Cert ID, A SUCCESSFUL EXAMPLE OF AN INDEPENDENT, THIRD-PARTY, PRIVATE CERTIFICATION SYSTEM

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Cert ID's mission is to provide third party, independent certification of food and agricultural products to a range of standards, including non-GMO, organic, and meat traceability. It is a subsidiary of Genetic ID, which offers testing and consultation services designed to provide comprehensive solutions related to GMOs and other emerging food issues, such as allergenicity. In this paper we review the development, implementation, and current operation of Cert ID as a "case study" for private certification programs, in general.

Certification Today: Creating a Bridge of Confidence between Buyer and Seller

The food system is undergoing massive and rapid transformation. In our grandparent's era, most food was produced locally. When Grandmother went shopping, she would look the farmer or butcher in the eye and ask, "Is this fresh and flavorful?" The supplier knew that if he/she did not answer accurately, Grandmother would go to a different vendor next week. In that day, there was a personal basis upon which trust was developed between buyer and seller.

The situation is quite different today. The food system is global. Soybeans may be grown in Iowa from seed produced in Brazil. They are then shipped to Japan, where they are combined with wheat from Australia and transformed into soy sauce, which is finally sold to consumers in Belgium. A single product can contain ingredients from three or four different continents. Many of the transactions at the industrial level are consummated sight-unseen. The anonymity of this system can create situations, especially at the retail end of the food chain, where confidence in the products is not strong. "Is this fresh locally grown French chicken, or is it inexpensive, defrosted Thai chicken?" "How can I know for sure?" In addition, confidence has been eroded in recent years, especially in Europe and Japan by a spate of food scares.

The role of certification is to re-create that bridge of confidence between buyer and seller. People generally want to know, and have confidence in, what they are eating. They want transparency. By creating transparency, certification helps sell products.

Certification also can be used to verify the quality of premium goods. As disposable income increases, health and status concerns motivate people to purchase higher quality, more expensive food products. For instance, they are prepared to pay 50 to 300 percent more for organic products because they contain little or no pesticides and are thus perceived as healthier. However, people are prepared to make the added financial outlay only if they are confident that they are receiving added value. They need to have confidence, trust, that the product is actually worth the extra money; they need reassurance that it is a *bona fide* premium product. Third-party, independent certification systems are a powerful tool that the food industry can use to provide these reassurances and thereby capture greater revenues from their higher quality products and from

products, such as the non-GMO products offered in Europe and Japan, which are designed to meet specific consumer needs or concerns.

Emergence of the Cert ID Program

Cert ID emerged in relation to the GMO issue, but it has expanded to encompass much more. It operates internationally to fulfill the growing needs of the globalizing food system for tools to verify a wide range of food characteristics. Examples include certification of products as non-GMO and organic certification, certification of the authenticity of premium meat products, and certification that products comply with specific national regulations, such as the new EU regulations on traceability.

Cert ID initially came into being as a result of convergence of two things, first, the recognition that a certified identity preservation and sourcing system was needed for non-GMO products, and, second, a concerted demand for such a program from the buyer end of the food chain.

The recognition of the need for non-GMO certification emerged from Genetic ID's experience in providing GMO testing services to the food and agricultural industries. Founded in 1996, Genetic ID provides ISO17025-accredited GMO analytical services and consulting services, and has built a network of 18 laboratories around the world—the Global Laboratory Alliance (GLA)—that including three laboratories owned by Genetic ID and another 15 that have licensed the Genetic ID GMO testing technology. All GLA members conduct GMO testing according to a uniform set of standard operating procedures, and all participate in ring trials and other quality assurance programs administered by Genetic ID to assure consistency of performance. GLA member-laboratories are listed in Table 1, below.

Genetic ID's testing services were quickly adopted by organizations in producer regions, such as North and South America. These organizations used our testing services to facilitate the export of their products into consumer regions, such as Europe, the Middle East, Japan, and other destinations in the Pacific Rim, where consumer concern regarding GMOs was rapidly growing.

During the first year of Genetic ID's operation, we gained a much deeper understanding of the food and agricultural industries. We had many opportunities to see how testing results were used by the industry and to assess the effectiveness of testing as a tool that industry could use to meet their business objectives. This led to the conclusion that, although testing is essential, it is not sufficient in itself to meet the needs of industry.

