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August 22,2000

Subfiled 9/18

Mr. Thomas Billy
Administrator
Food Safety and Inspection Service
U.S. Department of Agriculture
Room 331-E, Jamie Whitten Building
1400 Independence Avenue, S.W.
Washington, DC 20250

98-062P
98-062P-4
Robert G. Hibbert

Dear Mr. Billy:

We are writing on behalf of our client, the Alcide Corporation, in an effort to address misconceptions which may have arisen in your agency's review of its pending petition for rulemaking to provide regulatory acceptance for the suitability of its Sanova™ process for use in federally inspected poultry processing establishments as the antimicrobial component of systems designed for continuous on-line processing. For your convenience, we are enclosing an additional copy of this November 22, 1999, petition.

As the document discusses, the petition is an outgrowth of Alcide's completion of a rigorous data generation process, under FSIS supervision, in federally inspected poultry establishments. We continue to believe, as stated in the petition, that these data establish that through use of the Sanova™ process, poultry processors can achieve significant food safety enhancements. It is therefore in the best interest of both the regulated industry and the public as a whole for FSIS to modify its current regulations to accommodate this technology. I would note that to the best of our knowledge, Alcide has never received any notice of receipt or any other written feedback from FSIS regarding this submission.

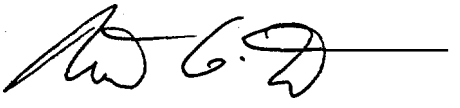
From our perspective, this petition is obviously still pending. The reason for our emphasis of such an apparently self-evident point is our concern that this fact may not be fully or universally understood within FSIS. Along these lines, we have received reports, perhaps erroneous, that in discussions with various representatives of the poultry industry on this issue, some FSIS representatives have expressed the view that one and only one petition in this area, submitted by a competitor of Alcide, is presently pending before FSIS. If this is the case, we would appreciate your efforts to clarify this point within the agency.

We would also note that at the time of our submission of this petition, there was some suggestion by **FSIS** representatives that we might be confronted with a timing issue. In essence, we were advised that since publication of a rulemaking proposal based upon a competitor's petition was imminent, it would be impractical for the agency to adjust the proposal to accommodate our client's additional data. Obviously this is no longer a valid point of concern, since **FSIS** has now had our request under review for a period of some nine months. It is therefore our present hope and expectation that if any proposal in this area is to be issued, it will fully address our request and the underlying data which supports it.

In this regard, it is our general understanding that **FSIS** is now at a point where it is reviewing additional data and assessing various options for future rulemaking in this area. We welcome this review and will be happy to participate further in any appropriate fashion. Under any circumstances, it is our continuing belief that Alcide's pending petition provide a clear, well-documented basis for significant achievable food safety enhancements and therefore should provide a strong foundation for FSIS' rulemaking.

Thank you for your consideration of this information.

Sincerely,



Robert G. Hibbert

Enclosure

cc: G. Kere Kemp, B.V.Sc., **M.R.C.V.S.,**Alcide Corporation, Redmond, Washington
P. Derfler, **FSIS, USDA,** Washington, **DC**

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November 22,1999

Mr. Philip Derfler
Deputy Administrator
Office of Policy, Program Development and Evaluation
FSIS, USDA
Room 350-E, Jamie Whitten Bldg.
1400 Independence Ave., S.W.
Washington, DC 20250

Dear Mr. Derfler:

We are writing on behalf of our clien the Alcide Corporation, developers f the Sanova™ antimicrobial intervention process for poultry. On Alcide's behalf, we are hereby petitioning FSIS to conduct rulemaking which will provide regulatory acceptance for the suitability of the Sanova™ process for use in federally inspected poultry processing establishments as the antimicrobial component of a system designed for the continuous on-line processing of food and fecal contaminated carcasses. We are also requesting that any regulatory proposals on this overall subject which are currently in the development process, not be published until FSIS has had the opportunity to evaluate this request in order to ensure that any such proposal can properly accommodate the Sanova™ system.

Regulatory Relief Request

Alcide requests that FSIS promulgate regulations which will permit the use of continuous online processing systems the use of which, as documented by appropriate supporting data, can result in statistically significant reductions in the incidence of Salmonella spp. and the levels of E. *coli* on finished poultry carcasses. As discussed in further detail below, Alcide has already provided FSIS with data which demonstrates that establishments using the Sanova™ system will generate product which will achieve such results.

Alcide recognizes that other parties may have previously supplied FSIS with data which has led to the development of a regulatory proposal specifying somewhat different criteria. As discussed in further detail below, however, we believe that acceptance of our suggested approach will lead to significant food safety enhancements which are equal to, or better than those suggested by other petitioners' data. Under such circumstances it would be arbitrary and unfair to propose any new regulatory criteria which would fail to properly accommodate the Sanova™ process.

