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Detection of new or modified proteins in novel foods derived from GMO – future needs

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Abstract

The capability of immunoassays to quantitatively detect proteins, be implemented commercially on a wide scale and generate validated data for regulatory compliance in a cost-effective manner is evidenced by the existing immunoassay industry. The use of immunoassays in the food industry is well established. To enable immunoassay testing of foods for the presence of genetically modified organisms (GMO), proprietary proteins must be available for test development. Standard reference materials are required for method development, to translate test results in terms of % GMO, and to ensure uniform test performance throughout the EU. Data are presented demonstrating quantitative detection of Roundup Ready® Soy Bean Certified Reference Material using a commercial ELISA. Strategies for successful implementation of testing are discussed.

Keywords: Food; GMO; Immunoassay

1. Testing for novel foods

In recent years food crops have been engineered to have novel genes in them which impart new characteristics to the plants containing these genes. The engineered plants are referred to as genetically modified organisms (GMO) and foodstuffs derived from such crops have been called novel foods. A number of GMO have been approved for human consumption but concerns over safety persist in the public. Allergenicity and toxicity, which are caused by proteins, are the major concerns. It has been mandated (EC 258/97) that novel foods and ingredients that can be demonstrated to possess characteristics that are different than conventional foods must be labeled as such to allow consumers to make informed decisions regarding the foodstuffs they purchase. An essential element of this process is the availability of reliable and quantitative analytical methods for the detection of novel foods.

Successful testing depends not only on identifying analytical methods that can quantify the novel components of such foods, but on the capability of the testing technology to be implemented on a large scale in a cost-effective manner. It has been demonstrated that novel foods and ingredients may contain new or modified proteins that can be detected by existing, well established methods. Established protein detection methods make up a large, highly organized industry which is dominated by the medical diagnostics market and includes many immunoassay methods.

2. Immunoassays

Immunoassays are highly quantitative, analytical methods which comply with strict regulatory requirements mandated by government agencies such as the US Food and Drug Administration and are exemplified by the clinical diagnostics industry. Annual sales of clinical immunoassay tests are approximately $6 billion dollars. The number of tests sold each year worldwide is approximately 2.5 billion, and the average cost-per-test ranges from approximately $0.75–$5.00 (Theta Reports, 1997). Table 1 lists the different test categories of clinical diagnostic immunoassays. It is important to note that most of the categories listed in Table 1, such as infectious diseases, fertility, proteins, tumor markers, etc., are made up of many different tests for the detection of specific proteins.

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Table 1
Clinical diagnostic immunoassays

Infectious diseases
Cardiac markers
Thyroid
Fertility
Proteins
Therapeutic drugs
Tumor markers
Anemia
Drugs of abuse
Allergy
Autoimmune

In addition to clinical diagnostics, immunoassays are sold commercially as precise analytical methods in a variety of markets representing such diverse applications as testing for atrazine in soil, active ingredients in finished product formulations, and cryptosporidium in drinking water (Table 2). The capacity of immunoassay testing technology to specifically and quantitatively detect proteins from a wide variety of samples, be implemented commercially on a wide scale, and generate validated data for regulatory compliance in a cost-effective manner is evidenced by the existing immunoassay industry.

3. Food immunoassays

Immunoassays for the detection of substances in food are well established. Selected applications include detection of allergens, hormones, toxins, pesticides, microorganisms, antibiotics, species identification, adulteration with other food substances and food quality. An essential component of testing for novel foods is the availability of reliable analytical methods with proven, validated performance. AOAC International publishes *Official Methods of Analysis of AOAC International*, which is recognized as an authoritative source of analytical methods used worldwide. Table 3 lists selected immunoassays which have been rigorously validated and adopted by the AOAC® Official Methods Validation Program. It is important to note that all of the immunoassay methods listed here are for the detection of substances in food. While most of these assays are for detection of microorganisms many of the antibodies are directed against proteins. Of particular interest here are methods for the detection of wheat gluten and soy protein.