The approach that the industry was using at the time was based on a Quality Control, a simple test and reject model. This approach is expensive, because it requires high frequency testing, and carries with it high risk of costly product rejection. We recognized that migrating to a Quality Assurance approach would be much more beneficial to all parties. Using this approach, one builds a production system in which each element is *designed* to produce a product that meets predefined specifications. Such a system includes documented monitoring and testing to verify that the system is working properly.

With this approach, the role of testing changes significantly. Instead of functioning as a gate-keeper that determines whether each product lot meets specifications and therefore can be released for sale, it is used to assure whether or not the system is operating properly. This change in roles usually leads to significant reductions in testing frequency, and thus cost. One of the many attractive features often reported about Cert ID is that it often proves to be self-financing. The cost savings resulting from implementation of certification are often greater than the costs of that implementation. It also increases the reliability of delivery of product that meets the desired specifications, and reduces the risk of costly rejection of product lots due to failure to meet specifications. Instead of investing large amounts of money in testing to verify with high statistical strength that each lot of product leaving the production facility meets specifications, one invests more in the production system and the controls on that system, which assure that the system is operating at every point in a manner that should produce products that meet the pre-defined specifications.

Based on our experience, we concluded that third-party independent certification of identity preserved production systems would enable the producer to deliver a product that more consistently met or exceeded specifications and to do so at significant cost savings. Moreover, such systems would provide a high degree of credibility and good will, leading to increased success in the marketplace.

Development of the Cert ID System

Based on this analysis, we initiated a three-year research program aimed at developing a practical non-GMO certification program. This research program focused on two basic questions related to non-GMO foods and agricultural products:

- What do buyers need?
- What is practical for producers?

We worked with individuals and organizations at every level of the food system, including seed producers, farmers, traders/brokers, transport/shipping/storage, processors and ingredient manufacturers, manufacturers of products for end-users, distributors, retailers, and the end-users themselves. We also consulted with government regulators in several countries.

The focus of these consultations was to develop and refine standards for non-GMO products, and to develop a system of procedures for effectively administering certification to those standards.

This development and consultation process required about two years, coming to completion in late 1998. At that time we undertook two beta-test projects, one in Japan, certifying traditional soy products, and another in Australia, certifying wine.

As these projects came to completion, developments in Europe precipitated the emergence of the Cert ID system, as it exists today. At that time, the major food retailers in Europe were grappling with the challenge of delivering products to the marketplace that responded to the demands, voiced by European consumers, that they be given access to non-GMO products. Our work came to the retailer’s attention and we were invited by a consortium of retailers, which included

Sainsbury's, Marks and Spencer, Carrefour, Esselunga, Migros, and Delhaize, to partner with a European food testing and consulting organization to structure a certification program that would enable the retailers to handle the GMO dimension of their products.

The results of our nearly three years of research were immediately integrated with input from retail organizations and their suppliers, to quickly structure a standard that met their needs. Central to their concerns were exactly the same questions that we had built our research around: What do buyers want? What is practical for the producer? However, for the EU retailers, these questions came into sharper focus: What do our customers, European consumers, want? What is practical for the suppliers of our own-brand products?

The Cert ID Standard

Out of the dialogue with these organizations came the first draft of the Cert ID Standard. This draft was circulated more broadly to companies in the supply chain and also to consumer groups. The resulting feedback was used to further refine the standards, resulting in Issue 1.00 of the Cert ID Standard. The key elements of this standard have remained constant as the years have passed. However, we continue to keep our ear to the ground, refining the Standard, now in Issue 3.02.2, to fulfill more effectively the two questions posed above.

Cert ID non-GMO certification involves the following elements:

- Inspection of facilities to verify that production/storage/shipping/etc. systems are operating in compliance with the Cert ID standard,
- Auditing of documentation verifying that the system is actually operating in compliance with the certification program plan,
- Sampling and testing at critical control points to verify the non-GMO status of the inputs and outputs of the production system,
- Storage of all relevant information in an integrated database.

The information technology system is a key element of the Cert ID program. It enables rapid, complete traceability of any lot of certified product, and can conveniently be used to source needed ingredients.

The non-GMO certification standard is structured in modules. Each focuses on a specific element within the food chain as follows:

- Certification of seed production system,
- Certification of an agricultural production system,
- Certification of storage and transport systems,
- Certification of brokerage and trading operations, and
- Certification of food manufacturing facilities.

The Range of Cert ID Programs

Cert ID offers, not only non-GMO certification, but several other programs as well. At present, these include the following:

- Non-GMO certification,
- Certification to organic food standards (primarily in the Pacific Rim),
- Certification that the product complies with specific national regulations regarding GMOs, and
- Meat traceability and authenticity certification.

