Traceability of biotech-derived animals: application of DNA technology

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Summary

Traceability is increasingly becoming standard across the agri-food industry, largely driven by recent food crises and the consequent demands for transparency within the food chain. This is leading to the development of a range of traceability concepts and technologies adapted to different industry needs. Experience with genetically modified plants has shown that traceability can play a role in increasing public confidence in biotechnology, and might similarly help allay concerns relating to the development of animal biotechnology. Traceability also forms an essential component of any risk management strategy and is a key requirement for post-marketing surveillance.

Given the diversity of traceability concepts and technologies available, consideration needs to be given to the scope and precision of traceability systems for animal biotechnology. Experience to date has shown that conventional tagging and labelling systems can incorporate levels of error and may not have sufficient precision for biotech-derived animals. Deoxyribonucleic acid (DNA) technology can overcome these difficulties by tracing animals and animal by-products through their DNA code rather than an associated label. This offers the possibility of tracing some by-products of animal biotechnology through the supply chain back to source animals, offering unprecedented levels of traceability. Developments in both DNA sampling and analysis technology are making large-scale applications of DNA traceability increasingly cost effective and feasible, and are likely to lead to a broader uptake of DNA traceability concepts.

Keywords

Animal identification – Animal tracing – DNA identification – Post-market surveillance – Product identification – Risk management – Traceability.

Introduction

Despite the central role of traceability in quality control within the manufacturing sector, traceability systems have been adopted on a significant scale only relatively recently within the agri-food industry. Uptake has largely been precipitated by the bovine spongiform encephalopathy (BSE) crisis, which highlighted the difficulties in tracing meat products through the supply chain. However, ongoing food scares, biosecurity concerns and consumer desire for products with specific attributes have ensured that traceability systems are becoming standard. It is broadly recognised that traceability is essential for good safety and quality control: the better and more precise the tracing system, the faster food safety or quality problems can be identified and resolved. Furthermore the ability to segregate and trace products is seen as key to providing consumers with information and choices about the food they consume (9) and represents a central component of consumer confidence (36).

The recent controversy surrounding the commercialisation of genetically modified (GM) plants serves to highlight the difficulties that may arise in some markets when technology does not have the confidence of the public. Consumer concerns over the safety, environmental consequences and ethics of GM technology were compounded by an inability to distinguish between GM and non-GM foods, and led to a rejection of the technology in many regions of the world.

Recent surveys conducted in the United Kingdom (UK) suggest that while some of this concern, particularly over the health consequences of GM foods, may be abating, consumers are likely to continue to want to be able to make an informed choice between GM and non-GM products (21). This will require clear product labelling and the ability to trace products of GM origin. Indeed, traceability has become a central component in legislative efforts by the European Union (EU) to restore consumer confidence in GM foods. Regulation 1830/2003, the latest of a number of EU GM labelling regulations 'provides a framework for the traceability of products consisting of or containing genetically modified organisms (GMOs), and food and feed produced from GMOs, with the objectives of facilitating accurate labelling, monitoring the effects on the environment and, where appropriate, on health' (13). It is argued that this increased emphasis on transparency and traceability will help restore public confidence in the regulation of the technology and lead to a lifting of the *de facto* moratorium on GM approvals that has been in place since June 1999 (18).

Large-scale adoption of biotech-derived animals is likely to encounter similar or even greater challenges than GM plants. A report in the UK found that public opinion on animal biotechnology is being shaped in a climate of unease about political and regulatory oversight, and a perception that the technology is being driven by scientific and commercial priorities rather than public interest (1). A more recent survey by the Pew Initiative on Food and Biotechnology found that consumers in the United States of America (USA) voiced greater concern over the genetic modification of animals than of plants (43). Animals, unlike plants, are mobile and there are thus potential challenges in containing them once released into the environment (39). They are sentient and frequently require special care, opening up issues relating to welfare and how they are produced.

This paper seeks to describe the role that traceability can play in both engendering confidence in the regulatory process for animal biotechnology, and in helping manage risks associated with the introduction of biotech-derived animals to the commercial marketplace. While not intended as a comprehensive treatment of the subject, the paper outlines the key characteristics of traceability systems and some of the issues that need to be considered when tracing biotech-derived animals. In particular the paper focuses on deoxyribonucleic acid (DNA) based traceability as a means of both identifying and providing traceback capability for biotech-derived animals and their by-products.

