

**Global Traceability and Labeling Requirements**  
**for Agricultural Biotechnology-Derived Products:**  
**Impacts and Implications**  
**for the United States**

A report prepared by the USDA Advisory Committee  
on Biotechnology and 21<sup>st</sup> Century Agriculture

## **Executive Summary**

This report from USDA's Advisory Committee on Biotechnology and 21<sup>st</sup> Century Agriculture (AC21) examines the implications of the current different mandatory biotechnology labeling and traceability requirements in other countries on the United States agricultural food and feed supply chain, and how elements of that supply chain are responding to these requirements.

This report focuses on the impacts and implications of the varying labeling and/or traceability frameworks in place. The wide range of frameworks reflects varying political, cultural and scientific perspectives. This report does not attempt to discuss the merits or values of the frameworks. This report addresses current plant-based products only.

The range of requirements instituted in other countries with respect to labeling and traceability for current plant-based products of modern agricultural biotechnology is broad. Although most countries have sanitary and phytosanitary regulatory requirements, some countries have no regulatory or labeling frameworks specific for products of modern biotechnology, some have evolving frameworks, and some have agricultural biotechnology-specific regulatory frameworks that may or may not require mandatory biotechnology-specific labeling. In the countries that have mandatory biotechnology-specific labeling systems, these requirements range from mandatory labeling for all products to mandatory labeling only for certain products or uses to labeling based on compositional differences.

Additionally, countries may incorporate a variety of rules or protocols under which particular products may be exempted from labeling requirements. At this time, only the European Union has instituted the double requirement for mandatory biotechnology-specific labeling and biotechnology-specific traceability. On the other hand, the United States neither requires that labels of food and feed products derived from genetically engineered plants indicate the method by which the plants were produced nor requires specific tracing of biotechnology products through the food and feed chain.

For regulatory frameworks without mandatory biotechnology-specific labeling requirements, products are sourced and delivered using existing commodity and finished-product markets without any special identification of transgenic products. In countries where there are mandatory biotechnology-specific labeling requirements, food manufacturers generally have chosen to avoid labeling their products based on such requirements. Supply chains that source non-biotech grain and grain products have been evolving to successfully avoid labeling or permit exemption of the products from labeling, depending on the particular requirements and exemptions established. With such supply chains involving specific grain sourcing and special programs to avoid commingling of sourced grain with bulk commodity grain, the fungibility of the product and the flexibility of the production systems are reduced and increased costs are absorbed somewhere along the supply chain. The greater the commercial requirements for documentation and segregation from the commodity chain, the greater the costs associated with originating and manufacturing particular food or feed ingredients. In addition, the greater the potential for pass-

back of various liability claims back up the food and feed chain, the greater the potential impacts on costs and on the sustainability of production and delivery systems.

The EU's requirements for labeling and traceability for biotech grains and grain products, which includes the unique requirement for labeling irrespective of detectability have additional commercial implications for grain and grain product trade with the EU. Under the EU's regulatory framework, suppliers who do not wish to label are required to show through documentation that the grains and grain products are originated through identity preservation (IdP) systems and as such are exempt from labeling and traceability requirements. The documentation requirements and the challenge of supplying products that are exempt from labeling in the EU have significant impacts on the ability of U.S. producers to compete in the EU market.

Two international fora, the Codex Alimentarius and the Cartagena Protocol on Biosafety (the Protocol or BSP), are also involved in the issue of biotechnology labeling and traceability. Codex, which establishes international quality and food safety standards, is currently having discussions on transgenic traceability and labeling. The BSP, which establishes requirements for the movement of "living modified organisms" (LMOs) between countries, is in the process of setting forth documentation requirements for commodity shipments of LMOs for food and feed purposes. The U.S. is not a Party to the Protocol. Requirements relating to documentation of the presence of LMOs in shipments of products in international commerce provide an additional challenge for U.S. exporters.

The following are other issues that are raised by the labeling and traceability requirements and the food and feed chain's efforts to implement them in practice.

- "Adventitious presence" or AP, defined in this case as the unintended presence of a small amount of transgenic material in seed, grain, or feed and food products, poses challenges both in terms of regulatory compliance and consumer/commercial expectations. The issue is complicated by the lack of applicable standards or guidelines and has led to some disruption of trade flows and trade disputes.
- IdP systems are increasingly important tools for preventing commingling of biotech and non-biotech grain and grain products and for documenting the handling and processing steps for particular products. Those systems can capture added value, manage regulated products, and segregate products with limited marketability, but they may also impose new costs and commercial risks.
- Tracing and testing are interrelated tools for origin or process certification, meeting customer traceability needs, safety verification, recalls, and inventory control. For many uses, tracing has evolved independent of transgenic product labeling requirements and different members of the supply chain use different approaches to address their specific needs. Traceability systems are evolving today from both ends of the supply chain to meet different market needs.

- Contracting requirements and any potential liability that might arise from biotechnology-specific labeling requirements vary depending on one's position in the food and feed chain and the type of product or ingredient involved. Contracts are typically used in all transactions along the chain except in consumer purchase of end products. However, contract terms relative to liability transfer with a transaction are not uniform along the chain.
- A variety of test methods have been developed to detect specific biotechnology-derived products, but no single test works for all food products or for all genetic events. There are as yet no internationally accepted standards for testing and the tests themselves can give variable results. Under some labeling systems, commercial risk exists because a grain product grown from compliant seed, delivered as compliant grain to a processing facility, processed to produce a compliant grain product, and incorporated into the finished food may not test "in compliance" under some national compliance testing programs.
- When food manufacturers and ingredient suppliers comply with labeling regulations by sourcing ingredients that are exempt from labeling, contractual specifications with respect to IdP and tolerances can vary depending on the level of the manufacturers' commercial risk aversion. In some cases, the contractual specifications can be far greater than actual regulatory requirements.
- Increasingly stringent product requirements could lead to market segmentation, increased commercial risks, increased testing, and a narrowing of the group of suppliers. Product value becomes less transparent in the marketplace. These trends have different impacts on the commodity system, the food system, and in the political sphere.
- Consumers' interest in seeking additional information about their food is increased by variability in retail requirements in different countries and associated debates regarding safety, environmental concerns, and general acceptability of biotech crops.

The report also highlights, in a separate section, a series of policy concerns and issues raised by these analyses.

## **I. Introduction**

### Charge

This report was prepared by the AC21 in response to a request from the Office of the Secretary of Agriculture to examine the current issue of the proliferation of traceability and mandatory labeling regimes for biotechnology-derived products in other countries, discuss the implications of those regimes, and describe what actions the food and feed supply chain is taking in response to those requirements for products shipped to those countries.

### Process

To draft this report, a work group was formed after the AC21's third plenary session on December 4-5, 2003. The Traceability and Labeling Work Group benefited from participation by *ex officio* members of the AC21 and USDA staff. The Work Group members drew on both their own experience and expertise as well as information provided by outside experts, *ex officio* members of the AC21, and employees of USDA with relevant expertise. The Work Group met via conference call 8 times to discuss the mandate of the committee and draft a report that would address the Secretary's charge.

The working group activities and their written products were reviewed by the whole AC21 at the next 5 plenary meetings held between March, 2004 and February, 2005. The results of those discussions were incorporated into this final document. Thus, this report is submitted to the Secretary on behalf of all the members of the AC21<sup>1</sup> and is the product of the whole committee.

### Scope

This report focuses on the impacts and implications of the various labeling and/or traceability frameworks currently in place globally. The wide range of frameworks reflects varying political, cultural and scientific perspectives. This report does not attempt to discuss the merits or values of the frameworks. This report addresses current plant-based food and feed products only. Grain and grain products, as the most widely traded genetically engineered crops, are used as the prime examples throughout this document. However, the implications of traceability and labeling requirements are the same for non-commodity or specialty food crops.

This report was developed in response to a specific request from then-Agriculture Secretary Ann Veneman for a summary limited to the current state of global traceability and labeling systems and their impacts on U.S. agriculture and food and feed industries. The report is being submitted along with a second report entitled, "Preparing for the Future," which is part of the AC21's continuing effort to address its main charge to examine how biotechnology is likely to affect agriculture and USDA over the course of the next 5 to 10 years.

