

REPORT OF THE COMMITTEE ON PHARMACEUTICALS

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The Committee met on Tuesday, October 23, 2007 from 8:00 a.m. to 12:00 p.m. at John Ascuaga's Nugget Hotel, Reno, Nevada. There were 13 members and guests in attendance. The Committee held a theme-based meeting focused on the issue of lack of harmonization in the pharmaceutical approval process that jeopardizes trade in U.S. meat and poultry product in the global marketplace.

John Nappier, Pfizer Animal Health discussed the science behind the drug approval process in the realm of human food safety, highlighting the similarities and differences between the United States, Japan, Codex and European Union (EU) reviews. These differences lead to different minimum residue limits standard (MRLS) and subsequent withdrawal periods. The point was made that all review methods result in the safe production of meat, milk and eggs.

Kevin Smith, U.S. Meat Export Federation, provided a background on the economic impact of meat exports and emphasized that in a world with expanding free trade residue detection may be a barrier that countries will use to protect their native production.

Paul Sundberg, National Pork Board, presented the U.S. pork experience with the implementation of the Japan "positive list," a minimum residue limit (MRL)-based residue protection program. No violations have occurred in the 17 months post-implementation.

Jim Bradford presented for Collette Kaster, Smithfield Foods, on the implications the rapid change in withdrawal times required due to the enforcement of the positive list. Economic hardship fell on companies heavily reliant on Japan exports that could have been avoided with better understanding of the situation by pharmaceutical companies and the pork industry. Better communication in the future and active participation in international standard setting organizations is required by all associated with the production of livestock products.

Michael Senn, Pfizer Animal Health, described the risk analysis and communication plan employed by a pharmaceutical company in the rapid distribution of new requirements in meat destined for export.

Jennifer Greiner, Elanco Animal Health, described the interaction of U.S. and global standard-setting agencies and described the necessity for communication from all stakeholders. The full report is included in these proceedings at the end of this report.

Challenges, Opportunities and Working Together for Global Meat Trade

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The demand for animal protein is rapidly increasing due to a growing population, improving diets and rising per capita incomes. Pork, beef and poultry meat serve as an excellent source of protein to meet this global demand. Based on the geographical location of the population growth compared to areas of food animal production, meat trade will be necessary to more efficiently meet the dietary needs and desires of consumers worldwide. Sanitary and Phytosanitary (SPS) aspects of animal diseases, pathogens and residues are rapidly developing to be significant barriers to global meat trade.

In order to provide for the free trade of meat, international standards and guidelines can serve as the reference points to ensure consumers globally of safe meat products. The Codex Alimentarius Commission (Codex) and the World Organization for Animal Health (OIE) serve as the globally recognized bodies to advance and establish SPS standards and guidelines.

The Codex mandate is to develop food standards, guidelines and related text for protecting the health of consumers and for ensuring fair trade practices in food trade. The OIE mandate is to develop standards, guidelines and recommendations regarding animal diseases and zoonoses for ensuring the sanitary safety of international trade in terrestrial animals and their products. Collectively these two international governmental bodies provide reference points for addressing SPS aspects of animal diseases, pathogens and residues.

The meat sector (including farmers, processors, and the merchandising chain) and governments have a collective role and responsibility in providing consumers safe food products. Working together, all stakeholders need to support independent, science-based, international standards, thereby providing consumers confidence in the regulations that protect public health.

The unique and collective roles of each in the meat sectors allow for the global sourcing of meat products while ensuring public health. The roles include:

- Input suppliers: provide a safe and effective product
- Food animal producers: raise a healthy, high quality animal by providing proper care and sanitation
- Processors: harvest a safe and high quality meat product
- Trading companies: source product globally to meet customer needs
- Distribution companies: provide safe and efficient transport of products
- Retailers: provide a safe, high quality choice of nutritious meat products
- Governments: ensure regulatory structure and oversight supporting food safety, animal and zoonoses disease control, as well as consumer handling and nutrition information

The meat sector, in cooperation with government regulators, needs to work to provide for the production and choice of quality, nutritious and safe products. Together, input suppliers, food animal producers, processors, traders, distributors and retailers need to work with governments to rapidly establish international standards and guidelines to provide for global meat trade. As science evolves, based on the newest science, stakeholders need to work together to implement the appropriate animal disease controls, pathogen protection levels and maximum residue levels to protect

public and animal health. Sound, science-based, domestic and international regulations serve to provide consumers confidence in their domestic regulatory authorities, a safe food supply and a choice of meat products sourced globally. Ultimately, these actions will minimize the constraints on trade.