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Assessing Exposure to Cry9C Protein in StarLink Corn

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STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this report on the basis of its falling within the scope of FIFRA Section 10 (d) (1) (A), (B), or (C).

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GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT

The following exposure assessment is not subject to the principles of 40 CFR 160, GOOD LABORATORY PRACTICE STANDARDS (FIFRA), as promulgated in Federal Register, 54, No. 158, 34067-34704, 17 August 1989.

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QUALITY ASSURANCE STATEMENT

REPORT TITLE: Assessing Exposure to Cry9C Protein in StarLink Corn

REPORT
IDENTIFICATION: StarLink 05-01

This report was audited and reviewed with respect to the environmental modeling and the exposure assessments. The results of the modeling and assessments, and the development of the data summary tables were verified. The information in the report accurately reflects the data.

Carolyn G Scrafford 11-16-05

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I. OBJECTIVE

This assessment was conducted to determine the current levels of consumer exposure to unavoidable residues of Cry9C protein in food containing forms of milled corn. These estimated exposures were compared to exposures previously estimated by the US Environmental Protection Agency (EPA) for potential exposures from Cry9C in wet milled corn alone in order to confirm that any remaining unavoidable residues do not present a human health risk.

II. OVERVIEW

This assessment estimates consumer exposure by utilizing the results of monitoring of Cry9C residues in the US corn supply by government and industry, additional confirmation, quantification and processing studies, and food consumption surveys for the US population collected by the US Department of Agriculture (USDA). The samples were collected "in market" as corn is stored, shipped and/or milled.

A. Quantification of Remaining Cry9C Residues

For the last five years corn has been extensively screened for the presence of Cry9C as the corn is stored, shipped and milled and the results have been reported on a voluntary basis in the Quality Check Program (QCP) and/or in databases maintained by North American Millers Association (NAMA) and by the USDA Grain Inspection, Packers and Stockyards Administration (GIPSA). Since 2001, almost 4 million analyses for Cry9C residues in more than 4 billion bushels of corn have been conducted. The percent of bushels determined to have some residues of Cry9C corn has steadily declined each year. In the past year less than 0.01% of bushels have been reported to contain residues of Cry9C. Detection of residues of Cry9C is seen more often in some months than in other months; however, comparisons of the same month over the 5-year period show consistently declining residues.

In order to reflect current market place conditions, for this assessment, the estimates of the residues of Cry9C in corn products, as consumed, was determined from "in market" screening of corn grain over the past year from September 2004 – August 2005. The assessment uses data for the past year that reflects the results of approximately 60,000 tests reflecting more than 441 million bushels. These samples were tested using an enzyme-linked immunoadsorbent assay (ELISA) strip test, a "qualitative" analytical method that is sufficiently sensitive to detect Cry9C residues from 1 kernel of corn out of 800 kernels of corn. When the protocol calling for testing of 3 800-kernel sub-samples is used, this represents a detection threshold of about 20 ppb for the Cry9C protein.

During the last five years both the prevalence of samples containing Cry9C and the Cry9C residues in those samples testing positive have declined dramatically. Cry9C protein is present in pure StarLink corn at about 12,000 ppb. More than 99.96% of the corn tested in the past 12 months contained no detectable Cry9C residues and the highest residue seen in any corn sampled in the past 12 months was 96 ppb. These low levels are close to the levels of detection so that confirmation of the findings has become particularly important. Also, for this risk assessment, the ability to assign quantitative values to each sample was necessary in order to quantify potential consumer exposures. Therefore, in order to further characterize the remaining residues of Cry9C in corn, two additional studies were conducted for this assessment:

(1) **USDA/ARS Quantification Study Using USDA FGIS QA Samples**
In this survey, the USDA/ARS Laboratory in Raleigh, North Carolina analyzed more than a thousand corn samples collected by FGIS from mid-April through mid-August 2005, using both the ELISA strip test (LOD ~ 20 ppb) and the more sensitive ELISA plate test (detection threshold = 0.0655 optical density units, corresponding to about 0.1 ppb). In addition to its enhanced sensitivity (lower threshold of detection), the ELISA plate test allows quantification of the amount of Cry9C residues present in the sample.

(2**)** **USDA/ARS Confirmation of Tests Reported Positive to the QCP**
The USDA/ARS Laboratory in Raleigh also reanalyzed samples of corn testing positive in the field from March 2004 to September 2005 and reported to the QCP. Whenever possible, USDA/ARS reanalyzed the same extract using fresh ELISA strip tests and the ELISA plate test.

The datasets described above were used together to determine Cry9C residues in corn as a raw agricultural commodity (RAC). In addition, the impact of processing on residues in corn was estimated. Food processing and cooking of dry and wet milled corn affect the level of protein as well as its physical state. A StarLink processing study estimated Cry9C residues remaining in foods and food ingredients made from 100% StarLink corn grain after each type of processing (MRID 453866-03). The EPA Science Advisory Panel (SAP) in 2001 concluded that some of those forms of processing would reduce the potential allergenicity, while additional data would be required to conclude that other forms of processing would reduce potential allergenicity. Therefore, for the current assessment only the processing factors that the SAP identified as affecting potential allergenicity were used to adjust the Cry9C residues in the corn RAC.

B. Corn Consumption in the U.S.

Consumption of corn-containing products was determined using the USDA's Continuing Survey of Food Intake by Individuals (CSFII) conducted in 1994-96 and 1998. The analyses used the same probabilistic models that are used by the EPA Office of Pesticides to evaluate pesticide exposures. The assessment was conducted for the US population as well as for children and the subgroup with the highest consumption of corn – Hispanics. All corn-containing foods were considered in the analysis.

C. Safety Determination

Ordinarily, safety is analyzed by comparing exposure to a no-effect level from toxicity testing. No such level is available here, because the only toxicity concern is potential allergenicity, and there is no method available to demonstrate that Cry9C protein has produced allergenicity at any level or that some lower level is nonallergenic. (No evidence of allergenicity has been identified despite extensive investigations by the US Centers for Disease Control and Prevention and others).

An exposure criterion is available, however. In 2001, the EPA prepared a white paper that estimated potential exposures to residues of Cry9C through corn processing using wet-milling procedures. In that assessment, EPA estimated that the maximum potential exposure to Cry9C residues would be 0.01959 μg Cry9C protein/day and concluded that those exposures would not present a risk to consumers. The assessment was reviewed by the SAP (EPA, 2001b) and the conclusions reached by the EPA regarding exposure were corroborated by the SAP. Moreover, when the Food and Drug Administration (FDA) issued its Cry9C sampling guidance, it called for testing only of corn destined for dry milling. There was no concern about Cry9C residues remaining in corn that was destined for wet milling. Therefore, in the absence of a known toxicity endpoint for Cry9C protein, exposure estimates in this report are compared to estimates of exposure to Cry9C in corn processed through wet milling that EPA has previously concluded presented no risk to consumers (EPA, 2001a).

In this assessment, total consumer exposures to Cry9C residues from all sources of corn (wet and dry milling) have been estimated and compared to the value determined by EPA for wet milling as posing no risk to consumers. The upper 99.5% percentile exposures range from 0.002 μg/day for children 1-6 years of age to 0.003 μg/day for the entire U.S. population. Even with these conservative assumptions, the upper bound (99.5^{th} percentile) exposure estimate from wet-milled corn products alone (i.e., 0.01959 μg Cry9C protein/day or less) that the EPA and SAP in 2001 determined did not present a human health concern to consumers.

III. BACKGROUND

StarLink corn was approved in the United Sates for use as an animal feed, but not for food destined for humans. As a result 247,694 acres of StarLink corn were planted in 1999 and 350,420 acres were planted in 2000, representing 0.32 % and 0.43% of the total acres of corn planted in 1999 and 2000, respectively (EPA, 2000a). Although contracts were established to ensure that the corn was used only for feed, in mid 2000, it was learned that the program was not effectively controlling the destination of StarLink corn. During this time, trace amounts of Cry9C DNA were detected in taco shells and other finished corn products. The presence of Cry9C DNA was not considered to be a safety concern but only provided a marker for the potential presence of Cry9C protein. The EPA has published a final rule exempting nucleic acids from the requirement for a tolerance (66 FR 37817, July 2001).

The approval for use of StarLink corn in foods destined for humans was delayed in order to further assess the potential for the Cry9C protein (Cry9C) in StarLink corn to induce allergenicity in susceptible individuals. Extensive discussions were undertaken by the EPA, Aventis CropScience (Aventis), and others, and several meetings of the SAP were held to further consider the potential for allergenicity. Although no individuals have been documented to have developed an allergic reaction to Cry9C, as a result of the extensive publicity, the potential for disrupting the food supply and associated concerns about causing a "food scare," Aventis withdrew the StarLink technology from the market and initiated an aggressive program to identify corn that contained Cry9C to ensure that it was removed and wouldn't reach the human food supply.

The StarLink Enhanced Stewardship Program was initiated in October 2000 to purchase corn that was determined to contain residues of Cry9C protein, in order to direct that corn to approved nonfood uses. This program and a process aimed at tracking the results of testing taking place in the US called the Quality Check Program (QCP) are being administered by StarLink Logistics, Inc., (SLLI). Inclusion of the results in the QCP is a prerequisite for reimbursement of the testing costs by SLLI. Therefore, most testing results are likely to have been included in the QCP. The USDA in cooperation with the seed industry also initiated a program in 2001 to purchase and destroy any corn seed grown in the US that tested positive for Cry9C, to assure that the contaminated seed not be sold for planting.

The results from the QCP show that the proportion of corn bushels testing positive for the presence of Cry9C residues in the US corn supply has been decreasing with time (Figure 1). The data show a higher incidence of positive results in the summer months as compared to the rest of the year possibly reflecting the shipping of corn stored in elevators (older corn) due to a decrease in the fresh corn supply in the summer months and/or anticipation of the approaching fall harvest. Nonetheless same month comparisons also show a continuing decline in the prevalence of positive bushels. For example, in typically the highest month, July, the percent of

bushels that screened positive for Cry9C residues decreased from 8.5% to 0.01% between 2001 and 2005. As a result of the safeguards implemented by the government, and the stewardship programs established by industry, levels of Cry9C protein residues have declined dramatically over the past 5 years. The carryover of Cry9C residues in the few samples testing positive in 2004 and 2005 were less than the residues that would be found if one kernel were present in each 2400 kernels and are expected to continue to decline with time, as no new StarLink corn will be planted.

Confirming safety is paradoxically difficult since no effect level has been established because no evidence of any toxicity due to consumption of products containing Cry9C protein has been identified. However, in 2001, EPA considered the potential consumer exposures to residues of Cry9C protein from wet milling and determined that the highest exposure levels would be 0.01959 µg Cry9C protein/day (EPA, 2001a; see Section IV, Table 4). EPA further concluded that this level would not present a human health concern to consumers and based on this conclusion, FDA did not include corn destined for wet milling in its testing guidance. The present exposure assessment updates the EPA assessment for wet milling to reflect current levels of Cry9C residues in corn and adds to it exposures that could occur as a result of potential residues in dry milled corn if screening and redirecting of corn testing positive for Cry9C residues is discontinued. In order to evaluate the potential risks of these exposures, the results are compared to the same value EPA determined to present no risk to consumers, e.g. 0.01959 µg Cry9C protein/day (EPA, 2001a).

IV. METHODS

A. Determining the Prevalence of Cry9C in US Corn Supply

1. Analytical Methods

Two analytical methods were used to determine the prevalence and level of Cry9C in the US corn supply. These methods are summarized below and a more detailed description is provided in Appendix A.

a. ELISA Lateral Flow Strip Test Method

Lateral flow strip tests are used in the field and the laboratory to determine if a corn sample contains Cry9C residues. The strip tests are manufactured by Strategic Diagnostics Inc. (SDI) and Envirologix (see Appendix A for SDI's description of this test). The lateral flow strip tests do not provide the actual level of Cry9C residues in the corn sample but rather provide a "yes/no" answer to the question of the presence of Cry9C in the corn with a limit of detection (LOD) of approximately 20 ppb.

b. ELISA Plate Test Method

The ELISA plate test is a laboratory test that can be conducted to measure the level of Cry9C in the corn sample. Current laboratory results indicate that the average LOD of the ELISA plate test is approximately 0.115 ppb but can range from 0.076 to 0.156 ppb.

2. Data Sources

a. "In-market" Test Results

There has been extensive testing of corn in channels of trade. Almost 1 million samples of corn have been tested for Cry9C protein each year since 2000. The results of most of these tests have been compiled into one or more datasets. Exponent reviewed these datasets in order to select the most appropriate data for this exposure assessment. The datasets are summarized below:

i. Quality Check Program Database

The Quality Check Program (QCP) has compiled the results of extensive screening for the presence of StarLink corn in the human food supply. US corn is currently screened in the field (elevators, mills, export terminals, etc…) through the use of lateral flow strip tests (Appendix A). The lateral flow strip test is calibrated to detect 1 in 800 kernels, and testing is conducted on three samples of 800 kernels each, and if any of these samples is positive the entire lot is recorded in the QCP database as positive. The lateral flow strip tests do not provide the actual level of Cry9C in the corn sample but rather provide a "yes/no" answer to the question of the presence of Cry9C in the corn with a LOD of approximately 20 ppb. Therefore, the screening results as reported in the QCP are a "negative" or "positive" distinction allowing for the estimation of the percent of bushels of corn that are testing positive in the US for a given month, year, etc. The QCP was implemented as a means of collecting and analyzing the data generated from the approximately 70,000 tests that are conducted each month to conform with the Food and Drug Administration recommended GIPSA Directive "Testing for StarLink Corn" (http://www.cfsan.fda.gov/~dms/starguid.html (accessed 08/12/05)). Results are collected from tests conducted at elevators (both inbound corn and outbound corn) and mills in addition to barges and trucks. The screening program is not limited to locations known to have StarLink corn and the results are therefore likely to be representative of the true status of the presence of StarLink corn in the US corn supply. The database generated by the program contains results for more than 3 million tests conducted on more than 4 billion bushels of corn.

Over 400 sites have reported results to the QCP since it began in October 2000. Most of the data contained in the USDA GIPSA database and the NAMA database are also contained in the QCP database. The data contained in the QCP, while collected and documented on a voluntary basis, should be representative of the US corn supply.

ii. USDA's GIPSA Database

USDA's GIPSA began providing official testing services for exporters of StarLink corn in November 2000 (Appendix B). The USDA GIPSA data are collected from a variety of locations throughout the corn industry (ports, mills, elevators, etc.) and results of testing show a similar decline in percent positive tests as the QCP database (Figure 2). Samples are targeted towards trying to identify lots that contain StarLink corn. In fact, the EPA SAP stated in July of 2001:

> "However, the GIPSA data are not necessarily representative of grain inventories. They represent primarily tests of trucks and railcars bound for export, grain entering wet milling operations, and samples which for any reason grain handlers submitted to GIPSA. The submitted samples likely come from grain firms trying to confirm suspected lots of corn, in which case they would provide an upward biased estimate of Cry9C protein levels in the grain stream" (p. 24; EPA, 2001b).

Therefore, the USDA GIPSA database appears to provide results that would indicate higher prevalence than is the actual case. In addition, it is likely that the same lot could have been tested multiple times as the corn moved through the channels of trade.

iii. North American Millers Association (NAMA) Database

The members of NAMA have conducted analyses of their corn using the lateral flow strip test and compiled the results into a database and submitted these data to the QCP. The results of analyses collected by NAMA are available through July 2005 and confirm the declining trend and the seasonal variation observed in the QCP and USDA databases (Figure 3). The detection rates observed in the NAMA database are lower than those observed in the other two programs. This may be due to the fact that corn may have undergone screening before reaching the mills and therefore any positive lots had already been redirected to non-food uses.

b. "In market" Test Dataset Selected for Risk Assessment

Data from the QCP, NAMA, and USDA's GIPSA databases consistently show the same declining trend in the prevalence of Cry9C in the US corn supply. A summary of the number of tests conducted within each database during 2004 and the estimated prevalence of StarLink corn is presented in Table 1 and in Figure 4. The NAMA database only contains data from mills, which most likely underestimates the prevalence of Cry9C in the corn supply since most of the corn will have undergone screening before reaching the mills. The USDA database is focused on obtaining samples from corn destined for expert and/or targeted samples and is therefore the least representative of the three databases of the US corn supply destined for dry milling processing in the US.

Based on Exponent's analysis of each of the available datasets, we concluded that the QCP database is the most complete and inclusive database available with the highest likelihood for detection of Cry9C while not specifically targeting those locations suspected of containing StarLink corn. Therefore, in the risk assessment presented in this report, the QCP database was used to estimate the prevalence of detection of Cry9C in the US corn supply. The proportion of corn testing positive was evaluated based on data from September 2004 through August 2005. This corresponds to the most recent past year of data available at this time and is therefore representative of the current prevalence of StarLink corn in the US corn supply.

c. Datasets Used to Confirm "In market" Test Results and to Quantify Levels of Cry9C for the Samples Reported in the QCP

i. USDA/ARS Confirmation of Tests Reported Positive to the QCP

The results of the three testing programs described above all show that the proportion of positive bushels of StarLink corn in the food supply is decreasing to extremely low levels. The proportion of StarLink versus non-StarLink corn in any lot is also declining since no StarLink corn has been planted since 2000 and any presence is likely due to kernels or dust remaining in equipment, etc. Therefore, it is anticipated that the likelihood of misinterpreting test results will increase (that is, there will be an increase in false positives as residues of Cry9C in corn continue to decline). In addition, the accuracy of the test result is affected by how closely the testing protocol is followed at different testing sites, and several factors such as water quality, age of test strip, temperature and grain treatments. Given the very low levels of Cry9C residues in the system, sampling reliability and the results derived from those samples need to be confirmed. For this reason, SLLI requested the USDA/ARS Laboratory to develop methods for conducting additional confirmatory testing to ensure that the results received in the QCP are accurate and to understand the distribution of the Cry9C levels in the US corn supply. Finally the USDA/ARS

Laboratory also developed a protocol to allow quantification of the Cry9C protein in samples initially tested with the qualitative strip test method (See Appendix C for details of the study design).

Confirmatory testing of QCP samples that test positive in the field using the lateral flow test strip has been conducted at the USDA/ARS research facility at North Carolina State University (NCSU) in Raleigh, North Carolina by Dr. Thomas Whitaker. Starting in March 2004, locations participating in the QCP that had a positive test result in the field were asked to send the aliquots testing positive to the USDA/ARS laboratory where the aliquot was re-tested with the strip test. This request was voluntary and therefore it cannot be confirmed that all positive QCP samples were sent to the laboratory for confirmation. However, the results provide estimates of the proportion of samples that could and could not be confirmed. In June 2004, any sample that was confirmed to be positive with the strip test in the laboratory underwent further testing using the ELISA plate test to determine the actual levels of Cry9C in the sample. By the end of September 2004, all samples that were sent to the laboratory were analyzed using the ELISA plate test, regardless of the strip test confirmation results. A total of 56 samples have been tested in the laboratory with the strip test and 31 of these samples have been analyzed using the ELISA plate test. Of the 56 samples re-tested with the strip test, 25.0% have been confirmed to be positive samples (i.e., a positive strip test in the laboratory). Among the samples that were confirmed to be positive with the strip test, eight were then tested with the ELISA plate test and all (100%) showed detectable Cry9C levels. he level of Cry9C detected in these samples ranged from 5.3 ppb to 96.4 ppb. Among the 23 samples that were not confirmed to be positive with the strip test and that were analyzed with the plate test, 73.9% (N=17) had detectable Cry9C levels when using the ELISA plate test. The level of Cry9C detected in these samples ranged from 0.14 to 18.3 ppb. See Table 2 for a summary of these results.

ii. USDA/ARS Quantification Study Using USDA FGIS QA Samples

A special study was conducted at the USDA/ARS laboratory in order to allow a Cry9C level to be assigned to the qualitative results of the QCP.

This study was designed to update the results obtained from an early study that obtained similar data (Bushey, 2001[1]). The Bushey et al. study was conducted 2000 and 2001, and data

[1] Bushey et al collected corn samples from 1125 truckloads over two different periods of time – October through November 2000 and February 2001. Seventy-five composites of 15 samples each, representing 15 consecutive truckloads of grain testing negative with the lateral flow strip test at the mill were formed, and each of the 75 samples was split into 2 sub-samples and analyzed using the EnviroLogix Cry9C ELISA plate kit. The LOD of the ELISA test was 0.35 ppb, and the LOQ was about 1 ppb. The Cry9C protein level was below the detection limit (LOD) for about 80% of the 75 different lots (59 of 75 samples). Another 5 samples, or about 7%, had differing results from the two sub-samples, where one of the sub-samples was below the LOD, indicating that the Cry9C

from this study are not expected to reflect current Cry9C levels. Further the aliquots tested with the ELISA plate test were taken from the shipments from which samples had tested positive with the strip test, but were NOT the samples that tested positive with the strip test. The Bushey study was used to assist in the design of the USDA/ARS quantification study using USDA FGIS QA Samples.

Approximately one thousand corn samples were collected throughout the US by USDA as part of GIPSA's routine quality assurance program and shipped to the USDA ARS laboratory at NCSU. These samples were tested for the presence of StarLink corn by the strip test, followed by Elisa plate testing to quantify the level of Cry9C. USDA's FGIS routinely collects 2000 corn samples per month from corn shipments as they move through the system. They include, in addition to samples collected from corn destined for export and from corn destined for domestic uses, samples that have been submitted by industry. The approximately 1000 samples analyzed for this study excluded industry submitted samples (since it is not possible to determine why or where these samples were collected) as well as samples from corn collected at export terminals (since it is likely that this corn would have already been screened). Samples were to be selected from corn collected in 2005 in the 4-month period of mid-April to mid-August. These months overlap with the period that has historically been associated with a higher prevalence of StarLink detections both in the QCP and in USDA GIPSA StarLink testing (Figures 1 and 2). Approximately two hundred fifty samples were collected per month from corn samples that are known to have been taken from shipments leaving elevators (See Appendix C for details of the study design). A total of 1132 samples have been analyzed from March through August of 2005. The number of samples per month varies (Table 3). However, based on a comparison with the QCP data that shows a fairly consistent level of testing during those same months, Exponent gave equal weight to results from each month. All of the 1132 samples (100%) tested negative with the strip test in the laboratory and 11.4% of these samples had detectable levels of Cry9C when tested with the ELISA plate test. The levels of Cry9C in all detect samples ranged from 0.10 ppb to 2.73 ppb. See Table 2 for a summary of these results.

d. Metric Used for Estimating the Percent of Samples that were Positive for Cry9C

Results in the QCP are reported in terms of bushels, tests, and shipments. Exponent selected the proportion of bushels of yellow corn testing positive to be the most representative and accurate estimate of the proportion of StarLink corn in the US corn supply. The number of

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levels were extremely low. Finally, 11 lots or 14% of the samples had measurable Cry9C protein levels confirmed in the replicate sub-samples. One lot had a significantly high value (17 ppb). In addition, an analysis of the actual Cry9C protein levels found in grain that was rejected from the mill was also performed on grain samples from 42 truckloads. The majority of the samples tested negative using the ELISA test. Of the 5 samples that contained measurable Cry9C protein, the highest level was 262 ppb.

tests reported in the QCP is likely to be influenced by the guidelines set forth by FDA. FDA's guidance calls for three aliquots to be tested per corn sample and if one is positive, the whole shipment is considered positive. If the first (or 2nd) test is positive, the remaining aliquots are most likely not tested and therefore the number of tests reported in the QCP for a lot testing positive is 1 (or 2). However, if all three tests are negative, the number of tests reported in the QCP will always be 3. Therefore, negative results will carry more weight if the number of "tests" is used to estimate the proportion of positive detections. The proportion of "shipments" testing positive from September 2004 through August 2005 among outbound shipments from elevators (0.013%) was less than the proportion of "bushels" testing positive (0.028%) for the same time period. Therefore, we used the more conservative estimate and based our assessment on bushels tested.

The QCP database includes yellow corn, white/yellow corn mix, white corn, and blue corn. The assessment was limited to yellow corn since StarLink corn is yellow corn. We could have included the "white/yellow corn mix" data in our prevalence estimate; however there were no positive results reported in the past year for this category of corn tested and therefore including this category of corn would have resulted in a lower percent positive.

There are two types of locations that test for StarLink corn within the QCP – mills and elevators (including export terminals). Elevator data are further classified into corn tested inbound to the elevator and outbound from the elevator. Since the same corn may have been tested at multiple locations, Exponent decided that a single site should be used for this assessment. In the QCP in the past year, 0.020% of yellow corn tested positive for Cry9C using the strip test. This is compared to 0.024% of corn tested at elevators (0.019% inbound and 0.028% outbound) and 0% of corn tested at mills testing positive. Therefore, to be conservative, results from testing conducted on outbound corn samples at elevators were used as an estimate of the prevalence of Cry9C in the US corn supply. The mill results in the QCP were not selected since these results historically show a lower prevalence of positive results; most likely because the corn has been previously screened at the elevator (similar to the NAMA database). In fact, there were zero positive results reported in the past year among mills participating in the QCP. Inbound elevators would intuitively be the most conservative estimate since the corn coming into elevators most likely has not been previously screened as it is coming straight from the field. However, the following statistics from the QCP in the past year summarize the results of testing at elevators as recorded in the QCP and confirm that there is higher prevalence of positive results in outbound corn when compared to inbound corn:

- 39% of all (yellow) corn tested in elevators is inbound, while the remaining 61% is outbound
- 0.019% of all inbound corn tested at elevators was reported as testing positive, while 0.028% of all outbound corn tested at elevators was reported as testing positive

Of all the corn tested outbound from elevators, 0.028% was reported as testing positive from 2004 to 2005. To be conservative, at EPA's suggestion, we added all positive results from corn tested inbound to elevators to the positive results from corn tested outbound from elevators, but did not adjust the denominator. The estimate of percentage positive increases to 0.04%. Exponent used this as a conservative estimate of corn testing positive in the field.
In summary the highest prevalence of positive samples was seen as corn is sampled at outbound elevators. Therefore, in order to be conservative this location was selected to estimate the proportion of StarLink corn in the US corn supply. Further, Exponent determined that most appropriate way to summarize the available test results is as the percent of yellow corn bushels testing positive for Cry9C among outbound elevators in the QCP.

3. Estimating Cry9C Levels in US Foods

In order to conduct a probabilistic exposure assessment using Monte Carlo methods, it was necessary to quantify the levels of Cry9C in corn and to express those results as a distribution. Exponent created an overall distribution by using the data described above to create component distributions based on the original QCP database and the USDA/ARS confirmation and quantification studies. The component distributions were selected so that the overall distribution would be representative of the US corn supply and would therefore consider the potential for high residues as well as the potential for no residues. In every case, conservative assumptions were applied to ensure that the resulting risk assessment does not under estimate exposures. The six component distributions represent corn without Cry9C, corn potentially containing Cry9C but below the limits of detection of the most sensitive detection method (the ELISA plate test), corn potentially containing Cry9C present between the limits of detection of the ELISA plate test and the limits of detection of the ELISA strip test, corn determined to contain Cry9C by the ELISA strip test, etc. The basis for each of the distributions is described in detail below.

a. Distribution of Cry9C Levels in US Corn Supply

The QCP database was used to determine the prevalence of Cry9C in the US corn supply (as described in the previous section). Based on the QCP data from the past year (September 2004 through August 2005), 99.96% of the corn tested in the field using the strip test is negative for Cry9C (Figure 5). In order to estimate exposure to Cry9C, the distribution of Cry9C levels in the US corn destined for dry milling had to be determined using the distributions outlined in Figures 6 and 7 and prevalence data from the QCP. The strip test has a high level of detection (20 ppb; see Appendix A) that was not appropriate to assign to negative results. Due to the high proportion of corn in the QCP that is negative for Cry9C (99.96%), the risk assessment is largely driven by the Cry9C level assigned to the negative results. Therefore, determining an appropriate distribution of levels in the negative results is critical to accurately estimate exposure. It was not practical to have all of the negative samples in the QCP shipped to the

USDA/ARS laboratory at NCSU and subsequently tested with the ELISA plate test to determine the levels in the negative samples. For this reason, the USDA GIPSA samples were analyzed. All samples were tested with the strip test to determine if positive or negative for Cry9C and then subsequently tested with the ELISA plate test. Among corn testing negative in the field with the strip test 88.6% subsequently tested negative with the Elisa plate test and is not likely to contain any StarLink and was assigned a zero Cry9C level. Approximately 11.4% of corn samples testing negative with the strip test subsequently tested positive with the Elisa plate test (Figure 6).

Among the QCP corn samples that were positive in the field and sent to the USDA/ARS laboratory for confirmation, 75.0% were found to be negative with the confirmatory strip testing in the lab and 26.1% of these were non-detects with the ELISA plate test (Figure 7). The rest of these samples (73.9%) had detectable Cry9C levels (Figure 7).

Among the samples testing positive in the field and in the lab with the strip test, 100% had detectable Cry9C levels with the ELISA plate test (Figure 7). No samples were determined to be positive in analyses conducted at the UDSA/ARS laboratory using the strip test and subsequently non-detect with the ELISA plate test (Figure 7).