A large body of scientific literature has been generated using immunoassays for the detection of pesticides in food and a selected bibliography is given in Table 4. Recently, the US EPA has approved the first immunochemical-based method (to detect the pesticide spinosad), to be used for tolerance enforcement. A number of books have been published regarding the use of immunoassays in foods (Beier & Stanker, 1996; Wyatt, 1992; Morgan, Smith & Williams, 1992; Paraf & Peltre, 1991; Vanderlaan, 1991; Rittenburg, 1990; Morris, Clifford & Jackman, 1988).

4. Proprietary antigens

To develop an immunoassay for a specific protein antigen, relatively pure preparations of that protein are required for immunizing animals and producing antibodies. Most of the novel proteins that have been introduced into transgenic crops are proprietary to the company developing the GMO and thus are not generally available to outside parties. To enable immunoassay testing, companies developing GMO containing novel, proprietary proteins must provide validated testing methods or make antigens and antibodies, or the means to produce them, available to outside parties for test development.

5. Sensitivity of immunoassays for GMO

The sensitivity of immunoassay methods has been the subject of intense scientific research over the last 30 years. It has been established that the sensitivity, i.e., the lower limit of detection, for a number of routine clinical diagnostic protein immunoassays is on the order of

Table 2
Non-clinical diagnostic immunoassay markets

Market	Selected applications
Agricultural	Plant pathogens; agronomic traits; GMO
Environmental	Soil and water testing of priority pollutants and pesticides
Food	Raw agricultural commodities and processed foods
Industrial	Incoming, in-process, and effluent streams; quality assurance; product formulation
Pharmaceutical	Near patient testing for dosing and monitoring
Veterinary	Medical diagnostic applications
Water quality	Microbial pathogens; water treatment chemicals; contaminants

Table 3
Selected rapid immunoassay methods adopted as AOAC® official methods

Method	Title
975.54	*Salmonella* in Foods, Fluorescent Antibody (FA) Screening Method
986.35	*Salmonella* in Foods, Colorimetric Monoclonal Enzyme Immunoassay Screening Method
987.06	Beef and Poultry Adulteration of Meat Products, Species Identification Test
987.11	*Salmonella* in Low-Moisture Foods, Colorimetric Monoclonal Enzyme Immunoassay Screening Method
988.10	Soy Protein in Raw and Heat-processed Meat Products: Enzyme-Linked Immunosorbent Assay
989.06	Aflatoxin B_1 in Cottonseed Products and Mixed Feed: Enzyme-linked Immunosorbent Screening Method
989.13	Motile *Salmonella* in Foods, Immunodiffusion Screening Method
989.14	*Salmonella* in Foods, Colorimetric Polyclonal Enzyme Immunoassay Screening Method
989.15	*Salmonella* in Foods, Fluorogenic Monoclonal Enzyme Immunoassay Screening Method
990.32	Aflatoxin B_1 in Corn and Roasted Peanuts, Enzyme-linked Immunosorbent Screening Assay
990.34	Aflatoxin B_1, B_2, and G_1 in Corn, Cottonseed, Peanuts, and Peanut Butter, Enzyme-Linked Immunosorbent Screening Assay
991.19	Gluten in Foods, Colorimetric Monoclonal Antibody Enzyme Immunoassay Method
991.31	Aflatoxins in Corn, Raw Peanuts, and Peanut Butter, Immunoaffinity Column Method
991.45	Total Aflatoxin Levels in Peanut Butter, Enzyme-linked Immunosorbent Assay Method
992.11	Motile and Non-motile *Salmonella* in Foods, Polyclonal Enzyme Immunoassay Method
993.06	Staphylococcal Enterotoxins in Foods, Polyvalent Enzyme Immunoassay Method
993.08	*Salmonella* in Food, Colorimetric Monoclonal Enzyme Immunoassay Method
993.16	Total Aflatoxins (B_1, B_2, and G_1) in Corn, Enzyme-Linked Immunosorbent Assay Method
994.01	Zearalenone in Corn, Wheat, and Feed, Enzyme-Linked Immunosorbent Method
994.03	*Listeria monocytogenes* in Dairy Products, Seafoods, and Meats; Colorimetric Monoclonal Enzyme-Linked Immunosorbent Assay Method
995.12	*Staphylococcus aureus* Isolated from Foods, Latex Agglutination Test Method
995.22	*Listeria* in Foods, Colorimetric Polyclonal Enzyme Immunoassay Screening Method
996.08	*Salmonella* in Foods, Enzyme-linked Immunofluorescent Assay Screening Method
996.09	*Escherichia coli* 0157:H7 in Selected Foods, Visual Immunoprecipitate Assay
996.10	*Escherichia coli* 0157:H7 in Selected Foods, Assurance® Polyclonal Enzyme Immunoassay
996.14	*Listeria monocytogenes* and Related *Listeria* spp. in Selected Foods, Assurance® Polyclonal Enzyme Immunoassay
997.03	*Listeria monocytogenes* and Related *Listeria* spp. in Selected Foods, Visual Immunoprecipitate Assay