The remainder of this report is divided into three parts. Section II consists of a description, in generic terms, of the range of systems that exist on a national level for labeling and

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<sup>1</sup> As of February 8, 2005.

traceability in other countries, as well as a description of current (and evolving) requirements under international agreements that impact trade in these agricultural products. That section, in its description of the range of current systems in other countries, also discusses how industry endeavors to meet the requirements for each. Section III delves further into commercial implications and realities around specific themes relevant to meeting traceability and labeling requirements, i.e., adventitious presence (AP), identity preservation (IdP) systems, the scope and range of traceability systems, contracting and liability, commercial risks associated with testing procedures and methodologies, the discrepancy between regulatory and true commercial requirements, and the impacts of market segmentation. Section IV is a discussion of policy concerns and issues that arise from this analysis.

### Terms Used

**Approved products** are products containing or consisting of transgenic events that have passed the necessary regulatory requirements for food and/or feed use in a particular country or region.

**Biotechnology** is a range of tools, including traditional breeding techniques, that: (1) alter living organisms (or part of organisms) to make or modify products; (2) improve plants or animals; or (3) develop microorganisms for specific uses. This report will focus on a subset of products, namely those produced through genetic engineering or recombinant DNA processes, and the derivatives of those products. In this report, the terms “products of modern biotechnology” and “transgenic (or genetically engineered) organisms” (or their products), are used interchangeably to refer to these organisms. The terms, “genetically modified” or “genetic modification” (or “GM”) are avoided except where they are part of a specific label indication.

**Biotechnology-specific labeling** refers to labeling that expressly indicates the means by which the product was produced, i.e., through the use of biotechnology, genetic engineering, or, according to some definitions, “genetic modification.”

**Commercial risk** refers to the financial exposure and/or potential market losses associated with the sale, transport, shipment, or use of the grain and grain products resulting from contracts or other mechanisms.

**Customers** are individuals or groups who purchase, are provided with, or use, products and services.

**Grain and grain products** refers to wheat, corn, soybeans, etc., and products or ingredients derived from them, including finished foods.

**Industry** or the **food and feed supply chain** refers to all of the technology providers, seed breeders and producers, farmers, elevator operators, domestic and international shippers, grain processors, food manufacturers, distributors, wholesalers and retailers, that are involved in bringing food and feed products to the consumer.

**Labeling** refers both to information that appears on products offered to consumers as well as to documentation requirements accompanying shipments of grains, oilseeds, fruits, and vegetables, except where distinctions between the food labeling and shipping documentation are specifically noted.

**Retail consumers** are individuals who personally use or consume a good or service from a retail establishment.

**Traceability** refers to the ability to document a history of the origin, participants, steps and handling involved in the production of a food or feed product.

## **II. National and international requirements with respect to traceability and labeling**

As products of modern biotechnology have entered commerce internationally, over the past decade or so, countries have developed, or begun to develop, safety and identification requirements for new products, and in this process have reviewed the adequacy or applicability of their existing broader regimes for conventional product categories to the new products. Some countries have adapted existing regulatory systems and labeling and identification requirements for new products while other countries have developed a new system(s) for some or all of these products. While these actions have been taken for a variety of reasons, these additional requirements impose additional costs and risks for the food and feed supply chain. Such costs and legal and/or commercial risks derive both from difficulties in reliably meeting biotechnology-specific specifications for ingredients derived from commingled, commodity-derived raw materials and from concerns about the responses of consumers to products with biotechnology-specific labels. The magnitude of the costs and commercial risks depends on the particular requirements in place.

The United States government, which does not require mandatory biotechnology-specific labeling for transgenic products, has argued in numerous international fora, especially the Committee on Food Labeling under the Codex Alimentarius, that there is no scientific justification for the imposition of mandatory labeling requirements based solely on the process by which the product was produced. At the same time, however, USDA has attempted to help markets meet customer demands around biotechnology content through the provision of tools and services relating to product testing and evaluation of testing services, process verification, and technical information for grain and seeds.

This report does not address the merits or implications of particular national regulatory systems or any requirements therein in the evaluation of food or environmental safety for transgenic products.

### **A. Regulatory Framework Categories and Compliance Implications**

A host of agricultural products move between countries through international trade. For products of modern biotechnology there may be regulatory compliance implications related to trade in these products depending on the status of the event approval or the decision of the food manufacturer regarding labeling of the final food product in a specific country. For this discussion, the section will focus on the commercial impacts of the various regulatory frameworks on supplying “approved” transgenic products.

There is a wide range of frameworks for transgenic products depending on both national and international requirements associated with trade with or in a particular country. While, at the most basic level, frameworks can be divided into those requiring biotechnology-specific labeling and/or traceability and those without such requirements, in practice, there are significant distinctions to be drawn among subcategories within these two. The nature of the overall regulatory framework for safety evaluation of agricultural biotechnology products is also relevant. By examining the spectrum of labeling and traceability requirements it is apparent that compliance in these markets is complex and in many cases requires additional processes and procedures and generates increased cost to supply grain and grain products.

The frameworks can be divided as follows:

### **1. Regulatory or labeling frameworks that have no specific provisions for products of modern biotechnology**

Most countries have not considered or adopted regulatory frameworks specific for agricultural biotechnology. Such countries have no biotechnology-specific regulatory restrictions on grain and grain products that are generally sourced and delivered using the established commodity systems for grain. Established phytosanitary procedures for the movement of grain apply for such products as they do for all grain and grain products. Grain and grain products are bought and sold based on national specifications for grain and grain products through buyer and seller contracts and in some cases international mechanisms. Participants in these markets capture the values associated with economies of scale and importers are able to maintain low costs based on flexibility and competition.

### **2. Regulatory frameworks specific for agricultural biotechnology products that do not require mandatory biotechnology-specific labeling**

A number of countries have adopted specific regulatory frameworks for agricultural biotechnology. For several of these countries, after approval, transgenic products are generally considered equivalent to conventional products and as such do not require specific labeling in the marketplace. After approval, there are no restrictions on these grain and grain products, and consequently these products are sourced and delivered using the established commodity systems. Grain and grain products containing approved transgenics are bought and sold based on national or customer specifications through buyer and seller contracts and in some cases international mechanisms. Participants in these markets capture the values associated with economies of scale and importers are able to maintain low costs based on flexibility and competition. In cases where

a food manufacturer may consider there to be a marketing advantage associated with labeling a product as “non-GM” or “not made from transgenic grain,” there may be a specification of identity preservation and/or sourcing from non-biotech grains. In this case, the manufacturer can label the food voluntarily in the above ways to differentiate the product in the marketplace. These additional requirements to serve this market, such as tolerances for AP or IdP requirements or expectations, are contractually negotiated and the added costs are priced according to market forces and availability of the product. (Part III of this report contains further discussions on AP and IdP.) The additional costs to originate and manufacture these products are sometimes passed along directly to the consumers.

### **3. Regulatory frameworks specific for agricultural biotechnology that require mandatory biotechnology-specific labeling.**

Several countries have adopted specific regulatory frameworks related to agricultural biotechnology that involve mandatory labeling for foods containing ingredients derived from transgenic products. These requirements are most often independent of the product risk assessment and often based on a “right to know” policy. The details of when such labeling is required and when products can be exempted from requirements are usually decided nationally. There are several compliance scenarios for grain/grain products based on national legislation and how national and local regulatory officials interpret that legislation. While there are multiple permutations, there are a number of different overall scopes for regulatory frameworks for labeling in the marketplace.

#### **a. Mandatory Biotechnology-Specific Labeling Frameworks: Scope**

##### *(1) Mandatory Biotechnology-Specific Labeling of all Products.*

In some countries, all grains and grain products that fall within the scope of a national definition of a transgenic or “genetically modified” organism are subject to mandatory transgenic product labeling regulation. In this case, if the grain or grain product is originated from a country that has commercialized a transgenic variety, then all products must be labeled unless they qualify for an exemption.

This framework places a significant number of grain and grain products within the scope of the regulation and can have significant impacts on the supply chain for grain and grain products. In general, food manufacturers have chosen to avoid labeling their products and, accordingly, in countries with mandatory labeling of all products, the development of supply chains to avoid or permit exemption of the products from labeling has been proceeding.

These supply chains usually require two basic specifications, IdP and a tolerance for AP. The requirements to source grain or grain products from non-biotech grain sources and to adopt specialty programs and systems to avoid commingling with commodity grains reduce fungibility and flexibility and increase cost. The greater the requirements for documentation and segregation from the commodity stream, the greater the costs associated with originating and manufacturing these ingredients. Most requirements for IdP allow for

a low level of accidental commingling. National requirements regarding the allowed level for AP often differ because the acceptable level of commingling is not dictated by scientific risk assessment. In many regulatory schemes, the allowed AP level may in effect be based on the level of testing detectability or on perception. In general, the lower the level of AP required, the greater the associated costs.