In order to characterize the distribution of Cry9C protein levels in the US corn supply, the corn was divided into 6 categories based on the levels of Cry9C protein:

- Category 1: corn testing negative in the field (QCP); negative in the ELISA plate test was assigned Distribution 1
- Category 2: corn testing negative in the field (QCP); positive in the ELISA plate test was assigned Distribution 2
- Category 3: corn testing positive in the field (QCP) but negative in the strip test and the ELISA plate test was assigned Distribution 3
- Category 4: corn testing positive in the field (QCP), negative with the strip test in the lab but with detectable levels with the ELISA plate test was assigned Distribution 4
- Category 5: corn testing positive in the field (QCP), positive with the strip test in the lab and non-detect with the ELISA plate test was assigned Distribution 5
- Category 6: corn testing positive in the field (QCP), positive with the strip test in the lab and detectable levels of Cry9C with the ELISA plate was assigned Distribution 6

The distribution of Cry9C protein levels that was defined for each category is described below:

i. Distribution 1

Corn testing negative in the field with the strip test and subsequently testing negative with the Elisa plate test is not likely to contain any StarLink. This corn was assigned a 0 ppb

Cry9C level (Distribution 1; Figure 6). The proportion of the US corn supply that fit into Distribution 1 (88.57%) is equal to the percent of corn testing negative in the QCP (99.96%) times the percent of results from the USDA GIPSA study that showed negative results (non-detect) with the ELISA plate test (88.6%) (Table 4). The decision to assign a zero value is validated by the very small proportion of the StarLink corn crop from the 1999 and 2000 crop that could still be present in the US markets. Using data on the amount of StarLink corn from the 1999 and 2000 crop that was unaccounted for and information on typical corn storage practices, the percent of the 2005 corn crop that might still be StarLink corn was estimated to be 0.0002% (Table 2).

ii. Distribution 2

Distribution 2 consists of corn testing negative in the field with the strip test and subsequently testing positive with the Elisa plate test (Figure 6). The empirical distribution of Cry9C levels detected in the corn testing positive with the ELISA tests were used to define this distribution (Figure 8). The proportion of the US corn supply that fit into Distribution 2 (11.39%) is equal to the percent of corn testing negative in the QCP (99.96%) times the percent of results from the USDA GIPSA study that had detectable Cry9C levels with the ELISA plate test (11.4%) (Table 2).

iii. Distribution 3

Distribution 3 refers to the corn samples that were positive in the field (QCP) but were then found to be negative with the strip test in the lab and non-detects with the ELISA plate test (Figure 7). The level of Cry9C in the corn assigned to this distribution was defined using a uniform distribution ranging from 0 ppb to the ELISA plate assay LOD (0.156 ppb). The proportion of the US corn supply that fit into Distribution 3 (0.008%) is equal to the percent of corn testing positive in the QCP (0.04%) times the percent of these positive results that are found to be negative with the strip test in the lab (75.0%) times the percent of these negative strip tests that are non-detects with the ELISA plate test (26.1%) (Table 2).

iv. Distribution 4

Distribution 4 contains the data from the corn samples that were positive in the field (QCP), negative with the strip test in the lab but had a detectable level of Cry9C with the ELISA plate test (Figure 7). The empirical distribution of Cry9C levels detected in the corn testing positive with the ELISA tests were used to define this distribution (Figure 9). The proportion of the US corn supply that fit into Distribution 4 (0.022%) is equal to the percent of corn testing positive in the QCP (0.04%) times the percent of these positive results that are found to be negative with the strip test in the lab (75.0%) times the percent of these negative strip tests that are non-detects with the ELISA plate test (73.9%) (Table 2).

v. Distribution 5

Distribution 5 refers to the corn samples that were positive in the field (QCP), positive with the strip test in the lab but had a non-detect level of Cry9C with the ELISA plate test (Figure 7). The level of Cry9C in the corn assigned to this distribution was defined using a uniform distribution ranging from 0 ppb to the ELISA plate assay LOD (0.156 ppb). The proportion of the US corn supply that fit into Distribution 5 (0%) is equal to the percent of corn testing positive in the QCP (0.04%) times the percent of these positive results that are found to be positive with the strip test in the lab (22.2%) times the percent of these negative strip tests that are non-detects with the ELISA plate test (0%) (Table 2).

vi. Distribution 6

Distribution 6 contains the data from the corn samples that were positive in the field (QCP), positive with the strip test in the lab and had a detectable level of Cry9C with the ELISA plate test (Figure 7). The empirical distribution of Cry9C levels detected in the corn testing positive with the ELISA tests were used to define this distribution. However, due to limited data points and awareness that Cry9C levels could potentially be higher than the maximum seen to date (96 ppb) Distribution 6 was defined to be a combination of a uniform distribution ranging from the minimum Cry9C level (5 ppb) to the maximum Cry9C level (96 ppb) measured in the laboratory with an exponential "tail" to allow for higher levels to be modeled. This approach is based on guidance from EPA (Figure 10). The proportion of the US corn supply that fit into Distribution 6 (0.010%) is equal to the percent of corn testing positive in the QCP (0.04%) times the percent of these positive results that are found to be negative with the strip test in the lab (25.0%) times the percent of these negative strip tests that are non-detects with the ELISA plate test (100%) (Table 2).

b. Method for Combining Distributions to Estimate Current Level of Cry9C in US Corn Supply

The six distributions of Cry9C levels were combined proportionally based on the probability of occurrence of the six scenarios described above (Table 4) using Monte Carlo methods. This method resulted in one final distribution of Cry9C levels that was assigned to foods included in the intake assessment.

c. Addressing the Potential for Hot Spots, Dilution and Commingling

Extensive mixing across lots of corn occurs as corn moves from the farm to elevators to mills and finally to food processors. Corn is delivered to elevators and stored in silos containing corn from multiple truck loads. Likewise corn delivered to mills is commingled with corn from more than a single truck or source. Therefore, it is unlikely for a single lot to be the sole source of corn in a finished product. The extent of commingling has been estimated by NAMA and presented to the SAP (Appendix D).

Detailed information from NAMA on whole corn handling and grain processing at dry mills is contained in a Corn Handling and Grain Handling Discussion prepared by NAMA and the National Feed and Grain Association (Appendix D). Based on this information, through storage, tempering, multiple grinding/sifting operations, transfer into product bins, further processing into retail products, there are at least 7-8 distinct points of dilution during the entire voyage from field to end-user.

In order to be conservative, only a single occasion of commingling has been incorporated into the present risk assessment. That occasion is based on the NAMA presentation to the SAP as described below:

A conservative (worst case) estimate of the commingling/dilution factor for grain at one specific dilution point, e.g., in an elevator, is on the order of 3 to 5 times, while the degree of dilution at the mill (another dilution point) is probably much greater than the factor of three, considered to be the “worst case” at the elevator level. Therefore, for this risk assessment we assumed, conservatively, only a five-fold dilution. This was accomplished as follows: Estimates of Cry9C levels for composite samples of 5 formed from the distribution derived as described above were calculated. To address the potential for “hot spots”, i.e., the potential for corn to be mixed with other local corn, the composites were formed from the stratified distribution of Cry9C levels.

Specifically, the distribution derived as described above was divided into ten strata representing the 10 deciles of the distribution before adjustment for dilution and commingling. This approach is conservative in that it forms composite samples within strata that have similar levels, and thus is not likely to form composite samples from corn with low Cry9C levels with corn with high Cry9C levels.

d. Cry9C Levels in Breakfast Cereals

Corn used in the production of breakfast cereals undergoes extensive blending, heating and processing (personal communication to Exponent from Cereal Industry and NAMA). Based on this knowledge, it is assumed that there will be no residues of Cry9C in cereals. A sensitivity analysis assessing the impact of assuming a more conservative scenario is presented in Appendix E (Analysis 4).

e. Adjusting Cry9C Levels to Account for Processing

Processing factors from the study submitted by Aventis to EPA and reviewed by SAP were used (MRID 453866-03). Based on the SAP's review, only the processing factors for non-heat treated fractions were used (see Table 6). No reduction due to any heat processing was included. Table 6 lists the processed foods made from 100% StarLink corn. The first column reports the levels of the Cry9C protein in those foods as determined using the EnviroLogix ELISA plate test. The second column shows the percent reduction in the level of the Cry9C protein in these analyzed foods and food ingredients due to the effects of processing. For the appropriate fractions (based on SAP recommendations; EPA, 2001b), a processing factor was derived from these data and applied to the levels estimated for the raw corn. This factor was applied as part of the probabilistic exposure analysis, e.g. a residue for raw corn was drawn from the distribution and then, based on how the CSFII survey participant reported consuming the product, a processing factor was applied if appropriate. The SAP agreed that the masa process would reduce residues. The reduction due to masa processing was 99.1%. Therefore, if a person ate a tortilla a processing factor of 0.009 would be applied to the residue value prior to multiplying the residue value by the amount of corn in the product consumed. This process was repeated for each corn product consumed and then summed to estimate the individual's exposure.

B. Consumption Data

Consumption data from the 1994-96, 1998 Continuing Survey of Food Intakes by Individuals (CSFII) (USDA, 2000) were used in the assessment. The CSFII is a nationally representative survey that collected 2-day food intake data for approximately 22,000 individuals. Only individuals with complete and reliable 2-day dietary records were included in the analysis (N=20,607). Households and individuals were surveyed in all four seasons and on all days of the week. In addition to information on food consumption, the survey collected physiological and demographic data such as sex, age, self-reported height and weight, ethnic group, pregnancy and lactation status, and household income. This information permits an assessment of food consumption by specific population groups of interest. The survey is designed to provide consumption estimates that are nationally representative of the US population. The intakes

presented in this report are based on average daily intakes among subjects with 2 days of valid intake data.

The Foods and Residue Evaluation Program (FARE™) software, developed by Exponent, Inc. utilizes data from USDA's CSFII to estimate dietary consumption. The food consumption data are reported in CSFII on an "as consumed" basis (e.g., pizza, mixed salad, etc.), and are translated into raw agricultural commodities (e.g., tomato puree, wheat flour, raw head lettuce, raw leaf lettuce, etc…) using an ingredient translation database developed by the USDA and Exponent. Foods are included in FARE™ analyses as the Raw Agriculture Commodity (RACs) (e.g., raw tomato, milk fat, wheat) or the finished food (e.g., lasagna). In this assessment, the proportion of processed corn ingredients (i.e., meal, bran, flour, starch, etc.) in foods was determined and Cry9C levels were applied after accounting for the appropriate processing factor. The proportion of each form of processed corn in foods was determined based on EPA's FCID recipe database that breaks down each "as consumed" food into the appropriate ingredient components.

V. EXPOSURE ASSESSMENT AND COMPARISON TO EPA'S 2001 EXPOSURE ESTIMATES FOR WET-MILLED CORN

An exposure assessment to quantify intake of Cry9C protein through consumption of foods containing corn grain was conducted using Exponent's FARE™ software version 7.80. The distribution of Cry9C levels in corn products was derived using Monte Carlo methods to combine the six distributions derived as described above. Each time a food containing corn was reported consumed by a respondent in the 1994-1996, 1998 CSFII database, that corn was assigned a residue level taking into account the appropriate blending factors and corn processing fractions (see Appendix F for the list CSFII food codes included in the assessment and the processing factors applied to each). As shown in Table 2, when a consumer reported eating an item containing corn, 88.6% of the time a value was selected from Distribution 1, e.g. the corn was assumed to contain 0 ppb Cry9C; 11% of the time a value was selected from Distribution 2, e.g. a Monte Carlo sampling selected one of the empirical values contained in Distribution 2; and so on for Distributions 3-6.

Exposure estimates for the US population and 3 subpopulations (children 1-6 years, children 1-7 years, and Hispanics) were derived (Table 7). The upper 99.5% percentile exposures range from 0.002 µg/day for children 1-6 years of age to 0.003 µg/day for the entire U.S. population. Even with these conservative assumptions, the upper bound (99.5th percentile) exposure estimate from wet-milled corn products alone (i.e., 0.01959 µg Cry9C protein/day or less) that the EPA and SAP in 2001 determined did not present a human health concern to consumers. It should be noted that the mean exposures are also presented in Table 7. The mean exposures are higher than the upper 99.5% percentile exposures because even though there are a high percentage of consumers (>90%), the Cry9C residue distribution has so many instances of essentially zero residues and very few residues greater than 50 ppb. Results of a sensitivity analysis to assess the impact of using non-zero concentrations for corn testing negative in the field with the strip test and in the lab with the ELISA plate test are summarized in Appendix E (Table E-1) and show that estimates of the mean exposures became lower than the estimated 95th percentiles, when no zero concentrations were used.

A. Comparison of Current Exposures to Cry9C from All Corn Sources to Estimated Exposures Considered Acceptable in 2001 for Corn Destined for Wet Milling

Absent any effect level or any other threshold, it was determined that the best comparison would be against the amount of Cry9C that the EPA determined would not indicate a consumer safety issue. The original EPA determination is summarized below and then compared to the results of this exposure assessment.

Some corn is milled with a dry process and some with a wet process. EPA concluded, in a follow-up report to the November 28, 2000 SAP meeting. "…that use of StarLink corn in wet-milling results in no (or essentially no) residues of Cry9C in human food fractions – corn oil, corn syrup, alcohol, corn starch." (EPA, 2001b).

In EPA's follow-up report (EPA, 2001a), several different exposure scenarios were evaluated using varying assumptions of the mixing rate of StarLink corn with non-StarLink corn. The most conservative estimates assumed that food containing corn starch made from grain containing 1.5% StarLink corn. The 1.5% mixing rate is based on the high end of the distribution of levels of Cry9C in corn grain and corn grain products in 2000 and assumes that "…whatever amount of StarLink grain was used to make processed food was used in the same percentage as it was planted in a particular state" (EPA, 2000). Using the conservative assumption that no screening for the Cry9C protein is being conducted, the EPA determined that an upper bound estimate of the potential exposure to Cry9C from wet-milled corn would be 0.01959 μg Cry9C protein/day or less. Therefore, even using a conservative mixing rate and assuming that 1.5% of the wet-milled corn was StarLink corn (i.e., use of corn from 2001 supply without testing for StarLink corn) it was concluded that the exposure levels presented in that evaluation did not present a human health risk to consumers (EPA, 2001a; EPA, 2001b). In addition, members of the November 2000 SAP panel indicated that EPA's preliminary evaluation illustrated the low exposure to Cry9C in wet-milled food products and the extremely low potential for these levels to cause any effects (EPA, 2000b).

This value (0.01959 μg Cry9C protein/day) is thus a reasonable, albeit conservative, benchmark to use in evaluating the levels of Cry9C protein present in the corn supply today. The results of this exposure assessment were compared to the results of the wet milling exposure assessment prepared by EPA in response to the last SAP meeting held to discuss StarLink corn (EPA, 2001a). This comparison is presented in Table 8. The mean estimated exposure to Cry9C residues ranges from 0.00005 μg/day for children to 0.00007 μg/day for the entire U.S. population. The upper 99.5% percentile exposures range from 0.002 μg/day for children 1-6 years of age to 0.003 μg/day for the entire U.S. population.

In all cases exposures are currently almost an order of magnitude lower than those previously estimated for wet milled corn sources only. This reflects the decline in the prevalence and levels of Cry9C protein in the US corn supply.

VI. SENSITIVITY ANALYSES

There are many assumptions that are involved in conducting an exposure assessment and each of these can affect the resulting exposure estimates. The assumptions made in this evaluation of the US population's exposure to Cry9C through the consumption of food products made from wet and dry milled corn are discussed in the methods section of this report and are summarized in Table 9. The assumptions were determined with the goal of estimating an exposure level that is representative of consumers' true exposure and are based on years of extensive data collection, knowledge of the corn grain industry, and expertise on dietary habits. However, to illustrate the effect different assumptions might have had on the final exposure estimate, Exponent has assessed the impact of several alternative assumptions. The alternative assumptions are summarized in Table 9 and if appropriate, a sensitivity analysis was conducted to determine the effect of an alternative assumption on exposure estimates (Appendix E). Four formal sensitivity analyses were conducted and all resulted in exposure estimates at or below the upper bound exposure estimate from wet-milled corn products alone (i.e., 0.01959 μg Cry9C protein/day or less) that the EPA in 2001 determined did not present a human health risk concern to consumers.

VII. CONCLUSION

Confirming safety is paradoxically difficult since no effect level has been established because no evidence of any toxicity due to consumption of products containing Cry9C protein has been identified. However, in 2001, EPA considered the potential consumer exposures to residues of Cry9C protein from wet milling and determined that the highest exposure levels would be 0.01959 µg Cry9C protein/day[1] (EPA, 2001a; see Section IV, Table 4). EPA further concluded that this level would not present a human health concern to consumers and based on this conclusion, FDA did not include corn destined for wet milling in its testing guidance

The present exposure assessment updates the EPA assessment for wet milling to reflect current levels of Cry9C residues in corn and adds to it exposures that could occur as a result of potential residues in dry milled corn. In order to evaluate the potential risks of these exposures, the results are compared to the same value EPA determined to present no risk to consumers, e.g. 0.01959 µg Cry9C protein/day (EPA, 2001a).

The estimated upper bound (99.5^{th} percentile) daily exposures of the US population to Cry9C from corn products processed either by wet or dry milling of today's corn is 0.00303 µg Cry9C protein/day or less which is almost an order of magnitude less than the upper bound exposure estimate from wet-milled corn products alone (i.e., 0.01959 µg Cry9C protein/day or less) that the EPA in 2001 determined did not present a human health risk concern to consumers.

Based on the evaluation of the results reported in this analysis and taking into consideration the assumptions listed above, the current anticipated exposure to Cry9C in corn grain does not present a human health risk concern.

[1] 99.5% percentile of exposure among consumers in the US population assuming food containing corn starch was made from grain containing 1.5% StarLink corn (EPA, 2001a).

VIII. REFERENCES

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EPA 2001a. White paper on the Possible Presence of Cry9C Protein in Processed Human Foods made from Fractions Produced Through the Wet Milling of Corn.

EPA, 2001b. SAP Report No. 2001-09. Assessment of Additional Scientific Information Concerning StarLink Corn.

EPA, 2001c. BEAD Estimate of Length of Time Corn Grain is Spent in Channels of Trade. July 2, 2001 memorandum from David W. Brassard to Janet Andersen and William Jordan.

MRID 453866-03. April 17, 2001. Detection of Cry9C protein in dry milled, wet milled, and masa processed fractions and processed foods made from 100% StarLink grain. R.D Shillito, S. MacIntosh, and W.J. Kowite. Aventis CropScience; Report Number CM00B014.

U.S. Department of Agriculture (USDA) (2000). CSFII Data Set and Documentation: The 1994-96 Continuing Surveys of Food Intakes by Individuals. Food Surveys Research Group. Beltsville Human Nutrition Research Center. Agricultural Research Service. April 2000.

FIGURE 1

PERCENT OF THE TOTAL BUSHELS OF CORN SAMPLED IN THE QUALITY CHECK PROGRAM SCREENING POSITIVE USING THE STRIP TEST FOR CRY9C FROM JANUARY 2001 THROUGH SEPTEMBER 2005

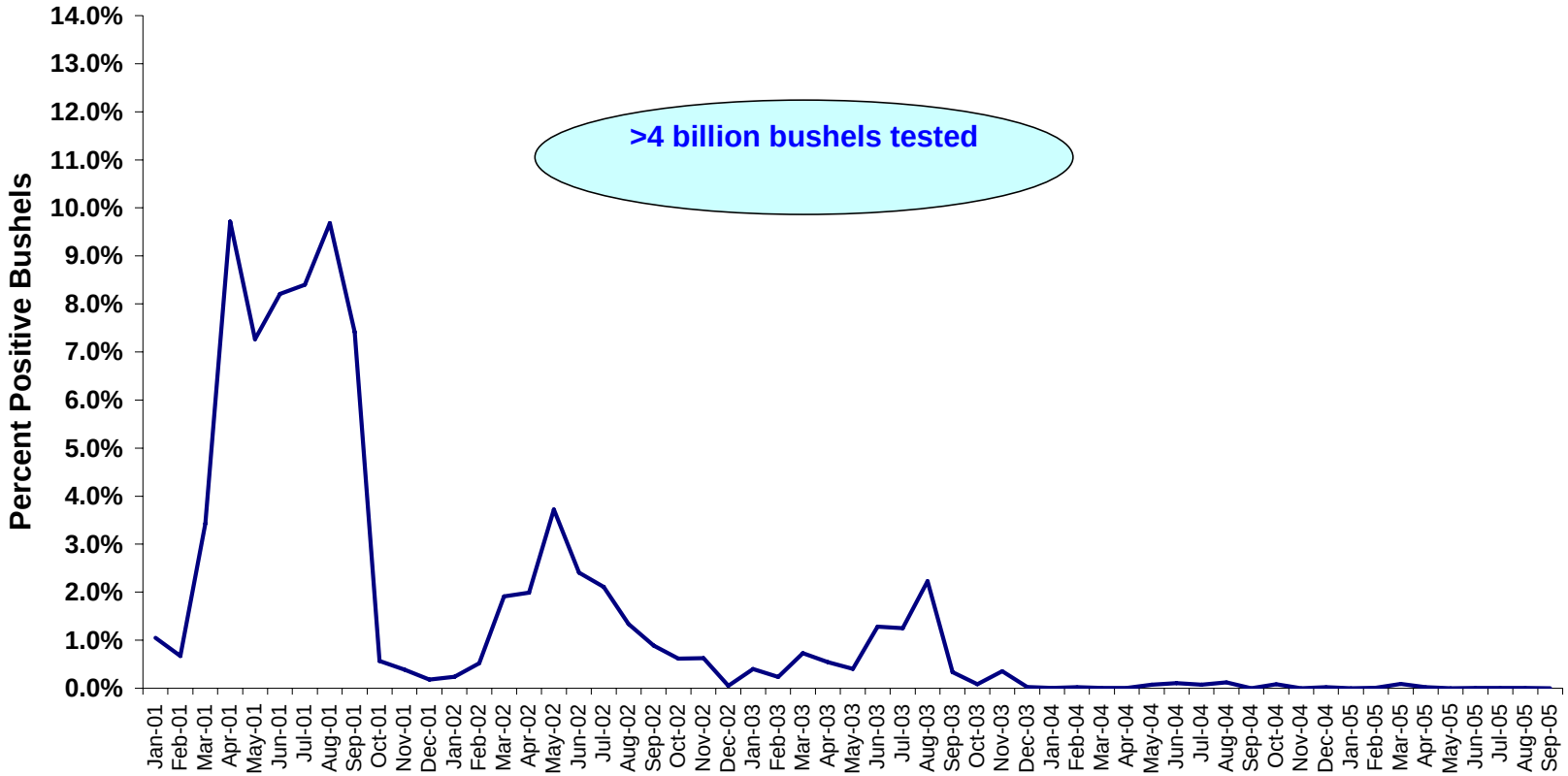


FIGURE 2

PERCENT POSITIVE TESTS (STATISTICS ON BUSHELS NOT AVAILABLE) BASED ON THE USDA SCREENING RESULTS USING STRIP TESTS FROM JANUARY 2001 THROUGH JULY 2005

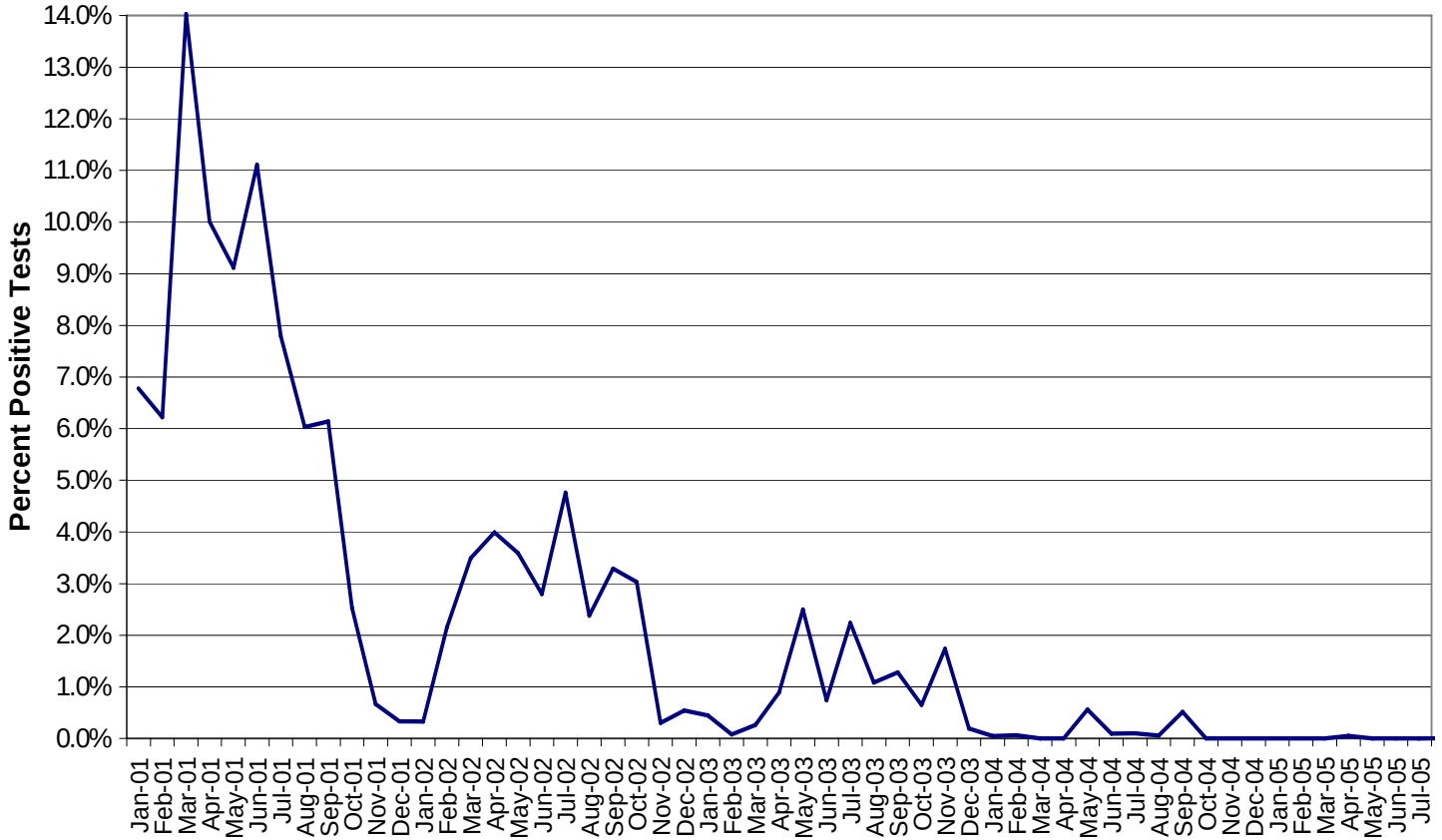


FIGURE 3

PERCENT POSITIVE LOTS BASED ON THE NAMA SCREENING RESULTS FROM JANUARY 2002 THROUGH JULY 2005

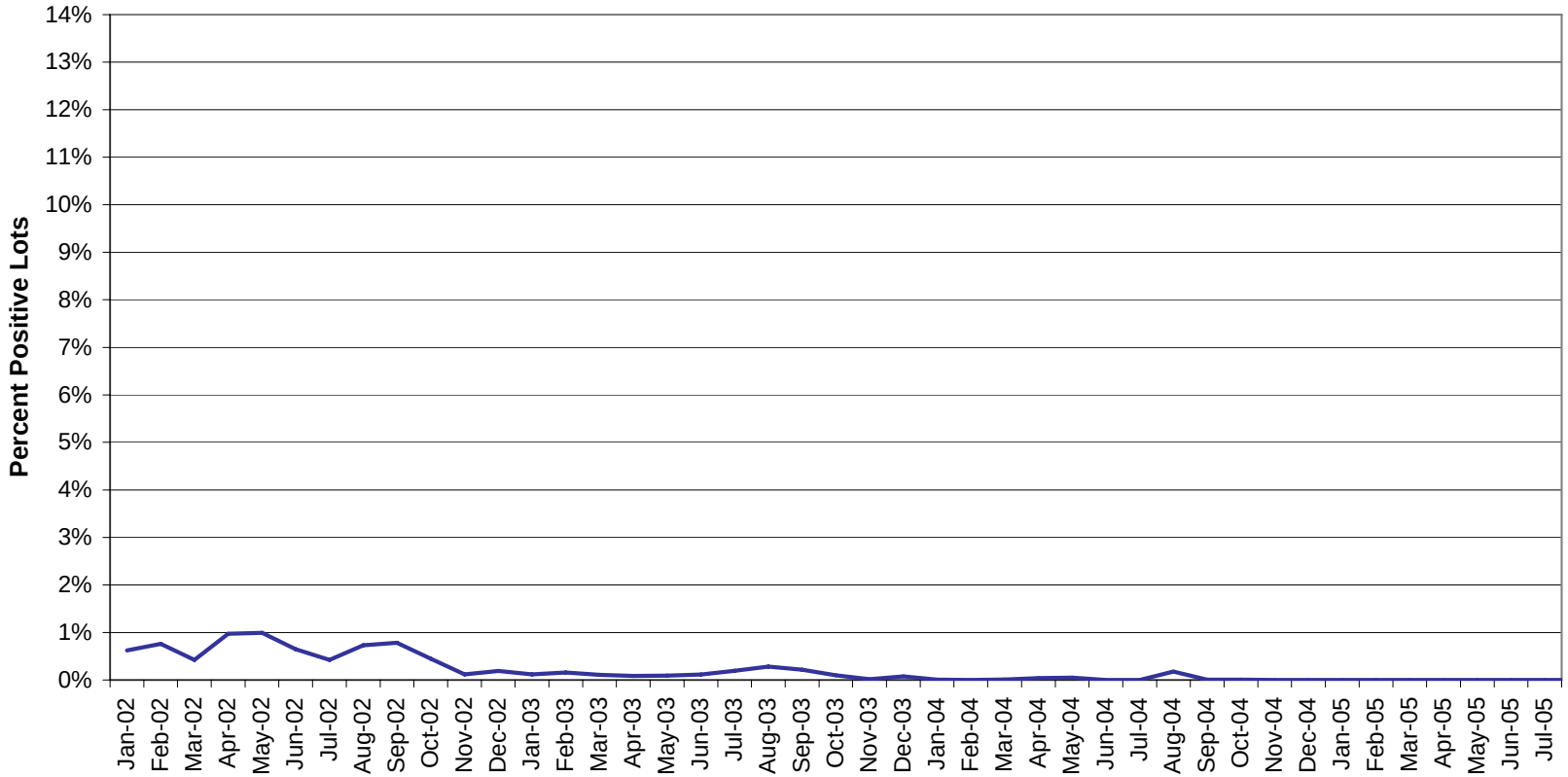


FIGURE 4

COMPARISON OF RESULTS OF SCREENING FOR CRY9C BASED ON THE QCP, NAMA, AND USDA DATABASES (JANUARY 2001 THROUGH DEC 2004)

