Comptroller General
of the United States

Washington, D.C. 20548

# Decision

**Matter of:** Neogen Corporation

**File:** B-237530

**Date:** February 16, 1990

Charles M. Boland, for the protester.
Jack L. Radlo, for the interested party, Vicam.
Miley Sutherland, Animal and Plant Health Inspection Service, Department of Agriculture, for the agency.
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## DIGEST

Sole-source award of a contract is proper where the contracting agency reasonably determined that only one source could supply the required item, a quantitative method for measuring aflatoxin levels in grain, and complied with the statutory procedural requirements for a sole-source award.

## DECISION

Neogen Corporation protests the sole-source award of a contract to Vicam under request for proposals (RFP) No. 143-M-APHIS-89, issued by the Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture (USDA), for equipment and supplies for measuring aflatoxin levels in grain.1/ APHIS rejected Neogen's offer based on a determination that the system Neogen offered for measuring aflatoxin levels had not been approved for use by the Federal Grain Inspection Service (FGIS). Neogen contends that APHIS improperly determined that Vicam was the only responsible source capable of meeting the agency's needs.

We deny the protest.

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1/ Aflatoxin is a carcinogenic chemical substance resulting from the metabolic process of certain molds found in stored agricultural crops such as corn and other foodstuffs.

By notices published in the Federal Register on October 17, 1988, and in the Commerce Business Daily (CBD) on December 9, 1988, and by letter dated October 24, 1988, to all known manufacturers of aflatoxin testing methods, FGIS announced that it was conducting a comparison study of aflatoxin test methodologies. The announcements informed manufacturers that the purpose of the study was to evaluate systems that could replace the black light and the Holaday-Velasco Minicolumn Test (HV minicolumn) then in use by FGIS for screening corn for aflatoxin. The announcements invited any "manufacturers, representatives, or distributors wishing to have their product(s) tested," to contact FGIS. Seven companies, including the awardee and the protester, requested that their products be evaluated.

On November 15, FGIS held a meeting with manufacturers who offered products for evaluation. At that meeting, FGIS and the manufacturers discussed and finalized the experimental protocol for the evaluation which detailed the experimental procedures and methodology to be used; defined sample preparation and data analysis; specified the conditions under which the comparisons would be conducted; and identified the laboratories that would conduct the evaluations. The protocol stated that the objective of the evaluation was to "determine if a single alternate screening test can be used to replace the two screening tests currently being used to test for aflatoxin." In addition, the protocol explained that each method submitted would be evaluated on the basis of its accuracy, safety, costs, ease of use, user preference, stability, and expiration date, with accuracy and safety weighing more heavily than the other factors. In addition, the protocol provided that an acceptable method would have to perform as well as or better than the HV minicolumn test currently in use. On November 21, Neogen's representative at the manufacturers' meeting signed the "Protocol Agreement Statement," certifying that he fully understood and approved of the finalized experimental protocol.

Of the seven manufacturers who initially submitted products for evaluation, six companies submitted one qualitative test each, and Vicam submitted both a qualitative test and a quantitative test. Subsequently, Vicam and another company voluntarily withdrew their qualitative tests from the study, leaving five qualitative tests, including the protester's

Agri-Screen method, and Vicam's Aflatest-P, the only quantitative test submitted for the evaluation.2/

The results of the comparison study showed that all qualitative methods submitted, with the exception of Agri-Screen, performed as well as or better than the HV minicolumn test and were therefore recommended to replace that method for screening samples for the presence of aflatoxin at the 20 ppb level in the official inspection system. Because Agri-Screen failed to match or surpass the HV minicolumn performance on all sample tests, it was not recommended to replace the HV minicolumn test at that time. After modification, the Agri-Screen system was subsequently approved as a qualitative screening test for replacing the HV minicolumn method on August 28, 1989.