Biotech-derived animals

Although animal biotechnology is still very much in its infancy, advances in this field promise great benefits to humankind. Many of the more widely discussed applications relate to the creation of transgenic livestock for disease resistance or more efficient food production, but developments in the technology are leading to applications in other fields of human endeavour. These may be broadly classified into four areas:

– development of transgenic livestock through the introduction of genes for disease resistance, enhanced growth, environmental adaptation, etc.

– production of biopharmaceuticals expressed in milk or other tissues

– production of animals as organ donors for xenotransplantation to prevent the acute rejection of transplanted organs

– medical research, such as the creation of animal models for the study of human disease or toxicity testing.

From a traceability perspective animals that are transformed to produce tissues/organs, or therapeutic proteins in milk, eggs or blood, present a different set of challenges to those engineered for food and agricultural purposes. In the latter case the actual animals will be engineered in larger quantities for deliberate release into conventional agriculture, whereas the former are likely to be reared in smaller numbers as part of research or in closed commercial herds, but with the potential for escape or inadvertent release.

A further issue relates to how 'biotech-derived' animals are developed. In the broadest sense they may be defined as animals generated through biotechnological methods, including:

– genetically engineered animals produced through the addition, deletion or silencing of genes

– clones derived by nuclear transfer from embryonic or somatic cells

– chimeric animals that have received transplanted cells from another animal

– interspecies hybrids produced by *in vitro* methods

– animals derived from *in vitro* cultivation.

This working definition, developed by the Canadian Food Inspection Agency (31), forms a basis for regulatory oversight and represents a useful description of the potential scope of methodologies covered. A further consideration relates to whether the modification is inherited or not. In germ-line modified animals, the modification will be represented throughout all animal tissues, including the germ-line, and is passed on from generation to generation. In somatic cell-modified animals, only specific tissues will have incorporated the new trait(s) while the rest of the animal remains genetically unaltered and the modification may not be passed on to subsequent generations.

In summary, biotech-derived animals could find application in a range of markets, be developed in different ways, reared through different production systems and incorporate modifications that may or may not be passed on to subsequent generations. These different facets need to be considered in any discussion of the traceability of such animals.

The case for traceability of biotech animals

Numerous reports have indicated that public acceptance of animal biotechnology will be essential if it is to realise its potential (1, 39, 42). To gain such acceptance, a range of consumer concerns will need to be addressed through a transparent and trustworthy regulatory process. A component of this process will be the inclusion of mechanisms to ensure that if a particular problem should arise, the affected animals and their by-products can quickly be tracked and traced. The discovery of a BSE-infected cow in the US herd in December 2001 demonstrates the difficulties faced in the absence of such a system. Out of a group of 81 animals shipped from Canada into the USA with the BSE-infected animal, only 28 could be located and destroyed after weeks of intensive searching (14). This undoubtedly magnified both the scale and depth of the crisis and contributed to delays in the reopening of international trade.

With particular reference to biotech-derived animals, there have already been a number of cases of unauthorised releases. Three transgenic pigs produced at the University of Florida and destined for destruction were stolen by a technician. According to media reports the carcasses were subsequently passed on to a butcher and processed into sausages for human consumption (45). The Food and Drug Administration have reported that 386 progeny of transgenic animals in the University of Illinois were sold into the feed chain (20). Due to an error in the identification of one sow, a transgenic pig was misidentified and included in this batch of 386; the other 385 apparently did not inherit the transgene and as a consequence it was assumed were not subject to regulatory oversight. Transgenic pig carcasses from a University of Guelph project ended up as chicken feed (2). The transgenic carcasses were apparently stored in a refrigerator at a university research station and were accidentally taken away for rendering as a result of a mix-up with other carcasses. These instances, though isolated, have been much publicised and are unlikely to engender public confidence in the technology. These incidents could arguably have been avoided or better managed through a more effective animal identification and traceability system.

From a slightly different perspective, if the labelling of products from animal biotechnology becomes necessary or desirable, whether for safety, nutritional, or other reasons, traceability will be essential to verify that products are labelled correctly. Moreover, organisations seeking to market animal products derived from biotechnology could use traceability as a tool to support marketing claims.