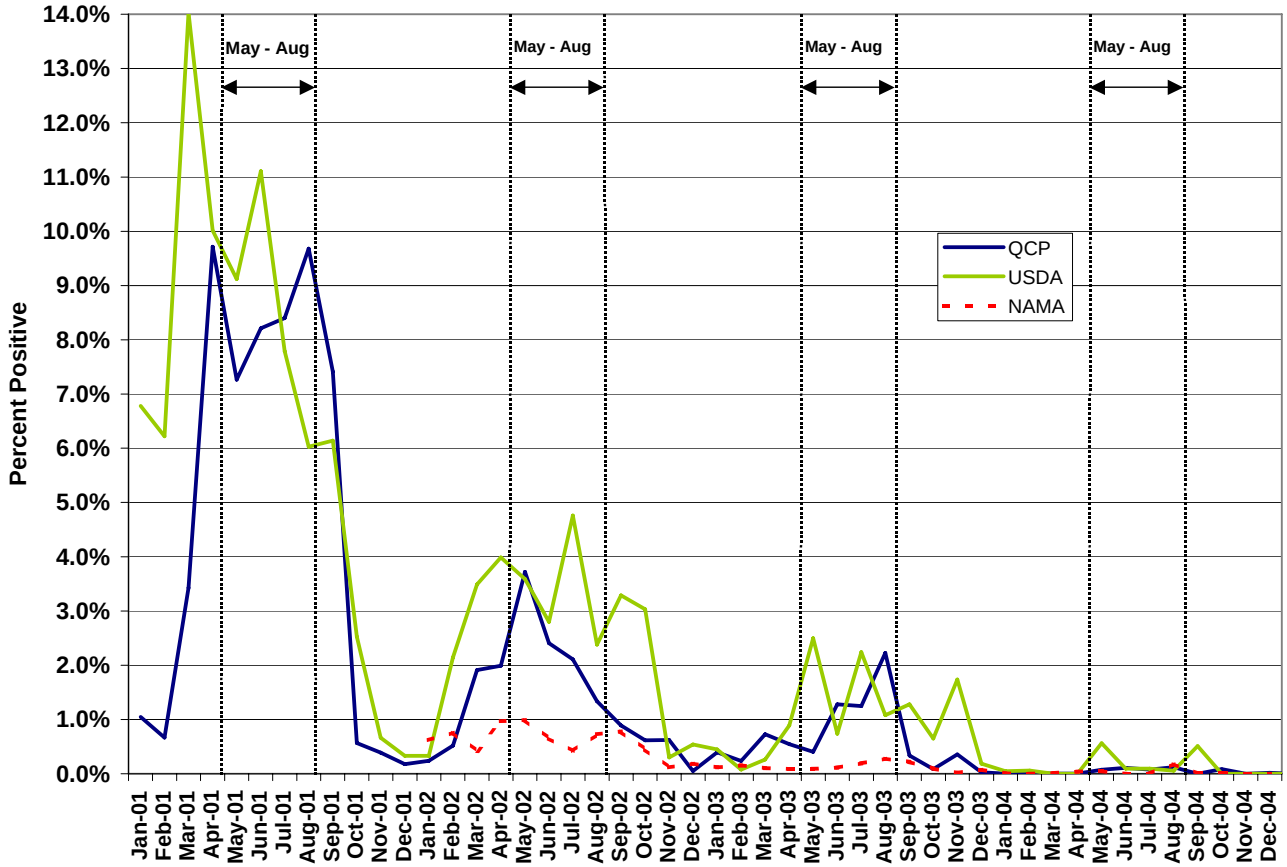


FIGURE 5

RESULTS OF TESTING FOR STARLINK CORN IN THE PAST YEAR AS REPORTED IN THE QCP

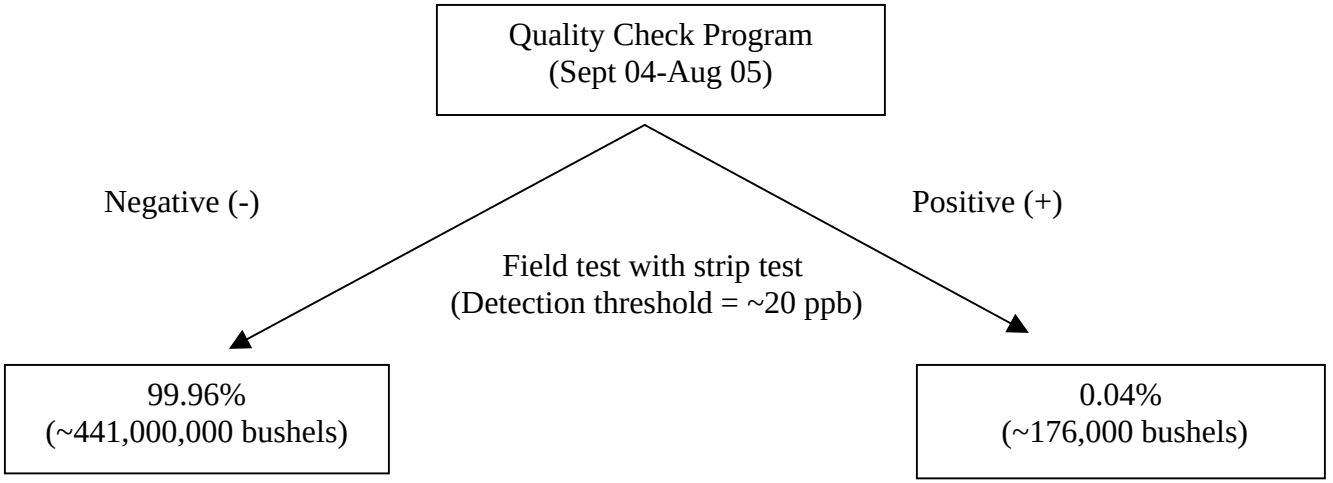


FIGURE 6

USDA/ARS RESULTS USED TO ASSIGN CRY9C LEVELS TO QCP NEGATIVE FIELD SAMPLES

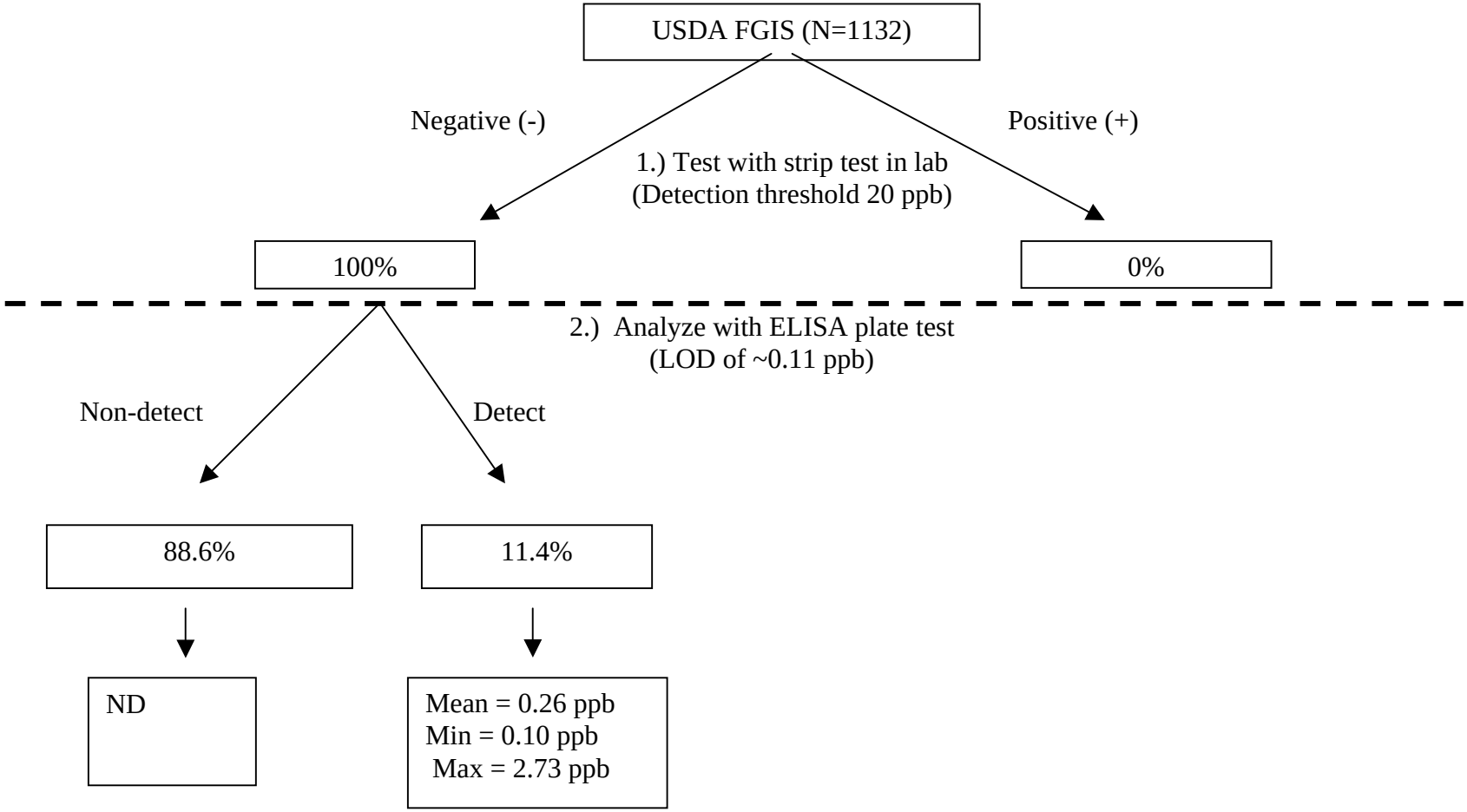


FIGURE 7

CRY9C LEVELS FOUND IN QCP POSITIVE FIELD SAMPLES

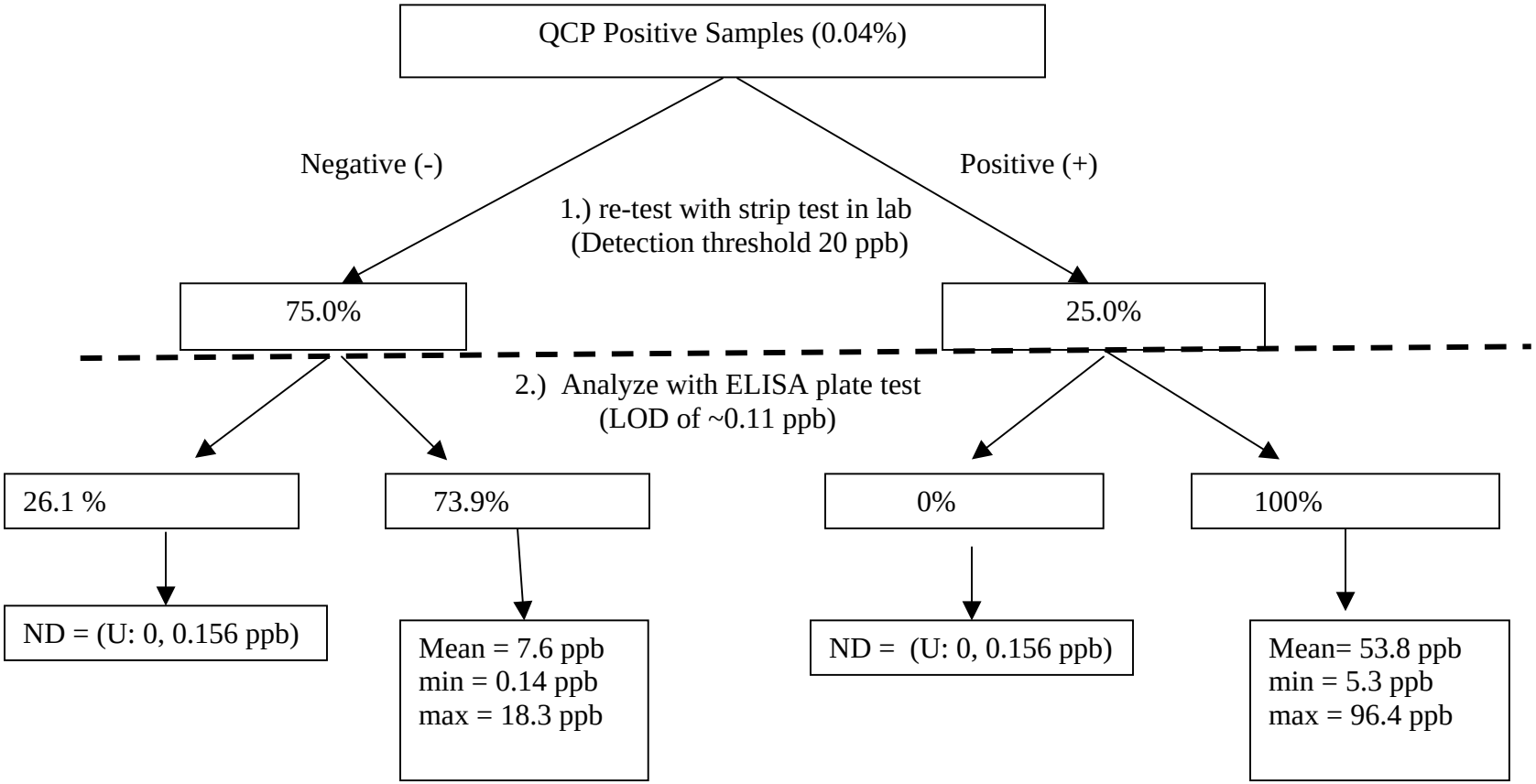


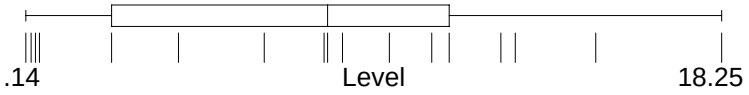
FIGURE 8

MEASURED CRY9C LEVELS IN DISTRIBUTION 2

Cry9C (ppb)

FIGURE 9

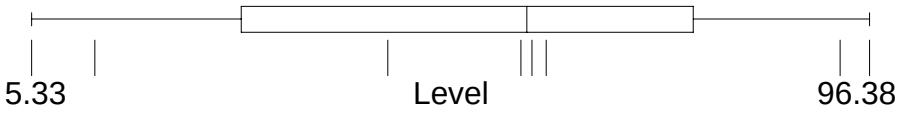
MEASURED CRY9C LEVELS IN DISTRIBUTION 4



Cry9C (ppb)

FIGURE 10

MEASURED CRY9C LEVELS IN DISTRIBUTION 6



Cry9C (ppb)

TABLE 1

A COMPARISON OF THE TESTING FOR STARLINK REPORTED BY NAMA, USDA, AND THE QCP

	Total number of tests (number positive)		
Month (2004)	**NAMA**	**USDA**	**QCP**
Jan-04	13519 (1)	2166 (1)	81267 (12)
Feb-04	7956 (0)	1613 (1)	58614 (19)
Mar-04	9108 (1)	2445 (0)	77594 (11)
Apr-04	8029 (3)	2550 (0)	63998 (17)
May-04	8461 (4)	1952 (11)	67711 (39)
Jun-04	9157 (0)	3140 (3)	70329 (84)
Jul-04	9123 (0)	2040 (2)	51194 (25)
Aug-04	10546 (19)	1775 (1)	55197 (80)
Sep-04	16610 (1)	3316 (17)	82382 (5)
Oct-04	21754 (1)	1787 (0)	100141 (32)
Nov-04	11939 (0)	2023 (0)	88487 (9)
Dec-04	8684 (0)	2616 (0)	74496 (8)
Total in 2004	134886 (30)	27423 (36)	871410 (341)

TABLE 2

CRY9C PROTEIN LEVELS IN VARIOUS CORN DISTRIBUTION GROUPS

	QCP Elevator Results Reported to SLLI, September 2004 –August 2005*					
	Negative Results 99.96%		Positive Results 0.04** %			
	USDA FGIS Samples		QCP Positive Field Samples			
Distribution group number	1	2	3	4	5	6
ELISA Strip Test Results						
Number of samples in group (percent of lab strip results)	1132 (100)		42[a] (75.0)		14[a] (25.0)	
Field result	n/a	n/a	+	+	+	+
USDA/ARS Laboratory result	–	–	–	–	+	+
ELISA Plate Assay Results (USDA/ARS Laboratory)						
Number of samples in group[a] (percent of plate results)	1003 (88.6)	129 (11.4)	6 (26.1)	17 (73.9)	0 (0.0)	8 (100)
USDA/ARS Laboratory result (positive or below LOD)	< LOD	+	< LOD	+	< LOD	+
ELISA plate range, ppb	0– LOD [b]	0.10- 2.73[c]	0 – LOD [b]	0.14 - 18.3 [c]	0- LOD [b]	5.33 - 96.4 [c]
ELISA plate mean, ppb	n/a	0.26	n/a	7.6	n/a	53.8
Percent of total sample values to be assigned to the Monte Carlo bin for this group	88.569	11.391	0.008	0.022	0.000	0.010

[a] Early in the confirmatory testing program (March-June 2004), the QCP samples from the field were tested only with the strip test. From June 14 until September 21, 2004, samples that tested positive with the strip were tested with the ELISA plate assay if their was enough sample to test. After September 22, 2004, all samples were tested with both the strip and the ELISA plate assay.

[b] Groups 1, 3, and 5 were negative in the ELISA plate assay, which has an LOD of 0.076 - 0.156 ppb. For Group 1, a zero value was assumed in the base run while a uniform distribution within the range of zero to the highest LOD was assumed in Sensitivity Analysis 1 (see Appendix E). For group 3 a uniform distribution of values within the range of zero to the highest LOD is assumed and the mean is assumed to be 1/2 the LOD. Group 5 is an empty set because, as one might expect, no sample tested negative in the plate assay after testing positive in both strip tests.

[c] Groups 2, 4, and 6 all tested positive (above LOD) in the plate assay; the empirical values are used.

* Percentages are based on the number of bushels of yellow corn tested at elevators participating in the QCP.

** A subset (N=56) of the lots testing positive in the QCP were sent to the Raleigh Laboratory for re-testing as part of a voluntary effort to determine Cry9C levels in corn testing positive in the QCP.

TABLE 3

NUMBER OF USDA FGIS SAMPLES COLLECTED PER MONTH

Month Sampled (2005)	Total	% of Total	% in QCP[1]
March	10	0.9%	14.3%
April	112	9.9%	18.5%
May	250	22.1%	21.0%
June	254	22.4%	20.0%
July	253	22.3%	16.3%
August	253	22.3%	10.0%
Grand Total	1132		

[1] Percent based on the number of tests conducted per month at outbound elevators participating in the QCP (Total number of tests from March through August 2005 was 26,349).

TABLE 4

PROBABILITY OF OCCURRENCE OF THE SIX CORN CATEGORIES

Distribution	% Occurrence
1	88.569%
2	11.391%
3	0.008%
4	0.022%
5	0.000%
6	0.010%

TABLE 5

ESTIMATE OF THE AMOUNT OF STARLINK CORN REMAINING THE US CORN SYSTEM BASED ON THE AMOUNT OF STARLINK CORN FROM THE 1999 AND 2000 CROP THAT WAS UNACCOUNTED FOR AND INFORMATION ON TYPICAL CORN STORAGE PRACTICES

	Millions of Bushels					Percent StarLink in dry milled corn crop
	A	B	C = A+B	D = 13.4% x C	E = C-D	F = E/165
Year	Bushels from previous year	New-Mixed with crop	Total mixed in year	Carry-over to next year[1]	Consumed in year	Assuming there is carryover[2]
1999	0	17.6	17.6	2.4	15.2	9.2%
2000	2.4	4.8	7.2	0.96	6.2	3.8%
2001	0.96	0	0.96	0.13	0.83	0.50%
2002	0.13	0	0.13	0.017	0.11	0.07%
2003	0.017	0	0.017	0.002	0.015	0.0090%
2004	0.002	0	0.002	0.0003	0.002	0.0012%
2005	0.0003	0	0.0003	0.00004	0.0003	0.0002%

[1] Assumes 13.4% of the year's crop is carried over to the next year (EPA, 2001c)
[2] Assumes 165 million bushels annually go through dry milling for food use (EPA, 2001c)

TABLE 6

EFFECTS OF PROCESSING FROM 100% STARLINK GRAIN TO FINISHED PRODUCT (MRID 453866-03)

Analyzed Foods and Food Ingredients made from 100% StarLink corn	Analyzed Level of Cry9C (ppb)	Percent Reduction Due to Processing	Processing Factor Used in Assessment
StarLink Whole Grain	14,275	NA	NA
StarLink Wet Milled Starch	13	99.90%	0.0009
StarLink Wet Milled Hull	12,950	9.30%	0.91
StarLink Dry Milled Corn Meal	15,075	-5.60%	1.06
StarLink Dry Milled Corn Flour	15,363	-7.60%	1.08
StarLink Masa (dough)	127	99.10%	0.009
StarLink Soft Tortillas	23.6	99.80%	No adjustment
StarLink Baked Taco Shells	ND	100.00%	No adjustment
StarLink Fried Tortilla Chips	20.3	99.90%	No adjustment
StarLink Corn Puffs	4.6	100.00%	No adjustment
StarLink “Ringed” Cereal	4.5	100.00%	No adjustment
StarLink Corn Flakes	ND	100.00%	No adjustment
StarLink Polenta	564	96.00%	No adjustment
StarLink Corn Muffins	790	94.50%	No adjustment
StarLink Corn Bread	2,316	83.80%	No adjustment
StarLink Hush Puppies	2,636	81.50%	No adjustment

NA - Not Applicable; ND= Not Detected.

No adjustment for effects of cooking on Cry9C levels in finished food products

TABLE 7

CURRENT PER USER DIETARY INTAKE ESTIMATES OF CRY9C (µG/DAY)

Population Group	Dietary Intake Estimates of Cry9C (µg per day)			
	Mean	95th percentile	99.5th percentile	99.9th percentile
US Population	0.00007	0.00005	0.00303	0.00821
US Children 1-6	0.00005	0.00004	0.00210	0.00577
US Children 7-12	0.00006	0.00007	0.00246	0.00677
Hispanic Population	0.00006	0.00006	0.00233	0.00642

TABLE 8

COMPARISON OF EXPOSURE ESTIMATES

Population Group	Comparison of Dietary Intake Estimates of Cry9C at the 99.5th percentile (µg per day)	
	Wet milling white paper (EPA, 2001a) [1]	Exponent's 2005 Assessment
US Population	0.01959	0.00303
US Children 1-6	0.00484	0.00210
US Children 7-12	0.00798	0.00246
Hispanic Population	NA	0.00233

[1] 99.5% percentile of exposure among consumers in the US population assuming food containing corn starch was made from grain containing 1.5% StarLink corn (EPA, 2001a).

TABLE 9

SUMMARY OF ASSUMPTIONS MADE AND SENSITIVITY ANALYSES CONDUCTED

Parameter	Assumption	Alternative	Impact of using alternative assumption when compared to baseline analysis	Sensitivity analysis conducted?
Database	QCP	NAMA	NAMA data may underestimate % positive.	No sensitivity analyses conducted; comparison of levels made and discussed in report. (Section IV.A.2.b.)
		USDA	USDA database not representative of US corn supply	No sensitivity analyses conducted; comparison of levels made and discussed in report. (Section IV.A.2.b.)
Measure of percent positive	Bushels of yellow corn (September 2004 - August 2005)	Tests	Underestimate percent positive	No sensitivity analyses conducted; comparison of levels made and discussed in report. (Section IV.A.2.d.)
		Shipments	Underestimate percent positive	No sensitivity analyses conducted; comparison of levels made and discussed in report. (Section IV.A.2.d.)
		White + yellow corn	Underestimate percent positive and levels	No sensitivity analyses conducted; comparison of levels made and discussed in report. (Section IV.A.2.d.)

Parameter	Assumption	Alternative	Impact of using alternative assumption when compared to baseline analysis	Sensitivity analysis conducted?
Location of sampling	Outbound elevator samples	All elevator data QCP	Lower percent positive	No sensitivity analyses conducted; comparison of levels made and discussed in report. (Section IV.A.2.d.)
		All data in QCP	Lower percent positive	No sensitivity analyses conducted; comparison of levels made and discussed in report. (Section IV.A.2.b.d)
Distribution 1	Point estimate of 0 ppb	Uniform (0, LOD)	Higher exposure estimate	Yes. Results summarized in Appendix E, Analysis 1
Distribution 1-6	Empirical or uniform distribution for each group	Fit a lognormal distribution to all available data (-5.2, 2.4)	Higher exposure estimate	Yes. Results summarized in Appendix E, Analysis 2
Hot spots/commingling	10 strata; composites of size 5	No dilution/commingling	Similar exposure estimate	Yes. Results summarized in Appendix E, Analysis 3
		More dilution/commingling	Lower exposure estimate	No
Processing factors	No reduction due to heat processing	Allow for reduction due to heat processing	Lower estimate of exposure	No
Cereals processing factor	No residues in cereals	Cereals assigned a point estimate of 0.036 ppb, equivalent to the weighted average of all available data.	Similar exposure estimate	Yes. Results summarized in Appendix E, Analysis 4

APPENDIX A

DESCRIPTION OF ANALYTICAL METHODS USED TO DETECT AND QUANTIFY CRY9C PROTEIN

APPENDIX A

DESCRIPTION OF ANALYTICAL METHODS USED TO DETECT AND QUANTIFY CRY9C PROTEIN

1. **Strip Test:** The screening test used in the field by those participating in the QCP and the USDA is the lateral flow immunoassay test kits (strip tests). Trait✓ Bt9 strips are used to screen corn documented in the QCP and by the USDA. Information from one of the strip manufacturers, Strategic Diagnostics Inc., (SDI) indicates that the strip sensitivity is at least 1 kernel in 800 or 0.125%. Therefore, a positive StarLink corn detection is equivalent to a concentration of at least 0.125% (or 1/800 kernels) StarLink corn. To convert the 0.125% concentration of StarLink corn into an equivalent concentration in ppb of the Cry9C protein, we multiplied the concentration of 0.125% StarLink corn by 14,275 ppb, the approximate mean amount of the Cry9C protein in StarLink corn grain. This resulting value of 17.84 ppb is then rounded up to 20 ppb and is considered the strip tests level of detection (LOD). The lateral flow strip tests do not provide the actual level of Cry9C in the corn sample but rather provide a "yes/no" answer to the question of the presence of Cry9C in the corn.

2. **ELISA Plate Test**: The ELISA plate test is a laboratory test that can be conducted to quantify Cry9C protein concentration in corn. Several companies such as SDI and EnviroLogix have developed ELISA plate technology. The EnviroLogix QuantiPlate Cry9C kit along with their "high sensitivity" measurement protocol was used in the USDA laboratory to quantify Cry9C concentration in shelled corn. Corn sample extract is added to test wells coated with antibodies sensitive to the Cry9C. The presence of Cry9C in the well is indicated by the development of color. The color development is proportional to Cry9C concentration in the sample extract. The Cry9C concentration in the unknown extract is determined by comparing the color intensity of the unknown to the color intensity of Cry9C standards. EnviroLogix states that the limit of detection (LOD) of the ELISA plate test using the "high sensitivity" protocol 0.079 optical density absorbance (OD) units and 0.070 ng/g or parts per billion (ppb) Cry9C protein concentration. The LOD of 0.070 OD units was determined using 3 standard deviations. Current laboratory results indicate that the LOD of the ELISA plate test is approximately 0.066 OD units, which translates through the standard curve to 0.11 ppb on the average, but can range from 0.076 to 0.156 ppb.

of the sub-samples will be discussed in more detail in the **Principle of the Screening Application** section.

Note: It is assumed that the samples collected are representative of the contents of the truck or container and are sufficiently mixed to contain a random distribution of the sample contents.

Sample Preparation: Weighing the Sample

The statistical sampling plan (see **Principle of the Screening Application**) is dependent on the number of corn kernels used. However, it is more practical for routine testing to weigh corn kernels instead of counting to obtain the desired number of kernels. The average weight of corn kernels depends on the variety of corn and environmental conditions.

It is recommended that the weight-to-corn kernel ratio for each variety be determined as follows.

1. Count 100 kernels of the variety to be tested.
2. Weigh the 100 kernels to the nearest 0.01 gram.
3. Divide the weight of the corn kernels by 100 to get the average grams per kernel.
4. Multiply this average weight by the desired number of corn kernels in the sub-samples (selected in **Tables C, D or E**) to determine the weight for the sub-samples.
5. Construct a weight-to-corn kernel ratio table for each variety for the different sub-sample sizes to be used.

Example: One hundred (100) corn kernels of Variety X weigh 25.00 grams. Each corn kernel then weighs 0.25 grams. Multiply the 0.25-gram per corn kernel times the number of corn kernels in each sample size to get the following table.

Table A: Example: Weight-to-Kernel Ratio

	Grams per Sample of			
No. Corn Kernels (a)	100	400	600	800
Sample Weight (g)	**25**	**100**	**150**	**200**

(a) From Tables C, D and E.

This average weight is then used to obtain the number of corn kernels for this corn variety.

Sample Preparation: Processing the Sample

The corn sample is ground and then extracted with water in a glass "Mason"-type jar. The sample preparation is important for the proper function of the test, especially the ratio of water to the weight of the corn sample. The volume of water in milliliters (ml) should be close to 1.25 times the weight of corn sample in grams (g).

Sample Weight (g) X 1.25 = Water Volume (ml)

The size of "Mason" jar required and the grinding time depends on the sample size to be analyzed. **Table B** lists those parameters.

Table B: Parameters for Preparing Samples

Number of Kernels in Sample	Jar Size (oz.)	Grind Time (sec)
25-125	4	10-20
125-250	8	15-25
250-500	16	20-35
>500	32	45-60

The processing parameters were determined using the laboratory grade Waring Model 31BL91 food processor with the standard blade (see **Materials Required but not Supplied**). Other food processors may require different parameters.

1. Weigh sub-samples from each truck or container.
2. Place each sub-sample in a clean, **dry** "Mason" jar of the appropriate size. See **Table B**.
3. Attach the jar adapter and clean, **dry** cutting blades.
4. Place the jar onto the food processor, place a shield over the jar and grind the sub-sample on high speed for the time indicated in **Table B**.

Caution: It is recommended to shield the jars during grinding with a "tri-cornered" 1-liter plastic beaker (P/N 6000037).