Table 4
Select technical references to immunoassays for detection of pesticides in food

Analyte	Food	Reference
Alachlor	Milk, eggs, and liver	J. Environ. Sci. Health B *29* (3), 395
Aldicarb, Carbofuran	Meat, milk	J. Agric. Food Chem. *41*, 2006
Atrazine	Fresh and canned corn and pineapples, macadamia nuts, whole milk, fruit juice, molasses, corn syrup, sugar, corn meal, corn oil, frozen corn, corn chip, and potatoes	Bull. Environ. Contam. Toxicol. *42*, 899
Atrazine	Corn and corn meal	Bull. Environ. Contam. Toxicol. *51*, 171
Benomyl	Fruit juice	Food Chem. *35*, 51
Benomyl	Blueberries	JAOAC Int. *75*, 323
Benomyl	Fruits and vegetables	JAOAC Int. *77* (5), 1243
Benomyl	Bulk fruit juice concentrate	JAOAC Int. *77* (5), 1237
Cyclodienes	Apple, tomato and lettuce	Bull. Environ.Contam. Toxicol. *49*, 342
Methoprene	Wheat grain and milling fractions	J. Agric. Food Chem. *39*, 1882
Organophosphates	Wheat grain and flour-milling fractions	JAOAC Int. *75*, 519
Paraquat	Milk, beef and potatoes	Bull. Environ. Contam. Toxicol. *39*, 490
Thiabendazole	Potatoes and apples	J. Agric. Food Chem. *41*, 996
Thiabendazole	Fruit juices and concentrates	J. Agric. Food Chem. *43*, 1407

10^{-12}–10^{-13} M (Khalil, 1991). Fig. 1 shows a typical dose response curve generated in our laboratory for a transgenic protein using a standard 'sandwich' ELISA method. From this it can be seen that the ELISA has a lower limit of detection of approximately 10^{-12} M, consistent with other well established protein immunoassays.

Our experience in developing immunoassays for transgenic crops indicates that the concentration of

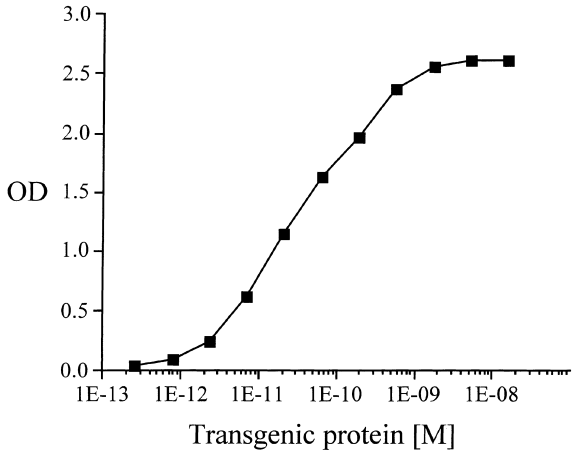

Fig. 1. Typical dose response curve for a purified transgenic protein in a sandwich ELISA. Assuming the protein has a molecular weight of 50 000, a minimum detection limit of 10^{-12} M translates to 50 pg/ml.

novel transgenic protein in the tissue of a commercial GMO is typically >10 μg per gram of tissue. The estimated concentration of a hypothetical transgenic protein (MW 50 000) extracted from a corn seed (approximately 0.3 g) in 1 ml of liquid is 6×10^{-8} M. Assuming a regulatory detection limit of 1% GMO, the concentration of protein that must be detected is 6×10^{-10} M, well within the detection limit of protein immunoassays.