As need arises, additional product certification programs can be quickly developed. This is one of the advantages of independent, private certification organizations. They are able to move quickly to respond to developments in the marketplace. Whereas implementation of a new government-sponsored certification program would, in most cases, take more than a year, a private certifier with broad certification experience can use that broad experience as a foundation upon which to build new certification programs in just a few months, thereby supporting the ability of first-movers within the industry to exploit new opportunities in the marketplace.

The Certification Process

As illustrated in Figure 1, there are two steps in every certification program. The first is certification of the *system* to assure that it operates in a fully traceable manner, that it thoroughly preserves the identity of product that moves through it. The second step is verification of the particular characteristics of a specific lot of *product*. An example would be verification that the product meets the Cert ID non-GMO Standard. These two steps are discussed in more detail in the following paragraphs.

Traceability and identity Preservation

Identity preservation and full traceability are the foundation of every product certification program. All of the Cert ID product certification programs, mentioned above, are built on the same foundation, the Cert ID Identity Preservation/Traceability System Certification Program, as illustrated in Figure 1.

This System Certification assures that the production, shipping, storage, processing, and/or manufacturing system is structured in such a manner that any product moving through that system will be fully traceable. Its identity will be preserved from start to finish.

The Cert ID IP/Traceability System Certification standards are compliant with the new EU traceability laws (part of Regulation EC No 178/2002, Regulation of the European Parliament and of the Council Laying Down the General Principles of Food Law), which become enforceable from January 1, 2005. This means that any system that achieves Cert ID IP/Traceability System Certification will also be in compliance with the new EU traceability regulations.

Certification of Specific Product Characteristics

If a system is structured to assure identity preservation and full traceability, then any characteristic of any specific lot of product can be efficiently preserved and verified from the point it enters the system to the point it is released. To achieve this, one superimposes on the identity preservation and traceability system additional requirements and procedures that (1) assure that only inputs that possess the required characteristics are introduced into the system; (2) verify at critical points in the system, using documented monitoring, sampling, and testing, that the product and its inputs possess the characteristics of interest, and have not been commingled with other materials that might compromise the characteristics of the product that are of interest.

For instance, for non-GMO certification, seed is verified by test to be non-GMO. During planting, cultivation, harvesting, and storage, control procedures are used, and their use documented, which are designed to prevent introduction of GM material into the production system, whether by admixture, cross-pollination, or other mechanisms. Later, at harvest, testing is carried out to verify that the control procedures were effective. Again, at critical control points in later steps such as shipping, storage, processing, and manufacturing, testing and document verification are used to confirm the effectiveness of control procedures in preserving the non-GMO status of the product.

The Cert ID Full Traceability Databrain[Ò]

Setting up a traceability and identity preservation system requires two things. The first is physical systems that segregate and control the identity of each lot of product and of inputs used in making that product. This creates a physical and operational chain of custody system for each ingredient and for the final products, themselves. The second requirement is information systems that capture and store the identity and custody information in a manner that will make it possible to trace back from any lot of product to the origin of each input used to make that product.

Achieving the first of these requirements entails the modification of the production/shipping/storage/processing/manufacturing system to achieve the required degree of segregation and identity preservation. This is called “developing an IP/traceability system.”

It should be emphasized that this process—developing an IP/traceability system—is distinct from the certification process, itself. IP system development involves rethinking and restructuring the production/ storage/shipping/processing/manufacturing systems to achieve new objectives—segregation, identity preservation, and traceability. Certification is distinct from this process; namely, it is the process of evaluating the newly restructured production/storage/ shipping/processing/manufacturing systems to ascertain whether they meet and are operating to the Cert ID Standard for IP systems. Although significant costs can be associated with the first process—restructuring the production/storage/shipping/ processing/manufacturing systems, the costs of certification are usually modest in comparison.

The second requirement for an identity preservation system can be achieved by storing traceability and custody documentation in filing cabinets. In contrast, Cert ID is employing cutting edge information technology to create a flexible, internet-accessible electronic database that conveniently stores traceability and custody information in a form that is rapidly and accurately accessible—the Cert ID Full Traceability Databrain®.

Figure 2A illustrates the reality of any supply chain. It is highly complex. Using systems that meet current industry standards, tracing back from any manufactured food product to the sources of the ingredients comprising that product is highly complex, costly and time consuming, particularly when important traceability information is often held in different continents/time zones; under the new EU Traceability Regulations enforcement authorities expect the food producer to be able to produce this information upon demand and retain it for 5 years.

