. GMPs are essentially performance standards, setting agency expectations and providing general guidance on how to meet them, without mandating prescriptive requirements to comply, with some exceptions.

The admittedly subjective terms used in

the regulations, such as adequate facilities, where appropriate, necessary precautions, adequate controls and the like, provide needed flexibility. This allows the application of one set of regulations to the broad U.S. food industry, with its wide variations in company size, products, and processes. This flexibility also fosters the use of new technologies as they become available, often without the need to revise regulations.

The GMPs have been well accepted by industry and have been very effective in preventing product adulteration. Because of their effectiveness and flexibility, NFPA members in general believe no significant changes are needed to modernize the regulations. Guidance to aid interpretation of the existing regulations with respect to specific areas of concern should be the approach taken.

Now, FDA notes that in almost 20 years since the GMPs were last revised, the food industry has undergone considerable change that warrants relooking at the GMPs. Well, what are the changes

that have occurred? We believe that some of the key changes are as follows:

First, the introduction of regulations mandating HACCP for certain foods and the widespread voluntary adoption of HACCP throughout the industry for controls of hazards.

There has been a recognition of allergens as a true food safety issue. We've seen the recognition of *Listeria monocytogenes* as a foodborne pathogen of significant concern with respect to ready-to-eat foods along with a growing body of knowledge on appropriate control measures.

We've seen the introduction of many new technologies, such as high-pressure processing, UV light, and pulse light to inactivate microorganisms, as well as the approval of irradiation for treatment of a number of goods.

We've seen the development of more effective cleaners and sanitizers. There's been the development of better test methods capable of detecting chemical contaminants at much more lower levels than ever before, and rapid test methods for

microbial contaminants, as well as tests to provide immediate feedback on the sanitary condition of equipment surfaces.

We've also found that there's a need to enhance our defenses against deliberate threats to food, which, if any of these, warrants modernization of GMPs. And where have we seen the problems?

Well, first, the food industry strongly believes that HACCP is the best way to control significant hazards, those that are of sufficient potential public health risk and that are reasonably likely to occur in the absence of controls. But HACCP must be supported by a foundation of prerequisite programs, many of which are addressed in FDA's GMP regulations. Thus, the adoption of HACCP, both mandatory and voluntary, throughout the industry has in turn put more focus on GMPs which can be key in ensuring that certain hazards are not likely to occur and, therefore, need not be addressed in a HACCP plan.

An examination of food-related recalls in

FDA enforcement reports for 2004 suggests that about two-thirds of these were related to unlabeled allergens or sulfites. Most unlabeled allergen problems and those likely to result in serious adverse public health consequences appear to be due to labeling errors.

The current GMPs and other regulations do address unlabeled allergens in foods. For example, 21 CFR 101.4 requires that all ingredients be declared on the label, and efforts are underway to ensure that consumers are informed of all allergen food ingredients in understandable language.

The presence of inadvertent allergens due to cross-contact is addressed in many parts of the current GMPs: the design and construction of equipment and utensils to preclude adulteration with contaminants; the taking of all reasonable precautions to ensure that production procedures do not contribute contamination from any sources; and all food manufacturing having to be conducted under such conditions and controls as are necessary to minimize the contamination of foods.

The problems that led to the majority of allergen-related recalls are not likely to be solved by revising the GMPs to provide specific controls for allergens. However, guidance in allergen control, developed in conjunction with all stakeholders, could provide information that will assist companies in establishing effective, verifiable programs. Such guidance would outline procedures that companies can use to manage allergens in food processing establishments, including measures to ensure products are appropriately labeled and employees are properly trained to minimize the risk from unlabeled allergens in foods.

The second largest reason for recalls in 2004 has been the presence of *Listeria monocytogenes* in ready-to-eat foods. As we have investigated the problem of *Listeria* over the last 20 years, we have learned a great deal about the organism and the difficulties in controlling it. Since contamination from the environment is generally recognized as the source of *Listeria*

monocytogenes, there are many parts of the existing GMPs that apply to minimizing the risks from this organism. As with allergens, it's not new GMP regulations that are needed but, rather, more in-depth guidance about specific procedures that have been demonstrated to be effective in managing the risk of contamination of those ready-to-eat foods that are more likely to be a source of listeriosis.

New technologies may be used as measures to destroy or prevent the growth of undesirable microorganisms, including those of public health significance, and thereby help prevent food from being adulterated, as specified in 21 CFR 110.80, Processes and Controls. More effective cleaners and sanitizers help ensure sanitary operations in compliance with 21 CFR 110.35, Sanitary Operations, and 21 CFR 110.37, Sanitary Facilities and Controls.