(2) *Biotechnology-Specific Labeling for Specific Products and Uses.*

In some cases, only specific grain and/or grain products fall within the scope of labeling. In general, a country's regulatory authority will publish a listing of specific grain and/or grain products that are "within the scope of the mandatory labeling regulation." Depending on the types of products listed, there may be significant impacts on how food manufacturers source these ingredients.

Specific product listing can be applied not only to ingredients, but also to specific end-use products. For example, based on the current Chinese regulatory framework, soybean oil derived from transgenic soybeans, bottled and used as a salad dressing, must be labeled as "soybean oil-genetically modified." However, soybean oil used as an ingredient in a food product does not have to be labeled in the final food.

In general, food manufacturers to date have chosen to focus on producing only products for which a biotechnology-specific label is not required, because of the concern that consumers could interpret a "biotech label" as a warning and this could threaten hard-won trust in their established brands. Therefore, in countries with biotechnology-specific product and use requirements, products are typically produced using specialty supply chains that enable manufacturers to avoid such labeling. However, food manufacturers and other elements in the food chain have also expressed practical concern about the whole approach due to the difficulty in reliably sourcing ingredients that would not trigger labeling requirements.

(3) *Labeling Requirements Triggered when Modifications Result in Compositional Novelty*

In this case, transgenic-derived products in which the composition or functional properties of the grain or grain product have been modified such that they are no longer substantially equivalent to their conventional counterpart require the mandatory labeling of the compositional change. In some countries, like Japan, compositional novelty also triggers mandatory biotechnology-specific labeling.

In practice, there are presently very few products that trigger this labeling requirement. There are no international standards that allow the regulator to determine if the product is outside of the range of substantial equivalence, although there are a number of initiatives to define this at an international level. In the case where the new product mimics a conventionally bred product, it may or may not be exempt from labeling depending on the country.

As more products come to market with modified functional/compositional characteristics, this labeling requirement may become commercially significant. It would not be unrealistic to anticipate that food manufacturers will look to avoid labeling of food ingredients that would fall within the scope of this mandatory labeling requirement. It is worth noting, however, that products may evolve with consumer benefits resulting from such novelty, and in such instances, manufacturers wish to inform consumers, in order to enable consumer-based demand.

#### (4) Evolving Regulatory Frameworks

In this case, the importing country is in the process of implementing a regulatory framework and the requirements for compliance are in transition and can be unclear. In some instances, regulatory requirements may be suspended during a transitional period; in others, regulations may be enforced immediately.

Between the initial enactment of labeling requirements and the time the biotech events in the “queue” have been authorized, there is generally a period of time where either no events are approved for import, or only some events are approved for import. Availability or lack of transitional measures can have significant commercial implications for food company compliance.

In some cases, the implementation and enforcement of these new regulations are variable and expanding in scope. These markets require a high degree of diligence and attention during this period. The availability of a transparent and predictable regulatory framework can enable international trade to continue without significant disruptions.

#### **b. Mandatory Biotechnology-Specific Labeling Requirements: Exemptions**

When a grain or grain product is within the scope of mandatory labeling requirements, most food manufacturers try to originate grain or grain products that do not require a biotechnology-specific label. The conditions under which products or ingredients are exempt from labeling requirements are determined nationally and supply chain requirements are diverse. These conditions can significantly impact the capability to supply and the costs associated with these ingredients.

##### *(1) Exemption from Labeling Requirements Based on Following Identity Preservation Protocols and Meeting Specific Tolerances*

This is the most common exemption from mandatory labeling. This exemption allows food manufacturers to originate grain and grain products from non-biotech grain through specialty programs in order to avoid process-specific labeling. It requires both the development of supply chains that are parallel to the commodity system and strict separation of these specialty grains from the commodity system.

In this case, the ingredient is exempt from labeling if it was originated from non-biotech grain and steps have been taken to avoid commingling with commodity grain products. The level of detail required in supply chain documentation is often dictated by national regulation and may be specific to country or product use. Guidance documents are sometimes available. In general, it is accepted that, in practice, IdP of non-biotech grain cannot completely exclude transgenic-derived grain. Consequently, some governments have assigned a tolerance level for the AP of biotech grains in a shipment of grain that is exempt from labeling. Tolerances set for AP are often country-specific and may be based on a variety of factors, including detectability, test method performance, marketplace, consumer, and political considerations.

The greater the requirements for documentation and segregation from the commodity chain, the greater the costs associated with originating and manufacturing these ingredients. Costs are also related to the degree and nature of regulatory requirements and enforcement. In general, the lower the level of AP allowed, the greater the associated costs. Commercially, the cost and the degree of difficulty to service these markets depends on the ability to source non-biotech grain, the ability to access systems to supply this grain to specific markets, the relative penetration of the biotech crop in a region, and the locations where transgenic grain types have been planted. In addition, the potential for the extension of liability related to either human, animal or plant health or environmental impact can affect the cost structure as well as the sustainability of production and delivery systems.

#### *(2) Exemption from Requirements based on Status of Ingredient*

Under these regulatory frameworks, only the major ingredients are subject to mandatory labeling and minor ingredients are exempt from labeling if they represent less than a certain proportion of the final food. For example, an ingredient might be exempt from labeling if it is not one of the top three major ingredients.

Whether or not the grain or grain products are major ingredients in the final food can therefore be significant for the food ingredient supplier. For major ingredients, the vast majority of food manufacturers are avoiding labeling through IdP and compliance with tolerance requirements. For minor ingredients, food manufacturers can source ingredients from commodity sources.

#### *(3) Exemption from Requirements based on Detectability*

This is a very common exemption in countries with mandatory labeling. Under this regulatory framework, a grain product derived from a product of modern biotechnology is exempt from labeling if it no longer contains detectable protein or DNA based on available detection methods.

Several food ingredients are derived from refining processes that remove the DNA and protein during processing. Such products can be produced from commodity grains and used in foods without labeling the final product as derived from modern biotechnology.

This exemption has significant commercial impacts as it exempts highly refined products from such labeling.

The only countries currently without this exemption are the members of the European Union (EU), Brazil, and China.

#### **4. Regulatory frameworks that require mandatory biotechnology-specific labeling and traceability.**

The requirement for mandatory biotechnology-specific labeling and traceability is unique to the European Union. “Traceability” in this instance refers to the ability to trace the transgenic events in the grain used to manufacture the food ingredient. All grain and grain products that are derived from commodity grains for which a transgenic variety has been commercialized in the producing country would be subject to EU labeling and traceability requirements, based on the fact that a grain or grain product was not intentionally sourced from an IdP system and therefore likely contains transgenic material. As such, the term “traceability” is specific to products that are within the scope of mandatory labeling requirements and would need to be labeled in the marketplace. The term “traceability” here does not apply to products exempt from labeling, as such products derived from conventional material do not have transgenic events to trace through the supply chain. In the absence of precise guidance from EU regulatory authorities, several different interpretations of this requirement are emerging in the marketplace.

The EU’s requirements for labeling and traceability for biotech grains and grain products, which includes the unique requirement for labeling irrespective of detectability have additional commercial implications for grain and grain product trade with the EU. Under the EU’s regulatory framework, suppliers who do not wish to label are required to show through documentation that the grains and grain products are originated through IdP systems and as such are exempt from labeling and traceability requirements. The documentation requirements and the challenge of supplying these niche products will have significant impacts on cost and ability to participate in this market. Based on the current infrastructure, originating these materials in large volumes may be difficult and expensive. In addition, compliance and enforcement mechanisms in the EU and its Member States for these new requirements are as yet uncertain.

### **B. International Requirements**

The issues of labeling and traceability have been introduced to some extent at the international level in two forums: Codex Alimentarius and the Cartagena Protocol on Biosafety. In addition, agreements under the World Trade Organization framework and the International Plant Protection Convention bear on the application of traceability and labeling regulations.

#### *1. Codex Alimentarius Commission*

Under the auspices of the United Nations Food and Agriculture Organization (FAO) and the World Health Organization (WHO), the Codex Alimentarius Commission was established to develop internationally acceptable standards for use in the area of food quality and food safety. The Codex Alimentarius is significant in international food trade in that both the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement) and the WTO Agreement on Technical Barriers to Trade (the TBT Agreement) encourage the international harmonization of food standards. In addition, the SPS Agreement specifically cites Codex standards, guidelines and recommendations as the preferred international measures for facilitating international trade in food.