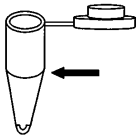
5. Remove the adapter and cutting blades.
6. Add the prescribed volume of water (see above) to the ground corn in the jar, place a lid on the jar and shake the jar until all the ground corn is well wetted (about 10-20 sec.).

Note: The sample will have a "thick" consistency but should contain some free liquid after a short settling time. **There should be no whole kernels remaining.**

7. Use this free liquid as sample in the **Test Procedure**.

Test Procedure

1. Transfer 0.5 ml of the liquid from the sample prepared above into a sample tube using the transfer pipette provided.

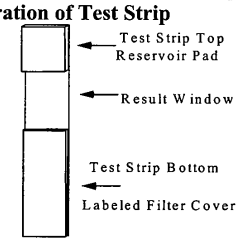


The sample tube has a 0.5-mL indicator at the top of the tapered section.

2. Place one Trait✓ Bt9 Test Strip into the sample tube. Let sit for 3-5 minutes.
3. The appearance of **one line** (control) on the strip indicates a **negative** result.
4. The appearance of **two lines** on the strip indicates a **positive** result.

Interpreting the Lateral Flow Strip Test

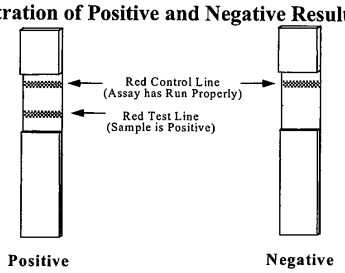
Illustration of Test Strip



Check the result window at five (5) minutes after inserting the strip. At least one line, the Control Line, should always develop approximately one (1) cm down from the Reservoir Pad. A red line in this position indicates that the device is functioning properly. A red line appearing below the Control Line is the Test Line and indicates a positive result. If the test strip displays two (2) red lines, the test is complete and the sample is positive for Cry9C Bt corn. If at 5 minutes the test strip only shows a clearly visible Control Line, then the sample is negative for Cry9C Bt corn.

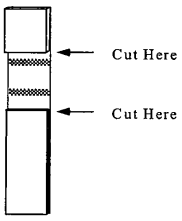
Note: ***Test strip results should be interpreted after 5 minutes. Test strips interpreted after 60 minutes are invalid.***

Illustration of Positive and Negative Results



Archiving Test Strips

If it is desired to archive test strip results, cut off the bottom and top strip pads as illustrated below within one (1) hour of test completion.



Equipment Cleaning and Drying

Caution: It is important to clean and dry the jars and cutting blades between samples.

1. The "Mason" jar should be emptied, rinsed thoroughly with water and completely dried with a paper towel between uses.
2. The cutting blades for the blender should be rinsed with water until **all ground corn** is removed, washed using standard household liquid soap, rinsed well and carefully dried. If available, spraying or rinsing with methanol or isopropyl (rubbing) alcohol will assist drying.

Principle of the Screening Application

The Trait✓ Bt9 Test Strip provides a yes/no answer for the presence or absence of Cry9C Bt corn in a given sample. Testing multiple statistically selected sub-samples allows an estimate of the percent of Cry9C corn. The test results provide information about the probability of the percent Bt corn in the sample.

Note: The test protocol does not determine the exact percent of Bt corn kernels. It determines the probability that a sample contains greater or less than a specified threshold concentration.

The statistical model for this application is based on the Poisson Probability Distribution, which provides good approximations to binomial (yes/no) probabilities when the number of items tested (i.e. corn kernels) is large but the probability of a positive result is expected to be small (i.e. low level of Bt corn). This Distribution can determine the probability of having no Bt kernels in a random sample of a given number of kernels at a given percent Bt. For example, a random sub-sample of 100 corn kernels selected from a larger population containing one- percent Bt corn has a 36.8% probability of containing no Bt corn kernels. The probability of a 75-corn kernel sub-sample (at one percent Bt) containing zero Bt corn kernels is 47.2%.

Screening at Very Low GM Levels

Screening grain at very low GM levels can be accomplished by using a sufficiently large sample size that tests negative for the GM trait. Lateral flow strips can be used by testing multiple sub-samples the size, of which, do not exceed the sensitivity of the strip test. **The Trait✓ Bt9 strip test sensitivity is at least one kernel in 800.**

The following tables provide information at five confidence levels with the use of multiple samples of 400 kernels 600 kernels or 800 kernels each. The tables provide the maximum percent GM levels that would be expected in the sample if all test-samples provide negative results. Either table can be used depending on the desired screening level and how the samples will be processed.

Table C: 400 Seed Sub-Samples
(All Sub-Samples Must be Negative)

No. Sub-Samples of 400 Seeds Each	Percent GM using Sub-Sample Sizes of 400 Seeds at Five Different Confidence Levels (%)				
	50	75	90	95	99
1	0.17	0.35	0.58	0.75	1.2
2	0.087	0.18	0.29	0.38	0.58
3	0.058	0.12	0.20	0.25	0.39
4	0.045	0.085	0.15	0.19	0.29
5	0.035	0.070	0.12	0.15	0.25
6	0.029	0.058	0.10	0.13	0.20
7	0.025	0.050	0.085	0.11	0.18
8	0.022	0.044	0.075	0.10	0.15

Table D: 600 Seed Sub-Samples
(All Sub-Samples Must be Negative)

No. Sub-Samples of 600 Seeds Each	Percent GM using Sub-Sample Sizes of 600 Seeds at Five Different Confidence Levels (%)				
	50	75	90	95	99
1	0.12	0.23	0.39	0.50	0.78
2	0.058	0.12	0.20	0.25	0.39
3	0.039	0.077	0.13	0.17	0.27
4	0.029	0.058	0.10	0.13	0.20
5	0.024	0.047	0.077	0.10	0.16
6	0.019	0.039	0.065	0.085	0.13
7	0.017	0.033	0.055	0.075	0.11
8	0.015	0.029	0.050	0.065	0.096

Table E: 800 Seed Sub-Samples
(All Sub-Samples Must be Negative)

No. Sub-Samples of 800 Seeds Each	Percent GM using Sub-Sample Sizes of 800 Seeds at Five Different Confidence Levels (%)				
	50	75	90	95	99
1	0.087	0.175	0.288	0.375	0.575
2	0.044	0.087	0.144	0.187	0.285
3	0.029	0.058	0.096	0.125	0.192
4	0.022	0.044	0.072	0.094	0.145
5	0.017	0.035	0.058	0.075	0.115
6	0.015	0.029	0.048	0.063	0.097
7	0.013	0.025	0.041	0.054	0.083
8	0.011	0.022	0.036	0.047	0.072

Choice of Confidence Level

The choice of the confidence level (and resulting sub-sample size) depends on how the test result information is to be used. If the primary concern is to have a very high confidence that the sample is below a certain GM screening level, then a higher confidence level and sample size is desired. However, this approach will "fail" some percentage of samples that are, in fact, below the screening level but somewhat close to it. The higher the confidence level chosen, the higher this failure rate will be.

Warranties and Liabilities

Strategic Diagnostics Inc. ("SDI") warrants the Products manufactured by it will be free of defects in materials and workmanship when used in accordance with the applicable instructions for a period equal to the shorter of one year from date of shipment of the Product(s) or the expiration date marked on the Product packaging. Application protocols published by SDI are intended to be only guidelines for the Buyers of the Products. Each Buyer is expected to validate the applicability of each application protocol to in their individual applications. **SDI MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED. THERE IS NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.**

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APPENDIX B

USDA STARLINK TESTING DIRECTIVE

APPENDIX B

USDA STARLINK TESTING DIRECTIVE

United States Department of Agriculture
Grain Inspection, Packers and Stockyards Administration
Federal Grain Inspection Service

Directive 9181.1 3-25-02

TESTING FOR STARLINK™ CORN - LATERAL FLOW TEST STRIP METHOD

1. PURPOSE

This directive establishes official procedures for testing corn (not processed corn products), using the lateral flow strip method, for the presence of StarLink™ corn and certifying the official results. This service is provided as official criteria under the authority of the United States Grain Standards Act (USGSA), as amended.

All official testing is performed as prescribed in this directive by authorized employees of the Federal Grain Inspection Service (FGIS) or licensed delegated/designated agency personnel. Individuals wanting official services should contact the nearest FGIS field office or delegated/designated agency. See section 13 for details.

2. REPLACEMENT HIGHLIGHTS

This directive is revised to include testing procedures for the Neogen Agri-Screen® CRY9C Strip Test and to modify the testing procedures for the test kits manufactured by Envirologix Incorporated, and Strategic Diagnostics (SDI).

This directive supersedes FGIS Program Directive 9181.1, dated 2/26/01, and FGIS Policy Bulletin Board Notice Number 195, dated 8-29-01.

3. BACKGROUND

StarLink™ corn, developed by Aventis CropScience, was developed through modern biotechnology by introducing genetic material from a bacterium, *Bacillus thuringiensis (Bt)*. As a result, StarLink™ corn produces a protein, Cry9C, which has insecticidal properties effective in controlling the European corn borer. The Environmental Protection Agency (EPA) approved StarLink™ in 1998 for use as animal feed only.

FGIS has verified the performance of lateral flow test kits; the Trait✓ Bt9 Lateral Flow Test Kit manufactured by SDI, the Cry9C QuickStix™ Test Kit manufactured by EnviroLogix Incorporated, and the Neogen Agri-Screen® CRY9C Strip Test Kit to detect the presence of the Cry9C protein in corn. (*The mention of firm names or trade products does not imply that the U. S. Department of Agriculture endorses or recommends them over other firms or similar products not mentioned.*)

Distribution: A, C, E Originating Office: PPB, FMD

The test protocol does not determine the exact percent of StarLink™ kernels present in the sample. It determines the probability that a sample contains or does not contain the Cry9C protein at a specified concentration based on the number and size of samples tested. See section 4 for further information.

4. TESTING CONFIDENCE

Based on sampling theory, lot size is an insignificant influence on sample size when the lot size is very large relative to the sample sizes. This is generally the case in grain inspection. The total sample size is dependent on the probability of accepting a specified concentration. The limitations of the analytical method determine how many sub-samples have to be tested. For example, if an applicant wants a sample of 2400 kernels tested but the analytical method can only reliably detect one kernel in a sample of 800 kernels, then the 2400-kernel sample must be tested as three sub-samples of 800 kernels.

Official sampling procedures have been developed as practical procedures to obtain samples that approximate random samples. Increasing the sample size can increase the confidence of detection at lower levels; however, the results of a larger sample size may only be reliably achieved by testing the sample as multiple sub-samples.

The following table illustrates the confidence levels achieved for the approved test kits based on the total number of kernels tested. The table provides information at five confidence levels regarding maximum percent StarLink™ levels that would be expected in the sample if all test samples provide negative results.

Total Kernels Tested	Percent StarLink™ at Five Different Confidence Levels (%) **Note: All Sub-Samples Must be Negative**				
	50	**75**	**90**	**95**	**99**
400	0.17	0.35	0.58	0.75	1.2
800	0.087	0.18	0.29	0.38	0.58
1200	0.058	0.12	0.20	0.25	0.39
1600	0.045	0.085	0.15	0.19	0.29
2000	0.035	0.070	0.12	0.15	0.25
2400	0.029	0.058	0.10	0.13	0.20
2800	0.025	0.050	0.085	0.11	0.18
3200	0.022	0.044	0.075	0.10	0.15

If 400 kernels are analyzed and the result is negative for the Cry9C protein, a 99 percent probability exists that a lot does not contain more than 1.2 percent StarLink™ corn. Likewise, if 800 kernels are analyzed and results are negative for the Cry9C protein, a 99 percent probability exists that a lot does not contain more than 0.58 percent StarLink™ corn.

Since different users of corn have different needs, FGIS will analyze the total number of kernels as requested by the applicant for service. See section 13 for additional information regarding the biotechnology sample planner.

5. WORK AREA REQUIREMENTS

The work area requirements covered under this section apply to FGIS-occupied space only.

Testing may be performed in the laboratory space provided for mycotoxin analysis or in other suitable locations (e.g., tabletop in inspection lab) as determined by the FGIS manager.

6. TYPES OF SERVICES

Three types of testing services are available as follows:

a. Submitted Sample Service. Analysis based on a sample submitted by the applicant for service.

b. Official Sample-Lot Service. Analysis based on an official sample obtained and analyzed by someone authorized or licensed by FGIS.

c. Warehouse Sample-Lot Inspection Service. Analysis based on an official sample obtained by a licensed warehouse sampler and analyzed by someone authorized or licensed by FGIS.

7. SAMPLE PREPARATION

a. Precautions.

Inspection personnel must employ additional care to protect against inadvertent commingling and to ensure sample integrity. A single kernel commingled with the official sample could affect test results. Ensure sample collection devices (e.g., sampling mat, collection buckets) and laboratory equipment (sample bags, containers, and dividers) are free from residual grain.

b. Sample Size.

Obtain samples according to the procedures in the Grain Inspection Handbook, Book I, "Grain Sampling." See section 13 for details. Use an approved divider to obtain the required analytical portion(s). Ensure the original sample size is sufficient to accommodate the requested analysis and provide for a file sample. General class scales are acceptable for weighing sample portions.

FGIS has adopted 2400 kernels as the standard sample size for StarLink™ testing on sublots for export ships and barges. Upon request of the applicant, official personnel may perform the testing on the basis of an alternate sample size (e.g., 1200 kernels). For all other types of samples (e.g., submitted samples, trucklots), the applicant must state the sample size (e.g., 400 kernels, 800 kernels).

Use the following table to determine the number of grams per test portion, or calculate the analytical portion (in grams) by weighing 100 kernels then multiplying the weight (in grams) by the appropriate sample size. For example, to determine the number of grams in an 800-kernel sample size, weigh 100 kernels (in grams), then multiply the weight by 8.

Test Portion (Kernels)	Test Portion (Grams)
100 kernels	29 (± 5 grams)
200 kernels	58 (± 5 grams)
300 kernels	86 (± 5 grams)
400 kernels	115 (± 5 grams)
500 kernels	143 (± 5 grams)
600 kernels	172 (± 5 grams)
700 kernels	200 (± 5 grams)
800 kernels	229 (± 5 grams)

c. Defining Subsample Size.

A "subsample" is defined as a sample portion of up to 800 kernels (approximately 229 grams) in size that is used to perform StarLink™ testing. Simplified, each lateral flow test strip used for a test is considered as a subsample. For example, at a detection level of 1 in 2400 kernels, use 3 subsamples of 800 kernels (3 test strips capable of detecting at the 0.125 sensitivity level) or 6 subsamples of 400 kernels.

d. Basis of Testing (Analytical Portion).

Base the analysis on the sample as a whole (before the removal of broken corn and foreign material), unless otherwise specified by the applicant for service.

8. TEST KITS

FGIS has verified the performance of lateral flow test kits manufactured by EnviroLogix, SDI, and Neogen. The Cry9C QuickStix™ Test Kit manufactured by EnviroLogix and the Neogen Agri-Screen® CRY9C Strip Test can detect the presence of the Cry9C protein in corn at a level of 0.125 percent (1 kernel in 800).

The Trait✓Bt9 Lateral Flow Test Kit, manufactured by SDI, has three separate test kits available for testing. SDI test kits identified with part number 7000034 are restricted to testing at the 1 in 400-kernel (0.25 percent) level. Test kits identified with part number 7000003 and 7000012 are approved for testing at the 1 in 800-kernel (0.125 percent) level.

Note: SDI Test Kits (part numbers 7000003 and 7000012) do not include buffer solution.

StarLink Test Kits (Lateral Flow Strip Method) Approved for Official Use

Test Kit Manufacturer	Test Kit	Part Number	Test Sensitivity	Buffer Solution	Type Water	Incubation Period
Envirologix	QuickStix™	AS 008 BG	1 in 800 kernels	No	Tap	5 minutes
Neogen	Agri-Screen® Cry9C Strip Test	8003	1 in 800 kernels	No	Distilled/ deionized	10 minutes
Strategic Diagnostics	Trait✓ Bt9™	7000034	1 in 400 kernels	Yes	Tap	10 minutes
Strategic Diagnostics	Trait✓ Bt9™	7000003	1 in 800 kernels	No	Tap	10 minutes
Strategic Diagnostics	Trait✓ Bt9™	7000012	1 in 800 kernels	No	Tap	5 minutes

9. TRAIT✓ Bt9 TESTING PROCEDURES

a. Part Number 7000034 (1 kernel in 400).

(1) Processing the Sample.

(a) Place each sub-sample 115 grams (± 5 grams) (approximately 400 kernels), in a **clean, dry "Mason" jar or similar container** used for blending purposes. **(Container must hold a minimum of 16 fluid ounces.)**

(b) Attach the container and **clean, dry cutting blades** to the mixing device (food processor or blender). Place a plastic shield over the container (for protection) in case the container breaks during sample processing.

(c) Grind the sub-sample on high speed until all whole kernels are broken (approximately 30 seconds).

Note: An alternative method to grind the sub-sample is permitted provided the particle size is comparable to the blender procedure and processes are in place to prevent cross-sample contamination.

(d) Remove the sub-sample container from the mixing device and add 143 to 145 milliliters (ml) of water.

Note: If the analytical portion size was adjusted to approximate 400 kernels, adjust the water volume using the formula:

Sample weight (grams) X 1.25 = Water volume (ml)

(e) Place a lid on the container and shake to thoroughly wet all corn particles (approximately 10 - 20 seconds). Let the slurry settle for 15 - 30 seconds. The sub-sample will have a thick consistency but should contain some free liquid.

(f) Transfer 0.5 ml of the free liquid from the container and place in a 1.5-ml sample tube using a transfer pipette provided with the test kit.

Note: Some corn material may be transferred with the free liquid in this step.

(g) Add 5 drops of the Trait✓ Sample Buffer into the sample tube.

Caution: Failure to add 5 drops of buffer to the tube may cause false positive results.

(h) Close the tube and shake for approximately 10 seconds.

(i) Place 1 Trait✓ Bt9 Test Strip into the sample tube. **Allow the strip to remain in the test tube for a full 10 minutes.** If a control line (top of the strip) does not develop, the test is invalid. Reading the strip prior to 10 minutes could result in false negative results.

Caution: The top of the liquid in the sample tube should not be higher than the top of the arrows on the test strip when it is in the sample tubes.

(2) Interpreting the Lateral Flow Test Strip.

Check the result window frequently after inserting the strip. At least one line, the Control Line, should always develop approximately 1 centimeter down from the Reservoir Pad. A red line in this position indicates that the device is functioning properly. A red line appearing below the Control Line is the Test Line and indicates a positive result.

The test line should be clearly discernible with a red color for samples that contain the Cry9C protein. If there is any doubt concerning the presence of a test line, transfer another aliquot (0.5 ml) of the sample extract into a reaction tube and repeat the test with a different lateral flow test strip.

Note: Development of the Control Line serves only to indicate that the device has functioned properly. Discard any test strip that does not develop a Control Line and re-test the sample using another strip.

(3) Alternate Test Levels.

Testing can be performed at different levels (e.g., 1 in 300 kernels, 1 in 200 kernels) by reducing the amount of sample and water volume. Use the following table to determine the appropriate sample size and water volume for alternate test levels.

Test Level	Sample Size (Kernels)	Sample Size (Grams)	Water Volume
1 in 300	300 kernels	86 (± 5 grams)	108 - 110 ml
1 in 200	200 kernels	58 (± 5 grams)	72 - 74 ml
1 in 100	100 kernels	29 (± 5 grams)	36 - 38ml

b. Part numbers 7000003, 7000012 (1 kernel in 800).

(1) Processing the Sample.

(a) Place each sub-sample, 229 grams (± 5 grams) (approximately 800 kernels), in a **clean, dry "Mason" jar or similar container** used for blending purposes. **(Container must hold a minimum of 32 fluid ounces.)**

(b) Attach the container and **clean, dry cutting blades** to the mixing device (food processor or blender). Place a plastic shield over the container (for protection) in case the container breaks during sample processing.

(c) Grind the sub-sample on high speed until all whole kernels are broken (approximately 30 seconds).

Note: An alternative method to grind the sub-sample is permitted provided the particle size is comparable to the blender procedure and processes are in place to prevent cross-sample contamination.

(d) Remove the sub-sample container from the mixing device and add 286 to 288 milliliters (ml) of water.

Note: If the analytical portion size was adjusted to approximate 800 kernels, adjust the water volume using the formula:

Sample weight (grams) X 1.25 = Water volume (ml)

(e) Place a lid on the container and shake to thoroughly wet all corn particles (approximately 10 - 20 seconds). Let the slurry settle for 15 - 30 seconds. The sub-sample will have a thick consistency but should contain some free liquid.

(f) Transfer 0.5 ml of the free liquid from the container and place in a 1.5-ml sample tube using a transfer pipette provided with the test kit.

Note: Some corn material may be transferred with the free liquid in this step.

(g) Place 1 Trait✓ Bt9 Test Strip into the sample tube.

1 Part Number 7000012.

Allow the strip to remain in the test tube for a full 5 minutes. If a control line (top of the strip) does not develop, the test is invalid. Reading the strip prior to 5 minutes could result in false negative results.

2 Part Number 7000003.

Allow the strip to remain in the test tube for a full 10 minutes. If a control line (top of the strip) does not develop, the test is invalid. Reading the strip prior to 10 minutes could result in false negative results.

Caution: The top of the liquid in the sample tube should not be higher than the top of the arrows on the test strip when it is in the sample tubes.

(2) Interpreting the Lateral Flow Test Strip.

Check the result window frequently after inserting the strip. At least one line, the Control Line, should always develop approximately 1 centimeter down from the Reservoir Pad. A red line in this position indicates that the device is functioning properly. A red line appearing below the Control Line is the Test Line and indicates a positive result.

The test line should be clearly discernible with a red color for samples that contain the Cry9C protein. If there is any doubt concerning the presence of a test line, transfer another aliquot (0.5 ml) of the sample extract into a reaction tube and repeat the test with a different lateral flow test strip.

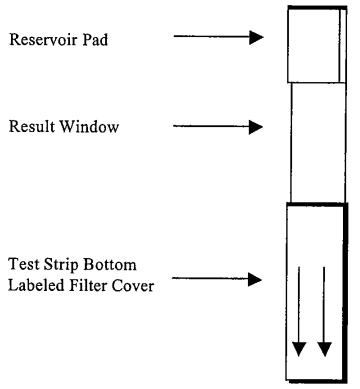
Note: Development of the Control Line serves only to indicate that the device has functioned properly. Discard any test strip that does not develop a Control Line and re-test the sample using another strip.

(3) Alternate Test Levels.

Testing can be performed at different levels (e.g., 1 in 400 kernels, 1 in 600 kernels) by reducing the amount of sample and water volume. Use the following table to determine the appropriate sample size and water volume for alternate test levels.

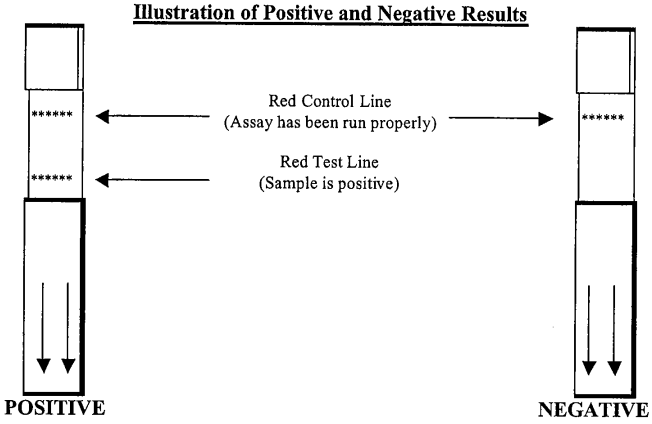
Test Level	Sample Size (Kernels)	Sample Size (Grams)	Water Volume
1 in 700	700 kernels	200 (± 5 grams)	250 - 252 ml
1 in 600	600 kernels	172 (± 5 grams)	215 - 217 ml
1 in 500	500 kernels	143 (± 5 grams)	179 - 181 ml
1 in 400	400 kernels	115 (± 5 grams)	143 - 145 ml
1 in 300	300 kernels	86 (± 5 grams)	108 - 110 ml
1 in 200	200 kernels	58 (± 5 grams)	72 - 74 ml
1 in 100	100 kernels	29 (± 5 grams)	36 - 38 ml

Illustration of Test Strip



As illustrated in the example below, the appearance of **one line** (control) on the strip indicates that the sample is **negative** for StarLink™ corn. The appearance of **two lines** on the strip indicates that the sample is **positive** for StarLink™ corn.

Illustration of Positive and Negative Results



Note: If the sample contains high levels of StarLink™ corn, the control line may be faint and the test line very strong in color.

c. Reporting and Certifying Test Results.

See section 12 for detailed certification procedures.

d. Equipment Cleaning and Waste Disposal.

(1) Clean mixing containers and cutting blades with soapy water, rinse with clean water, and thoroughly dry before reusing. **Failure to do this could result in cross-contamination resulting in errors.**

(2) Dispose solid material (e.g., test strips, sample tubes, ground corn) into a solid waste container for routine disposal. Liquid materials (excess sample solution) may be poured down the drain.

e. Equipment and Supplies.

(1) Test Kit Materials

(a) Trait✓Bt9 Lateral Flow Test Strips

(b) Trait✓ Sample Buffer (included with kit number 7000034 only)

(c) Sample Tubes (1.5 ml)

(d) Transfer Pipettes

(2) Laboratory Equipment

(a) Blender/processor equipped with cutting blades, gasket, and mixing container (minimum 16 fluid ounces for 400 kernel test, minimum 32 fluid ounces for 800 kernel test)

(b) Plastic blender shield

(c) Sample tube rack

(d) Graduated cylinder (minimum size 300 ml)

(e) Timer

f. Storage Conditions.

Store the Trait✓ Bt9 Test Kits at room temperature (60° to 85°F). Storage conditions higher than room temperature may adversely affect performance.

Keep the test strips in the foil pouch with the indicating desiccant. Do not use the test strips or the buffer if the desiccant is not blue in color.

10. QUICKSTIX™ TESTING PROCEDURES

a. Processing the Sample.

(1) Place each sub-sample, 229 grams (± 5 grams) (approximately 800 kernels), in a **clean, dry "Mason" jar or similar container** used for blending purposes. **(Container must hold a minimum of 32 fluid ounces.)**

(2) Attach the container and **clean, dry cutting blades** to the mixing device (food processor or blender). Place a plastic shield over the container (for protection) in case the container breaks during sample processing.

(3) Grind the sub-sample on high speed until all whole kernels are broken (approximately 30 seconds).

Note: An alternative method to grind the sub-sample is permitted provided the particle size is comparable to the blender procedure and processes are in place to prevent cross-sample contamination.

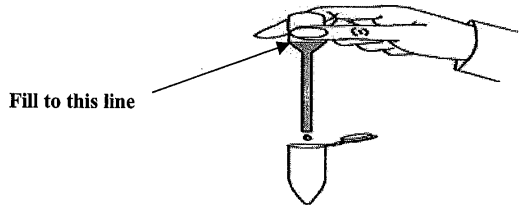
(4) Remove the sub-sample container from the mixing device and add 366 to 368 milliliters (ml) of water.

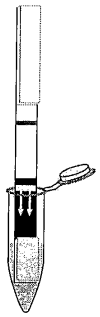
Note: If the analytical portion size was adjusted to approximate 800 kernels, adjust the water volume using the formula:

Sample weight (grams) X 1.6 = Water volume (ml)

(5) Place a lid on the container and shake to thoroughly wet all corn particles (approximately 10 - 20 seconds). Let the slurry settle for 15 - 30 seconds. The sub-sample will have a thick consistency but should contain some free liquid.

(6) Using the transfer pipette provided with the test kit, draw up enough liquid portion to fill the long narrow tip of the pipet up to the line at the top of the pipet bulb. Avoid pulling up particles of corn.





(7) Dispense the extract into a reaction tube.

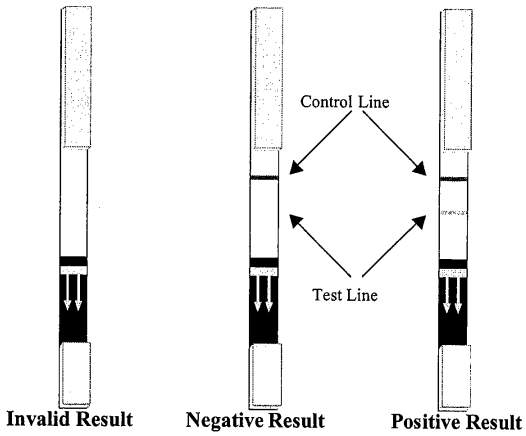
(8) Place 1 QuickStix™ Test Strip into the sample tube. After inserting the strip into the reaction tube, you will observe liquid travelling up the membrane strip toward the absorbent pad at the top of the strip. **Allow the strip to remain in the test tube for a full 5 minutes.** If a control line (top of the strip) does not develop, the test is invalid. Reading the strip prior to 5 minutes could result in false negative results.

b. Interpreting the Lateral Flow Test Strip.

At least one line, the Control Line, should always develop. A red line in this position indicates that the device is functioning properly. A red line appearing below the Control Line is the Test Line and indicates a positive result.

The test line should be clearly discernible with a red color for samples that contain the Cry9C protein. If there is any doubt concerning the presence of a test line, transfer another aliquot (0.5 ml) of the sample extract into a reaction tube and repeat the test with a different lateral flow test strip.

Note: Development of the Control Line serves only to indicate that the device has functioned properly. Discard any test strip that does not develop a Control Line and re-test the sample using another strip.



c. Alternate Test Levels.

Testing can be performed at different levels (e.g., 1 in 400 kernels, 1 in 600 kernels) by reducing the amount of sample and water volume. Use the following table to determine the appropriate sample size and water volume for alternate test levels.

Test Level	Sample Size (Kernels)	Sample Size (Grams)	Water Volume
1 in 700	700 kernels	200 (± 5 grams)	320 - 322 ml
1 in 600	600 kernels	172 (± 5 grams)	275 - 277 ml
1 in 500	500 kernels	143 (± 5 grams)	229 - 231 ml
1 in 400	400 kernels	115 (± 5 grams)	183 - 185 ml
1 in 300	300 kernels	86 (± 5 grams)	138 - 140 ml
1 in 200	200 kernels	58 (± 5 grams)	92 - 94 ml
1 in 100	100 kernels	29 (± 5 grams)	46 - 48ml

d. Reporting and Certifying Test Results.