In contrast to Figure 2A, the Cert ID Full Traceability Databrain® "puts the supply chain (for a specific lot of product) in a box", as illustrated in Figure 2B. Tracing the origins of a given lot of product becomes a task that takes just a few keystrokes and a few minutes, instead of days. In physical terms, the supply chain unavoidably remains complex, as illustrated in Figure 2A, but in information terms, the Cert ID Full Traceability Databrain® compresses, organizes, and systematizes traceability and custody information, "putting the supply chain in a box" for rapid and timely access of traceability information.

In addition to supporting the business objectives of the food and agricultural systems, traceability systems have been identified as a key element in strategies for protecting the food chain from the ever-present danger of globally organized terrorism. The vulnerability of the food and feed chains has not been lost on many governments. It is recognized that, due to the global character if the food system, a food-related bio-terrorist incident could have far reaching consequences affecting several continents. It is also recognized that rapid access to essential traceability information is a critical element in strategies for protecting against food-related bio-terrorism. In particular such systems can:

- Facilitate a controlled and targeted withdraw of suspect food and feed product
- Reduce the impact of interruptions to the provision and availability of foods without compromising safety
- Minimize product recall cost
- Reassure consumers

Independent Third Party

Another key element of the Cert ID Program is that it is an independent third party organization. We feel that the independent, private, and impartial nature of the certification organization plays a key role in strengthening the confidence of buyers. This confidence is based on the following two factors:

(1) the technical capabilities of the certifier in verifying the characteristics of interest (e.g. the non-GMO status of a product)
(2) the intent of the certifier to provide accurate information.

The third-party, independent status of the certifier is critical in assuring the latter factor. The certifier has no stake in the outcome of the transaction between buyer and seller, as would be the case when sellers "self certify". Likewise, government certifiers are viewed by some as having a stake in the transaction, since a core mission of organizations such as the USDA is to expand agricultural export sales. Thus, consumers, especially in the EU and Japan, are often distrusting of government assurances.

In contrast, continued prosperity of the independent, private certifier's enterprise depends solely on recognition in the marketplace that they can deliver accurate and impartial information regarding product specifications. For the certifier to favor either the buyer's or the seller's interests, would interfere with their impartiality and jeopardize the foundation of their business, namely market recognition of their credibility and impartiality. Thus, the best interests of certifiers are served by impartiality. Because the certifier has no stake in the outcome of the transaction, and because the certifier's publicly stated priority is to assess the compliance of systems, processes, and products with specific transparent and publicly available standards, confidence can be placed in the information that they provide.

In summary, we have examined the basis for certification programs, and have offered our experience with Cert ID as an example of how private organizations can provide certification services that facilitate expansion of international trade in foods and agricultural products. We conclude that independent private certification organizations can offer flexible, innovative services and can respond quickly to support industry's needs to address new issues.

Table 1—Global Laboratory Alliance Members	Location
Genetic ID USA	Fairfield, USA
Genetic ID Japan	Yokohama, Japan
Genetic ID Germany	Augsburg, Germany
FALCO Biosystems Ltd	Kyoto, Japan
Intertek Testing Services	Kowloon, Hong Kong
Korea Government Consumer Protection Board	Seoul, Korea
KoGene Biotech	Seoul, Korea
Avestha Gengraine Technologies PVT LTD	Bangalore, India
NSF International	Ann Arbor, USA
Oregon Department of Agriculture	Portland, USA
Nisshinbo	Tokyo, Japan
PSB Corporation	Singapore
Laboratório ALAC Ltda	Garibaldi –RS, Brazil
Worcestershire Scientific Services UK	Worchester, United Kingdom
Medway Italy	Cuggiono, Italy
EMATER	Porto Alegre, RS, Brazil
Agrifood Technology	Victoria, Australia
Genalabs Life Science Corp.	Taipei, Taiwan

Figure 1 Identity Preservation and Full Traceability—The Foundation of All Certification Programs