Supporting Data

We have attached, for your information and review, a copy of the final report on the Sanova™ system dated, November 17, 1999. This report has already been presented to FSIS and discussed during a meeting on that same date with Dr. Arshad Hussain and several other FSIS scientists. We also understand that copies of this report have already been circulated informally within FSIS.

This document does not constitute Alcide's entire submission to FSIS in support of its petition. Prior to that date, ten separate data reports of in-plant testing results have been submitted to FSIS. In addition, we are preparing, at Dr. Hussain's suggestion, a complete *summary* of these data in CD-ROM format in order to facilitate further FSIS scientific review. While we assumed that it would not be necessary or productive to direct copies of all of these underlying data to the attention of your office, we can provide you with copies if that is your preference. In addition, we plan to take steps with the appropriate offices within FSIS to ensure that all such data are placed on record in support of our petition.

Collectively, these data provide overwhelming support for regulatory acceptance of the Sanova™ system. More specifically, use of the Sanova™ system will (1) enhance an establishment's ability to maintain ongoing compliance with zero fecal tolerance requirements; (2) significantly improve the microbiological quality of poultry carcasses; (3) achieve statistically significant reductions in the pre-chill levels of *E.* coli and the incidence of Salmonella spp. in such carcasses; (4) enhance the further reduction of Campylobacter spp. levels and incidence; (5) lower labor costs; and (6) improve plant yield and efficiency.

Data Generation Process

The submission of this petition and supporting data complete an extensive data collection process conducted cooperatively amongst Alcide, FSIS, and several federally inspected poultry establishments. More specifically, a series of five evaluations of the system were conducted between July 1998 and October 1999. Consistent with FSIS-approved protocols each study was separated into two phases. During Phase 1, whole carcass rinse samples were collected from identified fecal contaminated carcasses from a series of four defined points on a single evisceration line in each test facility. During Phase 2, whole carcass rinse samples were again collected from identified fecal contaminated carcasses from the same sample points, once a week in each test facility for a period of eight weeks. Reductions in the microbial population between the post evisceration and post Sanova™ sites represent the performance of the COP system, i.e. the combination of an effective carcass wash system and the Sanova™ antimicrobial intervention process. Likewise, comparison of the microbial population between the post evisceration and post offline reprocessing sites represent the performance of normal plant practice for handling fecal or food contaminated carcasses.

In simplest terms, the data establishes that through utilization of the Sanova™ process, poultry processors have achieved significant food safety enhancements. It is therefore in the best interest of both the regulated industry and the public as a whole for FSIS to modify its current regulation to accommodate this technology.

Other Petitioners

Alcide is generally aware of work on alternative continuous online processing systems, which has been conducted under the sponsorship of the Rhodia organization. It is Alcide's further understanding that, based upon the submission and FSIS review of Rhodia's experimental data, your agency has been working for some time on the development of a proposed rule which will authorize the utilization of certain continuous online processing systems. It is our further understanding that publication of such a document may occur in the near future, and that it will propose standards for such systems, which may be compatible with Rhodia data, and with Rhodia data alone.

Based upon the information we have received to date, we have some specific questions about the underlying methodology which supports the Rhodia data. We understand, assuming your agency chooses to go forward with such a regulatory proposal, that the comment process is probably the most appropriate vehicle for resolution of these concerns. Our larger concern, however, is more basic. It is a product of our understanding that, independent of any methodological issues, any performance standards to be proposed by FSIS based upon these data would be strictly quantitative. That is, they would focus upon absolute levels of reduction rather than upon degrees of reduction, as Alcide has focused in the development of its own data. Our concern therefore, is that in any upcoming proposal, Alcide may face an "apples v. oranges" dilemma which could, in all probability lead to the establishment of rules based solely on what we consider to be a flawed experimental procedure. Further, any such proposals will not sufficiently accommodate the food safety benefits to be achieved from the Sanova™ system or indeed from any other future systems. If this is the case, there is a distinct possibility that there will not be a basis for resolution of Alcide's own concerns and interests within such a comment process. We are therefore requesting that, within any upcoming proposal, FSIS take effective measures to ensure that, at a minimum both "apples and oranges" can be accommodated in the proposal and comment process, and in any regulation they will ultimately generate.

FSIS Performance Standards

Our analysis of this issue is complicated by our limited understanding of FSIS' performance standard objectives. At present, all poultry processors are required to simply (1) conform to FSIS' zero fecal tolerance policies, and (2) achieve E. *coli* level and Salmonella spp. incidence results which are compatible with baseline values codified by the agency at 9 C.F.R. 381.94. The particular process used by an establishment to achieve these results is not mandated by any particular regulation.