See section 12 for detailed certification procedures.

e. Equipment Cleaning and Waste Disposal.

(1) Clean mixing containers and cutting blades with soapy water, rinse with clean water, and thoroughly dry before reusing. **Failure to do this could result in cross-contamination resulting in errors.**

(2) Dispose solid material (e.g., test strips, sample tubes, ground corn) into a solid waste container for routine disposal. Liquid materials (excess sample solution) may be poured down the drain.

f. Equipment and Supplies.

(1) Test Kit Materials

(a) QuickStix™ Test Strips

(b) Sample Tubes

(c) Transfer Pipettes

(2) Laboratory Equipment/Supplies

(a) Blender/processor equipped with cutting blades, gasket, and mixing container (minimum 32 fluid ounces)

(b) Plastic blender shield

(c) Sample tube rack

(d) Graduated cylinder (minimum size: 400 ml)

(e) Timer

g. Storage Conditions.

Store the QuickStix™ Test Kits at controlled room temperature (64° to 77° F) or refrigerated (39° to 46° F) for longer shelf life.

Protect the test kits from excessive humidity and extreme hot and cold temperatures when not in use.

Do not open the dessicated cannister until you are ready to use the test devices.

11. **AGRI-SCREEN® CRY9C STRIP TEST PROCEDURES**

a. Processing the Sample.

(1) Place each sub-sample, 229 grams (± 5 grams) (approximately 800 kernels), in a **clean, dry "Mason" jar or similar container** used for blending purposes. **(Container must hold a minimum of 32 fluid ounces.)**

(2) Attach the container and **clean, dry cutting blades** to the mixing device (food processor or blender). Place a plastic shield over the container (for protection) in case the container breaks during sample processing.

(3) Grind the sub-sample on high speed until all whole kernels are broken (approximately 30 seconds).

Note: An alternative method to grind the sub-sample is permitted provided the particle size is comparable to the blender procedure and processes are in place to prevent cross-sample contamination.

(4) Remove the sub-sample container from the mixing device and add 366 to 368 milliliters (ml) of **distilled or deionized water.**

Note: If the analytical portion size was adjusted to approximate 800 kernels, adjust the water volume using the formula:

Sample weight (grams) X 1.6 = Water volume (ml)

(5) Place a lid on the container and shake to thoroughly wet all corn particles (approximately 10 - 20 seconds). Let the slurry settle for 15 - 30 seconds. The sub-sample will have a thick consistency but should contain some free liquid.

(6) Remove the appropriate number of sample tubes and place in the tube rack.

(7) Using a new transfer pipette for each sample, transfer approximately 0.5 ml of extract to a sample tube. Avoid pulling up particles of corn.

(8) Remove the appropriate number of test strips from the foil pouch. Place a new Cry9C strip, with the green end down, into a sample tube.

(9) **Allow the strip to remain in the test tube for a full 10 minutes.** If a control line (top of the strip) does not develop, the test is invalid. Reading the strip prior to 10 minutes could result in false negative results.

b. Interpreting the Lateral Flow Test Strip.

At least one line, the Control Line, should always develop at the top of the strip. A red line in this position indicates that the device is functioning properly. A red line appearing below the Control Line is the Test Line and indicates a positive result.

The test line should be clearly discernible with a red color for samples that contain the Cry9C protein. If there is any doubt concerning the presence of a test line, transfer another aliquot (0.5 ml) of the sample extract into a reaction tube and repeat the test with a different lateral flow test strip.

Note: Development of the Control Line serves only to indicate that the device has functioned properly. Discard any test strip that does not develop a Control Line and re-test the sample using another strip

c. Alternate Test Levels.

Testing can be performed at different levels (e.g., 1 in 400 kernels, 1 in 600 kernels) by reducing the amount of sample and water volume. Use the following table to determine the appropriate sample size and water volume for alternate test levels.

Test Level	Sample Size (Kernels)	Sample Size (Grams)	Water Volume
1 in 700	700 kernels	200 (± 5 grams)	320 - 322 ml
1 in 600	600 kernels	172 (± 5 grams)	275 - 277 ml
1 in 500	500 kernels	143 (± 5 grams)	229 - 231 ml
1 in 400	400 kernels	115 (± 5 grams)	183 - 185 ml
1 in 300	300 kernels	86 (± 5 grams)	138 - 140 ml
1 in 200	200 kernels	58 (± 5 grams)	92 - 94 ml
1 in 100	100 kernels	29 (± 5 grams)	46 - 48ml

d. Reporting and Certifying Test Results.

See section 12 for detailed certification procedures.

e. Equipment Cleaning and Waste Disposal.

(1) Clean mixing containers and cutting blades with soapy water, rinse with clean water, and thoroughly dry before reusing. **Failure to do this could result in cross-contamination resulting in errors.**

(2) Dispose solid material (e.g., test strips, sample tubes, ground corn) into a solid waste container for routine disposal. Liquid materials (excess sample solution) may be poured down the drain.

f. Equipment and Supplies.

(1) Materials Supplied in Test Kits.

(a) 100 Cry9C test strips

(b) 100 transfer pipettes

(c) 100 sample tubes

(2) Materials Required but not Provided.

(a) Blender/processor equipped with cutting blades, gasket, and mixing container (minimum 32 fluid ounces)

(b) Plastic blender shield

(c) Sample tube rack

(d) Graduated cylinder (minimum size: 400 ml)

(e) Distilled or deionized water

(f) Timer

g. Storage Conditions.

Store the Cry9C Test Kits at controlled room temperature (64° to 86° F) to assure their full shelf life. Storage conditions higher than room temperature may adversely affect performance.

Do not use kit components beyond the expiration date.

13. ADDITIONAL INFORMATION

The following information is available from the USDA web site:

a. Official Service Providers.

http://www.usda.gov/gipsa/aboutus/servicemap/usmap.htm

b. Biotechnology Sample Planner.

http://www.usda.gov/gipsa/biotech/biotech.htm

c. Official Grain Sampling Procedures.

http://www.usda.gov/gipsa/reference-library/handbooks/grain-insp/grbook1/gihbk1.htm

Contact the Policies and Procedures Branch at (202) 720-0252 if additional information is needed.

/s/David Orr

David Orr, Director
Field Management Division

APPENDIX C

USDA/ARS LABORATORY STUDY DESIGNS

APPENDIX C

USDA/ARS LABORATORY STUDY DESIGNS

I) USDA/ARS Confirmation of Tests Reported Positive to the QCP for Cry9C Protein

1. Field Sampling

- Sampling corn in the field will follow a protocol consistent with the guidelines in "FDA recommendations for sampling and testing yellow corn and dry-milled yellow corn shipments intended for human food use for Cry9C protein residues" (http://www.cfsan.fda.gov/~dms/starguid.html)

- A representative sample of at least 2400 kernels will be collected from each vehicle or carrier (e.g., each rail car, barge, truck, etc.) in each incoming shipment by using sample selection methods recommended by GIPSA. (For details, see the Grain Inspection Handbook, Book I, Grain Sampling, http://www.usda.gov/gipsa/reference-library/handbooks/grain-insp/grbook1/gihbk1.htm.) If the collected sample is larger than 2400 kernels, it should be mixed thoroughly and reduced to 2400 kernels for testing using an appropriate divider. This sample should then be divided into 3 sub-samples of 800 kernels each.

- Corn samples collected will receive an initial code following the same coding scheme that is currently used in the QCP. SLLI will be responsible for maintaining the QCP. In the QCP, each sample will be identified by the site name, date of test, and whether it is inbound or outbound. Further identifying information, to allow differentiation between corn shipments tested on the same day, such as the lot number of the corn shipment will also be used.

- Each corn sample will be tested for the presence of Cry9C protein using ELISA strip technology.

2. Method of Analysis

- Aliquots of water extract from corn samples will be analyzed for Cry9C protein by the field laboratory following procedures outlined by the QCP.

- Only ELISA test strips that have been performance certified by USDA GIPSA for the detection of one Cry9C corn kernel in 800 non-Cry9C kernels will be used to detect the presence of Cry9C protein. Strips manufactured currently certified by USDA GIPSA are SDI and EnviroLogix.

- The test strip manufacturers' documentation are available at: (http://www.sdix.com/PDF/Products/7000012 7000013 User Guide TraitChk HS Bt9 5 Min 100-T Grain 1.1.pdf), http://www.envirologix.com/artman/publish/article_39.shtml), and (http://www.envirologix.com/artman/publish/article_38.shtml)

- Aliquots from the water extract testing positive by the strip for Cry9C will be shipped along with an aliquot of "blank" water from the source water used in the extraction process by air courier to the designated USDA/ARS laboratory at North Carolina State University in Raleigh, NC within 36 hours of sample analysis in the field laboratory. Test strip suppliers have determined that under refrigerated and room temperature conditions, sample aliquots can be analyzed after storage for up to 6 days.

3. Incoming Sample Registration by the USDA/ARS Confirmation Lab

- Upon receipt of the shipping package from the field lab, remove the two sample bottles (blank water and corn extract) and ID form from shipping package. Log the two sample bottles into the USDA/ARS Lab database and file the ID form (Figure 1).

- A USDA/ARS Lab log sheet will be used to record each field sample set (represented by two sample bottles) once the shipment package arrives. The log sheet will have fields for USDA/ARS Lab sample number, field control number, shipped date from field lab, received date by the USDA/ARS Lab, test strip manufacturer, test strip lot number, condition of sample set, and confirmation results.

- Each field sample set will be given a unique sequential USDA/ARS Lab sample number (AV-#####) from the log sheet where ##### represents the unique sequential sample number from 1 to 99999.

- Write USDA/ARS Lab sample number on field ID form top right corner, blank water bottle and field extract bottle using a permanent marker.

- Examine field ID form for completeness of information and contact field lab if information is not complete.
- Examine blank water and corn extract aliquots and note condition (discoloration, etc.) on log sheet.

- File field ID form in notebook for field ID forms.

- Bind blank water and field extract bottles together with rubber band and refrigerate both bottles until time for confirmatory test.

- If it takes more than several hours after receipt by the USDA/ARS Lab to log in sample bottles from the field lab, refrigerate until samples can be logged in.

- Confirmatory test should be conducted within 48 hours.

4. Conducting Confirmatory Tests

- Place each field sample set (one bottle with blank water and one bottle with corn extract) in a holding block (Figure 2). Holding blocks have cavities to hold field sample set (2 bottles from field lab) and 5 sample tubes. Order holding blocks along the lab bench.

- If refrigerated, allow the sample set (both blank and extract water bottles) 60 minutes warm-up. No more than 20 sample sets may be processed at one time.

- Select 5 test strips from USDA/ARS Lab inventory for each sample set and place on lab counter adjacent to sample set holding blocks. AVL test strips should be from same manufacturer as field test strip, but from a different manufacturing lot (refer to log sheet).

- Place 5 sample tubes in each holding block.

- For each sample set, pipette 0.5 ml blank water into tube labeled “Blank”, and using the same pipette tip, place 0.5 ml field corn extract into each of the 4 remaining tubes (extract 1-4) in the holding block. Discard the pipette tip, install new tip and repeat for next sample set. At this point, all sample sets should have 5 sample tubes (1 blank, 4 extracts) loaded with 0.5 ml aliquots. Discard all pipette tips.

- For each sample set, put a test strip into each sample tube. Set timer for 6 minutes.

- After six minutes, record the results (positive or negative) on the field ID form USDA/ARS Lab log sheet. The Field ID form will have fields for USDA/ARS Lab sample number, blank test, field extract tests 1-4 and notes.
- Discard all sample tubes. Check Field ID form for completion of test results. Return all unused strip to the proper container according to manufacturer and lot. Do not mix test strips.

- Record results on field datasheet and fax to SLLI. SLLI will enter results of validation test from the USDA/ARS Lab into the QCP database and notify Exponent and the appropriate laboratories of test result.

5. Confirmation Decision Rules

- If the strip in the blank water is positive (Outcome 1, Figure 3), the field result was a false positive. There is no need to test the 4 extracts. Test indicates bad blank water used in the extraction.

- If the test strip in the blank water is negative, place a single antigen strip from the USDA/ARS Lab into each of the four aliquots of extract water.

- If all aliquots test negative (Outcome 2, Figure 3), the field result was a false positive. This result suggests a bad strip used by the field lab.

- If at least 1 strip among the 4 aliquots of extract water is positive (Outcome 3, Figure 3), the field result can be classified as a true positive. If all 4 aliquots are not positive, then analytical variability may be reason for inconsistencies.

- Report results of the USDA/ARS Lab test on the identification form supplied by the field laboratory and report results to the field lab.

- Enter test results and all identification information in a spreadsheet database.

6. Quantification of Cry9C protein with ELISA plate test

- At the request of SLLI, the Cry9C protein concentration in the water extract used for the strip confirmation test was quantified in a subset of the samples received using the EnviroLogix QantiPlate test kit and the high sensitivity quantification protocol. The limit

of detection (LOD) is stated to be 0.07 optical density units or 0.07 ng/g (parts per billion, ppb) in corn extract.

- The ELISA plate consists of 96 antigen-coated wells fastened together as a plate in an 8x12 grid. The 96 wells are used for the standards, negative controls (blanks), and unknown extracts.

- Four standard solutions (0.2, 0.8, 2.5, and 5.0 ng Cry9C per ml solution) were used in duplicate taking up 8 wells.

- Four negative controls (0.0 ng/ml Cry9C solution) were used, which took up 4 wells.

- As many as 42 unknown water extract solutions (0.1 ml), in duplicate, can be quantified taking up 84 wells.

- The ELISA plate was placed into a reader where the optical density (OD) of each well was read. The OD of the negative controls was subtracted from all standard and unknown OD values. The reader compared the adjusted optical density of the unknown to the adjusted OD of the standards. Then taking dilution factors into account, the ng/ml were converted to ng/g or ppb of Cry9C protein for each unknown or test sample.

- All well values, both OD and computed ppb values were recorded in a computer database. The duplicate unknown concentration values along with the average of the duplicates were recorded in the spreadsheet with the strip test results, and all other identifying information recorded when the field samples arrived at the USDA/ARS lab.

7. Testing Non-QCP Samples for Cry9C

At the request of SLLI and commercial handlers, the USDA/ARS Lab will also test samples not part of the QCP Program for the presence of Cry9C protein using either the SDI or EnviroLogix strip test. These non-QCP samples could be either corn or water extract. The non-QCP samples will be received, documented, and analyzed for Cry9C protein in a manner similar to that described above for QCP samples. Only verified QCP samples will be included in Exponent's exposure assessment to estimate exposure to Cry9C in the US population.

8. USDA/ARS Lab Location and Contacts:

Thomas B. Whitaker
124 Weaver Lab
Box 7625
North Carolina State University
Raleigh, NC
27695-7625
Phone: 919 – 515 – 6735
Email: Tom_Whitaker@ncsu.edu

FIGURE 1

EXAMPLE OF LOG-IN INFORMATION RECORDED BY THE USDA/ARS LAB UPON RECEIPT OF SAMPLE SET FROM FIELD LABS

AVL Sample Number	Field Control Number	Company	Company Location	Shipment Date	Receive Date	Meets 36 Hour Shipment	Field Test Strip Manufacturer	Field Strip Lot Number	AVL Test Strip Lot Number	AVL Test Date	Condition of Sample Set
AV-1											
AV-2											
AV-3											
AV-4											
AV-5											
AV-6											
AV-7											
AV-8											
AV-9											
etc.											

FIGURE 2

HOLDING BLOCK

	O
O	
O	
O	
O	
O	
O	

Field Blank
Field Extract
Blank
Extract 1
Extract 2
Extract 3
Extract 4

FIGURE 3

POSSIBLE OUTCOME CHART

Possible Test Results	Lab	Blank Water From Field	Field Extract 1	Field Extract 2	Field Extract 3	Field Extract 4	Analytical Conclusion about Field Result
1	AV	+	NA	NA	NA	NA	False Positive
2	AV	-	-	-	-	-	False Positive
3	AV	-	At least one "+"				True Positive

"-" Indicates negative test strip result
"+" Indicates positive test strip result
"+/-" Indicates either/or
AV = strips used by the USDA/ARS Lab
NA = No analysis necessary

Procedures for Field Laboratories To Follow In The Event Of A Positive Cry9C Test Result

NOTE:

Until field laboratory results for any test are determined, be sure to retain a minimum of 10ML of the water blended with the corn sample (test mix solution).

If a positive result is detected, this additional portion (aliquot) of the original test mix solution (10 ML) and a separate (10 ML) of the source water used in the extract process needs to be sent to the validation lab (shipping containers provided) as described in the following procedure:

1. Retain a 10 ML (minimum) aliquot of the test solution from the positive test mixture. Label aliquot container with a control number to distinguish between positive test result samples.

2. Obtain a 10 ML (minimum) aliquot of the source water used in the original test mixture. Label aliquot container with a control number to allow for source water to be linked to the appropriate positive test mixture.

3. Complete the attached information document to be included with the shipment of #1 and #2 above to the validation lab.

4. Refrigerate aliquots obtained in #1 and #2 (when possible) until you can ship to the validation lab.

5. Ship #1, #2 and #3 to the validation lab by overnight courier as soon as possible, but no longer than 36 hours after sample preparation (overnight courier container provided) to the USDA/ARS Lab address at:

   North Carolina State University
   124 Weaver Lab
   Box 7625
   Raleigh, NC
   27695-7625

6. Notify USDA/ARS Lab of overnight shipment:
   Phone: (919) 515 - 6735

7. Direct any questions to: StarLink™ Logistics Inc (SLLI).
   Email: StarLink™admn@SLLI.net
   Phone: (919) 678- 6065
   Fax: (919) 678- 6069

Cry9C Positive Test Result Information Sheet to Analytical Validation Lab

CONTROL #: _____

Company: _____ **Date of Test:** _____

Test Location: _____ **Telephone Number:** _____

Corn Source: (check one per line) _____ **Inbound** _____ **Outbound** _____ **Storage Site**
Unit: _____ **Truck** _____ **Rail Car** _____ **Barge** _____ **Sorage Site**

Number of Bushels: _____ **Unit ID #:** _____ **Source Name:** _____

Strip Manufacturer: _____ **Strip Lot #:** _____ (on tube container)

Any Additional Tests on the Same Unit: _____ **Number of** _____ **Positive** _____ **Negative**

GIPSA Representative Name: _____
(Please Print below line and sign above line)

Testing Operator Name: _____
(Please Print below line and sign above line)

Do not complete below line - for Analytical Validation Lab completion only

AVL Number	Blank Water	Field Extract 1	Field Extract 2	Field Extract 3	Field Extract 4		AVL Test Result

II. USDA/ARS Quantification Study Using USDA FGIS QA Samples

Study Objectives

- The objectives of the study were: (1) to determine the levels of Cry9C protein in shelled corn moving in the domestic market from the elevator to the miller and (2) determine the level of Cry9C protein in corn lots that test negative by the ELISA strip test. The USDA/ARS lab in Raleigh, NC will quantify Cry9C protein in a minimum of 1000 shelled corn samples collected by USDA Federal Grain Inspection Service (FGIS).

Survey Sample Selection

- Shelled corn in the U.S. domestic market system is graded for various grade factors by the USDA/FGIS, Grain Inspection, Packers and Stockyard Administration (GIPSA). In addition to samples collected for the grading process, FGIS also collects, nationwide, about 2000 samples per month as part of a quality assurance program to monitor the performance of FGIS field offices in the grading process.

- Arrangements were made with GIPSA to collect 250 samples per month over a four month period (May to August, 2005) when the frequency of positive detections of Cry9C appears historically to be at its highest. USDA/FGIS collected a total of 1132 shelled corn samples from six field offices in the Midwest area of the U.S. The number of samples collect by month is shown in Table 1.

- The FGIS packaged each survey sample in a plastic bag and included with each sample an information sheet with date sample taken, field office location, and FGIS ID code. The 500 g samples were mailed to the USDA/ARS lab in Raleigh, NC for analysis of Cry9C protein.

Survey sample receipt by USDA/ARS Lab

- Upon arrival at the USDA/ARS lab, survey samples were given a unique lab ID number, segregated by month graded by FGIS, stored in cold storage facilities, and all data (Lab ID and information on the information sheet) was recorded in a spreadsheet.

- A test sample consisting of 800 kernels (about 240 g) plus an additional 10 g of kernels (about 240 + 10 = 250 g) was removed from each 500 g survey sample and placed into a paper bag with the lab ID noted. The mass of the test sample was recorded in the

spreadsheet. The test sample was analyzed for Cry9C protein using both the ELISA strip test and the ELISA plate test.

Analytical methods

- The Cry9C concentration in each test sample was estimated using two different analytical tests: (1) the SDI ELISA strip test (Bt9 Lateral Flow Cry9C test kit, www.sdix.com) and (2) the EnviroLogix ELISA Plate test kit (QuantiPlate Cry9C kit, www.envirlogix.com).

- The SDI ELISA strip can detect at least one Cry9C kernel in a sample of 800 non-Cry9c kernels. The estimated threshold is about 15 ng Cry9C protein per g of corn. The SDI strip test doesn't quantify the Cry9C concentration, but only indicates if the sample concentration is below or above the threshold (15 ng/g).

- The ELISA Plate test kit is a quantitative method of measuring the Cry9C concentration in comminuted shelled corn. The high sensitivity protocol was used to measure Cry9C in one-gram subsamples taken from the 250 g comminuted test sample. The limit of detection (LOD) is stated to be 0.07 optical density units or 0.07 ng/g (parts per billion, ppb) in corn extract.

Test sample preparation procedure

- Each 250 g test sample was comminuted in a blender jar for 60 second, which left no large particles in the grinder. After grinding, a ten-gram subsamples of comminuted corn were removed from the test sample, placed into a plastic bag, identified, and placed in cold storage for later analyses if needed. The remaining 240 g comminuted test sample was transferred to a 1000 ml glass jar.

- Using the SDI strip test protocol, a volume of deionized water equal to 1.25 ml times the mass of corn was added to the comminuted test sample in the 1000 ml jar. The volume of water was approximately 1.25 times 240 g or 300 ml. The corn/water mixture was shaken for 30 seconds to thoroughly wet all corn particles. After shaking, the corn/water mixture was allowed to sit for about 30 minutes until enough corn settled to the bottom of the jar. A 15 ml aliquot of water extract was removed from the 1000-ml jar and placed into a 20-ml jar and sealed.

- The 15 ml aliquot was centrifuged to provide a cleaner extract for Cry9C analysis by the ELISA Plate test. As many as 36 250 g test samples were prepared and analyzed each day by the strip and the ELISA plate methods.

Analytical test procedure

- The Cry9C protein concentration was determined from the 15 ml extract taken from each test sample using both the strip test and ELISA plate test.

- Strip test - From the 15 ml water extract, two 0.5 ml aliquots of water were each placed into an SDI sample tube and a single strip was placed into each sample tube for 6 minutes. After 6 minutes the strips were read either positive (two red lines indicated >15 ng/g) or negative (one red line indicated <15 ng/g) and the results of the strip test were recorded in the spreadsheet. Two strips were used detect Cry9C in each test sample extract.

- ELISA plate test – The ELISA plate consist of 96 antigen-coated wells fastened together as a plate in an 8x12 grid. The 96 wells are used for the standards, negative controls (blanks), and unknown extracts.

- Four standard solutions (0.2, 0.8, 2.5, and 5.0 ng Cry9C per ml solution) were used in duplicate taking up 8 wells.

- Four negative controls (0.0 ng/ml Cry9C solution) were used, which took up 4 wells.

- Thirty-six unknown solutions (0.1 ml) were used in duplicate taking up 72 wells.

- Twelve wells are left free for unexpected analyses.

- The ELISA plate was placed into a reader where the optical density (OD) of each well was read. The OD of the negative controls was subtracted from all standard and unknown OD values. The reader compared the adjusted optical density of the unknown to the adjusted OD of the standards. Then taking dilution factors into account, the ng/ml were converted to ng/g or ppb of Cry9C protein for each unknown or test sample.

- All well values, both OD and computed ppb values were recorded in a computer database. The duplicate unknown concentration values along with the average of the duplicates were recorded in the spread sheet with the strip test results, and all other identifying information recorded when the survey samples arrived at the USDA/ARS lab.

- The strip test and the ELISA plate test were conducted on a total of 1132 survey samples. The numbers of samples tested for Cry9C by location and by month graded are shown in Table 1.

Table 1. Number of survey samples tested for Cry9C protein by location and month graded by FGIS.

Month Sampled (2005)	Total
March	10
April	112
May	250
June	254
July	253
August	253
Grand Total	1132

APPENDIX D

CORN HANDLING AND GRAIN PROCESSING DISCUSSION

APPENDIX D

CORN HANDLING AND GRAIN PROCESSING DISCUSSION

Whole Corn Handling Operations from Farm to Elevator

Virtually all farmers harvest corn with a combine with an attached corn header, and transfer the harvested grain from the combine to a truck to deliver either to on-farm storage or a commercial grain elevator. Farm trucks typically hold 200 to 800 bushels with the average size about 400 bushels.

When the grain is delivered to a local elevator, the grain is dumped into a pit covered by an iron grate (which removes large foreign objects). The pit may be able to hold one or more truck loads of grain at a given time. From the pit, the grain is normally conveyed (via belt or drag conveyor) to a bucket elevator which elevates the grain to the top of grain storage bins where it is dropped to the bottom of the bin, or onto other grain. Bin sizes at elevators generally range from 10,000 bushels to 1,000,000 bushels, with an average of 70,000 to 80,000 bushels

When the grain is loaded out of the elevator, it is drawn from the bottom of the bin. The grain flows out of the bin onto a belt or a drag conveyer, and then elevated to again be dumped into a truck, barge or railcar for transshipment to a feeding operation, to a terminal elevator (for additional storage), to a grain processor or to an export location.

From the time of receipt through load-out, there is a continuous blending and commingling of the corn received from individual farmers. The farm truck often carries corn taken from different fields on the farm. Truckloads are dumped successively on top of each other, but the necessary handling, conditioning and management of elevator storage space ensures that individual truckloads lose their identity. Corn that is dried is handled in a different stream through the dryer prior to going to a bin, adding to the commingling process. At some elevators, multiple truck dump pits are combined into one grain stream entering storage. At all facilities, the need to move grain from bin to bin for conditioning of the grain and to open up additional empty bins forces the contents of multiple bins to be commingled into one during handling. Further commingling occurs during load-out as the elevator manager often draws grain from multiple bins to intentionally blend the grain to meet quality specifications for different customers.

As grain is dropped from the top of storage bins at the elevator, the grain forms an inverted conical shape, as the grain enters at the center and flows out to the sides of the bin. There is a “layering” effect of the grain entering the bin. When the grain is drawn from the bottom of the bin, a different flow pattern develops. The grain flowing out will form a “core” in

the center. The center portion of the grain bin flows out first, then a cone develops, with the upper portions of the grain flowing out toward the early part of the removal process. As the bin empties, the grain at the sides of the bins starts to flow inward toward the center "core." All the grain deliveries used to fill the bin are commingled in the storage/handling process. The degree of mixing of the grain will depend in part on the point at which the grain entered the bin---near the beginning of the bin-filling process or near the end. The last lot of grain dumped into the bin is likely to have the least amount of commingling in the stream of grain exiting the bin, because the top portion of the grain tends to flow out earlier. Those trucks dumped near the middle of the bin-filling process are commingled most extensively.

If an average farm truck load of 400 bushels of pure StarLink corn was delivered to an elevator and placed into a small 10,000 bushel bin, a commingling/dilution of that grain on the order of 3 to 5 times is a conservative expectation, with 3 probably a "worst case" situation. This worst case situation would assume the very minimum number of handlings for drying, conditioning and blending (to meet quality specifications) in the elevator prior to load-out.

Grain Processing at Dry Mills

Grain is delivered from elevators to dry corn mills via trucks or rail cars. Trucks typically haul 1,000 bushels with rail cars holding about 3,500 bushels. The initial receiving process is much like that at the elevator, dumping into a pit and elevating grain into storage bins, which hold the grain until it enters the processing stream.

Most dry corn mills are continuous process (rather than batch). The corn is transferred from the storage bins to a "surge" bin that holds the grain prior to going into a tempering process (where water is added to condition the grain for efficient processing). After tempering, the corn enters the milling process where a series of grinding and sifting operations take place. The germ and the bran are removed from the kernel, and the remaining endosperm portion is reduced to the appropriate size for the product being manufactured. The wide variety of products manufactured includes flaking grits, cereal grits, brewers' grits, corn meal, corn flour, etc.

The various products from milling are transferred into different mill product storage bins depending on intended shipment method. No single bushel goes into any one product bin. The milling of each bushel of corn will create many different particle sizes, each of which goes into a different product bin. From these bins, product may be loaded out in bulk truck or rail or into bags for delivery to a packaging operation or company which may further process or mix the product with other ingredients to produce retail products.

Each handling process into and out of storage, and each processing operation causes the corn and its products to be diluted further. Through storage, tempering, multiple grinding/sifting operations, transfer into product bins, further processing into retail products, there are at least 7-8 distinct points of dilution during the entire voyage from field to end-user.

Because the grain in a milling operation is being continuously mixed through tempering, milling, and handling, the degree of dilution at any one stage is probably much greater than the factor of three, considered to be the "worst case" at the elevator. However, assuming conservatively that there are only seven handling and processing operations, each of which is assumed to dilute the grain by a factor of three, suggests that one truckload of pure StarLink™ corn would be diluted by several orders of magnitude, prior to reaching the consumer.

