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Analysis of UMD Comments on JIFSAN Proposal

Food DefenseTQ™ Technical Team

June 5, 2009

O-1 Neither the briefing or the proposal are clear in terms of the type of funding that you are seeking or the magnitude of the resources needed.

R We provided a preliminary draft proposal in order to initiate a dialogue with the University of Maryland (UMD). We felt it would be presumptuous to cost the draft proposal in the absence of UMD input and agreement on the plan outlined in the proposal first.

O-2 Direct non-competitive funding by FDA or FSIS is not likely since both are committed to competitive funding of research and development projects and as far as we know there is no RFP covering this area.

R We prepared the draft proposal and contacted the UMD only after a meeting with senior USDA NIFSI program representatives. During that meeting, government officials expressed keen interest in the development of a Food DefenseTQ™ like product and the world class technical team that we have assembled to undertake the task. They suggested that we review an on-going effort funded by USDA involving the Carnegie-Mellon University as the model for a proposal. They encouraged us to look for a strong university partner to develop the proposal for submission as part of a September 2009 USDA call. We were told that the Carnegie-Mellon effort involved a non-competitive grant to develop a next generation food protection modeling and simulation system.

O-3 The proposal provides a great deal of general information but little detail into what actually you are going to be testing.

R The key to differentiating between what may appear to be general information and the detail Dr. Buchanan seeks lies in understanding the technical workings of the underlying CSM METHOD® architecture and exactly what it does. In retrospect, we were remiss in not providing Dr. Buchanan with a more detailed technical briefing of the system prior to his review of the draft proposal.

O- 4 As currently written, the role that the University of Maryland would play is primarily as a facilitator via JIFSAN between you and the FDA and/or USDA…

R We provided the draft proposal to initiate a dialogue on the possible role and contribution that could be played by UMD. We felt that it would have been presumptuous for us to pre-define the role of UMD. One thing that we did know, however, is UMD's close ties with both the government and industry. These relationships are absolutely invaluable and vital to the success of the project. In any event, we envision much more than a facilitative role for our university partner. A key operating and technical requirement for the functioning Food DefenseTQ™ platform involves the research of event paths and scientific analysis of those event paths and much more. We also envision that our university partner will maintain a national fusion and analytics center in support of all system users. This is a very significant, central and long term research and operational role designed to be supported by a large standing university research infrastructure such as UMD.

O-5 In fact, the proposal leaves the impression that the key “research” parts of this project have been completed, hence the need to focus on funds for development projects.

R While it is quite correct to conclude that key research parts of the project have indeed been completed, this in no way limits the need for university research and development. A key operating and technical requirement for the functioning Food DefenseTQ™ platform involves the research of event paths and scientific analysis of those event paths and much more. We also envision that our university partner will maintain a national fusion and analytics center in support of all system users. This is a very significant, central and long term research and operational role designed to be supported by a large standing university research infrastructure such as UMD.

O-6 There are a number of steps in your work plan flow chart that are vague and need to be clarified in relation to why you consider them necessary. For example, the focus on developing databases of past events and performing statistical analyses on them is vague and poorly supported in terms of the benefit to the ultimate applications.

R The key to differentiating between what may appear to be vague information and the detail Dr. Buchanan seeks lies in understanding the technical workings of the underlying CSM METHOD® architecture and exactly what it does. In retrospect, we were remiss in not providing Dr. Buchanan with a more detailed technical briefing of the system prior to his review of the draft proposal.

O-7 The overall impression that we get is that you are attempting to develop a tool that is "all things to all people" and as a result to comes across as being unfocused. We believe that you need to make a decision on what specific sector will be the focus of the project and whether it is directed towards government needs or industry needs.

R Yes, the CSM Method® is truly remarkable because of it's tremendous scalability. And, while it is true that we have multiple applications that can and do use the CSM METHOD® architecture, this does not mean that our plan to develop Food DefenseTQ™ is not focused. Pages 10 through 16 discuss a carefully focused Phase I effort that addresses a single food product process in a yet to be determined area of high importance to both government and industry. We strongly believe that the problem of food safety is a shared responsibility between government and the private sector and so any successful solution must be squarely directed at these shared needs.

O-8 In thinking about applications you should also consider how you will validate both the software and the underlying models. Such validations need a high degree of transparency either if a government agency was going to use the software to make regulatory decisions or if a corporation was going to use it to support its position to a regulatory agency. It is also important that the proposal explicitly consider food safety, food defense and economic adulterations concerns.

R These are all valid observations that we carefully considered in preparing our proposal. Page 5 of the draft proposal explicitly states that our models rely on expert inputs. The CSM METHOD® requires that all performance criteria be both transparent and explicitly traceable as part of a comprehensive validation process. Throughout the proposal we speak extensively to the notion of “all hazards events” in the context of the FDA Food Protection Plan. This subsumes food safety, food defense, economic impacts and much more. If by this comment you mean that we should specifically use the words that the audience will understand then we can appreciate the observation.

O-9 We think that the most straightforward way for you to proceed is to explore the possibility of a SBIR submission.

R We do not agree with this observation based on our collective experience and the proposed scale of this effort. We would be happy to discuss our position in greater detail directly with UMD.