The Codex Commission has established subsidiary bodies to develop standards, guidelines, and recommendations. These subsidiary bodies (committees, ad hoc groups, etc) have participation from Member governments. In addition, international intergovernmental organizations, as well as representatives from international nongovernmental groups, attend as "observers". To initiate the development of a standard, proposals are brought forward by a national government or a subsidiary committee of the Commission. Once it is adopted as a draft standard, the proposal undergoes a stepwise process to achieve approval by national governments. It can take several years before the process is completed.

The issue of "traceability" has been introduced in several Commission subsidiary bodies (Committee on General Principles, Committee on Food Import and Export Inspection and Certification Systems, Committee on Food Labeling) with no major resolutions to date. One of the major issues is whether traceability requirements for food are appropriate specifically for the subset of food products that have been derived from modern biotechnology. The countries of the EU, having national legislation requiring traceability of 'GMOs', support broad definitions in Codex in order to advance their national requirements internationally. The U.S. maintains that those definitions are too broad and not based on existing Codex principles related to safety or quality of products. The subsidiary body established to deal specifically with biotechnology issues (Ad Hoc Intergovernmental Task Force on Food Derived from Biotechnology) has identified several specific potential applications for product tracing generally and recognized that product tracing can be applied outside of biotechnology applications. The Task Force has noted that these applications should be consistent with the provisions of the SPS and TBT Agreements and that application of tracing under these agreements is under consideration within Codex under its Executive Committee.

The issue of labeling of products derived from biotechnology has been introduced in Codex and discussions have dealt with labeling of products derived through biotechnology for food and food ingredients, feed and feed ingredients, and, most recently, prepackaged foods. Discussions on labeling have centered on consumer "right-to-know" rationales for labeling versus the desire to label only for safety related issues, and have reached no conclusions.

Discussions under Codex on these matters continue to evolve. If biotechnology-specific labeling does further develop in the Codex forum, issues such as development of thresholds, detection methods, lists for inclusions and exclusions, labeling language, and supporting documentation requirements, etc. will likely come under discussion. Given the number and complexity of these

issues, it may be difficult to come to an international agreement that can be effectively used in international food trade.

## 2. *Cartagena Protocol on Biosafety*

The Cartagena Protocol on Biosafety (the Protocol, or BSP), developed under the auspices of the Convention on Biological Diversity, was adopted in January 2000 and went into force in late 2003. A main focus of the Protocol is the establishment of an advance informed agreement (AIA) procedure to ensure countries are provided necessary information to make informed decisions before importation of a "living modified organism" (LMO) for intentional release. AIA is not required for LMOs intended for food, feed, or for processing. The U.S. is not a Party to the Convention and thus cannot be a Party to the Protocol. The Protocol also allows for Parties and non-Parties to enter into bilateral and multilateral agreements to implement requirements of the Protocol, consistent with the Protocol's objectives.

The Protocol defines requirements for documentation accompanying "transboundary" shipments of LMOs. The requirements are differentiated on the basis of use (destined for: contained use; release into the environment; or direct use as food or feed, or for processing) of the material. These documentation requirements are not labeling requirements for finished food products. The most controversial requirements are those for (typically commingled) commodity shipments that may contain one or many types of LMOs in a single shipment. The text of the Protocol allows the exporter to document that such commodity shipments "may contain" LMOs and are not intended for intentional introduction into the environment. However, the final language accompanying commodity shipments containing LMOs is still under discussion and must be completed by September 10, 2005. Major commodity exporting countries are in favor of retaining the "may contain" language as acceptable documentation, taking into account the practicalities of trade, while other countries desire more specific information (such as, most problematically for trade, identification of the specific LMOs in the cargo). Other specific aspects relating to documentation are also still under discussion.

The documentation requirements that will be established under the Protocol for shipments of LMOs from a country (Party or non-Party) to a Party, will play a major role in dictating how easy or difficult it will be for exporters to comply with Protocol requirements, depending on how much information will be required on documents accompanying shipments. The U.S., Mexico, and Canada recently developed an arrangement to address documentation needs for commodity shipments that was intended to be consistent with the objectives of the Protocol. This arrangement allows for the continued use of the "may contain" language for affected commodity shipments in trade. It also establishes that a shipment that has 95 percent non-LMO content does not require the 'may contain' language, provided that this does not conflict with the regulations of the importing country. Of particular importance to commodity trade is the stipulation that, under the arrangement, adventitious presence should not be considered to be a trigger for the LMO documentation requirements. The extent to which the arrangement could serve as a model to facilitate trade between Parties and non-Parties will likely be influenced by the success of its implementation in North America and the strength of commodity exporting countries in the continuing negotiations around implementation of the Protocol.

### 3. *International Plant Protection Convention (IPPC)*

The IPPC affirms that contracting Parties have sovereign authority to regulate, in accordance with applicable international agreements, the entry of plants, plant products, and other regulated articles, and may, among other things, prescribe and adopt phytosanitary measures concerning their importation, provided such measures are technically justified, transparent and not applied in a way that constitutes either a means of arbitrary or unjustified discrimination or a disguised trade barrier. To the extent that any traceability or labeling requirement is part of a phytosanitary measure (e.g., for surveillance or pest reporting) the provisions of the IPPC may be relevant. The WTO recognizes the IPPC as the standard-setting body for phytosanitary measures.

### 4. *World Trade Organization (WTO)*

The WTO is not prescriptive with regard to labeling/tracing requirements. The Technical Barriers to Trade (TBT) Agreement of the WTO requires that countries' technical regulations may not be more trade-restrictive than necessary to fulfill a legitimate objective. For many countries, consumers' "right to know" is considered to be a legitimate objective; thus, the TBT does allow for mandatory labeling and appropriate enforcement mechanisms, which could include some types of product tracing. However, the ability of all the various labeling and traceability regimes to meet the "no more trade-restrictive than necessary" requirement is not clear.

## **III. Commercial impacts/realities**

There are several specific parameters that affect the U.S. industry's ability, in practical terms, to meet marketplace or regulatory requirements for process-specific labeling and/or traceability. This section describes some of the issues involved, some of the tools evolving to meet market demands (and the limitations of those tools), and some of the overall impacts of the changes that are being seen. The topics are not provided in any specific order.

### **A. Adventitious Presence**

The term "adventitious presence" or AP refers to low levels of unintended material in seed, grain, or feed and food products. The key components of the definition are "low levels" and "unintended."

AP of materials in the food and feed supply chain has always existed, based on the fact that different materials often share either infrastructure, space, or both. It also occurs due to the biology of plants, which allow different varieties to sexually reproduce with one another. While AP can be minimized, as a practical matter it cannot be eliminated entirely and is not unique to crops enhanced through biotechnology. To deal with AP of different products, allowances for the unwanted material have been recognized in laws, regulations and standards that establish allowances for these materials. In the United States, under the

Federal Seed Act, for example, 5 percent of seed corn is allowed to be off-types and still be labeled as a specific corn seed hybrid. Allowances for AP also exist in grain and foods. With respect to grain, USDA has set grade standards for foreign material.<sup>2</sup>

Some amount of AP is to a large extent unavoidable in grain and grain products based on the realities of plant biology, seed production, and the distribution of commodity crops. There are a number of factors that contribute to commingling of grains. Pollen flow, volunteerism, mixing during harvesting, transport, storage and processing, human error, and accidents can all play a role in AP. In practice, material intentionally introduced into seed, grain or feed and food products does not meet the definition of AP.

AP for biotech, then, refers to unintended, low levels of transgenic material (or specific transgenic events) in seed, grain or feed and food products. AP can occur in four different ways creating different regulatory or commercial implications.

1. *Events that have met regulatory requirements in the U.S. and the importing country*

The AP of approved events is an issue for trade outside the United States as it impacts when a product may need to be labeled as containing transgenic material or is unwanted. In this case, there are no food or environment safety concerns and no legal or regulatory problems exist with the presence of these products. For food manufacturers who wish to avoid labeling (through tolerance exemption) or choose to exclude it for marketing reasons and for consumers who wish to avoid foods containing biotechnology-derived ingredients, AP of the biotech event can raise commercial and marketing issues.

