[1]Our last speaker this afternoon, who is going to be talking about the global perspective…

[2]…is Dr. Karen Hulebak who is currently the Chief Scientist in the USDA's Food Safety and Inspection Service.

[3]She is located in the Office of Public Health & Science where she provides science and science policy advice and counsel on domestic and international food safety issues. Dr. Hulebak is currently Vice Chair of the Codex Alimentarius Commission, which has a responsibility to set food standards for all foods to protect the health of the world's consumers and to ensure Fairfax is an international food trade. She is also Chair of the Codex Alimentarius Committee on Food Hygiene, which is responsible for setting microbiological food safety standards for all foods worldwide. Please join me in welcoming Dr. Hulebak. Thanks Bo, and I want to say what a real pleasure it is for me to be here today to be part of this particular panel and to share my thoughts with you all about the global food safety challenges facing the meat industry and consumers now and in coming years.

[4]Let me tell you first a little bit about the Codex Alimentarius Commission, which has come to take up most of my working life in the last few years. Codex was established in the mid '60s under the United Nations umbrella. It is jointly sponsored by the World Health Organization, WHO in Rome, and the Food and Agriculture Organization or FAO – I'm sorry. WHO is in Geneva, and FAO, the Food and Agriculture Organization, is in Rome. Codex is responsible for producing risk and science-based food safety standards that protect the health of consumers and facilitate world food trade – preferably trade in safe foods. For over four years now, I have been the Chair of the Codex Committee on Food Hygiene, CCFH, which sets microbial food safety standards for all foods worldwide including meat and poultry, of course, and last month in Rome, I was elected by the Codex Alimentarius Commission members, and more than one hundred and seventy countries are members of the Commission, as one of the three Vice Chairs of the Commission. As Vice Chair, I will work with this new team, and the new team members are – this is Ms. Noraini Mohd. Othman from Malaysia. The new Chair of the Codex Alimentarius Commission is Dr. Claude Mosha of Tanzania, your speaker, and Dr. Wim van Eck from the Netherlands. This new team, I hope, can work together to help Codex become more effective and more efficient and more timely in doing this important job that we have, because the Codex standards that we produce are used by the World Trade Organization as the Gold Standard against which claims of disputing parties in food trade disputes are measured. This is a very tall order. As I mentioned, there are more than a hundred and seventy member countries of Codex, and we work by consensus. As Elsa and Bo said about industry, if we are going to be moving forward, we have to be proactive, and we have to be efficient, and that … word applies very much to Codex. If we don't do our job, some other organization that is less inclusive and less open and transparent in the way it works will step in and establish standards, and we may not be involved to the degree that we are now. Now, today, I would like to talk with you about today's food safety challenges, the international organizations involved in them, and the government and public opinion environment in which these challenges are going to get worked through. First, let's talk about the global food safety environment and how we got to where we are today.

[5]You can read the litany of major incidents on either screen, and I suppose I could add to the list of these major events the current outbreak in Spain in which well over twelve hundred people

have been sickened with Salmonella that got onto poultry distributed by a Netherlands-owned plant; by any estimation, a major outbreak. These major events, which took place mostly in Europe and the United States, have had important consequences for consumer confidence in meat and in consumers' confidence in the government functions to ensure the safety of meat, and they have often affected trade adversely.

[6]The consequences of these events were numerous. Several involved serious illness and loss of human life. Some of these incidents caused the destruction of millions of valuable livestock with major economic consequences as well as all the problems environmental and otherwise associated with the destruction and disposal of millions of carcasses. It's also very clear and widely acknowledged that in all of these incidents there was poor communication about risks as well as what might be fairly described as suboptimal crisis management by government entities and sometimes by the private sector as well. As a consequence, the mainstream and tabloid media capitalized on the confusion and apparent bumbling by responsible parties, and the steady march of bad news over a decade eroded consumer confidence and regulatory systems in several countries. One consequence in fact was the fall of the Belgium government as a direct result of the dioxin animal feed contamination debacle. These crises naturally simulated a search for solutions by government agencies, and the solutions they tended to latch on to where found in the establishment of new, more independent regulatory entities designed to never let such things happen again.