While the above estimation does not account for protein losses or dilution during sample preparation, it suggests that detection of novel transgenic proteins is within the capabilities of existing immunoassay technology. Indeed, immunoassays employing higher sensitivity detection methods, such as chemiluminescence, have been demonstrated to detect protein concentrations on the order of 10^{-14} M (Khalil, 1991). Very low concentrations of GMO can be detected in raw agricultural commodities, such as seeds or grains, simply by testing greater numbers of individual seeds.

6. Precision of immunoassays for GMO

All analytical methods have inherent variability which results in errors of measurement. Measurement errors can be classified as either systematic or random. Systematic errors in measurement result in an assay bias and affect the accuracy of the test. Random errors result in assay values that are scattered about the mean. The degree of randomness inherent in a measurement is referred to as the precision of the assay and is generally represented as the standard deviation (SD) or coefficient of variation (CV). The precision of the assay is important because it determines the capability of the method to differentiate between two closely related concentrations. The greater the precision of the assay the closer two concentrations can be and still be differentiated by the assay. This is especially important at the lower limit of detection or threshold of the assay where increased precision translates into greater method sensitivity (Ekins, 1991).

The performance characteristics of immunoassays are well known and quality standards and validation guidelines have been published for many applications (Mihaliak & Berberich, 1995; Rittenburg & Dautlick, 1995). The accuracy of an immunoassay is generally considered acceptable if the measured concentration is between 80% and 120% of the actual concentration. The c.v. represents the relative amount of variability of a measurement as a percentage of the mean. A typical immunoassay exhibits a c.v. of <5% calculated on the actual response of the method, and a c.v. of <10% based on concentration determined by the assay (Poulsen & Bjerrum, 1991). To put this in perspective, an assay with a 10% c.v. will return a value that is ±20% of the actual concentration 95% of the time. A method to detect GMO with this precision would return a value between 0.8% and 1.2% GMO 95% of the time when the actual concentration is 1% GMO.

In a threshold assay it is important to consider precision because the variability of the method will determine the concentrations above and below the threshold that can be distinguished from the threshold. A method with 50% c.v. can not distinguish 1% GMO from 0.5% GMO and a significant percentage of foods will be labeled incorrectly. The US EPA has defined their willingness to accept incorrect results from immunoassays used for screening purposes in terms of false negative and positive rates. In this case, a sample result is considered falsely positive when the actual sample concentration is $\leqslant 0.5$ times the threshold, and falsely negative when the actual concentration is $\geqslant 2$ times the threshold.

7. Matrix effects

In order to test a particular food fraction it is necessary to extract the protein of interest from the sample to make it available for detection. Some proteins are easy to extract by simply grinding the sample in liquid, while others are extracted only after more rigorous procedures like homogenization and boiling in solvents, detergents, salts, etc. The number of different approaches to extracting a sample can be large and different proteins and food fractions may use different extraction methods to obtain optimal extraction efficiency.

Ultimately, the extracted sample must find its way to the immunoassay for testing, and any component from the extraction process remaining in the sample can affect the result. If the response of the method is affected

by a substance in the sample other than the specific novel protein, either from the sample itself (e.g., a co-extracted material) or a component of the sample preparation process (e.g., detergent), the substance causing the effect is referred to as an 'interferent' and the response is referred to as a 'matrix effect'.

One approach to managing matrix effects in an analytical method is to validate that the total method, including sample preparation, yields results identical to those generated without extracted samples. In this approach it is necessary to validate that there are no matrix effects in all sample types for which the assay is to be used. If the method is to be used with a large variety of different foods this can be a significant effort. To accomplish this task, all of the food fractions that the assay is intended to be used with must be available to the test developer during the course of development of the method.

An alternate approach to managing matrix effects is to incorporate into the test method standard reference materials containing known concentrations of GMO in the same matrix as the test samples. The standards and samples are treated in an identical fashion and in this way any effect of matrix that may be present is consistent between them both.

8. Extraction efficiency

Extraction efficiency refers to the percent of the protein to be detected which is extracted by any given sample preparation method. If less than a known concentration of protein is extracted from a sample it may not be easily determined whether protein was 'lost' due to incomplete extraction or modified by the sample preparation procedure in such a way as to render it undetectable by the method. As in the case of matrix effects, two general approaches to addressing extraction efficiency are possible. One is to determine and validate the extraction efficiency for each type of food fraction and GMO to be tested, and the other is to extract standardized reference materials containing known concentrations of GMO by the same procedure, test them along with the samples, and thus normalize the data with respect to extraction efficiency.