As noted above, in addition to the qualitative tests, one quantitative test, Aflatest-P, was submitted by Vicam. Aflatest-P was found to correlate with actual aflatoxin levels at least 71 percent of the time; in comparison, the results obtained with the TLC method, the quantitative test then in use by the agency, correlated with known aflatoxin levels present in samples only 35 to 53 percent of the time. Additionally, screening corn using the black light or the HV minicolumn test, and subsequent testing with the TLC method, required approximately 3 hours and 20 minutes to complete, and involved exposing employees to chloroform and diethyl ether.3/ The Aflatest-P method required only

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2/ According to FGIS, a qualitative test determines whether a particular substance is present in a sample being tested, and does not determine the actual amount of the substance in the sample. A quantitative test, by contrast, produces specific analytical (numerical) values for the tested substance. The three tests currently in use are each a different type. The black light test is a qualitative test. The HV minicolumn method is a semi-quantitative test because it determines the level of aflatoxin present in a sample relative to a specific known concentration, e.g., 20 parts per billion (ppb). The thin-layer chromatography (TLC) method is a more complex procedure and yields quantitative results. According to FGIS, either qualitative, semi-quantitative, or quantitative tests may be used to screen samples for the presence of aflatoxin in corn.

3/ FGIS considers chloroform a health hazard as it is toxic to humans and prolonged exposure is thought to cause liver damage and cancer. FGIS also states that acetone, aflatoxin, toluene, and diethyl ether, required by the TLC

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10 minutes to complete, and used relatively small amounts of methyl alcohol. Based on the results of the study, FGIS concluded that Vicam's Aflatest-P system was a more accurate and safer quantitative predictor of the aflatoxin present in corn samples.

On August 8, 1989, APHIS published in the CBD a notice of its intention to procure Aflatest-P from Vicam through the use of other than full and open competitive procedures. The notice stated that Aflatest-P was the only approved product for the intended procurement and invited responsible sources to submit proposals. The agency issued the RFP on August 16, specifying the Aflatest-P system and equipment as the only acceptable item.

The protester and the awardee were the only firms which submitted offers by the closing date of September 9. By letter dated September 12, however, the contracting officer rejected Neogen's offer on the basis that its product, Agri-Screen, had not been approved as a quantitative testing system by FGIS. This protest followed.

Neogen essentially argues that "screening test" as used in the experimental protocol, is a term of art that specifically refers to qualitative methods, and excludes quantitative testing methodologies. In support of its argument, Neogen points to various references in the protocol to screening tests and, with few exceptions, to the absence of any reference to quantitative tests. Neogen contends that the failure to include references to quantitative tests in the experimental protocol precluded FGIS from considering Aflatest-P, a quantitative method, in its comparisons. Neogen adds that had it known that FGIS was considering quantitative methods to replace the black light and HV minicolumn tests, Neogen would have submitted a quantitative testing method for evaluation. Neogen also contends that any reference to the Aflatest-P and TLC methods in the protocol biased the experiment towards quantitative methods. Neogen finally argues that award to Vicam was improper because its Aflatest-P tests are more expensive than Neogen's Agri-Screen system.

With regard to Neogen's challenge to the experimental protocol itself, we see no basis to conclude that the protocol was in any way limited to qualitative tests. FGIS

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3/(...continued)
method, represent significant health risks to laboratory employees and are highly flammable compounds posing serious fire hazards.

states that the term "screening" refers to the preliminary procedure by which it determines whether an aflatoxin positive sample is tested further; it does not describe any particular type of test. As noted above, FGIS points out that either a quantitative, semi-quantitative, or qualitative test may be used as a screening tool, depending on the desired level of accuracy.

With regard to Neogen's failure to submit a quantitative test for evaluation under the protocol, the letter FGIS sent to all known manufacturers of aflatoxin testing methods, including Neogen, specifically requested manufacturers to submit written procedures and a price list for "each" method to be evaluated. Additionally, the CBD and Federal Register announcements invited manufacturers, who wished to have their "product(s)" tested, to contact FGIS. Nothing on the face of the letter or in the published announcements indicated that the methods to be evaluated were limited to one product or that either quantitative or qualitative methods were excluded from the evaluation. Moreover, the language of the announcements and the letter, implied that manufacturers were invited to submit more than one product to be evaluated. Finally, if Neogen objected to any phase of the comparison study or the evaluation of any product, it had ample opportunity to voice its concerns at the manufacturers' meeting and seek clarification or modification to the experimental protocol.