[7]These solutions almost always included new institutional independence and a sharper official focus on public health. Across Europe, major institutional shifts had occurred to separate food safety regulatory bodies from those agencies with a more commodity/promotion set of responsibilities. Related trends include moves to separate risk assessment functions from risk management functions and inspection and compliance activities from policy making. These trends are being seen not just in Europe but in Japan, Australia, New Zealand, and Canada, and the subject continues to have life in the United States. Although, in the United States, as Elsa mentioned, the issue tends to be framed as the need for a single food agency. There has been a new emphasis on full supply chain perspective, and this means that there is developed, especially in Europe, a significant focus on product tracing and traceability. The importance of HACCP is now well entrenched. Indeed, trade requirements are increasing pressure on developing countries to implement HACCP within their borders, and new Codex standards are further strengthening this HACCP trend. The use of scientific risk assessment in standards development is also now very well established, but as I mentioned earlier, there is also a trend to separate risk assessment and risk management functions in regulatory agencies, and this trend is being seen in many countries. Anxiety about the food safety incidents of the last fifteen years and of course the new emphasis on food security and bioterrorism has resulted in intensified border inspections, certainly for pathogens, but contaminants like dioxin or markers of antibiotic resistance could be receiving special attention at borders in the near future.

[8]Additional responses by government entities have included greater transparency in government activities with a trend increasingly to involve consumers in the development of policy and the public in the risk assessment process. This is occurring in Europe and even starting in Latin America and in Asia to some degree. In the U.S., of course, these approaches have long been our policy. So, there is not such a dramatic change here. It's also clear that there

has developed a greater stringency and broader application of standards, certainly in the aftermath of the dioxin disaster in Europe in the late '90s as just one example. The European Commission established a regulation applying to all member countries requiring rigorous dioxin testing of domestic and imported meat and meat products and many other products as well with plans for increasingly stringent testing in the near future. Well, many of us questioned whether this testing program was truly implementable. For example, was there even really the lab capacity in Europe to do all the testing that was required for dioxin and all of these products, but it is certainly clear that the EC felt that it had to show the European public that it was doing something stringent and preventive, and this was clearly a regulatory program strongly shaped by public pressure.

[9]I mentioned the new concerns about bioterrorism possibly affecting food and…

[8]…certainly concerns about bioterrorism are among the many factors, including several others, that I've mentioned already that are encouraging the implementation of animal ID systems, an obvious trend to watch in coming years, and finally for this slide, precaution. The so-called precautionary principle refers to a government's action to put in place very conservative control measures in cases where scientific evidence is not really sufficient or felt not to be sufficient to enable truly adequate evaluations of risks associated with food-borne hazards. I do believe that precautionary approaches are likely to continue to be a factor for some years. Now, let's look at current major global food safety issues and the international organizations concerned with them looking first at pathogens and pathogen standards.

[9]WHO's 2002 global strategy for food safety focuses on Salmonella, Campylobacter, and E. coli as concerns in meat, and WHO lists four major factors contributing to these concerns. First, WHO lists changes in farming practices, and they focus especially on intensive animal husbandry. Second, WHO looks at more extensive food distribution systems; third, the increasing preference for meat and poultry in developing countries, which WHO suggests as causing increased potential for food-borne illness; fourth, manure disposal from large-scale animal and poultry facilities, which WHO sees as a growing food safety problem as manure frequently contains pathogens. WHO's global strategy does not propose more than very general risk management guidance for countries regarding these meat-borne pathogens, but Codex, through CCFH, the Committee that I Chair, is actively developing new pathogen risk management strategies intended for use by governments. Codex also adds Listeria monocytogenes to the list of concerns for pathogens in meat and meat products. The new types of risk-based standards for pathogens that CCFH is developing are very likely to incorporate the food safety objective or FSO concept. They aren't likely to establish more traditional bright line pass/fail pathogen levels for products, but rather it will establish more flexible processes for developing standards that countries will be able to use as they deem appropriate within their own borders, their own regulatory systems, and industry systems. CCFH's approach is likely to get attention around the world as more countries develop pathogen reduction regulations, especially likely in developing countries that do not already have well established regulatory frameworks, and this is a thought to keep in mind as they United States open and develops new trading partnerships, especially with developing countries, but the new CCFH approach is likely to get attention in developed countries as well, and certainly, the FSO concept has gotten a lot of air time in Europe and in the U.S., Australia, New Zealand, and Canadian official circles. With