9. Strategies for determining GMO in foods

Two general approaches can be envisioned for determining GMO in food – quantitative and threshold. The quantitative approach seeks to provide methods which have been rigorously developed and validated to have defined sensitivity, specificity, precision, accuracy, matrix effects and extraction efficiencies for each food fraction and novel protein the assay is claimed to detect. Since all of the attributes of the method are rigorously defined, purified protein standards can be used to construct standard curves and the precise concentration of protein in a sample determined from the response in the assay using the standard curve. The concentration of GMO is determined by relating protein concentration to %GMO using standard reference materials.

Quantitative immunoassays include most clinical diagnostic methods and environmental immunoassays used to register new pesticides. Significant effort is required during quantitative test development to validate method performance and generate a data package substantiating the claims of the method. In these applications, regulatory authorities like the US FDA and EPA review the data package versus the performance claims and approve the use of the method for each application.

The threshold approach to determining the concentration of GMO in food involves comparing the response of a test sample with the response of a Certified Reference Material (CRM) containing a known concentration of GMO. In this approach it is not an absolute requirement to rigorously define, validate and approve method performance for each food fraction and novel protein. Instead, a result is deemed to be valid in each individual assay based on the response to the CRMs.

A possible application of the threshold approach for determining GMO in foods is to prepare and test samples in the same way, and in the same assay, as a negative reference (one containing no GMO), and a threshold reference (e.g., 1% GMO). The assay would be deemed to be valid if the mean response of replicate determinations of the threshold reference was statistically greater than the mean response of the zero reference, thus establishing the assay had sufficient sensitivity to detect the threshold concentration. Similarly, the concentration of GMO in the sample would be determined to be less than or greater than the threshold concentration with a certain confidence based on statistical techniques applied to replicate determinations.

In this approach it is important to run replicates in order to determine with confidence that the method can distinguish the threshold from the zero and the sample. If only a single determination were made it would be necessary to determine and validate in advance the method variability with each food and application. The great value of regulating reference materials instead of approving application-specific methods is the time and money it saves developing and approving tests. Testing replicates of both zero and threshold reference materials minimizes method development and approval, simplifies testing and provides validation of performance with every test.

10. Detection of IRMM Roundup Ready Soy Bean Certified Reference Materials by ELISA

In collaboration with Monsanto Company, we have developed a rapid, laboratory-based, commercial ELISA to detect a novel protein from Roundup Ready® (RR) crops in food. The ELISA employs both monoclonal and polyclonal antibodies in a standard sandwich format and uses horseradish peroxidase as a means of generating signal. The response of the method to purified RR protein at the low limit of detection of the method can be seen in Fig. 2.

To determine the sensitivity of the ELISA for GMO in food, CRMs of dried Soy Bean (SB) powder with different mass fractions (0, 0.1, 0.5, 2%) of genetically modified RR SBs were purchased from Fluka Chemie AG, Switzerland, and tested in the ELISA method. A 1% GMO sample was prepared in our laboratory by mixing equal amounts of SB-0 and SB-2.0. The CRMs were produced by the Institute for Reference Materials and Measurements (IRMM) for use in an interlaboratory comparison of the polymerase chain reaction screening method for detection of GMO in food.

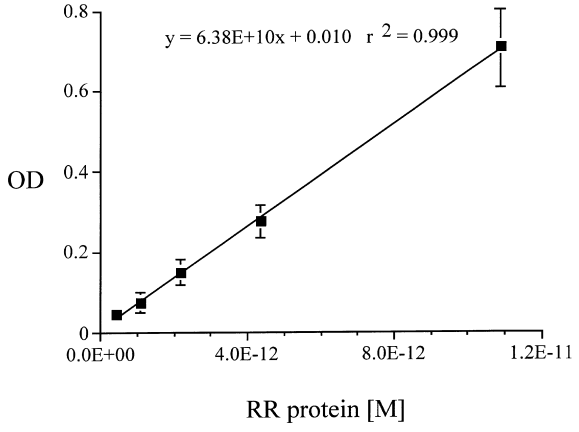

Fig. 2. Detection of the purified, novel protein found in Roundup Ready® (RR) crops by a commercial ELISA. The equation represents the linear regression estimate of the line defined by the data points. The correlation coefficient is given by r^2. Error bars represent ±2 standard deviations (95% confidence) around the means ($n = 3$).