Better test methods help manufacturers comply with GMP requirements to test where necessary to identify sanitation failures or

possible food contamination, as specified in 21 CFR 110.80, Processes and Controls.

With respect to food defense, we have new laws and regulations addressing this area, as well as numerous industry and government guidelines providing approaches to enhance our existing protections. Certainly the GMPs are not the place to address this issue.

So many of the changes that have occurred over the last 20 years help meet the existing GMP requirements, but they're not changes that warrant new requirements. Any changes to modernize the GMPs should specifically consider the Codex Alimentarius General Principles of Food Hygiene in order to provide additional flexibility for food businesses and increased international harmonization.

The Codex General Principles of Food Hygiene lay a foundation for practices essential for ensuring the safety and suitability of food, stating the objectives to be achieved along with the rationale behind the objectives, and I think

that's very important. This approach combined with appropriate guidance documents could provide the effective means of ensuring safe and sanitary food manufacturing, storage, and distribution.

FDA requested input on whether to mandate or recommend a number of programs that help ensure that preventive controls are carried out adequately, including training programs, audit programs, written sanitation standard operating procedures, and testing programs. Most of the programs listed are routinely practiced to various degrees by the food manufacturing industry. Such programs should not be mandated, as this would compromise the flexibility of industry to implement the types of programs that work best for a specific company, product, and operation.

In conclusion, the food industry always welcomes the opportunity to improve the safety of the food supply. We recognize our responsibility to produce safe, unadulterated products. NFPA will be submitting more extensive comments that will address the specific questions raised by FDA in the

Federal Register notice.

We look forward to working with FDA as modernization of GMPs is considered. Any changes should be structured to encourage industry to invest in and implement appropriate food safety practices and not serve as an impediment to this. Our current thinking is that flexible GMPs, supplemented with guidance documents for specific products and/or processes in those instances where more detailed information could enhance consumer protection, provide the best approach.

Thank you.

[Applause.]

MS. SCOTT: Questions from the panel?

MR. KELLER: I have one question.

Regarding the showing that the procedures are effective and being able to comply to the GMPs, how would FDA be able to have access to records? How would we be able to say, okay, this is effective, this is a safe way to conduct the business?

MS. SCOTT: That's a question we intend to address in our written comments after consulting

with legal counsel.

DR. ZINK: Next on my list is Diana Judge with Shell Lubricants. Diana, are you here? Okay. She's coming down now.

I have on my list that Diana is the last one that signed up to make any public comments. Have I missed anyone? Is there anyone out there that wants to make a public statement that I somehow missed?

[No response.]

DR. ZINK: Okay. Diana, would you like to use this microphone?

MS. JUDGE: Good morning. I'm Diana Judge, the food-grade lubricants manager from Shell Oil Company. I'm here today to bring your attention to the need for regulation regarding the use of food-grade lubricants used to maintain food processing equipment in the food and beverage manufacturing industry and to propose stricter compliance procedures to assure food safety for consumers in America. Europe is well ahead in this area.

Research shows that 60 percent of U.S. food and beverage manufacturers, when making food or beverage products, are still using non-food-grade oils and greases, the same oils and greases that are also used in steel mills, mines, and trucks. These oils are derived from crude oil and contain additives which are harmful if ingested and which could potentially end up in the food we eat.

Food and beverage manufacturers in America should be using food-grade lubricants in food and beverage manufacturing, and yet 60 percent are not. The potential from non-food-grade lubricants contamination is real, and this poses a threat to food and beverage safety in this country.

Machinery used in food and beverage processing has many moving parts, and they require lubricants to maintain efficient and reliable operation. Such applications include hydraulics, gear boxes, bearings and chains, to vacuum pumps and compressors. Food and beverage contamination can occur from drips off chains, which is common in

bakeries and meat and poultry plants; hydraulic hose failure, where oil is sprayed around under pressure, again, common in meat plants and also dry food manufacturing; oil leaks from seals and gear boxes--one chocolate company had to dump a quarter of a million dollars worth of product that was contaminated--or a release of compressed oily mist.

If you think about a packet of potato chips or a packet of bread, when the product is packaged, compressed air is required to blow the bag open. That compressed air often contains 300 parts per million of non-food-grade oil which is blown into the bag just prior to the potato chips or bread being dropped in.

Current FDA regulations have a zero parts per million tolerance of non-food-grade oil with food, and yet every time you eat a packet of potato chips or bread, you are being exposed to up to 300 parts per million of non-food-grade oil. Non-food-grade oil is not designed to be eaten. However, we inadvertently eat it every day.

Many lubrication contamination incidents

go unreported, especially if they're caught before the food or beverage leaves the plant. Most companies you expect, too, will have had a lubricant contamination; however, it seems to go unreported and an issue which is not openly debated. Some recently reported contamination examples around the world include 86,000 pounds of sliced turkey inadvertently exposed to a non-food-grade lubricant during processing. Consumers complained of off-color, off-odor turkey, and some consumers reported temporary intestinal discomfort.