Arguably therefore, establishments ought to be free to utilize the Sanova™ process, or any other competitive process, so long as continuing compliance with these regulatory requirements is maintained. In evaluating new technologies, however, FSIS seems to adhere to a different standard. The underlying assumption throughout Alcide's data generation process has been that, in order for such technologies to be accommodated by regulation, statistically significant food safety enhancements need to be achieved and documented. Exactly what is and is not "statistically significant" in this context, however, has not, to our knowledge, been defined.

In essence, FSIS seems to be telling Alcide and others similarly situated that in order for the agency to go to the trouble of modifying its regulations (and the inspection procedures which underly them), processors must have a innovation with significant potential impact and must go to the trouble of documenting it. Alcide has, in full cooperation with FSIS, gone through just such a laborious, time-consuming and expensive process, and has now provided your agency with extensive documentation of its effectiveness and its potential value. Under such circumstances, it would be both irrational and fundamentally unfair for the agency, at the precise point in time that such an exercise has been successfully completed, to propose modifications in its regulations which fail to accommodate it.

Procedural Issues

We understand that the regulatory development process within FSIS can be a difficult and time-consuming exercise. If your agency has been engaged for some time in development of such a regulation based upon data supplied by one party alone, we also can understand some potential for reluctance to take steps to modify this process if, as has been suggested to us, the process is nearing its completion. Nevertheless, we believe that any such concerns are outweighed by a number of factors.

The first is fundamental fairness. The completion and submission of these data hardly comes as a surprise to your agency. To the contrary, it reflects the successful completion of an ongoing process of communication and information sharing with FSIS. During this process, the methodology and data collection preferences of Alcide have been considered fully acceptable by FSIS scientists. Obviously, it could not have been the agency's intention to lead our client down a blind alley by encouraging the development of data which would be incompatible with future rulemaking efforts. Common sense therefore dictates the need to reconcile these data distinctions before the agency moves forward.

Second, there are related questions regarding the potential flexibility of any rulemaking process initially driven by only one set of experiments. For this reason, we are seriously concerned with any potential suggestion by FSIS that the issues we raise can and should be resolved through the public comment process. Questions involving how far an agency can go in modifying a proposed rule based upon comment do not lend themselves to definitive answers, and our ability to fully discuss this question is obviously complicated by the fact that we have not had the opportunity to examine the pending proposal itself. It seems clear however that if a proposal is fundamentally based in one company's set of data, and that such data, and the regulatory standards that it generates, are the only issues for public comment, it would be very difficult for FSIS to accommodate, within the scope of such a proposal, alternative approaches advocated by Alcide or any other interested party.

Third, there is the aforementioned issue of delay in the regulatory development process. Given this reality, we are also deeply concerned about any possible response from FSIS which would suggest that the agency will address our concerns through the development of some new proposal supported by the Sanova™ data. This, almost inevitably, would create a scenario whereby our competitor would, for a period of several years, be provided with what amounts to a monopoly over an FSIS-sanctioned process, despite the fact that the agency has already been provided with data which demonstrates that other parties can achieve equivalent or superior results with alternative technologies.

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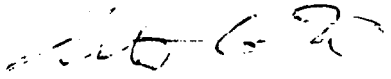
Fourth, this raises more fundamental concerns about the **FSIS** rulemaking approach in this area, concerns which, at a minimum, should be carefully evaluated. Ultimately, **FSIS** regulations should not be technology-specific, and should not be for the sole benefit of Alcide, Rhodia, or any other private interest. Rather they should attempt to establish reasonable performance standards for all regulated establishments which will encourage such establishments to utilize the best available technologies. It is not in the public interest for **FSIS** to define these standards so narrowly that they can be achieved in one particular way, nor is it in the public interest for **FSIS** to insist, as each innovation comes along, that a new time-consuming regulatory process be eliminated before the public can enjoy its benefits. Beyond the particular interest of Alcide, therefore, **FSIS** should take pains, prior to the publication of any proposal regarding such technology, to ensure that its proposal is sufficiently broad to advance such public interests.

Conclusion

Alcide seeks publication of a regulation which would establish performance standards consistent with the data generated by its Sanova™ process. For the reasons discussed above, it is our hope that the FSIS regulation under current development can be modified to accommodate this request. We will be happy to work further with your agency to achieve this result. If we can be of any further assistance in this regard, please do not hesitate to contact me.

Sincerely,



Robert G. Hibbert
Counsel to Alcide Corporation