In their report on animal biotechnology, the National Academy of Sciences cited environmental issues as the greatest science-based concern associated with the technology (39). They identified two principal environmental risks: an invasion of new environments by biotech animals that displace other species through increased competition, and the introduction of maladapted 'Trojan genes' into wild populations through interbreeding with transgenics, leading to the extinction of both biotech animals and wild relatives. The detection of transgenic DNA sequences in some landraces of maize in Mexico, where no formal approval for transgenic maize has been given, clearly illustrates the potential for interbreeding to happen (11). Naturally, not all biotech species would present the same ecological risks. Those that are highly mobile, able to escape captivity and that can easily return to a wild state would present greater dangers (42). Mice, insects and fish would give cause for the greatest concern, while chickens, cows and pigs with lower mobility would be seen as of less concern.

The only way to ensure that biotech-derived animals will have no environmental impact is to make their escape or intentional release into the wild a complete impossibility, something which may be neither achievable or desirable. In the absence of this certainty, traceability provides a risk management tool, helping contain the scale and potential environmental impact of problems that may arise through intentional or unauthorised releases. The recent withdrawal of Coca-Cola's bottled water product, which was found to contain higher than permitted levels of the chemical bromate, serves to illustrate this point. Due to the implementation of a traceability system the recall of over half a million bottles in the UK took less than 24 hours, and resulted in much less damage to the company than a previous recall which had cost over US$100 million (19).

Closely related to risk characterisation is the issue of post-marketing surveillance, which can assist in ensuring the longer-term safety of biotech-derived products. Studies have shown that the level and specificity of transgene expression in animals is predictable only to a limited extent (27). Moreover, the lack of a single definitive assay to predict the allergenic potential of a protein limits pre-market evaluations of novel food products as a predictor of allergenicity (26). Post-release monitoring and general surveillance underpinned by traceability could form part of an overall risk management assessment to help ensure the longer-term safety of animal biotech products in the marketplace. A report by the National Academy of Sciences on the safety of genetically engineered foods indicated that 'given the possibility that food with unintended changes may enter the marketplace, despite premarket safety mechanisms', post-market surveillance of exposures and effects may be warranted, especially for foods with compositional changes (40). The report went on to recommend the improvement of traceability measures to assist in such post-market studies. In this context traceability would also be necessary to obtain population-level estimates of dietary exposure and/or nutritional consequences of animal biotech-derived foods. Finally, traceability can assist organisations that have invested heavily in the development of biotech-derived animals to protect intellectual property and ensure that only authorised organisations/individuals are using their technology.

In short, traceability of biotech-derived animals and animal products would benefit a number of different stakeholders, including consumers, regulatory bodies, the agri-biotech industry and livestock industries, as it would:

– help ensure public confidence in both the technology and the ability to regulate it effectively

– form the basis for a product labelling system, whether voluntary or mandatory

– assist in environmental monitoring and risk management

– assist in post-market surveillance, dietary exposure estimates and product recall

– enhance protection of intellectual property.

Characteristics of traceability systems

As the benefits of traceability are becoming clearer, there has been a huge increase in the number of concepts/systems developed, particularly in recent years. These concepts and systems have been promoted through both private and public sector initiatives and thus have sought to address different needs; not surprisingly, different concepts and technology solutions have therefore evolved. The basic characteristics of traceability systems are similar, requiring product identification, product tracking and the maintenance of information relating to the product and its movement. Yet there remains a lack of clear consensus as to how traceability is achieved in practice. For example, does traceability of a meat cut indicate an ability to trace it to the animal, farm, slaughter batch or processing batch of origin? All entail different levels of traceability.

The ISO 8402 standard defines traceability as 'the capacity for establishing a product's origin, process history, use and provenance by reference to written records' (28). However, like other traceability definitions, ISO 8402 does not define what parameters are to be measured or how history or origin should be determined. In a report on traceability systems, Golan *et al*. (23) outline three key parameters that can be used to characterise traceability systems, as follows:

– the breadth of a system: the amount of information recorded (e.g. details of an animal's veterinary care, feed regime, or pedigree)

– the depth of a system: how far back or forward the system tracks (to a grain elevator, farm or field); in many cases, the depth of a system is determined by its breadth or attributes of interest

– precision: the degree of assurance with which the tracing system can pinpoint the movement of a particular product, and is described with reference to an acceptable error rate, or what would happen if there were mistakes in tracking the product.

In practice the shape of any traceability system represents a dynamic interplay between costs and benefits, which are likely to be determined by the sector and specific supply chain needs.

As indicated above, the fundamentals of a traceability system require:

– the unique identification of the product (or batch) throughout its entire product history

– the collection of information on the product and its movements

– integrated information management.