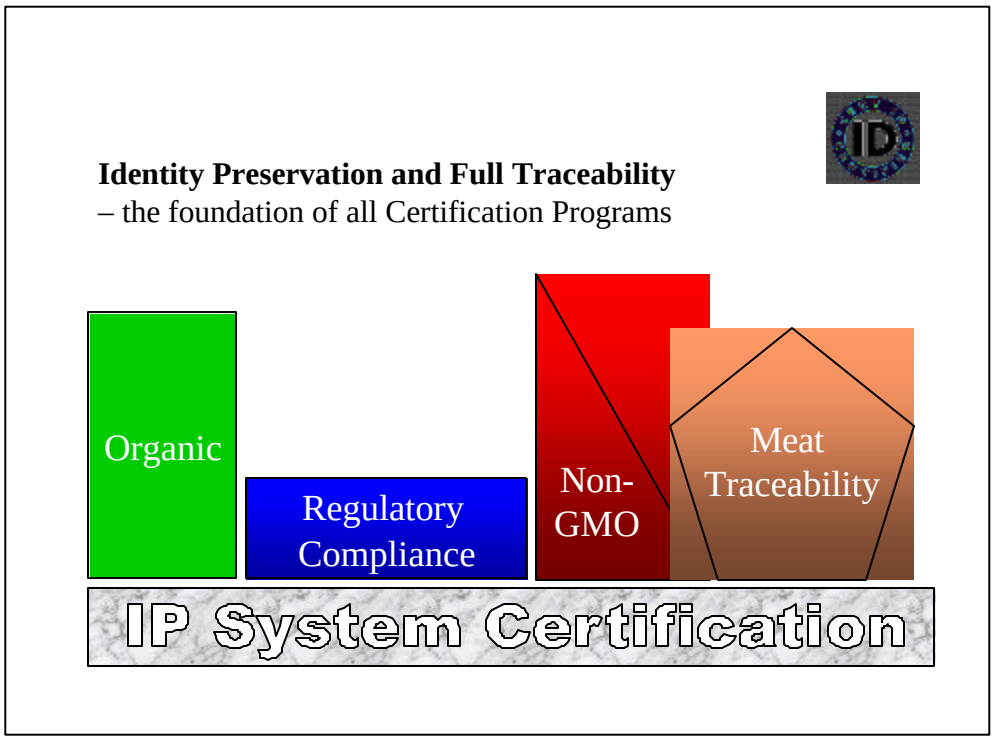

Figure 2A The Physical Supply Chain

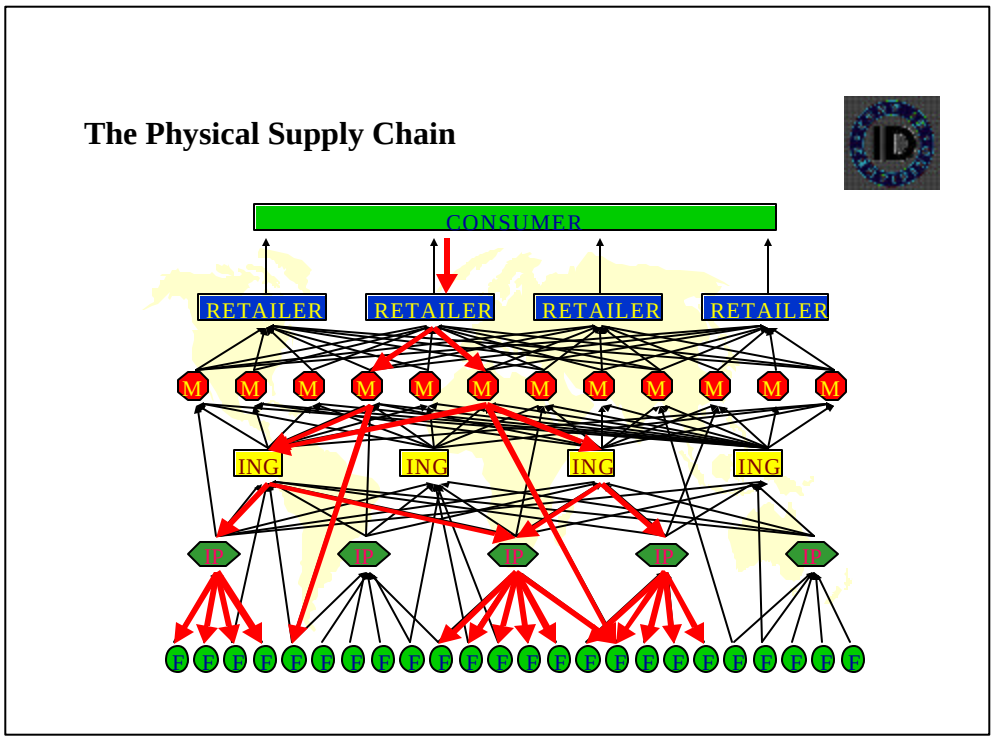

Figure 2B Using Information Technology to Put the Supply Chain in a Box