

Mall West, Philadelphia, PA 19106. The petition proposes to amend the food additive regulations in § 176.170 Components of paper and paperboard in contact with aqueous and fatty foods and § 176.300 Slimicides to provide for the safe use of 4,5-dichloro-2-n-octyl-3(2H)-isothiazolone as a preservative and slimicide in the manufacture of paper and paperboard for use in contact with food.

The agency has determined under 21 CFR 25.32(q) that this action is of the type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: March 30, 1999.

Laura M. Tarantino,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 99-9674 Filed 4-16-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute: Opportunity for a Cooperative Research and Development Agreement (CRADA) for the Research and Development of Software for Managing Distributed Knowledgebases Consisting of Large Numbers of Objects of Diverse Categories Spanning Administrative, Scientific and Other Knowledge Domains

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute seeks a Cooperative Research and Development Agreement (CRADA) with a software company with demonstrated excellence in the development and deployment of software applications for the enterprise and individuals. NCI has recently developed a powerful but user-friendly computer-based system which enables its users to create, use and share a knowledge base of information consisting of diverse objects related to each other by semantically meaningful links. This system, provisionally called "KBTool", can be considered a new class of software application since it is sufficiently different from existing applications. The system provides a knowledge base that is seamless, allowing individuals to store information on a virtually unlimited

range of objects and concepts. In addition, dense and informative links between many types of concepts are constructed. The system is extensible so that it is suited for use in distributed systems in which information is shared between users and stored at different physical locations. Because of the power of the system and its relevance to many domains of knowledge and types of applications, the NCI is seeking a commercial partner for its continued development and deployment. The software was originally created to organize and link vast quantities of scientific data; however, NCI predicts that KBTool's functionality will be applicable to a wide variety of fields. The Collaborator must have a demonstrated record of success in privately producing and marketing information resources.

DATES: Interested parties should notify this office in writing of their interest in filing a formal proposal no later than June 18, 1999. They will then have an additional thirty (30) days to submit a formal proposal.

ADDRESSES: Inquiries and proposals regarding this opportunity should be addressed to Holly S. Symonds, Ph.D. (Tel. #301-496-0477, FAX #301-402-2117), Technology Development and Commercialization Branch, National Cancer Institute, 6120 Executive Blvd., Suite 450, Rockville, MD 20852. Inquiries directed to obtaining patent license(s) needed for participation in the CRADA opportunity may be addressed to John Fahner-Vihtelic, Office of Technology Transfer, National Institutes of Health, 6011 Executive Blvd., Suite 325, Rockville, MD 20852, (Tel. 301-496-7735, ext. 270; FAX 301-402-0220).

SUPPLEMENTARY INFORMATION: A Cooperative Research and Development Agreement (CRADA) is the anticipated joint agreement to be entered into by the NCI pursuant to the Federal Technology Transfer Act of 1986 and Executive Order 12591 of April 10, 1987 as amended by the National Technology Transfer Advancement Act of 1995. The NCI is looking for a CRADA partner to collaborate in the development of the properties of the KBTool data management system. The expected duration of the CRADA would be from one (1) to five (5) years.

KBTool is a data management system and process for efficiently storing and retrieving data. The Experimental Immunology Branch of the NCI has designed KBTool to combine maximum data management flexibility and stability into unified knowledgebase applications. As a result, it has a diverse

functionality which can replace users' fragmented world of specialized applications such as contact manager, administrative database, bookmark keeper, and fact finder. Some unique features of this software-based invention are: (1) ability to handle any number of conceptually distinct categories of items (such as people, events, institutions, tasks, concepts, processes, document types); (2) tools for creating relationships between any two or more objects, with the ability to categorize types of relationships and decide which categories they apply to; (3) use of parent-child relationship as a singularly important relationship to organize, view and navigate information; (4) flexibility in adding diverse categories of objects and relationships, while maintaining a simple underlying data structure and programming environment; (5) ability to view complex relationships in flexible and informative ways; (6) tools for managing names which are indispensable for finding the relevant objects; and (7) efficient ways to search information and filter retrievals to limit to relevant information.

The prototype implementation of KBTool is already a highly functional system. For example, it manages information on more than 50,000 "concepts". These concepts are classified into more than 200 distinct categories. The 10 most highly represented categories are biased towards biological and software knowledge domains: genes, transcripts, proteins, protein spots; humans, institutions, journals, scientific publications, visuals, software applications, and scientific methods. However, its diversity is reflected in categories such as tasks, events, equipment, accounts, documents, areas of expertise and geographical locations. It has more than 50,000 links between these items; each of which conveys not simply the existence of a relationship, but the character of that relationship. This data is distributed into multiple linked databases. The most remarkable feature of the design of the data engine and knowledge representation is its simplicity and generality.