A packing company had to recall 490,000 pounds of smoked boneless hams after some were tainted with gear lubricant. Several consumers reported a bad taste and burning in the throat for up to three hours.

A grocery store chain had to issue a recall of a manufacturer's soft drinks due to possible contamination by a lubricant that may cause irritation if consumed.

A baby-food producer had to recall its

infant formula and milk powder after a reported contamination by industrial oil and metal in their products, and yet another manufacturer received complaints that jars of baby food smelled of tar. Investigators found that the product was contaminated with mineral oil lubricant, possibly from the manufacturing process.

While most product recalls result from foodborne bacteria or processing and labeling errors, nevertheless, lubricant contamination plays a costly role. Brain damage from a contamination incident far exceeds the cost of lubrication.

If the risk of contamination and the costs are so high, why aren't 60 percent of U.S. food and beverage manufacturers not using food-grade lubricants? We've discovered a number of reasons for this.

Firstly, many companies don't know that you should be using them and that lubricants can get into the food that we eat. The cessation of the USDA White Book approval system for lubricants has left a void for food and beverage manufacturers

when choosing machinery maintenance lubricants for use in food and beverage manufacturing applications.

The USDA formally approved lubricants as H1 for incidental food contact and published the list commonly known as the White Book. The USDA ceased this activity in 1998, and Michigan-based NSF International has since replicated the White Book procedures, registering food-grade lubricants as H1 food-grade in their E White Book.

Registration of food-grade lubricants with NSF by lubricant manufacturers, however, is voluntary, and unless a food and beverage manufacturer knows where to go, they may not know that a food-grade lubricant exists.

It is also important that the food processor fully understands the potential physiological risk that a lubricant may pose to the consumer if a contaminated food or beverage is ingested. But it's equally imperative to implement more stringent lubrication procedures for assessing food and beverage safety in manufacturing

processes, particularly in reviewing the current good manufacturing practice regulations by the FDA.

The second reason why the majority of American food manufacturers don't use food-grade lubricants is that they cost more up front. However, with technology advances by the use of synthetic high-performance food-grade lubricants, the overall cost of plant maintenance can be lowered because the lubricant lasts longer and you use less. They also provide better protection to plant and machinery which will mean lower parts and repair bills. So food manufacturers no longer have to sacrifice plant efficiency for food safety and, in fact, they can help you reduce your overall costs.

There really isn't an excuse why food and beverage manufacturers are still not using food-grade lubricants, and this is where the FDA can assist to improve food safety by making it law to use food-grade lubricants from the time raw materials are brought to the plant to the time when the product is finally packaged.

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You will find that very few of the 40 percent of food manufacturers that do use food-grade lubricants in the U.S. only use food-grade in the manufacturing area. A plant will often apply the rule if it's above the table, in other words, where the food is being produced, processed, it must be food-grade; and if it's below, then it's okay to use non-food-grade lubricants. Why then in a plant that has this policy and uses a white-colored food-grade grease for above the table and a red-colored grease for non-food-greases below the table are all the grease points in the plant colored pink?

[Laughter.]

MS. JUDGE: Mistakes and misapplications happen all the time, and for food safety you can't afford to make a mistake when applying a non-food-grade lubricant in a food-grade application. When consumed, non-food-grade lubricants can burn the back of your throat, cause intestinal discomfort, and poison you.

In summary, 60 percent of U.S. food

manufacturers still rely on non-food-grade conventional lubricating oils and greases to lubricate their food and beverage production machinery, either because they don't know about the need to use food-grade lubricants or they have tried food-grade lubricants and then reverted back to using non-food-grade because the food-grade could not handle the application.

With the technological advances that have taken place with the introduction of synthetic food-grade lubricants, food manufacturers no longer have to compromise plant efficiency for food safety. There is something that can be done about reducing and eliminating this food safety risk; however, regulation is required to enforce.

It is imperative that the FDA extends current food and beverage safety regulations to meet today's changing needs, including more rigorous oversight and quality assurance standards that match programs adopted widely in other parts of the world. Assuring the safety of our food supply goes beyond the borders of the United

States. We live in a global economic community and, therefore, should embody the highest universal standards of compliance, quality, and safety at every stage of food and beverage manufacturing. For greater food safety in the United States, food-grade lubricants should be used in every production plant wherever food and beverage products are being produced. A non-food-grade lubricant should not be allowed to be used within the production plan from a place receiving raw material through to product packaging. It is only with proactive FDA support through updating these regulations that we can work together to eliminate this food safety risk.