For markets where companies wish to avoid labeling of products (exemption from mandatory labeling), the requirement to source products below a specific tolerance is likely to increase the costs and exposure to liability and risks associated with compliance and non-conformance. In addition, there are no international standards for allowable trace amounts of biotech products in non-biotech products and this has created a very complex marketplace. Commercial requirements can add another layer of complexity. For example, some commercial market requirements for AP at times exceed the requirements of government regulations.

In some cases, companies wish to exclude biotech materials for marketing reasons and may or may not decide to claim it on the package (voluntary labeling). In the case where complete avoidance is required, AP becomes a difficult issue to manage. A primary driver of this commercial practice is consumer expectation with respect to AP in the product. It is expected that some customers want zero tolerance for

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<sup>2</sup> Foreign material is extraneous material other than the predominant grain. The actual technical definition for foreign material varies from grain to grain. Grain standards for individual grains set by USDA's Federal Grain Inspection Service may be viewed at <http://www.usda.gov/gipsa/reference-library/standards/standards.htm>.

AP. In practice, food manufacturers require some tolerance for AP and as such struggle with what constitutes an “acceptable zero”. This has yet to be defined. Moreover, it is not clear who will ultimately define “acceptable zero” on a commercial basis.

*2. Events that have met regulatory requirements in the U.S. but not elsewhere*

Adventitious presence can involve material that has completed the federal regulatory process in the U.S. and has been commercialized domestically but has not yet met regulatory requirements in countries that may import the grain or grain products. Once a biotech product is widely commercialized in a production area and handled through the same handling systems as commodity grains, the ability to supply grain with zero risk of adventitious presence is not possible. The adventitious presence of this type of biotech event raises legal, commercial and marketing issues because without regulatory approval in the importing country, there is generally a zero tolerance policy for the presence of these events in a grain or grain product.

Given the biology of plants and the increasing ability to detect ever more minute traces of genetic material, zero tolerance is in practice an unachievable standard. Concerns about the commercial implications of AP of this kind may result in alteration of the geographic patterns of raw material sourcing. Contracts often will require modification and new controls such as IdP systems may need to be implemented. The location, number and scale of manufacturing facilities may be affected. Each change has cost implications.

For events that have met regulatory requirements in the U.S. but not in importing countries, AP can result in blockage in the trade of seed, grain or feed and food to those countries.

*3. Events that have met regulatory requirements elsewhere but not in the U.S.*

In this case, the issues are comparable to those for events that have met regulatory requirements in the U.S. but not elsewhere. While there are few examples of this at the time of writing this report, the US government is working to further address this issue. Currently, USDA and the Environmental Protection Agency (EPA) maintain a zero tolerance specification for events that have not yet completed federal regulatory requirements.<sup>3</sup>

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<sup>3</sup> The U.S. has begun to address a number of the issues arising from the deployment of certain biotech-derived crops. In August, 2002, the White House Office of Science and Technology Policy (OSTP) published a notice of proposed Federal actions by FDA, USDA, and EPA updating field test requirements for biotechnology derived plants and establishing a process for early food safety assessments for new proteins, with the aim of preventing low levels of biotechnology-derived

#### *4. Events that have not met regulatory requirements in the U.S. or elsewhere*

AP, involving biotech material that has not gone through the federal regulatory process or that has not successfully completed the federal regulatory process, can occur, ending up in seed, grain or food that is marketed to customers. In this case, presence of this biotech material in the food or feed supply chain would create significant commercial disruptions and likely impacts on international trade. The presence of such biotech material in food or feeds and these products could be considered illegal by the U.S. government and could require removal from the marketplace. Like government policy in other countries, the United States' policy on AP of transgenic plant material intended for food use that has not yet completed U.S. regulatory reviews is evolving.<sup>4</sup>

In general, the policy and commercial issues around AP in the context of plant biotechnology internationally relate to unapproved and approved transgenic events, to inconsistencies in applicable rules and regulations and their enforcement, and in the range of differing commercial market expectations. The consequences of AP in different contexts create both regulatory issues and commercial or contractual ones.

AP requires governmental and commercial responses. As a consequence of AP, governments and industry must deal with disruption of trade flows, including product recalls and shipment rejections, which may lead to trade disputes and WTO cases. The current uncertainty and costs associated with AP in general will continue to be significant issues until workable policies are instituted and common understandings reached among countries and in the marketplace. Special arrangements, such as the one developed by the U.S., Mexico and Canada to facilitate movement of biotech and non-biotech grain in a manner intended to be consistent with the Cartagena Protocol on Biosafety, may be devised to attempt to deal with legal requirements and AP.

Internationally, the issues around AP are complicated by the involvement of government and international organizations and treaties and the lack of standards or guidelines. As was described above, labeling and traceability requirements vary among countries, and can be either voluntary or mandatory. Regulatory policy development and enforcement

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genes and gene products derived from products intended for use in food that have not yet completed all applicable regulatory requirements from being found in commercial seed, commodities, and processed food and feed until appropriate safety standards can be met. The notice spelled out actions that each of the regulatory agencies would take to address low levels of these genes and products according to their specific regulatory authorities. The FDA published draft guidance in November, 2004, which describes procedures companies can use for an early consultation with FDA on the safety of new proteins in crops that are under development and have not gone through the full FDA consultation process. According to conversations with agencies, work is underway in EPA and USDA to complete the other proposed actions, but neither has yet been promulgated to the public as of the time of publication of this report.

<sup>4</sup> See footnote #3.

mechanisms also vary widely. Creating greater regulatory consistency or harmonization of AP requirements and compliance by the U.S. government may improve the current impacts of AP in the marketplace.

## **B. Identity Preservation Systems**

Identity Preservation (IdP) is the process of managing a product so that: 1) the product does not become unintentionally commingled with unlike product; 2) the handling and processing steps in producing the product are documented; and 3) intrinsic or management-related product characteristics may be capitalized upon or marketed. IdP relies on documentation, communication, and coordination of all parties involved in the process, and can also include external verification or certification parties.

In the context of biotechnology, IdP is used in agriculture today to segregate biotech products from non-biotech products or particular varieties with specific biotech traits from other varieties. IdP can be used to accomplish one or several goals:

Capturing Added Value. Added-value products are those that have a real (tangible or functional) value for a specific purpose or products that have a perceived value developed by meeting particular customer specifications. The value may come from specific properties intrinsic to the end product or from specific procedures followed in its production. Sometimes the value derives from the producer's ability to provide consistency in the delivered product, but it also may derive from verification of product origin or the production practices used to manufacture the product. To maintain value in these systems and protect the integrity of an added value product, all steps in the value chain typically must be explicitly identified. This is usually executed through the use of contracts and Standard Operating Procedures (SOPs) for production, storage, and delivery of the product. Depending on the system, the end user may supply the seed but generally the producer is provided guidance on the expectations required to meet the system specifications. The complexity of the SOP is related to the value of the product and the level of purity required by the end user. Generally the lower the tolerance or the greater the complexity, the higher the costs are for supplying such a product to the end user. Marketing usually occurs through a contractual arrangement between the producer and an end user.

Some producer groups have been formed to pool resources and talents attempting to create and capture added value opportunities for the production of specific products that meet specific market segment needs. Value can be created where premium prices are received, market share is captured, or productivity gains arise somewhere in the chain through preserving identity and possibly end product labeling.

Several traditional agricultural organizations<sup>5</sup> have established producer certification systems to establish a higher level of education and certify that they are equipped to operate under various SOP or IdP requirements. A “Cost of IdP Calculator” is available on the internet<sup>6</sup> to assist growers in determining the added cost of various contract opportunities. The producer then can predict whether the added value will offset the additional cost incurred to meet the specifications required by the end user or regulatory requirements required to avoid labeling.

A number of grain handlers, processors, and food companies have established proprietary programs to meet particular markets and specific customer needs. They have their own SOPs and pay variable premiums depending on the value in manufacturing or in the ability to capture higher value at the customer level. Since the main focus is on creating or capturing value through enhanced functionality or meeting consumer preferences, the market tends to allow the most efficient methods to evolve, tolerances tend to vary, and testing requirements are tailored to each situation. As such, IdP systems and requirements vary across geography, among importing countries, and all the way to specific end-use customer requirements. No system or set of requirements fits all circumstances.