KBTool was designed to allow the maintenance of a "fabric" of information regarding biological systems. It's current implementation can be viewed as the first in a sequence of many steps towards a "virtual cell", which allows modeling of the enormous complexity of a human cell. Having taken this first step, NCI would like to solidify the prototype and subsequent steps in the process. Because of the myriad of components in a biological cell, KBTool had to be designed with

great flexibility. As a result, it has matured into an approach which is unusually broad in its cope, and its ability to create a fabric of information out of very disparate data types.

The described methods are the subject of a patent application, USPA SN 09/203,037 filed November 30, 1998 by the Government.

Under the present proposal, the goal of the CRADA will be to enhance the development in one or more of the following areas:

1. Client Software Development

The prototype client software, KBTool is written in Microsoft Visual Basic 6.0 running under Windows operating systems. Planned evolution includes steps such as the following:

- (a) flexible interfaces for information viewing and update via the WWW;
- (b) rewriting parts of the application in C++ and Java;
- (c) porting to other operating systems (or re-writing in portable code);
- (d) enhanced graphical interfaces to view and manipulate the thought objects in a graphical way; and
- (e) development of specific enhancement for use for specific tasks such as workflow management, document and library management, simulation of biological processes, expert systems.

2. Database Engine/Server Development

The prototype knowledge base is stored in a standard relational database manipulated primarily via SQL. In the long run, the application will likely benefit from using a database engine optimized for it. This would likely include speed improvements, and ability to handle validation and integrity issues at the level of the engine rather than the client software.

3. Content Development

The design of this system is well adapted to many different kinds of content. Such content can be added by a range of strategies: human input, automated transfer from existing information resources, and combinations thereof. NCI seeks collaborative partner for optimizing input in areas related to cancer which encompasses many aspects of biology. For example, NCI seeks sophisticated textual analysis tools to facilitate harvest information from existing sources such as MEDLINE.

Party Contributions

The role of the NCI includes the following:

- (1) Provide staff, expertise and materials for the further development of the KBTool system;

- (2) Evaluate the work product of the Collaborator to ensure progress toward meeting the CRADA goals;

- (3) Provide work space and equipment for production and testing of any components or improvements of the KBTool system.

The role of the successful Collaborator will include the following:

- (1) Provide funding, if and as necessary, in support of the development of the KBTool system;
- (2) Provide expertise and assistance in the extension of KBTool in areas outlined above and in the production and market of any products resulting from CRADA;
- (3) Provide expertise and materials to aid in the development of the KBTool system during this CRADA collaboration; and
- (4) Provide, assist, or advise the NCI in quality assurance testing, operator training, and user support for any products resulting from this CRADA.

Selection Criteria

Proposals submitted for consideration should fully address each of the qualifications shown below. The importance of individual criteria will differ between the three areas for a proposed CRADA: client software development, database engine/server development, and content development. Please address the criteria that relate to the area(s) in which your proposal will contribute.

- (1) Expertise:
 - A. Demonstrated expertise in the creation of important new approaches in software design, database design, data visualization, and data mining, or expert systems.
 - B. Demonstrated expertise in software engineering, data warehousing, data visualization, textual analysis;
 - C. Demonstrated ability to secure national and international marketing and distribution of software;
 - D. Demonstrated expertise in overseeing all aspects of product development;
 - E. Demonstrated expertise in serving and supporting a significant client base;
 - F. Familiarity with application of knowledgebase techniques to biomedical fields.
- (2) Demonstrated experience in the software industry with regards to:
 - A. Producing, marketing and supporting knowledgebase and related applications;
 - B. Indications of high levels of satisfaction by software experts and users of knowledgebase products; and
- C. The range of products and services it produces.
 - (3) Physical Resources:

- A. An established headquarters with offices, space and equipment;

- B. Access to the organization during business hours by telephone, mail, email, the Internet, and other evolving technologies; and

- C. Sufficient financial and technological resources to support, at a minimum, the then current activities of the CRADA to meet the needs of the NCI.

- (4) Other:

- A. The willingness to accept the legal provisions and language of the CRADA with only minor modifications, if any. These provisions govern the distribution of patent rights to CRADA inventions. Generally, the rights of ownership are retained by the organization that is the employer of the inventor, with (1) the grant of a license for research and other Government purposes to the Government when the CRADA Collaborator's employee is the sole inventor, or

- (2) the grant of an option to elect an exclusive or nonexclusive license to the CRADA Collaborator when the Government employee is the sole inventor.

- B. The willingness to cooperate with National Cancer Institute in the timely publication of research results.

- C. The level of financial support the CRADA Collaborator will provide for CRADA-related Government activities.

- D. The willingness to commit best effort and demonstrated resources to the research and development of this technology, as outlined in the CRADA Collaborator's proposal.

Dated: April 8, 1999.

Kathleen Sybert,

Chief, Technology Development and Commercialization Branch, National Cancer Institute, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute (NCI); Opportunity for a Cooperative Research Agreement (CRADA) for the Scientific and Commercial Development of an Improved Cytologic Sampler for the Early Detection of Esophageal Cancer

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice of a Cooperative Research and Development Agreement (CRADA) opportunity.