To the extent that the protester argues that the protocol was biased towards a quantitative test, the record shows that FGIS had not established a formal procedure for evaluating quantitative methods when it conducted the study. Accordingly, in an effort to evaluate all products objectively and on an equal basis, the protocol provided for conversion of quantitative results from the Aflatest-P and the TLC methods to qualitative results.4/ We fail to see how reference to these procedures in the context of equalizing the results biased the protocol.

As to Neogen's objections concerning the sole-source award to Vicam, the Competition in Contracting Act of 1984 (CICA), 41 U.S.C. § 253(c)(1) (Supp. IV 1986), permits an agency to use noncompetitive procedures where there is only one responsible source that can satisfy the government's needs. Before using noncompetitive procedures, an agency must execute a written justification for doing so that includes a

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4/ Values of 20 ppb or greater were converted to aflatoxin positive and values below 20 ppb were considered aflatoxin negative.

description of efforts made to ensure that offers are solicited from as many sources as is practicable. 41 U.S.C. § 253(f); Federal Acquisition Regulation §§ 6.303 and 6.304.

Because the overriding mandate of CICA is for "full and open competition" in government procurements, 41 U.S.C. § 253(a), our Office will closely scrutinize sole-source procurements under the exception to that mandate provided by 41 U.S.C. § 253(c)(1). A/E Group, Inc., B-227886.2, Nov. 5, 1987, 87-2 CPD ¶ 447. Where an agency has substantially complied with the procedural requirements of CICA for the written justification for and higher-level approval of the contemplated sole-source action and publication of the requisite CBD notice to solicit offers, we will not object to the sole-source award unless it is shown that there is no reasonable basis for it. North American Biologicals, Inc., B-234583, May 22, 1989, 89-1 CPD ¶ 487.

Here, the contracting officer prepared a justification and approval for the procurement of the Aflatest-P method on a sole-source basis, citing the authority in 41 U.S.C. § 253(c)(1). In support of the sole-source award to Vicam, the justification stated that results of the study showed that the TLC analytical method then in use by FGIS proved accurate only 35 to 53 percent of the time, while the Aflatest-P method was accurate 71 percent of the time, or more. The justification further stated that Vicam's Aflatest-P method was proven capable of improving the accuracy of FGIS quantitative testing for aflatoxin levels, thus reducing the public health hazard represented by aflatoxin levels in food, and would reduce the occupational hazards to which its testing personnel are exposed. In addition, while recognizing the distinct advantages of accuracy, safety, and timeliness offered by the Aflatest-P system, the justification stated that a more accurate system may become available in the future, and that it intends to develop procedures for evaluating and approving such products in fiscal year 1990.

We find that the decision to make award to Vicam on a sole-source basis clearly was proper since Vicam was the only firm with an approved quantitative test. In this regard, contrary to Neogen's argument, the fact that Neogen's test was lower priced than Vicam's is not significant given that Neogen's price was for a qualitative test rather than the quantitative test the agency sought. Further, the agency clearly complied with the procedural requirements of CICA for a sole-source procurement. A written justification was prepared and higher-level approval obtained; letters were sent to all known manufacturers of aflatoxin testing methods advising them of the objectives of the evaluation study and

inviting them to submit their products for evaluation; and the CBD and Federal Register notices clearly advised prospective offerors of the objective of the evaluation. Finally, the CBD notice of the sole-source award specified that Aflatest-P was the only approved item for the solicitation and invited offerors to submit proposals. Accordingly, since the agency complied with the procedural requirements and the record shows that Vicam was the only approved source for the item sought, the sole-source award to Vicam was proper.

The protest is denied.

James F. Hinchman
General Counsel