* Discussion prepared by Betsy Faga, President of the North American Millers Association and Kendall Keith, President of the National Grain and Feed Association

APPENDIX E

SENSITIVITY ANALYSES

APPENDIX E

SENSITIVITY ANALYSES

Analysis 1

Corn testing negative in the field with the strip test and subsequently testing negative with the Elisa plate test is not likely to contain any StarLink. In the original assessment, this corn was assigned a 0 ppb Cry9C level (Distribution 1). The decision to assign a zero value is validated by the very small proportion of the StarLink corn crop from the 1999 and 2000 crop that could still be present in the US markets. In this sensitivity analyses, instead of assuming there is no Cry9C in this corn, we assigned Distribution 1 a uniform distribution ranging from 0 ppb to 0.156 ppb, the highest limit of detection seen with the ELISA plate test. This distribution is identical to the distribution that was assigned to Groups 3 and 5. All other assumptions were kept constant. The exposure estimates resulting from this analysis are presented in Table E-1.

Analysis 2

In the original assessment, an empirical or uniform distribution was used to determine the level and distribution and Cry9C protein in the US corn supply. An alternative approach would be to look at the available data as one continuous dataset and fit a parametric distribution. In this analysis, the weighted combined distribution of the available data on the prevalence and level of Cry9C in the US corn supply was examined and a lognormal distribution (-5.2, 2.4) was used to represent the combined distribution. All other assumptions were kept constant. The exposure estimates resulting from this analysis are presented in Table E-2.

Analysis 3

In the original assessment, the process of commingling and the potential for “hot spots”, i.e., the potential for corn to be diluted with other local corn was addressed by dividing the distribution of Cry9C levels into ten strata representing the 10 deciles of the distribution before adjustment for dilution and commingling. This approach is conservative in that it forms composite samples within strata that have similar levels, and thus is not likely to form composite samples from corn with low Cry9C levels with corn with high Cry9C levels. An alternative approach would be to assume no commingling. In this analysis, there was no assumption of commingling and composites of size 5 were not formed; all other assumptions were kept constant. The exposure estimates resulting from this analysis are presented in Table E-3.

Analysis 4

In the original assessment, it was assumed that there were no detectable residues of Cry9C in cereals due to the extensive blending and mixing that is involved in the processing. Alternatively, we could assume that there is some residual level of Cry9C found in cereals. In this analysis, we assigned a Cry9C level of 0.036 ppb to all cereals. This level was determined as the weighted average of the Cry9C levels from the six distributions described in the report. All other assumptions were kept constant. The exposure estimates resulting from this analysis are presented in Table E-4.

Table E-1. Analysis #1

Per User Dietary Intake Estimates of Cry9C (µg/day)

	Dietary Intake Estimates of Cry9C (µg per day)			
Population Group	Mean	95th percentile	99.5th percentile	99.9th percentile
US Population	0.000207	0.00106	0.004543	0.009298
US Children 1-6	0.000143	0.000667	0.003266	0.007549
US Children 7-12	0.000178	0.000856	0.003737	0.008441
Hispanic Population	0.000159	0.000728	0.003664	0.007748

Table E-2. Analysis #2

Per User Dietary Intake Estimates of Cry9C (µg/day)

	Dietary Intake Estimates of Cry9C (µg per day)			
Population Group	Mean	95th percentile	99.5th percentile	99.9th percentile
US Population	0.000178	0.000269	0.007082	0.023896
US Children 1-6	0.000124	0.000185	0.004864	0.017023
US Children 7-12	0.000149	0.000276	0.00584	0.01921
Hispanic Population	0.000139	0.000227	0.00525	0.018151

Table E-3. Analysis #3

Per User Dietary Intake Estimates of Cry9C (µg/day)

Population Group	Dietary Intake Estimates of Cry9C (µg per day)			
	Mean	95th percentile	99.5th percentile	99.9th percentile
US Population	0.000069	0.00003	0.002677	0.008257
US Children 1-6	0.000047	0.000022	0.001867	0.005734
US Children 7-12	0.000061	0.000046	0.002219	0.006553
Hispanic Population	0.000055	0.000045	0.002079	0.006609

Table E-4. Analysis #4

Per User Dietary Intake Estimates of Cry9C (µg/day)

Population Group	Dietary Intake Estimates of Cry9C (µg per day)			
	Mean	95th percentile	99.5th percentile	99.9th percentile
US Population	0.000205	0.000999	0.003386	0.008526
US Children 1-6	0.000237	0.000931	0.002655	0.006011
US Children 7-12	0.000325	0.00125	0.003373	0.006863
Hispanic Population	0.000227	0.001075	0.00303	0.006702

APPENDIX F

CSFII FOOD CODES INCLUDED IN ASSESSMENT AND APPLIED PROCESSING FACTORS

APPENDIX F

CSFII FOOD CODES INCLUDED IN ASSESSMENT AND APPLIED PROCESSING FACTORS

Table F-1. Foods Determined to be Made from Masa and Included in the Analysis.

NFCS Food Code	Food Description
58306010	~Beef enchilada dinner, NFS (frozen meal)
58306020	~Beef enchilada, chili gravy, rice, refried beans (frozen meal)
58100150	~Burrito with beef and potato, no beans
58104260	~Chalupa with beans, cheese, lettuce and tomato
58104310	~Chalupa with beans, chicken, cheese, lettuce and tomato
58306070	~Cheese enchilada (frozen meal)
58306050	~Cheese enchilada with beans and rice (frozen meal)
58306100	~Chicken enchilada (diet frozen meal)
58100370	~Chilaquiles, tortilla casserole with salsa and cheese, no egg
58100360	~Chilaquiles, tortilla casserole with salsa, cheese, and egg
58100720	~Enchilada with beans and cheese, meatless
58100710	~Enchilada with beans, meatless
58100510	~Enchilada with beef and beans
58100530	~Enchilada with beef and cheese, no beans
58100520	~Enchilada with beef, beans, and cheese
58100400	~Enchilada with beef, no beans
58100800	~Enchilada with cheese, meatless, no beans
58100610	~Enchilada with chicken and beans, tomato-based sauce
58100630	~Enchilada with chicken and cheese, no beans, tomato- based sauce
58100620	~Enchilada with chicken, beans, and cheese, tomato- based sauce W/ MONTEREY CHEESE (INCLUDE MONTEREY JACK
58100600	~Enchilada with chicken, tomato-based sauce
58100560	~Enchilada with ham and cheese, no beans
58100900	~Enchilada with seafood, tomato-based sauce
58101240	~Flauta with chicken

NFCS Food Code	Food Description
52208760	~Gordita/sope shell, plain, no filling, fried in oil
52208750	~Gordita/sope shell, plain, no filling, grilled, no fat added
32105180	~Huevos rancheros
58101820	~Mexican casserole made with ground beef, beans, tomato sauce, cheese, taco seasonings, and corn chips
58101830	~Mexican casserole made with ground beef, tomato sauce, cheese, taco seasonings, and corn chips
41501000	~Mexican dinner with fried beans, frozen
54420010	~Multigrain mixture, pretzels, cereal and/or crackers, nuts
58104120	~Nachos with beans and cheese
58104140	~Nachos with beef and cheese
58104130	~Nachos with beef, beans, and cheese
58104080	~Nachos with beef, beans, cheese, and sour cream
58104180	~Nachos with beef, beans, cheese, tomatoes and onions
58104090	~Nachos with cheese and sour cream
58104100	~Nachos with cheese, meatless, no beans
58104250	~Nachos with chicken or turkey and cheese
58104160	~Nachos with chili
58104710	~Quesadilla with cheese, meatless
54402200	~Salty snack mixture, mostly corn or cornmeal based, with pretzels, without nuts
54401210	~Salty snacks, corn based puffs and twists, cheese puffs and twists, lowfat
54401020	~Salty snacks, corn or cornmeal base, corn chips, corn-cheese chips
54401090	~Salty snacks, corn or cornmeal base, corn chips, corn-cheese chips, unsalted
54401050	~Salty snacks, corn or cornmeal base, corn puffs and twists; corn-cheese puffs and twists
54401010	~Salty snacks, corn or cornmeal base, nuts or nuggets, toasted
54401080	~Salty snacks, corn or cornmeal base, tortilla chips
54401120	~Salty snacks, corn or cornmeal base, tortilla chips, fat free, made with Olean
54401100	~Salty snacks, corn or cornmeal base, tortilla chips, light (baked with less oil)
54401150	~Salty snacks, corn or cornmeal base, tortilla chips, lowfat, baked without fat

NFCS Food Code	Food Description
54402080	~Salty snacks, corn or cornmeal base, tortilla chips, unsalted
54402600	~Salty snacks, multigrain, chips
58101400	~Soft taco with beef, cheese, and lettuce
58421080	~Sopa de tortilla, Mexican style tortilla soup
58101910	~Taco or tostada salad with beef and cheese, corn chips
58101720	~Taco or tostada with beans and cheese, meatless, with lettuce, tomato and salsa
58101730	~Taco or tostada with beans, cheese, meat, lettuce, tomato and salsa
58101710	~Taco or tostada with beans, meatless, with lettuce, tomato and salsa
58101300	~Taco or tostada with beef, cheese and lettuce
58101310	~Taco or tostada with beef, lettuce, tomato and salsa
58101320	~Taco or tostada with beef, lettuce, tomato and salsa
58101510	~Taco or tostada with chicken or turkey, lettuce, tomato and salsa
58101520	~Taco or tostada with chicken, cheese, lettuce, tomato and salsa
58101540	~Taco or tostada with fish, lettuce, tomato, salsa
52215300	~Taco shell, corn
58104810	~Taquitoes
52215100	~Tortilla, corn
52215000	~Tortilla, NFS

Table F-2. Foods Determined to be Made from Non-Masa Ingredients and Included in the Analysis

NFCS Food Code	Description
11340000	~Milk, imitation, fluid, non-soy, sweetened, flavors other than chocolate
11424000	~Yogurt, vanilla, lemon, maple, or coffee flavor, nonfat milk, sweetened with low calorie sweetener
11425000	~Yogurt, chocolate, NS as to type of milk
11426000	~Yogurt, chocolate, whole milk
11427000	~Yogurt, chocolate, nonfat milk
11460410	~Yogurt, frozen, flavors other than chocolate, nonfat milk, with low-calorie sweetener
11519000	~Milk beverage, made with whole milk, flavors other than chocolate
11519050	~Milk, flavors other than chocolate, whole milk-based
11525000	~Milk, malted, fortified, natural flavor, made with milk
11542100	~Carry-out milk shake, chocolate
11542200	~Carry-out milk shake, flavors other than chocolate
11613000	~Instant breakfast, powder, sweetened with low calorie sweetener, milk added W/ 0.02 MILK~
11710450	~Similac Special Care 24, with iron, infant formula, NS as to form
11710800	~Pediasure, with iron, infant formula, NS as to form
11710801	~Pediasure, with iron, infant formula, ready-to-feed
11710900	~Carnation Good Start, with iron, infant formula, NS as to form
11710901	~Carnation Good Start, with iron, infant formula, ready-to-feed
11710902	~Carnation Good Start, with iron, infant formula, prepared from liquid concentrate
11710903	~Carnation Good Start, with iron, infant formula, prepared from powder
11720451	~Isomil SF (sucrose-free), with iron, infant formula, ready-to-feed
11720452	~Isomil SF (sucrose-free), with iron, infant formula, prepared from liquid concentrate
11720502	~Soyalac, with iron, infant formula, prepared from liquid concentrate
11720503	~Soyalac, with iron, infant formula, prepared from powder
11720600	~Carnation Alsoy, with iron, infant formula, NS as to form (formerly I-Soyalac)
11720601	~Carnation Alsoy, with iron, infant formula, ready-to-feed (formerly I-Soyalac)
11720602	~Carnation Alsoy, with iron, infant formula, prepared from liquid concentrate (formerly I-Soyalac)

NFCS Food Code	Description
11720603	~Carnation Alsoy, with iron, infant formula, prepared from powder (formerly I-Soyalac)
11740300	~Nutramigen, with iron, infant formula, NS as to form
11740301	~Nutramigen, with iron, infant formula, ready-to-feed
11740302	~Nutramigen, with iron, infant formula, prepared from liquid concentrate
11740303	~Nutramigen, with iron, infant formula, prepared from powder
11830180	~Cocoa (or chocolate) flavored beverage powder with low calorie sweetener, dry mix, not reconstituted
11830210	~Milk, malted, dry mix, fortified, not reconstituted, flavors other than chocolate
11830400	~Milk beverage, powder, dry mix, not reconstituted, flavors other than chocolate
11830940	~Meal replacement, high protein, milk based, fruit juice mixable formula, powdered, not reconstituted
11830970	~Meal replacement, protein type, milk-based, powdered, not reconstituted
11832000	~Meal replacement, protein type, milk- and soy-based, powdered, not reconstituted
11835100	~Meal replacement, Amway's Nutrilite brand Positrim Drink Mix, powdered nonfat dry milk-based, dry, not reconstituted
12220400	~Whipped cream substitute, non-dairy, lowfat, low sugar, made from powdered mix
12320100	~Sour cream, imitation (non-dairy)
12350100	~Spinach dip, sour cream base
13120100	~Ice cream bar or stick, chocolate covered
13120110	~Ice cream bar or stick, chocolate or caramel covered, with nuts
13120500	~Ice cream sandwich
13126000	~Ice cream, fried
13140670	~Ice milk sundae, soft serve, fruit topping (without whipped cream)
13160150	~Milk dessert, frozen, nonfat, made with low-calorie sweetener, chocolate
13160160	~Milk dessert, frozen, nonfat, made with low-calorie sweetener, flavors other than chocolate
13160200	~Milk dessert, frozen, lowfat, flavors other than chocolate
13160400	~Milk dessert, frozen, milk-fat free, flavors other than chocolate
13160410	~Milk dessert, frozen, milk-fat free, chocolate
13160600	~Milk dessert, frozen, made with low-calorie sweetener, flavors other than chocolate
13160650	~Milk dessert, frozen, made with low-calorie sweetener, chocolate

NFCS Food Code	Description
13161600	~Milk dessert bar, frozen, made from lowfat milk and low calorie sweetener
13200110	~Pudding, NFS
13210220	~Pudding, chocolate, ready-to-eat, NS as to from dry mix or canned
13210250	~Pudding, chocolate, ready-to-eat, low calorie, containing artificial sweetener, NS as to from dry mix or
13210280	~Pudding, flavors other than chocolate, ready-to-eat, NS as to from dry mix or canned
13210290	~Pudding, flavors other than chocolate, ready-to-eat, low calorie, containing artificial sweetener, NS as to from
13210530	~Pudding, tapioca, chocolate, made with milk W/ SKIM MILK~
13210610	~Pudding, coconut W/ 0.02 MILK~
13210710	~Pudding, Indian (milk, molasses and cornmeal-based pudding)
13210750	~Pudding, pumpkin
13220110	~Pudding, flavors other than chocolate, prepared from dry mix, milk added
13220120	~Pudding, chocolate, prepared from dry mix, milk added
13220210	~Pudding, flavors other than chocolate, prepared from dry mix, low calorie, containing artificial sweetener, milk
13220220	~Pudding, chocolate, prepared from dry mix, low calorie, containing artificial sweetener, milk added W/ 0.02
13220230	~Pudding, canned, chocolate, reduced fat
13220235	~Pudding, canned, chocolate, fat free
13220240	~Pudding, canned, flavors other than chocolate, reduced fat
13220245	~Pudding, canned, flavors other than chocolate, fat free
13230110	~Pudding, canned, flavors other than chocolate
13230120	~Pudding, canned, low calorie, containing artificial sweetener, flavors other than chocolate
13230130	~Pudding, canned, chocolate
13230140	~Pudding, canned, low calorie, containing artificial sweetener, chocolate
13230200	~Pudding, canned, chocolate and non-chocolate flavors combined
13230500	~Pudding, canned, tapioca
13230510	~Pudding, canned, tapioca, fat free
13241000	~Pudding, with fruit and vanilla wafers
13310000	~Custard pudding, flavor other than chocolate, baby food, NS as to strained or

NFCS Food Code	Description
	junior
13311000	~Custard pudding, baby food, flavor other than chocolate, strained
13312000	~Custard pudding, baby food, flavor other than chocolate, junior
14108060	~Parmesan cheese topping, fat free
14202010	~Cheese, cottage, with fruit
14220000	~Cottage cheese with fruit, baby food, strained or junior
14410330	~Cheese, processed cheese product, American or Cheddar type, reduced fat
14410340	~Cheese, processed cheese product, American or Cheddar type, reduced fat, reduced sodium
14410450	~Cheese, processed cheese product, Swiss, reduced fat
14420000	~Cheese spread, NFS
14420100	~Cheese spread, American or Cheddar cheese base
14420160	~Cheese spread, Swiss cheese base
14420300	~Cheese spread, pressurized can
14501010	~Imitation cream cheese
14502010	~Imitation cheese, American or cheddar type
14502040	~Imitation cheese, American or cheddar type, low cholesterol
14503010	~Imitation cheese spread
14504010	~Imitation mozzarella cheese
14620100	~Dip, cream cheese base
14620120	~Shrimp dip, cream cheese base
14620150	~Dip, cheese with chili pepper (chili con queso)
14620200	~Dip, cheese base other than cream cheese
14640100	~Cheese sandwich, grilled W/ THIN SLICED BREAD, W/ 2 SLICES AMERICAN OR CHEDDAR IMITATION CHEESE,
14650100	~Cheese sauce
14650160	~Alfredo sauce
14710100	~Cheddar cheese soup
14710110	~Cheddar cheese soup, canned, undiluted
20000070	~Meat, baby food, NS as to type, NS as to strained or junior
21002000	~Beef, pickled

NFCS Food Code	Description
21104110	~Beef steak, battered, fried, NS as to fat eaten
21104120	~Beef steak, battered, fried, lean and fat eaten
21104130	~Beef steak, battered, fried, lean only eaten
21304200	~Beef, shortribs, barbecued, with sauce, NS as to fat eaten
21304210	~Beef, shortribs, barbecued, with sauce, lean and fat eaten
21304220	~Beef, shortribs, barbecued, with sauce, lean only eaten
21416000	~Corned beef, cooked, NS as to fat eaten
21416110	~Corned beef, cooked, lean and fat eaten
21601000	~Beef, bacon, cooked
21601500	~Beef, bacon, formed, lean meat added, cooked
21602000	~Beef, dried, chipped, uncooked
21602100	~Beef jerky
21603000	~Beef, pastrami (beef, smoked, spiced)
21701010	~Beef, baby food, strained
21701020	~Beef, baby food, junior
22003000	~Pork, dehydrated, oriental style
22300120	~Ham, fried, NS as to fat eaten
22300130	~Ham, fried, lean and fat eaten
22300150	~Ham, breaded or floured, fried, NS as to fat eaten
22300160	~Ham, breaded or floured, fried, lean and fat eaten
22311000	~Ham, smoked or cured, cooked, NS as to fat eaten
22311010	~Ham, smoked or cured, cooked, lean and fat eaten
22311200	~Ham, smoked or cured, low sodium, cooked, NS as to fat eaten
22311210	~Ham, smoked or cured, low sodium, cooked, lean and fat eaten
22311220	~Ham, smoked or cured, low sodium, cooked, lean only eaten
22311450	~Ham, prosciutto
22311510	~Ham, smoked or cured, canned, lean and fat eaten
22321110	~Ham, smoked or cured, ground patty
22421000	~Pork roast, smoked or cured, cooked, NS as to fat eaten
22431000	~Pork roll, cured, fried

NFCS Food Code	Description
22501010	~Canadian bacon, cooked
22600100	~Bacon, NS as to type of meat, cooked
22600200	~Pork bacon, NS as to fresh, smoked or cured, cooked
22601000	~Pork bacon, smoked or cured, cooked
22601020	~Pork bacon, smoked or cured, cooked, lean only eaten
22601040	~Bacon or side pork, fresh, cooked
22602010	~Pork bacon, smoked or cured, lower sodium
22605010	~Pork bacon, formed, lean meat added, cooked
22701030	~Pork, spareribs, barbecued, with sauce, NS as to fat eaten
22701040	~Pork, spareribs, barbecued, with sauce, lean and fat eaten
22701050	~Pork, spareribs, barbecued, with sauce, lean only eaten
22707020	~Pork, pig's feet, pickled
22708010	~Pork, pig's hocks, cooked
22810010	~Ham, baby food, strained
23410010	~Lamb, baby food, strained
23420010	~Veal, baby food, strained
24126110	~Chicken, breast, with or without bone, breaded, baked or fried, prepared with skin, skin/coating eaten
24146210	~Chicken, drumstick, with or without bone, breaded, baked or fried, prepared with skin, skin/coating eaten
24156210	~Chicken, thigh, with or without bone, breaded, baked or fried, prepared with skin, skin/coating eaten
24198540	~Chicken, canned, meat only, NS as to light or dark meat
24198570	~Chicken, canned, meat only, light and dark meat
24204000	~Turkey, rolled roast, light or dark meat, cooked
24701010	~Chicken, baby food, strained
24701020	~Chicken, baby food, junior
24703000	~Turkey, baby food, NS as to strained or junior
24703010	~Turkey, baby food, strained
24703020	~Turkey, baby food, junior
25220010	~Cold cut, NFS
25220210	~Blood sausage

NFCS Food Code	Description
25220350	~Bratwurst, cooked
25220360	~Bratwurst, with cheese
25220410	~Bologna, NFS
25220450	~Bologna ring, smoked
25220480	~Bologna, chicken, beef, and pork
25220500	~Bologna, beef and pork, lowfat
25221400	~Sausage (not cold cut), NFS
25221410	~Pork sausage, fresh, bulk, patty or link, cooked
25221420	~Pork sausage, brown and serve, cooked
25221430	~Pork sausage, country style, fresh, cooked
25221610	~Scrapple, cooked
25221860	~Turkey sausage, reduced fat, brown and serve, cooked
25221870	~Turkey and pork sausage, fresh, bulk, patty or link, cooked
25230210	~Ham, sliced, low salt, prepackaged or deli, luncheon meat
25230220	~Ham, sliced, prepackaged or deli, luncheon meat
25230610	~Luncheon loaf (olive, pickle, or pimiento)
25240110	~Chicken salad spread
25240220	~Ham salad spread
25240310	~Roast beef spread
26115130	~Flounder, breaded or battered, baked
27111050	~Spaghetti sauce with beef or meat other than lamb or mutton, homemade-style
27111410	~Chili con carne with beans
27111440	~Chili con carne with beans and cheese
27113100	~Beef stroganoff
27113200	~Creamed chipped or dried beef
27113300	~Swedish meatballs with cream or white sauce (mixture)
27114000	~Beef with (mushroom) soup (mixture)
27115000	~Beef with soy-based sauce (mixture)
27116200	~Beef with barbecue sauce (mixture)
27116300	~Beef with sweet and sour sauce (mixture)

NFCS Food Code	Description
27118110	~Meatballs, Puerto Rican style (Albondigas)
27118130	~Stewed dried beef, Puerto Rican style (Tasajo guisado, carne cecina guisada)
27120020	~Ham or pork with gravy (mixture)
27120030	~Ham or pork with barbecue sauce (mixture)
27120060	~Sweet and sour pork
27120090	~Ham or pork with (mushroom) soup (mixture)
27120100	~Ham or pork with tomato-based sauce (mixture)
27120110	~Sausage with tomato-based sauce (mixture)
27120120	~Sausage gravy
27120150	~Pork or ham with soy-based sauce (mixture)
27120210	~Frankfurter or hot dog, with chili, no bun
27121010	~Stewed pork, Puerto Rican style
27133010	~Stewed goat, Puerto Rican style (Cabrito en fricase, chilindron de chivo)
27142200	~Turkey with gravy (mixture)
27144000	~Chicken or turkey with (mushroom) soup (mixture)
27146000	~Chicken or turkey with barbecue sauce (mixture)
27146100	~Sweet and sour chicken or turkey
27146200	~Chicken or turkey with cheese sauce (mixture)
27146250	~Chicken or turkey cordon bleu
27146350	~Lemon chicken, Chinese style
27150160	~Shrimp with lobster sauce (mixture)
27150190	~Lobster sauce (broth-based)
27150510	~Scallops with cheese sauce (mixture)
27160010	~Meat with barbecue sauce, NS as to type of meat (mixture)
27162010	~Meat with tomato-based sauce (mixture)
27162050	~Spaghetti sauce with combination of meats, homemade-style
27163010	~Meat with gravy, NS as to type of meat (mixture)
27211170	~Beef and potatoes with (mushroom) soup (mixture)
27211400	~Corned beef hash
27212050	~Beef and macaroni with cheese sauce (mixture)

NFCS Food Code	Description
27212350	~Beef stroganoff with noodles
27212400	~Beef and noodles with (mushroom) soup (mixture)
27213150	~Chili con carne with beans and rice
27213400	~Beef and rice with (mushroom) soup (mixture)
27213420	~Porcupine balls with (mushroom) soup (mixture)
27213500	~Beef and rice with soy-based sauce (mixture)
27214500	~Corned beef patty
27218310	~Stewed corned beef, Puerto Rican style ("Corned beef" guisado)
27220010	~Meat loaf made with ham (not luncheon meat)
27220050	~Ham or pork with stuffing (mixture)
27220120	~Sausage and rice with tomato-based sauce (mixture)
27220150	~Sausage and rice with (mushroom) soup (mixture)
27220190	~Sausage and noodles with cream or white sauce (mixture)
27220310	~Ham or pork and rice, no sauce (mixture)
27220510	~Ham or pork and potatoes with gravy (mixture)
27220520	~Ham or pork and potatoes with cheese sauce (mixture)
27242250	~Chicken or turkey and noodles with (mushroom) soup (mixture)
27242310	~Chicken or turkey and noodles with cheese sauce (mixture)
27242350	~Chicken or turkey tetrazzini
27243400	~Chicken or turkey and rice with (mushroom) soup (mixture)
27250270	~Clams Casino
27250520	~Seafood restructured
27250630	~Tuna noodle casserole with (mushroom) soup
27250710	~Tuna and rice with (mushroom) soup (mixture)
27250830	~Fish and rice with (mushroom) soup W/ SARDINES~
27260110	~Hash, NS as to type of meat
27311210	~Corned beef, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), no sauce (mixture)
27311220	~Corned beef, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), no sauce (mixture)
27311610	~Beef, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), (mushroom) soup (mixture)

NFCS Food Code	Description
27311620	~Beef, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), (mushroom) soup (mixture)
27313150	~Beef, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), soy-based sauce (mixture)
27313160	~Beef, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), soy-based sauce (mixture)
27313310	~Beef, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), (mushroom) soup (mixture)
27313320	~Beef, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), (mushroom) soup (mixture)
27315310	~Beef, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), (mushroom) soup (mixture)
27315320	~Beef, rice, and vegetables (excluding carrots, broccoli, and dark-green leafy), (mushroom) soup (mixture)
27315510	~Beef, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), soy-based sauce (mixture)
27315520	~Beef, rice, and vegetables (excluding carrots, broccoli, and dark-green leafy), soy-based sauce (mixture)
27320120	~Sausage, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)
27320130	~Sausage, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy (mixture)
27320140	~Pork, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)
27320150	~Pork, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy (mixture)
27320500	~Sweet and sour pork with rice
27331150	~Veal fricassee, Puerto Rican style (ternera en fricase)
27345210	~Chicken or turkey, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)
27345220	~Chicken or turkey, rice, and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy (mixture)
27345410	~Chicken or turkey, rice, and vegetables (including carrots, broccoli, and dark-green leafy), (mushroom) soup (mixture)
27345420	~Chicken or turkey, rice, and vegetables (excluding carrots, broccoli, and/or dark-green leafy), (mushroom) soup (mixture)
27345440	~Chicken or turkey, rice, and vegetables (including carrots, broccoli, and dark-green

NFCS Food Code	Description
	leafy), cheese sauce (mixture)
27345450	~Chicken or turkey, rice, and vegetables (excluding carrots, broccoli, and dark-green leafy), cheese sauce (mixture)
27350030	~Seafood stew with potatoes and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-base sauce
27350050	~Shrimp chow mein or chop suey with noodles
27350100	~Fish, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), cheese sauce (mixture)
27350310	~Seafood stew with potatoes and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-base sauce
27350410	~Tuna noodle casserole with vegetables and (mushroom) soup
27360120	~Chow mein or chop suey, various types of meat, with noodles
27362000	~Stewed tripe, Puerto Rican style, with potatoes (Mondongo)
27363100	~Jambalaya with meat and rice
27410210	~Beef and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), no sauce (mixture)
27410220	~Beef and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), no sauce (mixture)
27414100	~Beef with vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), (mushroom) soup (mixture)
27414200	~Beef with vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), (mushroom) soup (mixture)
27415100	~Beef and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), soy-based sauce (mixture)
27415200	~Beef and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), soy-based sauce (mixture)
27416150	~Pepper steak
27416250	~Beef salad
27420020	~Ham or pork salad
27420080	~Greens with ham or pork (mixture)
27420160	~Moo Shi Pork
27420170	~Pork and onions with soy-based sauce (mixture)
27420460	~Sausage and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), tomato-based sauce (mixture)
27420500	~Pork and vegetables (including carrots, broccoli, and/or dark-green leafy), soy-

NFCS Food Code	Description
	based sauce (mixture)
27420510	~Pork and vegetables (excluding carrots, broccoli, and dark- green leafy), soy-based sauce (mixture)
27445110	~Chicken or turkey and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), soy-based sauce
27445120	~Chicken or turkey and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), soy-based sauce
27445150	~General Tso chicken
27445220	~Kung pao chicken
27445250	~Almond chicken
27446200	~Chicken or turkey salad
27446400	~Chicken or turkey and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), cheese sauce
27446410	~Chicken or turkey and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), cheese sauce
27450010	~Crab salad
27450020	~Lobster salad
27450030	~Salmon salad
27450040	~Shrimp chow mein or chop suey, no noodles
27450060	~Tuna salad
27450070	~Shrimp salad
27450090	~Tuna salad with cheese
27450100	~Tuna salad with egg
27450130	~Crab salad made with imitation crab
27450410	~Shrimp and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), soy-based sauce (mixture)
27450420	~Shrimp and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), soy-based sauce (mixture)
27450510	~Tuna casserole with vegetables and (mushroom) soup, no noodles
27450600	~Shellfish mixture and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), soy-base sauce
27450740	~Fish and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), soy-based sauce (mixture)
27450750	~Fish and vegetables (excluding carrots, broccoli, and dark-green leafy (no