The results of the ELISA evaluation of the IRMM CRMs are presented in Table 5. The response of the ELISA increased with increasing concentrations of GMO. The response to the SB-0.1 CRM was not significantly different from the negative reference (SB-0). SB powder containing GMO concentrations >0.5% resulted in significantly higher ELISA results than SB powder without GMO.

Applying the threshold detection scenario described above, and assuming a hypothetical regulatory threshold of 1% GMO, the SB-0 and SB-0.1 samples would be considered negative, the SB-0.5 sample would be equivocal, and the SB-2.0 sample would be positive (Fig. 3).

11. Implementation of testing

Before test development begins it is critical to identify exactly how testing will be implemented. The key factor to successful implementation is cost-effective testing. Companies handling GMO foods must analyze their processes and identify major commodities, process inputs, critical control points and key process intermediates. By establishing process controls and verifiable chain-of-custody procedures, testing can be limited to a small number of food fractions at critical control points. Labeling of final foodstuffs can be based on testing results of intermediate fractions, the characteristics of the defined process and chain-of-custody. Compliance can be enforced through audits of production documentation.

Once the production processes have been analyzed and food fractions to be tested identified, reference materials can be prepared. The reference materials are the key to implementation and serve many functions. From a technical point of view they serve as the means of relating analyte (e.g., protein or nucleic acid) concentration to % GMO. They are required for method development. They validate method performance in

Table 5
Detection of GMO soy beans in IRMM CRM using a commercial Roundup Ready® ELISA (each sample was extracted and run in the ELISA four separate times. The mean optical density (OD), standard deviation (SD), and coefficient of variation (%CV) were calculated for each sample. Analysis of variance (ANOVA) was used to establish the probability that the differences between the mean OD of SB-0 and SB-X values were due to random error)

Sample	Mean OD	SD	%CV	ANOVA *p*-value
Blank	0.120	0.0074	6.2	N/A
SB-0	0.186	0.0049	2.6	N/A
SB-0.1	0.190	0.0029	1.5	0.210
SB-0.5	0.219	0.0100	4.6	0.001[b]
SB-1[a]	0.236	0.0031	1.3	<0.0001[b]
SB-2	0.336	0.0073	2.2	<0.0001[b]

[a] SB-1 was prepared by mixing equal quantities of SB-0 and SB-2.
[b] Statistically significant detection over SB-0.

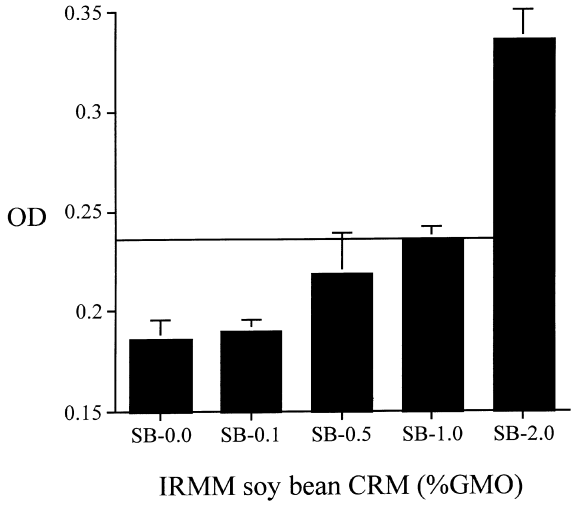

Fig. 3. Quantitation of GMO in soy bean powder. Certified Reference Materials (CRM) of dried soy bean (SB) powder containing different mass fractions (0, 0.1, 0.5, 1.0, 2.0%) of genetically modified Roundup Ready® soy bean were tested in ELISA. The CRMs were produced by the Institute for Reference Materials and Measurements (IRMM) for use in the interlaboratory comparison of the polymerase chain reaction screening method for detection of GMO in food. ELISA optical density (OD) values are shown as means of four replications. Error bars represent ±2 standard deviations (95% confidence) from the mean.

every test and they serve as a means of controlling variability and providing uniform testing throughout the European Community.