respect to the World Trade Organization, WTO, and pathogen standards, how such process-descriptive standards are going to play will be worth following closely, because a lot of observers believe that the WTO is expecting Codex to produce the more traditional bright line standards, and the WTO won't know how to deal with these more flexible process-based standards, but I think this underestimates the WTO and that the WTO will find that these new process-descriptive FSO type standards will work just fine in the SPS Committee. The WTO is not, in fact, a direct shaper of the global food safety agenda. Its activities would be much more likely to be for its two main committees – the Sanitary and Phytosanitary , SPS Committee or the Technical Barriers to Trade or TBT Committee to alert standard-setting bodies such as the Codex or OIE that disruptions in international trade are occurring because there is no standard in an area that needs a standard or where an existing standard is way out of date. For the SPS Committee, this could mean – this could be an issue like regionalization. For example, the SPS Committee might alert the OIE that there is a disruption in international poultry trade because of Avian Influenza outbreaks and that the OIE needs to clarify whether trade embargos should affect poultry only from specific regions of the country where an outbreak is occurring, or should the ban affect the entire country? By the TBT Committee, Codex could be called upon to resolve any one of the number of labeling issues such as country of origin labeling. Now, about the OIE, the world organization for animal health, which is based in Paris; hence, the French acronym – OIE's traditional focus has been on animal health and not human health issues, but there is obviously a connection, because many animal diseases are transmissible to humans. However, OIE has recently released its fourth strategic for 2006 to 2010, and this plan explicitly states that one of its key objectives is going to be and I quote "development of new standards in the area of animal production food safety for pathogens and contaminants that present hazards to human health, even if they do not always affect animal health." This certainly sounds to me like something very close to the Codex mission. So, certainly, clearly, Codex and the OIE are going to need to work out which organization has what responsibilities, because confusion about who's responsible for what in the setting of international food safety standards is not going to do anyone any good. Now, let's look at several non-pathogen food safety issues.

[10]Drug residues in contaminants are concerns of Codex, OIE, and WHO. Drug residue issues are handled in Codex in the Codex Committee on Residues of Veterinary Drugs and Foods or known to its friends at CCRVDF. CCRVDF has been having notable success in recent years in developing improved risk-based methods for setting MRLs, maximum residue limits, for animal drugs. OIE also has an important role with respect with veterinary drugs and vaccines, and OIE's role is to develop international guidance on the use of drugs and vaccines for animal health control, but as I've just mentioned, OIE views itself as having perhaps an ever broader mandate, which might affect its activities in the animal drug and vaccine area. With respect to contaminants of interest mainly to Codex and WHO, my first and best example is dioxin. This high profile meat contaminant is being dealt with in the Codex Committee on Food Additives and Contaminants called CCFAC. CCFAC's approach has been to develop a general code of practice providing very general guidance to governments on how to produce animals so as to avoid dioxin contaminants of those animals in the first place. CCFAC has, however, debated for years about the development of bright line standards for dioxin. That would be levels of dioxin set for meat and meat products and many other foods above which those foods would be considered unfit for human consumption. For the time being, the much more general and flexible code of practice approach is prevailing in CCFAC. Although, with respect to dioxin and

perhaps other environmental contaminants in the future, this approach may change. Certainly, the EC, the European Community, has taken the bright line approach in their regulations, and the EC is without a doubt becoming increasingly influential in Codex. WHO has worked on dioxin for years. WHO established the very influential toxicity equivalence factors or TEFs that are the internationally accepted means for normalizing the widely varying toxicity among the many different dioxin congeners. In the last several months, WHO has undertaken a compromise re-review of these TEFs, and this is a process that should be closely watched, because the outcome of this exercise could dramatically and greatly affect dioxin risk assessments around the world. One other example I'll give you of a chemical contaminant relevant to meat is PAHs, polycyclic aromatic hydrocarbons, produced when meat is grilled or subjected to high temperatures. Codex has been paying attention for some years of PAHs, and work has been going on to set levels for PAHs in grilled meats and other products in CCFAC, on its agenda for some time. Last year, the U.S. delegation attempted to get PAHs off CCFAC's agenda based on the argument that the public actually got relatively little return for the investment of so many international person hours of work spent on developing a standard, but this argument failed largely due to opposition by the European community, and CCFAC is likely to consider taking up new work on PAHs in the future.