NFCS Food Code	Description
	potatoes)), soy-based sauce (mixture)
27500100	~Meat sandwich, NFS
27510110	~Beef barbecue or Sloppy Joe, on bun
27510130	~Beef barbecue submarine sandwich, on bun
27510360	~Cheeseburger with mayonnaise or salad dressing, tomato and bacon, on bun
27510390	~Double bacon cheeseburger (2 patties, 1/4 lb meat each), on bun
27510400	~Bacon cheeseburger, 1/4 lb meat, with tomato and/or catsup, on bun
27510430	~Double bacon cheeseburger (2 patties, 1/4 lb meat each), with mayonnaise or salad dressing and
27510440	~Bacon cheeseburger, 1/4 lb meat, with mayonnaise or salad dressing and tomatoes, on bun
27510480	~Cheeseburger (hamburger with cheese sauce), 1/4 lb meat, with grilled onions, on rye bun
27510700	~Meatball and spaghetti sauce submarine sandwich, on roll
27510950	~Reuben sandwich (corned beef sandwich with sauerkraut and cheese), with spread
27513060	~Roast beef sandwich with bacon and cheese sauce
27515080	~Steak sandwich, plain, on biscuit
27516010	~Gyro sandwich (pita bread, beef, lamb, onion, condiments), with tomato and spread
27520120	~Bacon and cheese sandwich, with spread
27520130	~Bacon, chicken, and tomato club sandwich, with lettuce and spread
27520140	~Bacon and egg sandwich
27520150	~Bacon, lettuce, and tomato sandwich with spread
27520160	~Bacon, chicken, and tomato club sandwich, on multigrain roll with lettuce and spread
27520170	~Bacon on biscuit
27520350	~Ham and cheese sandwich, with spread, grilled
27520500	~Pork, barbecue sauce, onions and dill pickles on white roll
27520510	~Pork barbecue or Sloppy Joe, on bun
27520540	~Ham and tomato club sandwich, with lettuce and spread
27540110	~Chicken sandwich, with spread
27540130	~Chicken barbecue sandwich

NFCS Food Code	Description
27540190	~Chicken patty sandwich, with lettuce and spread
27540240	~Chicken fillet, (broiled), sandwich, on whole wheat roll, with lettuce, tomato and spread
27540270	~Chicken fillet, broiled, sandwich, with lettuce, tomato, and non-mayonnaise type spread
27540330	~Turkey sandwich, with gravy
27550000	~Fish sandwich, on bun, with spread
27550100	~Fish sandwich, on bun, with cheese and spread
27550710	~Tuna salad sandwich, with lettuce
27550720	~Tuna salad sandwich
27550750	~Tuna salad submarine sandwich, on roll, with lettuce
27560110	~Bologna sandwich, with spread
27560120	~Bologna and cheese sandwich, with spread
27560300	~Corn dog (frankfurter or hot dog with cornbread coating)
27560360	~Frankfurter or hot dog, with chili, on bun
27560370	~Frankfurter or hot dog with chili and cheese, on bun
27560910	~Submarine, cold cut sandwich, on bun, with lettuce
27563010	~Meat spread or potted meat sandwich
27570310	~Hors d'oeuvres, with spread
27601000	~Beef stew, baby food, toddler
27610730	~Beef with vegetables, baby food, toddler
27640810	~Chicken, noodles, and vegetables, baby food, toddler
27642130	~Turkey, rice, and vegetables, baby food, toddler
27642310	~Turkey vegetable dinner, baby food, strained
28101000	~Frozen dinner, NFS
28110000	~Beef dinner, NFS (frozen meal)
28110220	~Sirloin, chopped, with gravy, mashed potatoes, vegetable (frozen meal)
28110230	~Sirloin, chopped, or swiss steak with gravy, vegetable, potatoes, dessert or muffin (frozen meal)
28110250	~Sirloin tips with gravy, potatoes, vegetable (frozen meal)
28110260	~Sirloin tips, potato, vegetable, fruit (diet frozen meal)
28110290	~Sirloin tips and mushrooms in wine sauce with rotini (diet frozen entree)

NFCS Food Code	Description
28110310	~Salisbury steak with gravy, potatoes, vegetable (frozen meal)
28110390	~Salisbury steak, potatoes, vegetable, dessert (diet frozen meal)
28110500	~Beef, sliced, with gravy, barley and wild rice, vegetables (diet frozen meal)
28110510	~Beef, sliced, with gravy, potatoes, vegetable (frozen meal)
28110540	~Beef, sliced, with vegetable in sauce, au gratin potatoes (frozen meal)
28110600	~Beef with noodles, vegetable (frozen meal)
28110620	~Beef short ribs, boneless, with barbecue sauce, potatoes, vegetable (frozen meal)
28110640	~Meatballs, Swedish, in sauce, with noodles (frozen meal)
28110650	~Meatballs, Swedish, in sauce, with noodles and vegetable medley (frozen meal)
28110660	~Meatballs, Swedish, in gravy, with noodles (diet frozen meal)
28113040	~Beef, oriental style, with vegetable, rice, and fruit dessert (diet frozen meal)
28113140	~Beef with spaetzle or rice, vegetable (frozen meal)
28113150	~Beef steak with rice, vegetable (diet frozen meal)
28120230	~Pork, sliced, with gravy, mashed potatoes, vegetable, dessert (frozen meal)
28130000	~Veal dinner, NFS (frozen meal)
28133340	~Veal parmigiana with vegetable, fettuccine alfredo, dessert (frozen meal)
28133410	~Veal parmigiana with potatoes, vegetable (frozen meal)
28140100	~Chicken dinner, NFS (frozen meal)
28140150	~Chicken divan (frozen meal)
28140730	~Chicken patty, breaded, with tomato sauce and cheese, fettuccine alfredo, vegetable (frozen meal)
28140740	~Chicken patty, or nuggets, boneless, breaded, with pasta and tomato sauce, fruit, dessert (frozen meal)
28140810	~Chicken, fried, with potatoes, vegetable, dessert (frozen meal)
28141010	~Chicken, fried, with potatoes, vegetable, dessert (frozen meal, large meat portion)
28141060	~Chicken patty with vegetable (diet frozen meal)
28141200	~Chicken teriyaki with rice, vegetable (frozen meal)
28141250	~Chicken with rice-vegetable mixture (diet frozen meal)
28141300	~Chicken with rice and vegetable, reduced fat and sodium (diet frozen meal)
28141610	~Chicken and vegetables in cream or white sauce (diet frozen meal)
28141650	~Chicken and vegetables au gratin with rice-vegetable mixture (diet frozen entree)

NFCS Food Code	Description
28142000	~Chicken in cream sauce, with brown and wild rice, vegetable, and fruit dessert (diet frozen
28143010	~Chicken and vegetable entree with rice, Oriental (frozen meal)
28143020	~Chicken and vegetable entree with rice, Oriental (diet frozen meal)
28143030	~Chicken and vegetable entree, oriental (diet frozen meal)
28143040	~Chicken chow mein with rice (diet frozen meal)
28143050	~Chicken chow mein with rice, reduced fat and sodium (diet frozen meal)
28143080	~Chicken with noodles and cheese sauce (diet frozen meal)
28143110	~Chicken cacciatore with noodles (diet frozen meal)
28143150	~Chicken and vegetable entree with noodles (diet frozen meal)
28143170	~Chicken in cream sauce with noodles and vegetable (frozen meal)
28143200	~Chicken in soy-based sauce, rice and vegetables (frozen meal)
28143210	~Chicken in orange sauce with almond rice (diet frozen meal)
28143220	~Chicken in barbecue sauce, with rice, vegetable and dessert, reduced fat and sodium (diet frozen
28145010	~Turkey with dressing, gravy, potato (frozen meal)
28145100	~Turkey with dressing, gravy, vegetable and fruit (diet frozen meal)
28145110	~Turkey with vegetable, stuffing (diet frozen meal)
28145310	~Turkey with gravy, dressing, potatoes, vegetable, dessert (frozen meal)
28145610	~Turkey with gravy, dressing, potatoes, vegetable, dessert (frozen meal, large meat portion)
28145810	~Turkey breast with gravy, long-grain and wild rice, vegetable (frozen meal)
28150110	~Fish and chips (frozen meal)
28150510	~Fish in lemon-butter sauce with starch item, vegetable (frozen meal)
28150620	~Fish, batter-dipped, or fish cake, with vegetable, potatoes, dessert (frozen meal)
28154010	~Shrimp and vegetables in sauce with noodles (diet frozen meal)
28160650	~Stuffed green pepper (frozen meal)
28160710	~Stuffed cabbage, with meat and tomato sauce (diet frozen meal)
28310130	~Beef, broth, bouillon, or consomme, dry, not reconstituted
28310140	~Beef, broth, bouillon, or consomme, low sodium, dry, not reconstituted
28310210	~Chili beef soup
28310220	~Chili beef soup, chunky style

NFCS Food Code	Description
28315100	~Beef vegetable soup with potato, stew type
28315120	~Beef vegetable soup with noodles, stew type, chunky style
28315130	~Beef vegetable soup with rice, stew type, chunky style
28315150	~Meat and hominy soup, Mexican style (Pozole)
28317010	~Beef stroganoff soup, chunky style
28321130	~Bacon soup, cream of, prepared with water
28330110	~Scotch broth (lamb, vegetables, and barley)
28340210	~Chicken rice soup, Puerto Rican style (Sopa de pollo con arroz)
28340220	~Chicken soup with noodles and potatoes, Puerto Rican style
28340550	~Sweet and sour soup
28340590	~Chicken corn soup, home recipe
28340630	~Chicken vegetable soup with rice, stew type, chunky style
28340690	~Chicken vegetable soup with potato and cheese, chunky style
28340750	~Hot and sour soup
28345020	~Chicken or turkey soup, cream of, canned, made with milk, reduced sodium
28345030	~Chicken or turkey soup, cream of, canned, made with water, reduced sodium
28345110	~Chicken or turkey soup, cream of, NS as to prepared with milk or water
28345120	~Chicken or turkey soup, cream of, prepared with milk
28345130	~Chicken or turkey soup, cream of, prepared with water
28345140	~Chicken or turkey soup, cream of, canned, undiluted
28345160	~Chicken and mushroom soup, cream of, prepared with milk
28350050	~Fish chowder
28350210	~Clam chowder, NS as to Manhattan or New England style
28350220	~Clam chowder, Manhattan
28355140	~Clam chowder, New England, canned, reduced sodium, ready-to-serve
28355350	~Salmon soup, cream style
28355410	~Shrimp soup, cream of, NS as to prepared with milk or water
28355430	~Shrimp soup, cream of, prepared with water
28500050	~Gravy, giblet
28500100	~Gravy, mushroom

NFCS Food Code	Description
28500150	~Gravy, redeye
28520000	~Gravy or sauce, Chinese (soy sauce, stock or bouillon, cornstarch)
28520100	~Oyster-flavored sauce
28522000	~Mole poblano (sauce)
31105000	~Egg, whole, fried
32101500	~Egg, Benedict
32102000	~Egg, deviled
32103000	~Egg salad
32105000	~Egg omelet or scrambled egg, fat added in cooking
32105010	~Egg omelet or scrambled egg, with cheese
32105030	~Egg omelet or scrambled egg, with ham or bacon
32105080	~Egg omelet or scrambled egg, with cheese and ham or bacon
32105085	~Egg omelet or scrambled egg, with cheese, ham or bacon, and tomatoes
32105120	~Egg omelet or scrambled egg, with sausage and mushrooms
32105121	~Egg omelet or scrambled egg, with sausage and cheese
32105122	~Egg omelet or scrambled egg, with sausage
32105190	~Egg casserole with bread, cheese, milk and meat
32202010	~Egg, cheese, and ham on English muffin
32202050	~Egg, cheese, and sausage on biscuit
32202070	~Egg, cheese, and bacon on biscuit
32202080	~Egg, cheese, and bacon on English muffin
32202090	~Egg and bacon on biscuit
32203010	~Egg salad sandwich
33201110	~Scrambled egg, made from cholesterol-free frozen mixture with cheese
35001000	~Scrambled eggs, sausage, hash brown potatoes (frozen meal)
35002000	~Scrambled eggs, bacon, home fried potatoes (frozen meal)
41101010	~Beans, dry, cooked, NS as to type, fat added in cooking
41201020	~Baked beans, with tomato sauce
41202020	~Chili beans, barbecue beans, ranch style beans or Mexican- style beans
41203020	~Kidney bean salad

NFCS Food Code	Description
41205100	~Black bean sauce
41208030	~Pork and beans
41210100	~Stewed dry red beans, Puerto Rican style (Habichuelas coloradas guisadas)
41210110	~stewed dry lima beans, puerto rican style
41210150	~Stewed pink beans with viandas, ham, Puerto Rican style W/O FAT~
41221010	~Baked beans, low sodium
41310100	~Stewed pigeon peas, Puerto Rican style (Gandules guisados, Gandur, Gandules)
41310200	~Chickpeas stewed with pig's feet, Puerto Rican style (Garbanzos guisados con patitos de cerdo)
41420250	~Hoisin sauce
41430200	~Meal replacement or supplement, soy- and milk-base, powder, reconstituted with water
41440020	~Ensure with fiber, liquid
41440050	~Ensure plus liquid nutrition
41440100	~Meal replacement or supplement, liquid, soy-based
41601010	~Bean soup, NFS
41601020	~Bean with bacon or pork soup
41601070	~Soybean soup, miso broth
41601100	~Portuguese bean soup
41601110	~Bean and ham soup, chunky style
41601150	~Bean soup with vegetables and rice, canned, reduced sodium, prepared with water or ready-to-serve
41602010	~Chunky pea and ham soup
41602030	~Split pea and ham soup
41602070	~Split pea soup, canned, reduced sodium, prepared with water or ready-to-serve
41602090	~Split pea and ham soup, canned, reduced sodium, prepared with water or ready-to-serve
41810400	~Breakfast link, pattie, or slice, meatless
41810610	~Chicken, meatless, breaded, fried
41811400	~Frankfurter or hot dog, meatless
41811600	~Luncheon slice, meatless-beef, chicken, salami or turkey
41811800	~Meatball, meatless

NFCS Food Code	Description
41811910	~Vegetable burger or patty, meatless, no bun
41812400	~Vegetarian pot pie
41812900	~Vegetarian meat loaf or patties (meat loaf made with meat substitute)
41813000	~Vegetarian bouillon, dry
51115010	~Bread, cornmeal and molasses
51115020	~Bread, cornmeal and molasses, toasted
51121040	~Bread, garlic, toasted
51122300	~Bread, white, special formula, added fiber
51122310	~Bread, white, special formula, added fiber, toasted
51122400	~Bread, white, special formula, high calcium
51155000	~Roll, French or Vienna
51161030	~Roll, sweet, with fruit, frosted, diet
51202000	~Muffin, English, whole wheat, 100%
51202020	~Muffin, English, whole wheat, 100%, toasted
51303010	~Muffin, English, wheat or cracked wheat
51303020	~Muffin, English, wheat or cracked wheat, toasted
51303040	~Muffin, English, whole wheat, other than 1 or NS as to 100%, toasted
51420000	~Roll, rye
51421000	~Roll, pumpernickel
51421100	~Roll, pumpernickel, toasted
51602010	~Bread, multigrain, reduced calorie and/or high fiber
51602020	~Bread, multigrain, reduced calorie and/or high fiber, toasted
52101000	~Biscuit, baking powder or buttermilk type, NS as to made from mix, refrigerated dough, or
52101030	~Biscuit dough, fried
52101150	~Biscuit, baking powder or buttermilk type, made from refrigerated dough, lowfat
52102040	~Biscuit, baking powder or buttermilk type, made from refrigerated dough
52201000	~Cornbread, prepared from mix
52202060	~Cornbread, made from home recipe
52204000	~Cornbread stuffing
52206010	~Cornbread muffin, stick, round

NFCS Food Code	Description
52206020	~Cornbread muffin, stick, round, toasted
52206060	~Cornbread, muffin, stick, round, made from home recipe
52207010	~Corn flour patty or tart, fried W/ SOYBEAN OIL~
52208010	~Corn pone, baked
52209010	~Hush puppy
52213010	~Spoonbread
52301000	~Muffin, NFS
52302010	~Muffin, fruit and/or nuts
52307020	~Muffin, multigrain, with nuts
53102800	~Cake, black forest (chocolate-cherry)
53103000	~Cake, Boston cream pie
53103550	~Cake, butter, without icing
53103600	~Cake, butter, with icing
53104520	~Cheesecake, diet
53104550	~Cheesecake with fruit
53104570	~Cheesecake, diet, with fruit
53105300	~Cake, German chocolate, with icing and filling
53105500	~Cake, chocolate, with icing, diet
53105600	~Cake, chocolate, devil's food, or fudge, pudding-type mix, made by Lite recipe (eggs and water
53108200	~Cake, cupcake, chocolate, with icing or filling
53109200	~Cake, cupcake, not chocolate, with icing or filling
53116280	~Cake, pound, chocolate, fat free, cholesterol free
53116380	~Cake, pound, fat free, cholesterol free
53116490	~Cake, pumpkin, NS as to icing
53116510	~Cake, pumpkin, with icing
53118100	~Cake, sponge, without icing
53118200	~Cake, sponge, with icing
53201000	~Cookie, NS as to type
53203050	~Cookie, fruit, baby
53206100	~Cookie, chocolate chip sandwich

NFCS Food Code	Description
53207050	~Cookie, chocolate, with chocolate filling or coating, fat free
53209000	~Cookie, chocolate, chocolate sandwich or chocolate-coated or striped
53209010	~Cookie, chocolate-covered, sugar wafer, creme- or caramel-filled
53209050	~Cookie, chocolate-covered, chocolate sandwich
53209100	~Cookie, chocolate, sandwich, with extra filling
53209500	~Cookie, chocolate and vanilla sandwich
53210910	~Cookie, graham cracker with marshmallow
53220040	~Cookie, fig bar, fat free
53226500	~Cookie, marshmallow, with rice cereal (no-bake)
53226600	~Cookie, marshmallow and peanut butter, with oat cereal (no-bake)
53233020	~Cookie, oatmeal, with fruit filling
53234250	~Cookie, peanut butter with rice cereal (no-bake)
53235500	~Cookie, with peanut butter filling, chocolate-coated
53238000	~Cookie, sandwich-type, not chocolate or vanilla
53239000	~Cookie, shortbread
53239050	~Cookie, shortbread, with chocolate filling
53241500	~Cookie, butter or sugar cookie
53241600	~Cookie, butter or sugar cookie, with fruit and/or nuts
53242000	~Cookie, sugar wafer
53242250	~Cookie, teething, baby food
53243000	~Cookie, vanilla sandwich
53245000	~Cookie, vanilla waffle creme
53247050	~Cookie, vanilla wafer, reduced fat
53300100	~Pie, NFS
53300170	~Pie, individual size or tart, NFS
53301000	~Pie, apple, two crust
53301070	~Pie, apple, individual size or tart
53301080	~Pie, apple, fried pie
53301500	~Pie, apple, one crust
53301750	~Pie, apple, diet

NFCS Food Code	Description
53302000	~Pie, apricot, two crust
53302080	~Pie, apricot, fried pie
53303000	~Pie, blackberry, two crust
53303500	~Pie, berry, not blackberry, blueberry, boysenberry, huckleberry, raspberry, or strawberry; two crust
53303510	~Pie, berry, not blackberry, blueberry, boysenberry, huckleberry, raspberry, or strawberry; one crust
53303570	~Pie, berry, not blackberry, blueberry, boysenberry, huckleberry, raspberry, or strawberry, individual size or tart
53304000	~Pie, blueberry, two crust
53304050	~Pie, blueberry, one crust
53304070	~Pie, blueberry, individual size or tart
53305000	~Pie, cherry, two crust
53305010	~Pie, cherry, one crust
53305070	~Pie, cherry, individual size or tart
53305080	~Pie, cherry, fried pie
53307000	~Pie, peach, two crust
53307050	~Pie, peach, one crust
53307070	~Pie, peach, individual size or tart
53307080	~Pie, peach, fried pie
53308000	~Pie, pineapple, two crust
53308070	~Pie, pineapple, individual size or tart
53308300	~Pie, plum, two crust
53309000	~Pie, raisin, two crust
53309070	~Pie, raisin, individual size or tart
53310000	~Pie, raspberry, one crust
53310050	~Pie, raspberry, two crust
53311000	~Pie, rhubarb, two crust
53311050	~Pie, rhubarb, one crust
53312000	~Pie, strawberry, one crust
53313000	~Pie, strawberry-rhubarb, two crust
53314000	~Pie, strawberry, individual size or tart

NFCS Food Code	Description
53340500	~Pie, cherry, made with cream cheese and sour cream
53341000	~Pie, banana cream
53341750	~Pie, chess
53343000	~Pie, coconut cream
53343070	~Pie, coconut cream, individual size or tart
53344000	~Pie, custard
53344070	~Pie, custard, individual size or tart
53345000	~Pie, lemon cream
53345070	~Pie, lemon cream, individual size or tart
53346000	~Pie, peanut butter cream
53347000	~Pie, pumpkin
53348000	~Pie, strawberry cream
53365000	~Pie, vanilla cream
53370000	~Pie, chiffon, not chocolate
53381000	~Pie, lemon meringue
53382000	~Pie, chocolate-marshmallow
53385600	~Pie, praline mousse, with nuts
53386000	~Pie, pudding, flavors other than chocolate
53386050	~Pie, pudding, flavors other than chocolate, individual size or tart
53386250	~Pie, pudding, chocolate, with chocolate coating, individual size
53386500	~Pie, pudding, flavors other than chocolate, with chocolate coating, individual size
53410100	~Cobbler, apple
53410300	~Cobbler, berry
53410500	~Cobbler, cherry
53410800	~Cobbler, peach
53410860	~Cobbler, pineapple
53420000	~Cream puff, eclair, custard or cream filled, NS as to icing
53420100	~Cream puff, eclair, custard or cream filled, not iced
53420200	~Cream puff, eclair, custard or cream filled, iced
53430700	~Tamale, sweet

NFCS Food Code	Description
53430750	~Tamale, sweet, with fruit
53450000	~Turnover or dumpling, apple
53450300	~Turnover or dumpling, berry
53450500	~Turnover or dumpling, cherry
53450800	~Turnover or dumpling, lemon
53451000	~Turnover or dumpling, peach
53510100	~Danish pastry, with fruit
53511000	~Danish pastry, with cheese
53520120	~Doughnut, cake type, chocolate
53521210	~Doughnut, custard-filled
53521220	~Doughnut, chocolate cream-filled
53521230	~Doughnut, custard-filled, with icing
53530000	~Breakfast tart
53530010	~Breakfast tart, lowfat
53540000	~Breakfast bar, NFS
53540100	~Breakfast bar, cake-like
53540200	~Breakfast bar, cereal crust with fruit filling, lowfat
53540500	~Breakfast bar, date, with yogurt coating
53541100	~Breakfast bar, diet meal type
53541200	~Meal replacement bar
53544300	~Granola bar, high fiber, coated with non-chocolate yogurt coating
53544450	~PowerBar (fortified high energy bar)
54102090	~Crackers, graham, higher fat
54102200	~Crackers, graham, sandwich-type, with filling
54205100	~Cracker, snack, lowfat, low sodium
54304100	~Cracker, cheese, reduced fat
54304500	~Cracker, high fiber, no added fat
54309000	~Crackers, oat
54319050	~Puffed corn cake
54327950	~Crackers, cylindrical, peanut-butter filled

NFCS Food Code	Description
54406010	~Onion-flavored rings
54408070	~Pretzel, hard, multigrain
54440010	~Bagel chip
55101000	~Pancakes, plain
55101010	~Pancakes, reduced calorie, high fiber
55103000	~Pancakes, with fruit
55105000	~Pancakes, buckwheat
55105100	~Pancakes, cornmeal
55207000	~Waffle, multi-bran
55301050	~French toast sticks, plain
56101030	~Macaroni, cooked, fat added in cooking
56112030	~Noodles, cooked, fat added in cooking
56131000	~Spaghetti, cooked, fat added in cooking
56139990	~Pasta, cooked, corn-based, NS as to fat added in cooking
56140000	~Pasta, cooked, corn-based, fat not added in cooking
56200990	~Grits, cooked, corn or hominy, NS as to regular, quick or instant, NS as to
56201000	~Grits, cooked, corn or hominy, NS as to regular, quick, or instant, fat not added
56201010	~Grits, cooked, corn or hominy, regular, fat not added in cooking
56201020	~Grits, cooked, corn or hominy, regular, fat added in cooking
56201030	~Grits, cooked, corn or hominy, regular, NS as to fat added in cooking
56201040	~Grits, cooked, corn or hominy, NS as to regular, quick, or instant, fat added in
56201060	~Grits, cooked, corn or hominy, with cheese, NS as to regular, quick, or instant, NS
56201061	~Grits, cooked, corn or hominy, with cheese, NS as to regular, quick, or instant, fat
56201070	~Grits, cooked, corn or hominy, with cheese, regular, NS as to fat added in cooking
56201071	~Grits, cooked, corn or hominy, with cheese, regular, fat not added in cooking
56201090	~Grits, cooked, corn or hominy, with cheese, instant, NS as to fat added in cooking
56201091	~Grits, cooked, corn or hominy, with cheese, instant, fat not added in cooking
56201092	~Grits, cooked, corn or hominy, with cheese, instant, fat added in cooking W/ BUTTER, NFS~
56201110	~Grits, cooked, corn or hominy, quick, fat not added in cooking
56201130	~Grits, cooked, corn or hominy, quick, NS as to fat added in cooking

NFCS Food Code	Description
56201210	~Grits, cooked, corn or hominy, instant, fat not added in cooking
56201230	~Grits, cooked, corn or hominy, instant, NS as to fat added in cooking
56201240	~Grits, cooked, flavored, corn or hominy, instant, fat not added in cooking
56201250	~Grits, cooked, flavored, corn or hominy, instant, fat added in cooking
56201260	~Grits, cooked, flavored, corn or hominy, instant, NS as to fat added in cooking
56201300	~Grits, cooked, corn or hominy, NS as to regular, quick, or instant, NS as to
56201510	~Cornmeal mush, made with water
56201520	~Cornmeal mush, fried
56201530	~Cornmeal mush, made with milk
56201540	~Cornmeal, made with evaporated milk and sugar, Puerto Rican Style (Harina de maize con leche)
56201550	~Cornmeal dumpling
56201560	~Cornmeal sticks, boiled
56201600	~Cornmeal, lime-treated, cooked (Masa harina)
56201750	~Cornstarch, dry
56201800	~Cornstarch, hydrolyzed powder
56203050	~Oatmeal, cooked, regular, fat added in cooking
56203100	~Oatmeal, fortified, cooked, instant, fat added in cooking
56205420	~Rice, white, cooked, regular, fat added in cooking
56205430	~Rice, white, cooked, instant, fat added in cooking
56205440	~Rice, white, cooked, converted, fat added in cooking
56207230	~Wheat, cream of, cooked, quick, fat added in cooking
56208000	~Multigrain cereal, cooked, fat not added in cooking
57000100	~Oat cereal, NFS
57125000	~Cinnamon Toast Crunch
57344050	~Spider-Man, Ralston
58101800	~Ground beef with tomato sauce and taco seasonings on a cornbread crust
58103110	~Tamale with meat and/or poultry
58103250	~Tamale, plain, meatless, no sauce, Mexican style
58103310	~Tamale casserole with meat
58105100	~Pupusa, cheese-filled

NFCS Food Code	Description
58105110	~Pupusa, meat-filled
58106510	~Pizza with meat, NS as to type of crust
58106520	~Pizza with meat, thin crust
58106530	~Pizza with meat, thick crust
58106710	~Pizza with meat and vegetables, NS as to type of crust
58106720	~Pizza with meat and vegetables, thin crust
58106730	~Pizza with meat and vegetables, thick crust
58106740	~Pizza with meat and fruit, NS as to type of crust
58106750	~Pizza with meat and fruit, thin crust
58106760	~Pizza with meat and fruit, thick crust
58106780	~Pizza with meat and vegetables, lowfat, thin crust
58106910	~Pizza with seafood, thin crust
58106920	~Pizza with seafood, thick crust
58107000	~Ground beef with tomato sauce on a pizza crust
58108010	~Calzone, with meat and cheese
58109000	~Italian pie, meatless
58109010	~Italian pie with meat
58111200	~Puffs, fried, crab meat and cream cheese filled
58112110	~Dim sum, meat filled (egg roll-type)
58112510	~Dumpling, steamed, filled with meat, poultry, or seafood
58115110	~Tamale casserole, Puerto Rican style (Tamales en cazuela)
58116110	~Meat turnover, Puerto Rican style (Pastelillo de carne; Empanadilla)
58117110	~Cornmeal fritter, Puerto Rican style (Arepa; P.R. arepita)
58120110	~Crepes, filled with meat, fish, or poultry, with sauce W/ ALL TUNA~
58121510	~Dumpling, meat-filled
58125110	~Quiche with meat, poultry or fish
58126150	~Turnover, meat- and cheese-filled, tomato-based sauce
58126270	~Turnover, chicken- or turkey-, and cheese-filled, no gravy
58126280	~Turnover, chicken- or turkey-, and vegetable-filled
58127110	~Vegetables in pastry

NFCS Food Code	Description
58127150	~Vegetables and cheese in pastry
58127200	~Croissant, filled with broccoli and cheese
58127210	~Croissant, filled with ham and cheese
58127220	~Croissant, filled with chicken, broccoli, and cheese sauce
58127350	~Croissant with bacon, egg, and cheese
58128000	~Biscuit with gravy
58128110	~Chicken cornbread
58128120	~Cornmeal dressing with chicken or turkey and vegetables
58128250	~Dressing with meat and vegetables
58130010	~Lasagna with meat and/or poultry
58130013	~Lasagna with meat, canned
58131320	~Ravioli, meat-filled, with tomato sauce or meat sauce
58131323	~Ravioli, meat-filled, with tomato sauce or meat sauce, canned
58131523	~Ravioli, cheese-filled, with tomato sauce, canned
58132110	~Spaghetti with tomato sauce, meatless
58132310	~Spaghetti with tomato sauce and meatballs or spaghetti with meat sauce or spaghetti with meat
58132313	~Pasta with tomato sauce and meat or meatballs, canned
58132360	~Spaghetti with tomato sauce and meatballs, whole wheat noodles or spaghetti with meat sauce, whole
58132450	~Spaghetti with tomato sauce, meatless, made with spinach noodles
58132710	~Spaghetti with tomato sauce and frankfurters or hot dogs
58132910	~Spaghetti with tomato sauce and chicken or turkey
58133120	~Manicotti, cheese-filled, with tomato sauce, meatless
58134610	~Tortellini, meat-filled, with tomato sauce
58134613	~Tortellini, meat-filled, with tomato sauce, canned
58134650	~Tortellini, meat-filled, no sauce
58135110	~Chow fun noodles with meat and vegetables
58136130	~Lo mein with shrimp
58145110	~Macaroni or noodles with cheese
58145114	~Macaroni or noodles with cheese, made from dry mix