Controlling Products Not Approved for Food or Feed Uses. These products often require containment to prevent the adventitious commingling of these products in food or feed. Under specific regulatory systems, some regulated articles may have limited approval but may be eventually intended for traditional uses. Others, such as those intended for pharmaceutical or industrial enzyme production, may never be intended for food and feed use. For these products, identity preservation systems are integrated into SOPs to contain the product as well as to preserve the integrity of the product. Producers are subject to training and certification. To date, these non-traditional products have been produced on very small acreages and many of these non-traditional uses for crops will remain niche products in small highly contained spaces. The opportunity may be only for a few producers. Isolation and the incorporation of several redundant containment systems are becoming, or have become, standard requirements, and the systems and SOPs are continuing to evolve toward even greater rigor and additional oversight, including both physical and biological containment.

Controlling Limited Marketability Products. Products with limited marketability in this context are those that have full food and feed approval in the U.S. but not in other export destinations where grain, ingredients, or finished products are sold and marketed. In most cases, this is an outcome of asynchronous approval processes or time lags in the approval processes for some countries. This is challenging to the supply chain because regulatory frameworks often have zero tolerance for these products even though they have been approved for use in other countries.

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<sup>5</sup> e.g., the Illinois & Iowa Corn Growers and the Colorado Corn Growers

<sup>6</sup> Developed by the National Corn Growers Association and available on its website.

To deal with these export markets at the front of the supply chain, the seed industry and grower associations have developed informational systems to attempt to channel these products in markets where they are approved and attempt to exclude them from markets where they are not yet approved. For example, the Market Choices<sup>®</sup> certification program<sup>7</sup> was developed by the seed industry to provide a distinctive symbol for producers to identify which corn hybrids possess traits not yet approved for export to the European Union and should be marketed in specific channels.

“Know Before You Grow” and “Know Where To Go” programs have been developed<sup>8</sup> to better inform producers before they buy their seed and before harvest as to who is willing to accept and channel specific transgenic events in specific regions of the U.S.

For these types of products, IdP can start at the farm level with relationships, contracts and/or delivery mechanisms at the next stage of the supply chain (grain handling). Different companies have different positions on the acceptance and/or channeling of products with limited marketability. In addition, specific facilities may have restrictions or create opportunities for producers based on specific market forces that apply to their geographical area or the markets to which they ship product, whether for export or domestic consumption. Handling of limited marketability events continues to evolve in the marketplace but can be in conflict with high-throughput handling systems that are built solely for speed and rely heavily on blending or commingling to meet quality specifications. IdP is becoming more prevalent as new products and new market opportunities arise. In all cases, there are new requirements to execute these systems. In developing and utilizing these systems, the supply chain needs to make business decisions to incorporate the requirements for channeling versus segregation, the need for certification or third party verification, the impacts and commercial risks associated with testing tolerances, and the appropriate documentation to address compliance with market demands. With different supply infrastructures, expertise, and demands, several different systems are likely to evolve in the marketplace.

With new technology on the farm and throughout the food chain, the moving target of customer desires and market requirements will cause demand shifts in identity preservation systems as well. American agriculture and the U.S. food and feed chain have a strong history as an adaptable, market-focused integrated production system. This system is becoming better equipped and evolving towards meeting both the current and future opportunities and demands in the marketplace, but the challenges posed are greater for some chain segments than for others.

### **C. Traceability Systems**

The following are some comments about tracing practices, many of which do not involve biotechnology, that already exist and/or are evolving in the marketplace. These systems,

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<sup>7</sup> Owned and offered by the American Seed Trade Association.

<sup>8</sup> By the National Corn Growers Association.

however, may be applied for biotechnology products. The principles of tracing and the tracing systems set forth below could apply for any specific reason, including products of biotechnology, for following grain through or within various levels in the supply chain. Testing is added as appropriate.

Tracing and testing are two interrelated mechanisms for understanding product identity and flow, verifying identity, or addressing safety concerns. Tracing provides a trail and testing may be used to demonstrate or underscore compliance with prescribed or agreed parameters.

The type of tracing employed varies broadly depending on its purpose:

- Origin or process certification - Tracing is accomplished through a paper trail with almost no testing and relies on self-declaration by all parties. The process is certified, usually on an annual basis, by a third-party certifying agency. Blending occurs with most products as they move through the supply chain. Tracing focuses on certifying process or attributes, such as organic, rather than on tracing to a specific location.
- Meeting the traceability needs of customers - Tracing here relies primarily on layered spreadsheets built on units of delivery, i.e., the assembly of the cumulative record describing, as precisely as available data allow, what was delivered at each step in the value chain. The main concern is usually from where, as opposed to from whom, a product is coming. Testing is usually involved to verify the absence or presence of a specified event and may or may not equate with liability transfer if the event shows up later in the value chain. For export grain, for example, tracing would provide information that a particular vessel came from a specified port and contained a blend of grain from specified barges or railcars that came from specified elevators who bought from an identified group of farmers whose grain was again blended together through the elevator system.
- Safety verification – Safety verification, e.g., for mycotoxins, focuses primarily on testing of products and of ingredient streams (at various places). The amount of testing generally increases closer to the consumer in the value chain.
- Recalls – Tracing for recalls typically starts at the point in manufacturing or processing at which packaging takes place. In the U.S., this process is built on “one step forward one step back” model. Some product identifier, usually a bar code, allows tracing back in steps to the manufacturer, revealing when and where the product was made and what ingredients were used. Internal manufacturer records enable the determination of the source of ingredients and the narrowing of the possible time of manufacturing to a specified run, often within a few minutes. If the cause of a recall was a problem with an ingredient from a specific supplier, liability for all costs would generally pass to that supplier. The supplier may or may

not be able to trace the problem or pass the liability further up the supply chain, depending on the strength of its “one step forward, one step back” capabilities.

- Inventory control – Some systems utilizing newer technology are evolving in consumer-packaged goods and retail industries. Industry collaborations<sup>9</sup> will allow tracking of inventories all the way from the manufacturing process from whatever point the newer bar codes or identifiers are placed on the product. Costs are relatively high to set up such a system (perhaps as much as \$400,000 for an individual food warehouse). These structures could provide the basis for electronic product codes with “smart chips” in the future if they prove economically feasible and are accepted by consumers.

If all players in the value chain contribute to a “one step forward one step back” linkage, tracing could provide a trail through all the individuals or groups of individuals involved in blending components in ingredient streams.

The seed industry operates today by utilizing a highly documented trail governed by Federal and state seed laws and regulations from state certification organizations, including crop improvement associations. Every lot of seed is catalogued by variety through all stages from breeder to foundation to commercial seed. The respective parties in that chain keep all records of production, field inspections, inventories, transportation moves, cleaning, certification tags, etc. for a minimum of three years. Some movement toward the use of bar codes or electronic scanning is occurring. Spot inspections by state or crop improvement association personnel are conducted to verify compliance with regulations or certification requirements.

Currently, the commodity grain industry most often provides tracing by generating an identifying ticket, such as a scale ticket, at the point at which grain is first unloaded from the farm. Grain is primarily commingled; any partition of the commingled material is usually by quality or variety. Blending occurs to meet specifications of the sale contract. A shipment will be associated with an identifying number such as a bill of lading, railcar or barge number, container number, or vessel name. Testing is common at all points of transfer to verify quality, safety, or the absence or presence of a particular event or trait. It is not feasible to trace back to individual farmers, but tracing back today through the system of records to a group of elevators or farmers remains possible. All records from all steps are not on a common spreadsheet to allow instant recovery. However, a composite record probably could be reconstructed in a matter of hours or few days. Liability is usually passed with title verified by testing. If an undetected event showed up later, it is conceivable that there would be efforts to pass liability back up the chain, step by step, to the point where blending might render it impossible to find a more specific source. This possibility accounts for certain current insurance industry exclusions for unauthorized or illegal biotechnology-related presence in insurance policies for claims by grain elevators, as the “blending trail” may stop at the elevators.

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<sup>9</sup> Such as EPCglobal Inc., UCCnet GLOBALregistry, and Radio Frequency Identification (RFID) tags.

Several traceability systems are evolving today from both ends of the supply chain. Traceability software being developed and offered ranges in price from \$150,000 to \$4,000,000, depending on the depth of data needed. Systems that are designed from the farm level capture all details from type of seed, agronomic practices, handling, lists of all parties who dumped into common bin, unit numbers, etc. all the way to door-of-plant or feeding location. Such farm level systems are being marketed on a cost-per-bushel basis or through licensing of software to capture data. These systems thus far are costly, require entry of a great deal of data, and are focused on sectors of supply chain (farmers and elevators) that cannot or will not pay due to small margins. It is generally difficult to get upstream players to pay for these systems as they are not required today and often include more information than is needed. By contrast, the food industry and retailers already have traceability systems. They would probably desire or demand extension of their systems back up the supply chain rather than adopt a new farm-level-based system, as their costs have already been incurred and their systems are already integrated through to the consumer.