Understanding the food production process is also required in order to select specific test formats, testing locations and frequency of testing. Factors such as cost-per-test, turnaround time, user training (experience level), batch size, equipment costs, etc. will ultimately determine the success of implementation.

12. Future needs

It has been shown that novel foods derived from GMO may contain novel proteins which can be detected by established protein detection techniques. Immunoassays comprise a very large, very diverse group of tests which owe their commercial success to the performance characteristics inherent in the technology. Strong antibody binding to protein antigens translates into high sensitivity assays and antibody specificity minimizes sample preparation. The inherent precision of these methods makes them ideal for quantitative applications, and their low cost, ease-of-use, and flexible test format have resulted in wide-scale use in highly diverse markets.

The attributes of immunoassay that have made their application so successful in other markets make them ideal candidates for the detection of novel proteins in foods. The cost-per-test of an immunoassay compared to other analytical methods is low and a number of test formats exist which require little or no training to execute. This is important because if the cost of testing is high in terms of material and labor then the advantages of novel foods are diminished.

Immunoassays can be packaged as disposable kits which yield highly quantitative results in about an hour or they can be incorporated onto fully automated instruments capable of running hundreds of samples an hour. One-step 'strip' tests, such as home pregnancy tests, can be performed by untrained personnel and give yes/no type results in minutes. The time-to-result, or turnaround time, may be one of the most critical attributes of a test method in applications where a large lot of material is awaiting the results of the test before being pooled with other lots or proceeding to the next stage in a process. In these applications, on-site testing is generally the most cost-effective solution.

One of the greatest challenges facing the implementation of wide-scale, systematic testing for GMO in food is the development of standardized reference materials like the IRMM CRMs. Given the great number of different combinations of foods, fractions and GMOs, it will be difficult to develop detection methods that work uniformly across them all. Reference materials will be required as controls within methods and as a means of ensuring consistent testing from laboratory to laboratory. Reference materials are also required to relate the attribute of the test being measured (e.g., protein or nucleic acid concentration), to the characteristic being regulated, i.e., %GMO.

It seems unlikely that reference materials will be developed for every foodstuff that may contain GMO. A more practical solution may be to develop reference materials for major commodities and ingredients and institute testing at specific critical control points. Downstream from a critical control point, the concentration of GMO in the food could be calculated from the process characteristics and verified through documentation of chain-of-custody.

The mandate for labeling foodstuffs derived from GMO is intended to provide consumers with information that they can use to make decisions regarding product selection. Selection of a product by consumers is based on many factors of which GMO content is only one – cost is another. It is interesting to note that the commercial launch in the UK by Zeneca of a tomato paste clearly labeled and advertised as being derived from GMO, is generally viewed as a commercial success as measured by high levels of consumer acceptance and high market shares (Seymour-Cooke, 1997). Pre-launch opinion polls suggested that the vast majority of the UK population would not buy puree from GMO tomatoes. Following product introduction however, the overwhelming majority of consumers found the product to be as good as the standard product or better. The fact that the GMO product was priced about 20% cheaper

than the conventional brand is perhaps significant and should not be overlooked.

In this case, the apparent change in consumer acceptance of the GMO puree before and after product launch may lead one to question the weight consumers lend to GMO content when making product selections and, should be carefully considered when designing testing strategies since the cost of testing will most likely be borne by the consumer – by way of higher food costs and/or increased taxes. Given these considerations, it is likely that successful implementation of testing will ultimately be determined by such factors as cost-per-test, ease-of-use and turnaround time.

The public has stated that they want clear and concise information on the GMO content in food. Food processors need meaningful and unambiguous testing results in order to comply with labeling requirements. GMO and test developers must have incentive to invest in future technology development and testing infrastructure. Regulators must have a means for implementing the public mandate in a consistent manner throughout the Community, which includes compliance monitoring and is in accordance with the EU's international trade obligations. There is no question that existing technology can be used to determine the GMO content in foods. The next steps include analysis of food production processes, identification and creation of CRMs, development of cost-effective methods and implementation of testing.

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