NFCS Food Code	Description
58145120	~Macaroni or noodles with cheese and tuna
58145130	~Macaroni or noodles with cheese and beef
58145150	~Macaroni or noodles with cheese and pork or ham
58145160	~Macaroni or noodles with cheese and frankfurters or hot dogs
58145170	~Macaroni and cheese with egg
58146110	~Pasta with meat sauce
58146120	~Pasta with cheese and meat sauce
58146130	~Pasta with carbonara sauce
58146150	~Pasta with cheese and tomato sauce, meatless
58146200	~Pasta, meat-filled, with gravy, canned
58148110	~Macaroni salad
58148120	~Macaroni salad with egg
58148130	~Macaroni salad with tuna
58148140	~Macaroni salad with crab meat
58148150	~Macaroni salad with shrimp
58148160	~Macaroni salad with tuna and egg
58148170	~Macaroni salad with cheese
58148180	~Macaroni salad with cheese
58148500	~Pasta salad (macaroni or noodles, vegetables, dressing)
58148550	~Pasta salad with meat (macaroni or noodles, vegetables, meat, dressing)
58150310	~Rice, fried, with meat and/or poultry
58155110	~Rice with chicken, Puerto Rican style (Arroz con Pollo)
58155410	~Soupy rice with chicken, Puerto Rican style (Asopao de pollo)
58155510	~Soupy rice mixture with chicken and potatoes, Puerto Rican style
58155810	~Stewed rice, Puerto Rican style (arroz quisado)
58156210	~Rice with vienna sausage, Puerto Rican style (arroz con salchichas)
58156310	~Rice with Spanish sausage, Puerto Rican style
58156410	~Rice with onions, Puerto Rican style (arroz con cebollas)
58156610	~Pigeon pea asopao (Asopao de gandules)
58160140	~Rice with beans and pork

NFCS Food Code	Description
58163310	~Flavored rice mixture
58163330	~Flavored rice mixture with cheese
58163350	~Flavored rice, white and wild
58163360	~Flavored rice, brown and wild
58163380	~Flavored rice and pasta mixture
58164210	~Rice dessert or salad with fruit
58301010	~Lasagna with cheese, tomato sauce, vegetable, dessert (frozen meal)
58301020	~Lasagna with cheese and sauce (diet frozen meal)
58301110	~Vegetable lasagna (frozen meal)
58301150	~Zucchini lasagna (diet frozen meal)
58302000	~Macaroni and cheese (diet frozen meal)
58302010	~Macaroni and cheese with apples, vegetable (frozen meal)
58302060	~Spaghetti or noodles with beef in tomato-based sauce, lowfat, reduced sodium (diet frozen meal)
58302080	~Noodles with vegetables in tomato-based sauce (diet frozen meal)
58304010	~Spaghetti and meatballs dinner, NFS (frozen meal)
58304020	~Spaghetti and meatballs with tomato sauce, sliced apples, bread (frozen meal)
58304030	~Spaghetti and meatballs with vegetable, dessert (frozen meal)
58304050	~Spaghetti with meat and mushroom sauce (diet frozen meal)
58304060	~Spaghetti with meat sauce (diet frozen meal)
58304220	~Rigatoni with meat sauce and cheese (diet frozen meal)
58304230	~Ravioli, cheese-filled, with vegetable and fruit (frozen meal)
58304300	~Cannelloni, cheese-filled, with tomato sauce (diet frozen meal)
58304350	~Linguini with clam sauce (diet frozen meal)
58305100	~Macaroni or noodles, spinach, with chicken and cheese sauce (diet frozen meal)
58305200	~Pasta, spinach, with vegetables and cheese sauce (diet frozen meal)
58305250	~Pasta with vegetable and cheese sauce (diet frozen meal)
58306200	~Chicken fajitas (diet frozen meal)
58306500	~Chicken burritos (diet frozen meal)
58310310	~Pancakes and sausage (frozen meal)
58404040	~Chicken rice soup, canned, reduced sodium, prepared with water or ready-to-serve

NFCS Food Code	Description
58404050	~Chicken rice soup, canned, reduced sodium, prepared with milk
58404100	~Rice and potato soup, Puerto Rican style
58407000	~Instant soup, NFS
58407010	~Instant soup, noodle
58408010	~Won ton soup
58450300	~Noodle soup, made with milk
58503050	~Macaroni with beef and tomato sauce, baby food, toddler
58508300	~Macaroni and cheese, baby food, toddler
58508500	~Ravioli, meat-filled, with tomato sauce, baby food, toddler
58509100	~Ravioli, cheese-filled, with tomato sauce, baby food, toddler
63113030	~Cherry pie filling
63203700	~Blueberry pie filling
63401010	~Apple salad with dressing
63402950	~Fruit salad (excluding citrus fruits) with salad dressing or mayonnaise
63402980	~Fruit salad (excluding citrus fruits) with marshmallows
63403010	~Fruit salad (including citrus fruits) with salad dressing or mayonnaise
63403040	~Fruit salad (including citrus fruits) with marshmallows
63403100	~Fruit dessert with cream and/or pudding and nuts
63412010	~Pear salad with dressing
63415100	~Soup, fruit
63420200	~Fruit juice bar, frozen, sweetened with low calorie sweetener, flavors other than orange
67100100	~Fruit, baby food, NFS
67104040	~Applesauce with bananas, baby food, strained
67301010	~Apples and cranberries with tapioca, baby food, strained
67301020	~Apples and cranberries, baby food, junior
67308000	~Bananas with tapioca, baby food, NS as to strained or junior
67308020	~Bananas with tapioca, baby food, junior
67309010	~Bananas and pineapple with tapioca, baby food, strained
67309020	~Bananas and pineapple with tapioca, baby food, junior
67404000	~Fruit dessert, baby food, NS as to strained or junior

NFCS Food Code	Description
67404010	~Fruit dessert with tapioca, baby food, strained
67404020	~Fruit dessert with tapioca, baby food, junior
67404070	~Apple yogurt dessert, baby food, strained
67404110	~Banana apple dessert, baby food, strained
67404300	~Blueberry yogurt dessert, baby food, strained
67404500	~Mixed fruit yogurt dessert, baby food, strained
67404550	~Cherry cobbler, baby food, junior
67405000	~Peach cobbler, baby food, NS as to strained or junior
67405010	~Peach cobbler, baby food, strained
67405020	~Peach cobbler, baby food, junior
67410000	~Cherry vanilla pudding, baby food, strained
67412010	~Dutch apple dessert, baby food, strained
67412020	~Dutch apple dessert, baby food, junior
67413700	~Peach yogurt dessert, baby food, strained
67414000	~Pineapple dessert, baby food, NS as to strained or junior
67414010	~Pineapple dessert, baby food, strained
67414020	~Pineapple dessert, baby food, junior
67415010	~Tutti-fruitti pudding, baby food, strained
67415020	~Tutti-fruitti pudding, baby food, junior
71101120	~White potato, baked, peel eaten, fat added in cooking
71103020	~White potato, boiled, without peel, fat added in cooking
71201090	~White potato chips, fat free, made with Olean
71201210	~White potato, chips, restructured, fat free, made with Olean
71201250	~White potato, chips, restructured, baked
71204000	~Potato puffs, cheese-filled
71301020	~White potato, cooked, with cheese
71305010	~White potato, scalloped
71402040	~White potato, french fries, breaded or battered
71411000	~White potato skins, with adhering flesh, fried, with cheese and bacon
71501020	~White potato, from fresh, mashed, made with milk and fat

NFCS Food Code	Description
71501030	~White potato, from fresh, mashed, made with fat
71501040	~White potato, from dry, mashed, made with milk and fat
71501200	~White potato, from complete dry mix, mashed, made with water
71507030	~White potato, stuffed, baked, peel not eaten, stuffed with chili
71508030	~White potato, stuffed, baked, peel eaten, stuffed with chili
71508050	~White potato, stuffed, baked, peel eaten, stuffed with meat in cream sauce
71508060	~White potato, stuffed, baked, peel eaten, stuffed with bacon and cheese
71508070	~White potato, stuffed, baked, peel not eaten, stuffed with bacon and cheese
71508120	~White potato, stuffed with ham, broccoli and cheese sauce, baked, peel eaten
71601010	~Potato salad with egg
71602010	~Potato salad, German style
71603010	Potato Salad
71801000	~Potato soup, NS as to made with milk or water
71801010	~Potato soup, prepared with milk
71801020	~Potato soup, prepared with water
71801040	~Potato soup, instant, made from dry mix
71805010	~Vichyssoise soup
72125252	~Spinach, cooked, from frozen, with cheese sauce
72125260	~Spinach and cheese casserole
72201221	~Broccoli, cooked, from fresh, fat added in cooking
72201222	~Broccoli, cooked, from frozen, fat added in cooking
72201231	~Broccoli, cooked, from fresh, with cheese sauce
72202020	~Broccoli casserole (broccoli, rice, cheese, and mushroom sauce)
72302100	~Broccoli cheese soup, prepared with milk
73101110	~Carrots, raw, salad
73101210	~Carrots, raw, salad with apples
73102221	~Carrots, cooked, from fresh, fat added in cooking
73406010	~Sweetpotato with fruit
74404010	~Spaghetti sauce
74404030	~Spaghetti sauce with meat, canned, no extra meat added

NFCS Food Code	Description
74404050	~Spaghetti sauce, low sodium
74404060	~Spaghetti sauce, fat free
74406010	~Barbecue sauce
74406050	~Barbecue sauce, low sodium
74410110	~Sofrito, Puerto Rican seasoning
74602050	~Tomato soup, instant type, prepared with water
74603010	~Tomato beef soup, prepared with water
74604010	~Tomato beef noodle soup, prepared with water
74606010	~Tomato vegetable soup, prepared with water
74701000	~Tomato sandwich
75140500	~Broccoli salad with cauliflower, cheese, bacon bits, and dressing
75141000	~Cabbage salad or coleslaw, with dressing
75141100	~Cabbage salad or coleslaw with apples and/or raisins, with dressing
75141200	~Cabbage salad or coleslaw with pineapple, with dressing
75142500	~Cucumber salad with creamy dressing
75144100	~Lettuce, wilted, with bacon dressing
75145000	~Seven-layer salad (lettuce salad made with a combination of onion, celery, green pepper, peas, mayonnaise,
75202021	~Asparagus, cooked, from fresh, fat added in cooking
75205032	~Beans, string, green, cooked, from frozen, fat added in cooking
75211030	~Cabbage, green, cooked, fat added in cooking
75216050	~Corn, NS as to form, NS as to color, cream style
75216053	~Corn, from canned, NS as to color, cream style
75216123	~Corn, yellow, cooked, from canned, fat added in cooking
75216150	~Corn, yellow, NS as to form, cream style
75216153	~Corn, yellow, from canned, cream style
75216190	~Corn, yellow, NS as to form, cream style, fat added in cooking
75216193	~Corn, yellow, from canned, cream style, fat added in cooking
75216250	~Corn, white, ns as to form, cream style
75216253	~Corn, white, from canned, cream style
75217490	~Hominy, cooked, NS as to fat added in cooking

NFCS Food Code	Description
75217500	~Hominy, cooked, fat not added in cooking
75217520	~Hominy, cooked, fat added in cooking
75224031	~Peas, green, cooked, from fresh, fat added in cooking
75224032	~Peas, green, cooked, from frozen, fat added in cooking
75224033	~Peas, green, cooked, from canned, fat added in cooking
75233021	~Squash, summer, cooked, from fresh, fat added in cooking
75311022	~Mixed vegetables (corn, lima beans, peas, green beans, and carrots), cooked, from frozen, fat added
75340120	~Vegetable combinations (broccoli, carrots, corn, cauliflower, etc.), cooked, fat added in cooking
75340160	~Vegetable and pasta combinations with cream or cheese sauce (broccoli, pasta, carrots, corn, zucchini, peppers,
75402023	~Beans, lima, immature, cooked, from canned, with mushroom sauce
75403020	~Beans, string, green, cooked, NS as to form, with mushroom sauce
75403021	~Beans, string, green, cooked, from fresh, with mushroom sauce
75403022	~Beans, string, green, cooked, from frozen, with mushroom sauce
75403023	~Beans, string, green, cooked, from canned, with mushroom sauce
75405010	~Beets with Harvard sauce
75409012	~Cauliflower, from frozen, creamed
75409020	~Cauliflower, batter-dipped, fried
75414020	~Mushrooms, stuffed
75414030	~Mushrooms, batter-dipped, fried
75414500	~Okra, batter-dipped, fried
75415020	~Onion rings, NS as to form, batter-dipped, baked or fried
75415021	~Onion rings, from fresh, batter-dipped, baked or fried
75415022	~Onion rings, NS as to form, batter-dipped, baked or fried
75416500	~Pea salad
75416600	~Pea salad with cheese
75417021	~Peas, cooked, from fresh, with mushroom sauce
75418010	~Squash, summer, yellow or green, breaded or battered, fried
75439500	~Chop suey, meatless
75440100	~Vegetable combination (including carrots, broccoli, and/or dark-green leafy),

NFCS Food Code	Description
	cooked, with soy-based sauce
75440110	~Vegetable combination (excluding carrots, broccoli, and dark-green leafy), cooked, with soy-based sauce
75440170	~Vegetable sticks, breaded (including corn, carrots, and green beans)
75440500	~Vegetable combinations (including carrots, broccoli, and/or dark-green leafy), cooked, with cheese sauce
75440510	~Vegetable combinations (excluding carrots, broccoli, and dark-green leafy), cooked, with cheese sauce
75450600	~Vegetable combination (including carrots, broccoli, and/or dark-green leafy), cooked, with butter sauce
75601000	~Asparagus soup, cream of, NS as to made with milk or water
75601010	~Asparagus soup, cream of, prepared with milk
75603000	~Celery soup, cream of, NS as to made with milk or water
75603010	~Celery soup, cream of, prepared with milk W/ WHOLE MILK~
75603020	~Celery soup, cream of, prepared with water
75603030	~Celery soup, cream of, canned, undiluted
75604020	~Corn soup, cream of, prepared with water
75605010	~Leek soup, cream of, prepared with milk
75607000	~Mushroom soup, NFS
75607010	~Mushroom soup, cream of, prepared with milk
75607020	~Mushroom soup, cream of, prepared with water
75607030	~Mushroom soup, canned, undiluted
75607040	~Mushroom soup, with meat broth, prepared with water
75607050	~Mushroom soup, cream of, prepared with water, low sodium
75607060	~Mushroom soup, cream of, NS as to made with milk or water
75607090	~Mushroom soup, cream of, canned, NS as to made with milk or water, reduced sodium
75607100	~Mushroom soup, cream of, canned, prepared with milk, reduced sodium
75607140	~Mushroom soup, cream of, canned, prepared with water, reduced sodium
75607150	~Mushroom soup, cream of, canned, undiluted, reduced sodium
75608100	~Onion soup, French
75609050	~Pea soup, canned, prepared with water, low sodium
75611010	~Vegetable soup, cream of, prepared with milk

NFCS Food Code	Description
75649030	~Vegetable soup, canned, low sodium, prepared with water or ready-to-serve
75649050	~Vegetable soup, made from dry mix
75649060	~Vegetable soup, dry mix, not reconstituted
75649100	~Vegetable soup, cream of, made from dry mix, low sodium, prepared with water
75651010	~Vegetable bean soup, prepared with water or ready-to-serve
75651090	~Vegetable chicken soup, canned, prepared with water, low sodium
75651150	~Vegetable noodle soup, canned, reduced sodium, prepared with water or ready-to-serve
75656060	~Vegetable beef soup, chunky style
75657000	~Vegetable broth, bouillon
76401030	~Beans, green string, creamed, baby food, junior
76601020	~Vegetable and bacon, baby food, junior
76607020	~Vegetable and ham, baby food, junior
76607030	~Potatoes with cheese and ham, baby food, toddler
77250110	~Stuffed tannier fritters, Puerto Rican style (Alcapurrias)
77316010	~Stuffed cabbage, with meat, Puerto Rican style (Repollo relleno con carne) W/ ALL PORK~
77563010	~Puerto Rican stew (Sancocho)
81103041	~Margarine-like spread, made with yogurt, stick, salted
81104010	~Margarine-like spread, reduced calorie, about 40% fat, tub, salted
81104011	~Margarine-like spread, reduced calorie, about 40% fat, made with yogurt, tub, salted
81104020	~Margarine-like spread, reduced calorie, about 40% fat, stick, salted
81104050	~Margarine-like spread, reduced calorie, about 20% fat, tub, salted
81104070	~Margarine-like spread, reduced calorie, about 20% fat, tub, unsalted
81106010	~Butter replacement, fat-free powder
81201000	~Bacon grease or meat drippings
81302030	~Orange sauce (for duck)
81302040	~Sandwich spread
81302050	~Tartar sauce
81312000	~Tartar sauce, low calorie
83101500	~Bacon dressing (hot)

NFCS Food Code	Description
83101600	~Bacon and tomato dressing
83102000	~Caesar dressing
83103000	~Coleslaw dressing
83105500	~Honey mustard dressing
83107100	~Mayonnaise, made with yogurt
83108000	~Mayonnaise, imitation
83108100	~Mayonnaise, imitation, cholesterol free
83110000	~Mayonnaise-type salad dressing
83110010	~Mayonnaise-type salad dressing, cholesterol-free
83112500	~Creamy dressing, made with sour cream and/or buttermilk and oil
83115000	~Yogurt dressing
83201200	~Blue or roquefort cheese dressing, reduced calorie, fat-free, cholesterol-free
83202010	~French dressing, reduced calorie, fat-free, cholesterol-free
83203250	~Mayonnaise-type salad dressing, fat-free
83204000	~Mayonnaise, low-calorie or diet
83204010	~Mayonnaise, low-calorie or diet, low sodium
83204020	~Mayonnaise, reduced calorie or diet, cholesterol-free
83204050	~Mayonnaise-type salad dressing, low-calorie or diet
83204060	~Mayonnaise-type salad dressing, low-calorie or diet, cholesterol-free.
83210250	~Creamy dressing, made with sour cream and/or buttermilk and oil, reduced calorie, cholesterol-free
91304040	~Topping, marshmallow
91304070	~Topping, peanut butter, thick, fudge type
91304350	~Topping, chocolate flavor, fat free
91361010	~Sweet and sour sauce
91361020	~Fruit sauce
91361040	~Plain dessert sauce
91361050	~Duck sauce
91510100	~Gelatin powder, dietetic, sweetened with low calorie sweetener, dry
91511010	~Gelatin dessert, dietetic, sweetened with low calorie sweetener
91511020	~Gelatin dessert, dietetic, with fruit, sweetened with low calorie sweetener

NFCS Food Code	Description
91511090	~Gelatin dessert, dietetic, with fruit and vegetable(s), sweetened with low calorie sweetener
91511110	~Gelatin dessert, dietetic, with fruit and whipped topping, sweetened with low calorie sweetener
91611100	~Ice pop, sweetened with low calorie sweetener
91703350	~Bar None
91709000	~Gumdrops, chocolate covered
91721000	~Licorice
91723000	~Marshmallow
91723010	~Marshmallow, chocolate covered
91723020	~Marshmallow, candy-coated
91723050	~Marshmallow, coconut-coated
91731010	~M & M's Peanut Chocolate Candies
91731060	~M & M's Peanut Butter Chocolate Candies
91745010	~Gumdrops
91745100	~Skittles
91746010	~Sugar-coated chocolate discs
91746100	~M & M's Plain Chocolate Candies
91746120	~Sixlets
91750000	~Taffy
92121030	~Coffee and cocoa (mocha), made from powdered instant mix, with whitener and low calorie sweetener
92121040	~Coffee, made from powdered instant mix, with whitener and low calorie sweetener
92121050	~Coffee and cocoa (mocha), made from powdered instant mix, with whitener and low calorie sweetener,
92153100	~Coffee, decaffeinated, with cereal
92192040	~Coffee and cocoa (mocha) mix, dry instant powder, with whitener and low calorie sweetener, decaffeinated
92193020	~Coffee, dry instant powder, with whitener and low calorie sweetener
92201010	~Postum
92203000	~Cereal beverage
92203110	~Cereal beverage with beet roots, from powdered instant

NFCS Food Code	Description
92291300	~Postum, dry powder
92301080	~Tea, NS as to type, presweetened with low calorie sweetener
92301180	~Tea, NS as to type, decaffeinated, presweetened with low calorie sweetener
92305090	~Tea, made from powdered instant, presweetened with low calorie sweetener
92305110	~Tea, made from powdered instant, decaffeinated, presweetened with low calorie sweetener
92520910	~Lemonade, low calorie
92531020	~Orange breakfast drink, made from frozen concentrate
92541010	~Fruit-flavored drink, made from sweetened powdered mix (fortified with vitamin C)
92541020	~Lemonade-flavored drink, made from powdered mix, with sugar and vitamin C added
92541040	~Lemonade-flavored drink, made from powdered mix, low calorie, with vitamin C added
92542000	~Fruit-flavored drink, made from powdered mix, mainly sugar, with high vitamin C added
92552050	~Orange breakfast drink, low calorie
92613010	~Atole (corn meal beverage)
92613510	~Corn beverage with chocolate and milk (Champurrado, Atole de Chocolate)
92731000	~Fruit-flavored drink, non-carbonated, made from powdered mix, with sugar
92741000	~Fruit-flavored drink, non-carbonated, made from low calorie powdered mix
92751000	~Root beer, noncarbonated, made from powdered mix, with sugar
92900100	~Tang, dry concentrate
92900110	~Fruit-flavored concentrate, dry powder, with sugar and vitamin C added
92900200	~Fruit-flavored beverage, dry concentrate, low calorie, not reconstituted

Table F-3 List of Cereals Included in the Analyses

NFCS Food Code	Description
57000000	~Cereal, NFS
57100100	~Cereal, ready-to-eat, NFS
57101020	~All-Bran with Extra Fiber
57103000	~Alpha-Bits
57103020	~Alpha-bits with marshmallows
57103400	~Apple Cinnamon Oh's Cereal
57103500	~Apple Cinnamon Squares
57104000	~Apple Jacks
57105000	~Apple Raisin Crisp
57106100	~Basic 4
57106250	~Berry Berry Kix
57106530	~Blueberry Morning, Post
57107000	~Booberry
57111000	~Bran Chex
57117000	~Cap'n Crunch
57119000	~Cap'n Crunch's Crunch Berries
57119500	~Cap'n Crunch's Deep Sea Crunch
57120000	~Cap'n Crunch's Peanut Butter Crunch
57123000	~Cheerios
57124200	~Chocolate flavored frosted puffed corn cereal
57124500	~Cinnamon Grahams, General Mills
57126500	~Cocoa Blasts, Quaker
57128000	~Cocoa Puffs
57130000	~Cookie-Crisp
57131000	~Crunchy Corn Bran, Quaker
57132000	~Corn Chex
57134000	~Corn flakes, NFS
57135000	~Corn flakes, Kellogg
57137000	~Corn Puffs
57138000	~Total Corn Flakes

NFCS Food Code	Description
57139000	~Count Chocula
57144000	~Crisp Crunch
57148000	~Crispix
57205260	~Double Dip Crunch, Kellogg's
57206700	~Fiber One
57211000	~Frankenberry
57212100	~French Toast Crunch, General Mills
57213000	~Froot Loops
57213800	~Frosted Bran, Kellogg's
57213850	~Frosted Cheerios
57215000	~Frosty O's
57221700	~Fruit Rings, NFS
57221800	~Fruit Whirls
57222500	~Fruit Wheats
57223200	~Fruity Yummy Mummy cereal
57224000	~Golden Grahams
57229000	~Granola, lowfat, Kellogg's
57229500	~Granola with Raisins, lowfat, Kellogg's
57232100	~Healthy Choice Almond Crunch with raisins, Kellogg's
57232120	~Healthy Choice Multi-Grain Flakes, Kellogg's
57235650	~Hidden Treasures, General Mills
57237100	~Honey Bunches of Oats
57237300	~Honey Bunches of Oats with Almonds, Post
57238000	~Honeycomb, plain
57239100	~Honey Crunch Corn Flakes, Kellogg's
57240100	~Honey Nut Chex
57244000	~Just Right
57245000	~Just Right with raisins, dates, and nuts
57301100	~Kaboom
57302100	~King Vitamin

NFCS Food Code	Description
57303100	~Kix
57304100	~Life (plain and cinnamon)
57305100	~Lucky Charms
57305150	~Frosted oat cereal with marshmallows
57305170	~Malt-O-Meal Coco-Roos
57305180	~Malt-O-Meal Corn Bursts
57305600	~Malt-O-Meal Marshmallow Mateys
57306700	~Malt-O-Meal Toasted Oat Cereal
57306800	~Malt-O-meal Tootie Fruities
57307150	~Marshmallow Safari, Quaker
57307550	~Mini Buns Cereal (cinnamon)
57308150	~Mueslix cereal, NFS
57308160	~Mueslix with raisins, walnuts, and cranberries
57308170	~Muesli with raisins, peaches, and pecans
57308180	~Mueslix Crispy Blend (formerly Mueslix Five Grain Muesli Cereal)
57308190	~Muesli with raisins, dates, and almonds
57308200	~Mueslix golden crunch cereal
57308210	~Muesli with apples and almonds, Ralston Purina
57308220	~Strawberry muesli with pecans and raisins, Ralston
57308300	~Multi Bran Chex
57308400	~Multi Grain Cheerios
57308410	~Multi-Grain Cheerios Plus
57311800	~Nut and Honey Crunch (flakes)
57316100	~Nutri-Grain Almond Raisin
57316300	~Oat Bran Flakes, Health Valley
57316700	~Oh's, Crunchy Nut
57316710	~Oh's, Honey Graham
57316750	~Oh's, Fruitangy, Quaker
57322500	~Oreo O's cereal, Post
57323000	~Sweet Crunch, Quaker (formerly called Popeye)

NFCS Food Code	Description
57323200	~Pop Tarts Crunch Cereal
57325000	~Product 19
57327450	~Quaker Oat Bran Cereal
57327500	~Quaker Oat Squares
57328000	~Quisp
57334000	~Raisin Life
57335550	~Reese's Peanut Butter Puffs cereal
57339500	~Rice Krispies Treats Cereal (Kellogg's)
57340200	~Ripple Crisp Golden Corn
57340210	~Ripple Crisp Honey Bran, General Mills
57342500	~S'mores Crunch
57344100	~Sprinkle Spangles
57346200	~Sun Crunchers Cereal, General Mills
57347000	~Corn Pops
57348000	~Frosted corn flakes, NFS
57349000	~Frosted Flakes, Kellogg
57349010	~Cocoa Frosted Flakes, Kellogg's
57402000	~Team
57402600	~Temptations, French Vanilla Almond, Kellogg's
57402610	~Temptations, Honey Roasted Pecan, Kellogg's
57403100	~Toasties, Post
57406200	~Triples
57407100	~Trix
57409100	~Waffle Crisp, Post
57418200	~Wheaties Honey Gold
57802000	~High protein cereal, baby food, dry, instant
57803000	~Mixed cereal, baby food, dry, instant
57806000	~Mixed cereal with bananas, baby food, dry, instant
57824500	~Rice cereal with mixed fruit, baby food, jarred
57830100	~Gerber Graduates Finger Snacks Cereal, baby food

NFCS Food Code	Description
91703200	~TWIX Cookie Bars
91703300	~TWIX Peanut Butter Cookie Bars
91705030	~Kit Kat
91718100	~Butterfinger

TABLE F-4

FORMS OF PROCESSED CORN INCLUDED IN ANALYSIS AND PROCESSING FACTORS APPLIED TO EACH INGREDIENT TO CREATE THE DIETARY RESIDUE (.DRS) FILE

FARE Recipes Program version 1.07							
Ingredient Search in recipe set EPARCP98d.IND and EPARCP98d.ING							
CSFII 1994-96, 1998 FCID Recipes		Cry9C level in Whole Grain Starlink Corn: **14275 ppb**					
		"Non-Masa foods"		"Masa Foods"		Cereals[1]	
Search Ingredients		Cry9C level (ppb)[2]	PF[3]	Cry9C level (ppb)[2]	PF[3]	Cry9C level (ppb)	PF
15001200	Corn, field, flour All Foodforms	15363	1.08	127	0.009	0	0.0
15001201	Corn, field, flour-babyfood All Foodforms	15363	1.08	127	0.009	0	0.0
15001210	Corn, field, meal All Foodforms	15075	1.06	127	0.009	0	0.0
15001211	Corn, field, meal-babyfood All Foodforms	15075	1.06	127	0.009	0	0.0
15001220	Corn, field, bran All Foodforms	12950	0.91	12950	0.91	0	0.0
15001230	Corn, field, starch All Foodforms	13.2	0.0009	13.2	0.0009	0	0.0
15001231	Corn, field, starch-babyfood All Foodforms	13.2	0.0009	13.2	0.0009	0	0.0

[1] Cereals were assumed to have zero Cry9C residues. A sensitivity analysis was conducted to assess the impact of assigning cereals a residue equal to the weighted average of all available data (0.036 ppb; See Appendix E, Analysis #4).

[2] Analyzed Cry9C level in processed corn ingredients made from 100% StarLink corn based on results of a processing study conducted by Aventis (MRID 453866-03). In this study, the level of Cry9C in StarLink whole grain was 14,275 ppb.

[3] PF = processing factor; this factor was calculated by taking the ratio of the Cry9C level in the processed corn ingredients to the Cry9C level in whole grain StarLink corn (14,275 ppb).