#### **D. Contracting and Liability**

Contracting requirements and liability impacts vary widely depending on position in the supply chain and the type of product or ingredient involved.

In the seed sector, quality standards are high. Testing is performed on all production. Production and testing records are kept for a minimum of three years as required by the Federal Seed Act.

At the next stage, farmers usually market their production to an elevator network or directly to processors or feeders. A substantial portion of grain is also used directly on the farm for animal feeding. Contracts are governed by industry trade rules that have evolved with industry practices and most often prevail in the case of the commercial markets. Industry arbitration by peers, rather than legal action, is the normal method of dispute resolution. Liability can typically only be passed back if fraud or the occurrence of a specific incident that renders a product non-merchantable is subsequently discovered, since quality is defined by testing at time of title transfer. Discounts and premiums usually apply relative to contracted quality to adjust value to the market. The elevator system always strives to find markets for all grain produced in a particular growing season, regardless of quality.

The introduction of biotech grain and grain products and their potential liabilities may affect the insurance that certain members of the food and feed chain can obtain for business-related risks. Certain insurance companies have recently added exclusions to their policies for unauthorized biotechnology-related presence. With such new policies, there is uncertainty about who in the food and feed chain will bear the liability for a biotechnology related claim, which could have significant impacts on the marketplace.

Farther down the supply/value chain, buyers typically set minimum quality standards accepted or specific traits required or excluded under contracts. Lower quality materials are often rejected based on testing. Acceptance of product in most cases also implies that liability/risk transfer occurs. Tolerances or any other attributes of value such as process verification are usually covered in the contract. Liabilities that arise are typically for non-performance on shipment time or quantity or for non-payment, as testing handles quality issues within contracted tolerances.

Unlike the conditions for all the upstream transactions in the food chain, food manufacturers and retailers do not have contracts with consumers. Liability is defined on the basis of federal regulations/standards on product content, safety, labeling, etc. Consumer expectations as to their right to know certain information about food products purchased can create commercial risks for food manufacturers and retailers. Such risks can arise when consumers expect “zero tolerance” for certain materials, such as transgenic-derived AP, even if those materials have met all applicable government requirements and a “zero tolerance” standard is in practice unattainable.

#### **E. Testing-associated Issues**

There are three main categories of tests available for the detection of products of modern biotechnology: 1) direct DNA-based tests to detect the specific DNA sequences (transgenes) inserted into the plant; 2) indirect protein-based tests to detect the specific protein expressed by the new transgene, and 3) bioassays to test for the production of the trait. Each new genetically engineered event contains specific DNA (the transgene) that directs the plant to produce a desired characteristic or trait, plus additional DNA in flanking regions of the transgene that is required for the production of that desired trait, and, most often, additional marker genes used for the initial selection of the transgenic plants in the early stages of product development.

DNA-based tests such as those that use polymerase chain reaction (PCR) amplification include methods that either detect specific DNA sequences from the transgene or associated flanking regions.

Enzyme-linked immunosorbent assays (ELISAs) are antibody-mediated tests that detect the binding of the specific expressed protein product of an inserted gene in sample material to antibodies specific to the expressed protein attached to a fixed surface such as a microtiter dish. Lateral flow strips are a specific adaptation of ELISA technology using specific antibodies immobilized on a small nitrocellulose strip, on which binding of the expressed proteins is coupled to a colour reaction. Both types of tests are relatively fast.

Protein-based tests such as ELISAs and lateral flow strips tend to be simpler and less expensive than PCR but in some cases they can not identify the specific genetic change (the molecular insertional event). Similarly, ELISAs may not be able to distinguish between events producing the same protein. This is a significant consideration since the

identification of the specific event by DNA-based testing may be required to support regulations pertaining to regulatory compliance, food labelling or verification of claims pertaining to grain and food products.

Compared to seed and grain, detecting transgenic constituents in multi-ingredient products or foods is complicated by the effects of food processing. Processing can affect the sensitivity and validity of the assays and increases the technical complexity of detecting low levels of transgenic constituents in low percentage ingredients.

Although testing methods are currently available for the detection of specific traits in numerous plants, crops, and some foods, most methods are not internationally accepted and may have not been validated based on international standards. Additionally, no single test can presently detect all events. For routine use in international trade and compliance testing, these methods must yield predictable results. To meet this goal, methods should be validated and refined to address issues associated with method variability and comparability. This includes the development and use of appropriate controls and an accurate determination of the sensitivity and specificity of each method, the development and mutual recognition of reference materials, and harmonization of international standards related to testing.

In addition, the validation process must consider the different types of products being tested (e.g., corn leaves, corn seed, corn pollen, corn flour, corn chips, cornstarch, corn oil and corn sugar). Since products are tested along the supply chain and may undergo processing or compositional changes during the IdP process, it is critical that the grain and grain product test results are comparable for the percent transgenic material present in the test sample, and appropriate sampling protocols are followed.

Setting standard methods for testing samples for the presence of transgenic material in seed, grain and grain products is complicated by a number of factors:

- There is no international consensus on testing methods and thus there are no international standards for testing for transgenic material in products.
- Accurate testing requires defined limits of specific analytical measurements including required sensitivity, sample size, uncertainty measurements, and appropriate validation criteria.
- There are many possible products from transgenic plants, plant parts, and processed foodstuffs, including highly refined substances such as vegetable oil containing little or no detectable transgene-derived protein or DNA.
- Products from transgenic plants and from other transgenic or non-transgenic plants may be combined in varying proportions during processing or handling.
- Inspection, conformity and compliance plans need to be developed on a product-by-product basis for a large number of products.

- Both non-specific, qualitative detection methods (sufficient to address the claim “may contain transgenic or GM products”) and specific, quantitative detection methods (for percent determinations) need to be developed to meet different testing needs. Different tests exhibit different practical limitations and differences in sensitivity and specificity. A number of external factors beyond materials initially planted affect the results that will be obtained upon testing.

In the absence of international standards and harmonization of testing between regulatory authorities, there is significant variability associated with testing grain and food testing for transgenic content. Testing of the same product may produce different results under different test methodologies, at different places in the production chain, or in the final food. As such, there are commercial risks associated with supplying transgenic (or non-transgenic) ingredients based upon testing results.

This testing issue is associated with the lack of “predictability” in the marketplace. The lack of predictability in available testing methods creates commercial risk. This means that a given product may not predictably test “within” the specification of the contract all along the supply chain. The different results may not be associated with commingling of the product with transgenic commodity material, but rather with the statistics of sampling or differences in the sampling method, testing strategies, or capabilities of specific test methods. The possibility exists that a grain product grown from compliant seed, delivered as compliant grain to a processing facility, processed to produce a compliant grain product, and incorporated into the finished food will not test “in compliance” under another compliance testing program. This possibility illustrates the significant commercial risks associated with the supply and marketing of food products in countries that have specific regulations pertaining to foods derived from modern biotechnology, because it may not be possible to effectively manage compliance in those markets.

The development of international standards for test methods and the mutual recognition of reference materials would reduce the variability in testing related to international trade of grain and grain products with respect to transgenic materials. Reducing the variability between and within test methods will increase the predictability of testing compliance in these products and reduce the commercial risks associated with these products. The availability of internationally accepted methods may be facilitated through international organizations and formal and informal cooperation between industry and government organizations within countries.

#### **F. Discrepancy between Regulatory and Commercial Requirements**

A country’s regulatory framework for mandatory labeling of genetically engineered products most often specifies the requirements for a product to comply with labeling or be exempt from labeling. These requirements, in many cases, serve as the minimum contractual specifications for grain and grain products entering the country for use in food and feed.

In countries with mandatory labeling for transgenic-derived products, there are few food manufacturers who are willing to label their products as genetically engineered or “GM.” In most cases, food manufacturers who sell products in countries with mandatory labeling either reformulate and/or substitute with products from non-engineered crops or purchase from supply chains that allow the ingredients to be exempt from mandatory labeling (based on IdP and compliance with a specified AP tolerance). Another potential option for food manufacturers is to relocate manufacturing operations.

