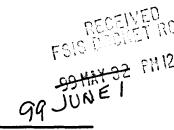
Don A. Franco, DVM, MPH
Diplomate, ACVPM
3309 Weymouth Court
Woodbridge, VA 22192



May 25, 1999

99-030N 99-030N-2 Don A. Franco

FSIS Docket Clerk, Docket #99-030N U.S. Department of Agriculture Food Safety and Inspection Service Cotton Annex, Room 102 300 12<sup>th</sup> Street Washington, D.C. 20250-3700

Dear Sir or Madam:

This references the request for public comment prior to the Executive Committee and full Codex Alimentarius Commission meetings in Rome on June 24<sup>th</sup> - 25<sup>th</sup> and June 28<sup>th</sup> - July 3<sup>rd</sup> 1999, published in the Federal Register (Volume 64, Number 99) on May 24, 1999.

I will limit my comments to items 5 and 6 respectively, consumers' involvement in the work of the Commission and the principles of risk analysis.

Consumers' involvement in the work of the Commission

Under the revised draft (9-15-95) Selection Criteria and Procedures for Delegation Membership in U.S. Codex, and specifically, selection criteria for U.S. (obviously applicable to other countries), there is clearly established protocol for non-government member participation, albeit, with restrictions. Member governments volunteer or are requested to prepare working documents relative to Codex' agenda e.g. new standards, recommendations or guidelines etc. In this era of global transparency, it would be in the best interest of the Commission to involve consumers and take their input seriously.

We clearly have a plethora of excellent minds in government in all industrialized societies, and historically and by tradition, activities within Codex have been led by government experts, predominantly from this sector. This has been accepted for years, and likely will continue to be the norm. In this era, however, it would seem ludicrous not to actively solicit the thinking of consumers worldwide to validate the objectives of Codex. In reality, consumers have a definite interest in the happenings of the organization, and could contribute readily if invited or encouraged to participate. Codex cannot continue operating in a select vacuum. It has to reach out and obtain the broadest views from a wide segment of the non-governmental populace who care to contribute. This heightens the concept of a global democracy, which should be advocated by Codex.

## Principles of Risk Analysis

I evaluate risk analysis based on the components of assessment, management, and communication of risks and will comment to demonstrate some of the blatant challenges as we attempt to ensure fair practices in food trade globally and to protect the health of the consumer.

Codex was established in 1962 and has been working since that time on a number of food standards, guidelines and recommendations. Member governments of Codex have been asked to accept these "standards", but, it has been left to governments to decide whether they should or should not implement them. So, in spite of the more than 200 plus standards, and 40 plus codes of hygienic and technological practices, including the maximum tolerances for thousands of residues (pesticides and veterinary drugs) in food, and concurrently tolerances for food additives and contaminants, food standards internationally are far from being harmonized. Has anyone seriously studied why that is so! A lot of good science went into the standards and guidelines. Outstanding epidemiologists, food hygienists, physicians, veterinarians etc. contributed to the efforts for harmonization, yet we are confronted by the continuing dilemma of an obvious impasse. To expect all countries to harmonize their regulations by using international standards as a basis for their sanitary measures would likely never be realized, in spite of the obvious attributes of harmonization. This is unfortunate, but realistic! The leaders of the industrialized world continue to debate the safety of hormones in beef. The World Trade Organization (WTO) ruled, and the issue remains frustratingly unresolved, accompanied by threats and likely trade restrictions as a result. The less and least of the

industrialized countries are saturated with educated sophisticates who examine the games of the "big fish" and conclude, this is just another game of trading tricks. Science, risk analysis, phyto-sanitary guidelines - get serious! The process actually puts science at risk. The irony of it all!

Our society is without doubt a technological marvel, and one to emulate; yet, analyzing and assessing the risk relevance pathway of microbial pathogen levels from production to consumption that will result in any definable prediction of source contamination remains an enigma in this country! The challenge is defiantly complex. Transform this problem into a global context and the issue seems impossible!! Something that we absolutely take for granted in this country, potable water, is at a premium in many countries of the world, and close to non-existent in some. And, water in one way or another is involved in just about every facet of food safety, and has a public health guideline for most countries. Risk then becomes totally relative!

The realization is that countries are not equal; never were, never will be. The challenge to Codex is to evaluate the pertinence of the existing variables globally and try to resolve the wide differences. Doubtless, the "big fish" will continue calling the shots, but they must be realistic and recognize that in "raising the bar" beyond reach for most, the impasse will continue indefinitely. We will continue to set standards and guidelines that most countries will be unable to comply with.

Codex, none the less, must continue to pursue its mission in spite of the challenging constraints. The Commission has done excellent work in the past, and doubtless will continue to objectify its vision for ensuring fair practices in food trade globally.

I appreciate the opportunity to share ideas and ideology with you, and encourage strongly inclusion of consumers and other subject matter experts who can contribute, while recognizing the immense challenge that the organization faces.

If I can be a further resource, please do not hesitate to call me at (703) 683-2633.

Sincer**e**ly,

Don A. Franco, DVM, MPH, DVPM