[11]Next, let's turn to some less traditional food safety issues that already do or might soon affect meat and trade in meat. I'll begin with BSE, an obvious food safety issue of global importance and in which WHO and OIE have the major roles. WHO calls BSE among the most virulent food safety – food-borne diseases. Although WHO cannot mandate any actions by governments on BSE or on any other food-borne hazard, WHO is without a doubt influential in shaping public opinion and government responses to food-borne hazards. In contrast, OIE takes a pretty pragmatic approach to BSE control, and it will continue working on further refinements of its BSE classification system over the next few years. Hormones in beef – not a new story, but a continuing saga, and I think interest, for our purposes today, for what it illustrates about the changing approach to international food safety decision making. Codex determined, in 1995, that MRLs for hormones in beef are, and I quote, "unnecessary because they are unlikely to pose a hazard to human health, and Codex's logic here was that beef treated with hormones contained hormone levels that were similar or lower to levels of hormones found naturally in beef. As you will recall, the U.S. prevailed, when we took our hormone to the WTO for testing in European trade embargos against U.S. beef. It's an important observation on the growing importance of risk assessment in the international arena that this seemingly compelling fact that the Codex had determined that no MRLs were necessary probably didn't play much of a role in WTO's decision making, and what probably carried the day for the United States was the fact that Europe did not have a risk assessment to back up their ban of U.S. meat from hormone treated animals. Antibiotic resistance is gaining an importance in WHO, Codex, and OIE. WHO identifies antibiotic resistance as a serious developing public health problem in its global strategy for food safety, and while WHO acknowledges that human clinical use and misuse of antibiotics play a role, WHO's primary focus is clearly on the trend – on the need to curve antibiotic use in food animals. WHO is pressing hard for a special Codex resistance task force immediately. In response, Codex agreed early last month to convene in principal, a task force on antimicrobial resistance but only after the Commission aggress on a clear scope for the task force or terms of reference. These terms of references, in fact, are open now for comment by a number of countries and until January of 2006. The U.S. Codex office will be looking to close down receipt

of comment in December. So, if you are going to attend, do it soon. Also last month, I should note that Codex adopted a general code of practice to minimize and contain antimicrobial resistance, and OIE also recently produced guidance on resistance management and will continue to monitor the activities of governments on resistance management. The bottom line – antimicrobial resistance is going to a very active area in coming years. One such possible development in the United States could be an extension of the request that FFIS currently sees from certain countries looking for certification that U.S. products exported to their countries do not contain Salmonella stereotypes that they believe do not occur in their countries. It would not be hard to imagine countries seeking certification that U.S. products don't contain pathogens that show resistance to certain antibiotics.

[12]The last two non-traditional global food safety issues I'll mention are biotechnology and Avian Influenza. Biotech, in particular, genetically modified animals is being taken up in Codex. Codex has established a second ad hoc task force in biotechnology hosted by Japan, as Japan hosted the first ad hoc biotech task force. There is a strong expectation among Codex member countries that genetically modified animals will be a major focus on this second task force. It is widely thought that the task force's output will be general guidance of some sort. Although, exactly what the task force will do will be worked out over the next several months, and the first meeting of this task force will be next month in Japan. Last, I'll mention Avian Influenza. You may be surprised to hear me refer to AI as a food safety challenge. I mention it only because – although it does not now present any real food safety risks, it is a changeable virus. It has shown the ability to mutate and jump species. Therefore, it could possibly become to be viewed as a food safety problem beyond poultry, because the virus is, strictly speaking, transmissible through contact with meat from infected animals. WHO's website cautions people not to eat poultry from endemic areas and to exercise all the standard food safety cautions; washing hands thoroughly, avoiding cross contamination, cooking meat thoroughly, etc. While exposure roots, other than food, clearly and overwhelmingly dominate the Avian Influenza risk profile, at least some media reports, from AI stricken areas in Asia, have made the food connection. For example, *The Washington Post*, just last week, reporting from Indonesia on the small and surprising outbreak of AI in a wealthy Jakarta suburb, about three weeks ago, quoted a woman from the suburb as saying that she has forbidden her children to eat food outside the home in case the virus spreads through food, and she said, "We've stopped going to Kentucky Fried Chicken."

[13]I'll conclude by talking about some possible future trends, and I'll pick up a thread from Jakarta woman's concern about fried chicken with the observation that WHO has been placing significant emphasis recently on nutrition, which does raise issues for the meat industry giving WHO's focus on the saturated animal fat and on cardiovascular disease and other chronic diseases associated with high levels of consumption of saturated animal fat, especially if this debate comes to be cast in food safety terms. I'll conclude by noting an interesting observation by WHO I eluded to a little earlier, which states, in its global strategy for food safety, that meat consumption is increasing in developing countries as their economic status improves. You might ask, "Why is this a problem?" Well, WHO also portrays this trend as increasing the likelihood of food-borne illness in these countries. WHO also points out that developing countries are putting major efforts into new programs to ensure the safety of food for the tourist trade. So, I suggest the combination of these two trends makes it quite likely that international organizations

are going to continue to focus on meat safety. With opportunity comes challenge, and I suppose vice versa.

[14]So, on that optimistic note, I will close and join the panel for a discussion of this afternoon's issues, and I thank you very much for your attention.