Thank you for the opportunity to make these comments.

[Applause.]

MR. KELLER: Would you share the source of your statistics with us?

MS. JUDGE: Sure. Some of it came from Klein & Company and [inaudible-off mike] Company. But we'll cover that in more detail in our written

submission.

MR. KELLER: Thank you very much.

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DR. ZINK: This concludes the agenda we had for the day. What I would like to do in the moments before we adjourn is go over some of the things I think we heard you say. Bear in mind I am not going to regurgitate everything you said, mercifully. However, I did want to mention a few highlights to let you know that we are listening and what we think we heard. Every word said here today, though, is being captured. A transcript will be available. I think that transcript is going to be, what, about 30 days? Fifteen days, okay. So a transcript of the proceedings will be available, and I can assure you that every word will be considered and will be managed in any rulemaking process.

Among the things I heard this morning is a need for integrated pest management approaches, label verification steps, validation of CIP systems, written SSOPs; that whatever we do, it should not be a program that is focused on the

program itself and documentation, but focused on the food safety impact.

There's a need for multilingual training, for written QA/QC programs; that we may need specify refrigeration temperatures; that we should mandate temperature monitoring devices and particularly as it relates to refrigerated shelf life or the importance of refrigerated shelf life; that there should be routine verification of controls, that we need to address harvest and transportation under the umbrella of good manufacturing practices; that inventory controls are important where we can identify time and place of harvesting of production; that the GMPs are very broadly interpreted currently, and that this is a very necessary thing to retain in the GMPs; that many states reference the GMPs in their own regulations, and obviously that causes us to be mindful of the very broad effect that any change in the GMPs might have; that we should in the regulation, wherever possible, use "shall" rather than "should"; that there should be a higher

standard of requirements for ready-to-eat foods; that we should consider banning bare-handed contact with ready-to-eat foods, even during manufacturing operations; that the issue of allergen cross-contamination--this has come up in a number of presentations, and I'll get more on that later.

That we should require SSOPs, including monitoring and verification; that we need to modernize and update our definitions and make them more relevant; that validation, where appropriate, be considered, training requirements be specified; that each processor should be responsible really for identifying the hazards associated with their process; and that food allergens should be incorporated into HACCP plans.

There is a problem currently with "may contain" statements not being uniformly applied and being confusing. There's a problem with some companies interpreting variously what food allergens they should be concerned about and which might not be allergens of concern; that presently there are no regulations that specifically address

rework; and that allergens need to figure prominently in GMP regulation revision.

Many commented that they believe that food GMP modernization is necessary and important and even long overdue. Some have commented that GMP revision is not necessary, at least not in a substantive way. That if the GMPs are to be revised, that the food safety as the guiding principle should be emphasized; that we need to start with the science; that we need to come up with a regulation that's flexible and accounts for a wide variation in the industries we regulate.

Several commenters mentioned the importance to take a look at the Codex food hygiene approach, and I have to tell you, internally we had that same thought ourselves, that we need to look very closely at what approach Codex has taken.

Several commenters mentioned the importance that guidelines are needed, and we recognize the importance that guidelines can have in expanding and going into more detail about how we expect compliance with the GMPs to take place.

One commenter asked us to extend the deadline by 30 days and said they would be formally requesting that. One commenter expressed concern about--while he was talking about seafood consumed in the United States, I think it might have been also general concern about foods produced abroad not being produced under inspection as if they were produced in this country; the need for the GMPs not to be prescriptive.

One comment felt that the changes that have taken place in the food industry, such as new technologies, the identification of *Listeria monocytogenes*, et cetera, could be handled by other parts of the regulation or are adequately handled by other parts of the regulation, and many things could be addressed through guidance.

Finally, there's need for stricter compliance with food-grade lubricants and that the agency needs to in its regulations emphasize the appropriate use of food-grade lubricants.

I think those are the highlights. Do any of you on the panel have anything you want to add?

PARTICIPANT: I think that sums it up pretty well.

DR. ZINK: Okay. Well, I guess that concluded what we had in mind for this morning, and I certainly thank everybody for coming, and I want you to rest assured that all of this is going to be taken into consideration.

[Whereupon, at 11:57 a.m., the meeting was adjourned.]

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C E R T I F I C A T E

I, **SUSAN A. HARRIS**, the Official Court Reporter for Miller Reporting Company, Inc., hereby certify that I recorded the foregoing proceedings; that the proceedings have been reduced to typewriting by me, or under my direction and that the foregoing transcript is a correct and accurate record of the proceedings to the best of my knowledge, ability and belief.

A handwritten signature in cursive script, appearing to read "Susan A. Harris", is written over a solid horizontal line.

SUSAN A. HARRIS