2007-0041
2007-0041-2
Bala Swaminathan

Dear David,

I would like to express my appreciation to USDA-FSIS for organizing a very informative and timely public meeting yesterday to discuss the public health significance and the regulatory complexities posed by non-O157 Shiga toxin-producing *Escherichia coli* (non-O157 STEC). I congratulate you for scheduling speakers with diverse backgrounds, interests and positions on the subject. Overall, it was an excellent start towards tackling an emerging problem of high public health significance. I participated in the meeting by audio conference, and I particularly appreciated the availability of the visual aids (MS PowerPoint images) for some of the presentations, notably those of Dr. Griffin, Dr. Hussein and a few others. However, the PowerPoint images for many other presentations (Dr. Tarr, Ms. Hurd, Dr. Koohmarie, Ms. Bopp, and Dr. Feng) were not available at the USDA-FSIS website yesterday. This made it extremely difficult for me to fully grasp the information presented in these talks. I realize that speakers do not always meet deadlines set by meeting organizers for advance submission of visual aids of their presentations. But this poses a serious challenge for those of us who participate via audio conference. I hope you will take appropriate steps to correct this deficiency in future public meetings on such important topics.

It was clear from Dr. Buchanan's presentation on Next Steps/Practical Limitations that the Center for Food Safety and Applied Nutrition/USFDA has taken the position that they are only empowered to take regulatory action by invoking Section 402(a) (1) and/or Section 402 (a) (4) of the Federal Food, Drug and Cosmetic Act, if a non-O157 STEC has been previously shown to be a human pathogen. He indicated that designation of a non-O157 STEC as an enterohemorrhagic *E. coli* (EHEC), based on its propensity to cause bloody diarrhea and/or hemolytic uremic syndrome and/or thrombotic thrombocytopenic purpura, would be sufficient to satisfy the requirements of the FD&C Act and allow the FDA to take regulatory action. Obviously, this position is not consistent with that of the representatives of consumer advocate organizations (CSPI, STOP) who would like all non-O157 STECs to be designated as adulterants in foods and regulated as such. However, given the high prevalence of non-O157 STEC in foods and the environment, and the incomplete array of virulence determinants possessed many non-clinical isolates of non-O157 STEC, it would not be prudent to take such a drastic step at this time. Any regulations designating all STEC as adulterants would be essentially unenforceable and will lead to significant waste of foods. Therefore, it would be prudent to begin by focusing regulatory policy development on a subset of non-O157 STEC that have been clearly demonstrated to be human pathogens. Since inventing another new designation would only cause further confusion, I believe that most stakeholders would be willing to accept EHEC as the focus of the next phase of development in regulatory policy.

However, despite the repeated assertions by the food regulatory agencies that EHEC is an important concept from regulatory policy development and enforcement standpoints, I am dismayed that neither CFSAN/FDA nor USDA/FSIS has a list of *E. coli* that can be classified as EHEC. Therefore, I propose that the first order of business as a logical follow up step for your excellent meeting should be the development of a comprehensive list of *E. coli* that can be

classified as EHEC. CDC, FDA and USDA should work with food industry representatives, academic experts, international experts, and consumer advocates to assemble and agree on a consensus EHEC list. For this purpose, one could start with a working definition of EHEC as an *E.* coli known to produce for Shiga toxin 1 and/or 2, and containing the LEE pathogenicity island and pO157 virulence plasmid. Of course, as Dr. Tarr pointed out in his presentation, some human pathogenic strains of STEC are/will be exceptions to this definition. They could be simply added to the list based on direct and incontrovertible evidence that they have caused human disease even though they may not possess all three virulence factors. Needless to add, this list will be dynamic with additions and deletions to it based on new findings from research, surveillance and outbreak investigations.

The development of a consensus EHEC list will go a long way towards focusing the combined efforts of the public health community and other stakeholders on problems of the highest priority, and will promote more effective use of scarce resources and encourage cooperation across the board. It will bring greater clarity to the problem and will be immensely helpful in developing an effective action plan.

Again, please accept my congratulations on a great meeting.

Best regards,
Swami

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