In cases where food manufacturers and ingredient suppliers are sourcing ingredients that are exempt from labeling, the contractual specifications can vary depending on the level of the manufacturers’ commercial risk aversion. In some cases, the contractual specifications are identical to the regulatory requirements to be exempt from labeling. If the level of risk aversion is greater, then some food manufacturers require product specifications in excess of the regulatory requirement. For example, in the United Kingdom it is common that the specifications for non-genetically engineered ingredients are IdP and a 0.1 percent AP limit, versus the 0.9 percent AP regulatory requirement for the EU as a whole.

The same variability exists in the requirements for identity preservation systems for exempt products. In general, there are minimum standards for the stringency of identity preservation that must be executed to qualify for product exemption from labeling. In some cases, the expectations are clearly defined through government guidance documents (e.g., Australia), while others may be spelled out by industry groups (e.g., the British Retail Consortium) or business councils. Government standards are readily adopted, while industry group guidance may be regionally adopted or implemented only by specific manufacturers. To reduce the commercial risk, some of these industry standards exceed the legal requirements.

We wish to note that it is not just countries that could have a significant input and impact on labeling and the marketplace. Mega-retailers and mega-customers could also drive rapid change in labeling.

## **G. Impacts of Market Segmentation**

Market segmentation is the process of dividing a larger market into several sub-markets. Market segmentation arises primarily out of the processes of capturing value or managing commercial risk. Some basic premises come into play:

- The tighter the product requirements (whether in terms of tolerances, regulatory requirements, demonstration of end use benefits), the more “value” segregates.
- The more “value” segregates, the more IdP must increase to insure the market captures the value created.

- Often, as the value of a product increases, so does the commercial risk, leading to the desire for more testing and more control.
- More control implies more tracing. This increases the probability or at least opens the door for liability transfer further back in the supply chain if an “incident” destroys value capture for succeeding parties.
- Increased commercial risk or control drives a shift toward integration or a dramatic narrowing of the group of suppliers. For some downstream entities, “bigger is usually better” in terms of their suppliers as it is easier to deal with a limited number or a single supplier than a broad market.
- The value of products becomes less transparent to others in the market.
- The market power of individual players dictates market rules and the sharing of value. Substitutability of products dilutes market power.

All of the above create differential returns to growers and different levels of access to particular markets by growers of different specialty varieties of the same crop.

Markets can segment for reasons that are not easily measurable. For transgenic products, market segmentation is further complicated by differing attitudes among the population of product developers, producers, suppliers, and consumers that range from the view that current products are very similar to traditional products and future products offer the promise of addressing future needs in the U.S. and elsewhere to a core concern about inherent differences between biotechnology-derived and traditional products and a focus on possible longer-term safety concerns or consequences to the environment.

Various sectors of the market view the segmentation issue or are affected by it in different ways:

Commodity system – This represents the largest sector of the market, one that relies on harmonization of rules and regulations to allow commerce to flow efficiently. Liability transfer has traditionally been defined through negotiated contracts or industry trade rules. Product commingling is unavoidable given high volumes, high speed, and the need to blend to meet defined quality standards. Margins tend to be small given large number of market participants, homogeneity of product, free-flowing information, and limited or no barriers to entry. Buyers often gravitate to broad, common quality specifications, as price spreads are often not wide enough to support several differentiated products. Any product segmentation is usually driven by broad quality factors such as oil content, protein level, etc.

Political system – Different countries base their traceability and labeling policies and regulations on different approaches, which may be more or less science-based or market-based and may blend in various “right to know” concepts or include various

measures for domestic economy protection. Issues of harmonization, liability transfer, etc. evolve very slowly through trade agreements, WTO rulings, and/or compromises through international groups. Multiple other external factors such as wars, political differences, economic imbalances, etc. also affect progress toward harmonization. Markets can segment via political or economic coalitions.

Food system – Before products are sold in any country, food manufacturers need clear, understandable guidelines as to what is necessary to meet all legal and regulatory requirements. However, in addition, consumer desires will drive actions of food manufacturers. Most food manufacturers believe strongly in a demand-pull marketplace, although current products of modern biotechnology in agriculture have not entered the marketplace via demand-pull. Lack of harmonization globally is forcing diversification of the food product manufacturing base to fit differing market needs. Trends are more towards “right to know” on a number of parameters, especially on nutrient content and origin. Growth in markets for differentiated products will intensify price segregation to participants in the supply chain. These price signals both communicate market needs and spread the distribution of value, driving more segmentation, more integration, more contracting, tighter tracing/ testing, and a general narrowing of the supply chain to insure the delivery of (specified) value to the end consumer.

#### **H. Consumer Implications of Various Labeling Regimes**

Consumers need access to certain basic information to make informed choices about food products they purchase, including nutritional composition and price. Consumer purchasing decisions are also influenced by personal and cultural factors such as familiarity, taste, and religious preferences. As markets have become more global, some consumers have sought additional information, such as where a product was produced, what environmental and employment practices were followed, and what processing methods were used. The food and feed supply chain has sought to establish economically efficient identity preservation and other marketing systems to provide the desired information.

Some countries have established mandatory labeling requirements for most food products that have been produced using biotechnology. These regulatory requirements and commercial decisions affect the amount and type of information available to retail consumers, and may influence product availability and choice. Any resulting cost increase is absorbed throughout the food system, from producer through final consumer.

Mandatory labeling for genetically engineered products has effectively prevented most biotech products from being marketed in countries with such regulations. In the U.S., where there is no mandatory process-based food labeling, many foods contain genetically engineered ingredients and no health or safety issues have arisen. Consumers purchase these products, frequently unaware that they were made using biotech ingredients. U.S. consumers who want non-biotech products have reduced choices that are generally higher priced.

Consumer research shows a substantial majority of U.S. consumers want more information about their food. When U.S. consumers are asked if they want food containing genetically engineered products labeled, they usually say “yes.” If they are not asked specifically, biotechnology labeling is rarely mentioned. The food label provides a simple way for consumers to get information although it may also be acquired at the point of retail purchase, by contacting the manufacturer, and increasingly, by seeking information on the internet.

#### **IV. Policy Concerns/Issues Raised by the Analysis of the Current Situation**

These are some of the key policy concerns and issues that emanate from the Committee’s discussions and deliberations captured in the full report.

- The complexity of complying with multiple labeling and traceability requirements that differ by market and country imposes additional costs and inefficiencies on the supply chain.
- Some tracing and labeling requirements are uncertain, the systems in some countries are rapidly evolving, and some systems lack specifics about what constitutes compliance. This increases commercial challenges for the production, marketing, and trade of grain and grain products.
- There are inherent difficulties in complying with biotechnology-specific traceability and labeling regulations governing product characteristics that cannot be detected. Government-imposed process certification requirements pose challenges for industry.
- There are significant sampling and testing issues when one is supplying grain or grain products that are required to meet specific tolerances or thresholds. This difficulty reflects the sampling and analytical challenges associated with the testing of grain for genetically-engineered content. Variability between tests relates to the absence of reference standards and internationally-validated and harmonized test methods. Without harmonization and standardization it will remain difficult to practically and reproducibly determine whether products are in compliance with a specific tolerance. The problem of variability among tests is exacerbated as tolerance levels decrease.
- Which test results take precedence in the movement of grain or grain products needs to be clarified. Mutual recognition of testing and sampling methods may enable downstream parties to accept testing at the origin of a grain or grain product without the need for additional testing. Development and recognition of testing certificates would reduce the commercial risks along the supply chain.

- Industry is grappling with how to address issues related to “acceptable zero” versus an absolute zero for both approved and unapproved events.
- The commercial marketplace is struggling with varying concepts of what product specifications (tolerances) trigger labeling of genetically engineered versus non-engineered products. Even where specific tolerances are provided by regulation, the marketplace may require suppliers to provide products at much lower, sometimes zero, tolerance levels, to allow them to make a zero claim to the eventual buyers, particularly on consumer products.
- Uncertainties as to liability transfer and exclusions for biotechnology-related claims by some insurance companies for certain portions of the supply chain can have significant impacts on the marketplace.
- There is a role for international organizations, as well as bilateral and multilateral efforts, to address some of these impacts and implications, but it not always clear which approach is best suited for the resolution of each. The U.S. government should continue to creatively explore different venues and approaches.
- Consumers’ interest in seeking additional information about their food is increased by variability in retail requirements in different countries and associated debates regarding safety, environmental concerns, and general acceptability of biotech crops.