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Docket Clerk Office      00-043N  
USDA-FSIS                    00-043N-3  
Washington, DC 20250      Alistair I. Webb

Dear Sir or Madam,

Please find enclosed a response to the call for comments on Residue in a HACCP Environment. I apologize for it's lateness but one of my colleagues was overseas and it delayed finalization of the submission.

Yours truly,

Alistair I. Webb  
Professor and Associate Chair  
Director, FARAD Florida Component

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We would like to thank the USDA's Food Safety and Inspection Service for this opportunity to provide information about FARAD's ability and potential to help FSIS and its stakeholders function optimally in the HACCP environment.

I am writing on behalf of the Directors of the Food Animal Residue Avoidance Databank [FARAD] in response to the call for comments on Residue Control in a HACCP Environment. FARAD, a collaborative project of the North Carolina State University, the University of California, and the University of Florida, originated with the Residue Avoidance Program in 1982. It provides expert-mediated advice to commodity groups, quality assurance programs, extension officers and veterinarians on drug and chemical contaminant kinetics as well as making recommendations on withdrawal times. With the advent of the Animal Medical Drug Use Clarification Act of 1994 [AMDUCA] and the legalization of extra-label drug use [ELDU] under defined conditions there has been a major increase in the use of FARAD's toll-free phone hotline and e-mail system. As the sole source of this type of information and service, we feel that we can speak on residue avoidance or prevention with unique authority. Additionally, as a body usually consulted by veterinarians involved in ELDU, FARAD is privy to which drugs are likely to be used and can act as resource to FSIS in its HACCP role to make both sides aware of problems being encountered in residue control from farm to table.

FARAD does not believe an emphasis on monitoring and punitive action helps change people's habits and ways of working. HACCP clearly is aimed at self-regulation for reduction of residues in food of animal origin and prevention where education of those who control exposure of animals to drugs and chemicals is key. The major animal operations already have access to the necessity and methods of controlling exposure and acting on that knowledge to ensure that their products come to slaughter or processing facilities in a correct time scale. We believe that there needs to be more emphasis on outreach to smaller operators to educate the involved producers, extension agents, and veterinarians to better inform them of what is involved in residue avoidance and what information is available for them in meeting this goal. This can be best done through community and commodity centers with expertise from groups like FARAD being used for both education material and personnel. As a majority of these small operations involve minor species, the information available is very limited [or non-existent] and drug therapy has to depend upon ELDU. Information on withdrawal requirements to avoid residues is not readily available and often requires extrapolation expertise currently limited to FARAD staff and those who have been trained by them. Additionally the unique kinetic databank makes these extrapolations not only possible but to have credibility. This expertise has been used repeatedly by various USDA agencies as well as overseas governments – usually without public attribution.

Outreach to veterinarians is extremely important as they are often the prime source of drug information to producers. FARAD has done this through presentations at a variety of meetings, printed matter, and providing a mentored advice system. Over the past 4 years FARAD has published a series of Digests in the Journal of the American Veterinary Association which featured information on withdrawal time calculation and details of common queries fielded by the FARAD Access Centers. These articles have wide readership and have markedly increased awareness of the need for appropriate withdrawal information under the requirements of AMDUCA. It would seem a logical next step to extend this type of information dispersion into

commodity publications and meetings. The calls into the FARAD Access Centers have numbered over 500 in the past year despite staff shortages incurred because of funding lapses. These calls, received from not only veterinary practitioners but also regulatory officials [including FSIS], covered both drugs and contaminants.

A new area that FARAD has entered and that is of vital concern to FSIS and US trade and food safety, is international trade. FARAD has initiated an international effort to provide its expertise in residue avoidance and amelioration to interested parties in overseas countries. This effort, termed Global FARAD or gFARAD has attracted the attention of FAO who is negotiating to have this expertise made available to its member countries. To date France, Spain, and the United Kingdom have established their own national access centers. The payback to FARAD and those who use it is that gFARAD partners are pledged to exchange drug approval data, tolerances and MRLs, as well as drug and contaminant kinetic data obtained in those countries for a wide variety chemicals and species. This is information that is currently inaccessible to US regulatory bodies and animal producer stake holders and that would be of major significance and benefit.

In all of this explanation of FARAD's activities and recommendations it is hard to ignore the precarious position this highly successful program, developed under CSREES guidance and funding, now finds itself. In 1999 FARAD suffered a lapse in funding when it was decided it should be funded through CSREES's Integrated Research, Education, and Extension Competitive Grants Program--National Food Safety Initiative. It has since then been decided that that is an inappropriate mechanism of funding and bridge funding has run out. Congress, in the current session, did include supplementary funding as a line item in the budget but this is half what was last awarded FARAD. FARAD remains viable but does not have sufficient funding to perform at its previous level let alone at any enhanced level in support of the FSIS HACCP environment.

In summary, our recommendations are:

- ◆ emphasis needs to be directed to prevention of residues and less on punitive regulatory efforts, this does not mean ignoring problem areas but rather use this information to concentrate on changing behavior through knowledge
- ◆ increased education of producer groups and involved veterinarians in the science and practice of residue prevention and amelioration
- ◆ maintenance of a strong advisory service to these same stake holders
- ◆ development of international associations that will provide data exchanges that promote access to overseas markets
- ◆ development of methods to allow extrapolation of existing data to other drugs, other species, and other field conditions where this data is just not available

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