The means of achieving these objectives can be as simple as giving a product a paper label and retaining paper records of its movements. In practice however, supply chains are growing in complexity, with multiple suppliers combining ingredients from different suppliers/countries and batch codes being generated as the product is processed along the value chain. Traceability in this context requires a more technology-enabled solution to facilitate accurate data capture, integration and management. In recent years a number of traceability guidelines and standards have been developed for different product categories within the agri-food industry (7, 8, 9, 16, 22). There are also a growing number of private-sector technology vendors who have developed the systems architecture and interfaces, either stand-alone or web-enabled, to facilitate data capture management and use. A number of such systems were featured at a meeting on animal identification hosted by the National Institute for Animal Agriculture in the USA (38).

Product identification

A key feature of any traceability system is the ability to clearly identify that which is to be traced. Ideally the product identifier should:

– uniquely identify the unit or batch
– be secure (fraud proof)
– be permanent
– retain identity throughout the product life-cycle
– be simple to read and capture identifying data
– not hinder its host.

In practice no single identification system is likely to meet all of these requirements and the choice of method(s) will ultimately be determined by the specific needs of the supply chain in question.

In general terms, two types of product identifier can be distinguished: external identifiers, and biometric identifiers that are integral to the animal or product. External types include both manual methods such as paper labels, ink brands (tattoos) and plastic ear tags, and electronic methods such as Radio Frequency Identification (RFID) tags and injectable microchips. The key advantage of these approaches lies in their ability to encode different types of information (barcode symbologies can contain information relating to the product and its process history), and the relative ease with which the data can be read, particularly from electronic identifiers. Data can thus be read in real-time, facilitating the use of electronic identifiers for monitoring animal movements.

The principal drawback of external identifiers is that they have to be applied to the animal/product and can become unwieldy to implement in more complex supply chains. For example, maintaining individual animal traceability within a meat processing environment could lead to a proliferation of labels to track all the pieces of an animal post slaughter. But possibly of greater concern is that the fact that external identifiers may become separated from the product through tag/label loss or removal, and are susceptible to fraud. A report commissioned following an outbreak of foot and mouth disease in the Irish Republic found that, despite an officially mandated traceability system for animal movement between jurisdictions, 'it was recognised that tags were often removed to facilitate free movement [of animals] within the island, between the Republic and Northern Ireland' (10). Similar difficulties have more recently been encountered in Japan (25). Within the meat processing sector, a EU report found that through the use of a conventional meat labelling system 'in many member states serious deficiencies were found in the ability to traceback meat from retail and distribution centres, even to the preceding stage of the production chain' (17).

Biometric labelling systems incorporate biological data and cannot easily be faked, altered or appropriated. Technologies here include DNA profiling, retinal scanning and nose printing. In addition to being less prone to error or fraud, these labelling methods are permanent, covering the life history of the animal, and in the case of DNA the full product life history (except in products where the DNA is removed or destroyed). However, one of the drawbacks of biometric identifiers is that they are typically non-visible and require specialised technology to read, e.g. DNA cannot be read in real-time using current technology, but must be read retrospectively following analysis in a laboratory. Notwithstanding these drawbacks, biometric identifiers, and DNA in particular, show considerable promise for the identification and traceability of biotech-derived animals, particularly given the nature of the animals/by-products and their associated risks. In the following sections the potential of DNA-based traceability will be further explored as the foundation for a risk management and traceability system.

DNA-based traceability

The basic principle underpinning DNA-based traceability is that each animal (excluding identical twins) is genetically unique and that the animal's own DNA code can be used to identify it and products derived from it. In simple terms, the product acts as its own label. Use of this form of identification has a number of distinct advantages. The code is permanent, unique to the individual (except in the case of identical twins) and remains intact throughout the life history of the animal or product. As a consequence there is no requirement to establish an external product labelling system. DNA taken from any point along the production chain can be matched with the history of the animal, providing the foundation for an individual animal traceability system.

In practice, implementation of DNA-based traceability requires the collection of DNA samples (reference samples) from animals/carcasses to enable the DNA code to be read. Samples can either be archived for subsequent analysis, or analysed and the resultant DNA profiles stored in a database along with information on animal origins. Storing samples or their associated DNA profiles does not in itself constitute a traceability system, rather it provides traceback capability, which could potentially be used to locate the source of a product should a particular need arise; this model has become popular within the Australian beef industry (34). DNA traceability is effected through combining reference sampling with DNA sampling at a further point in the supply chain: verification sampling.

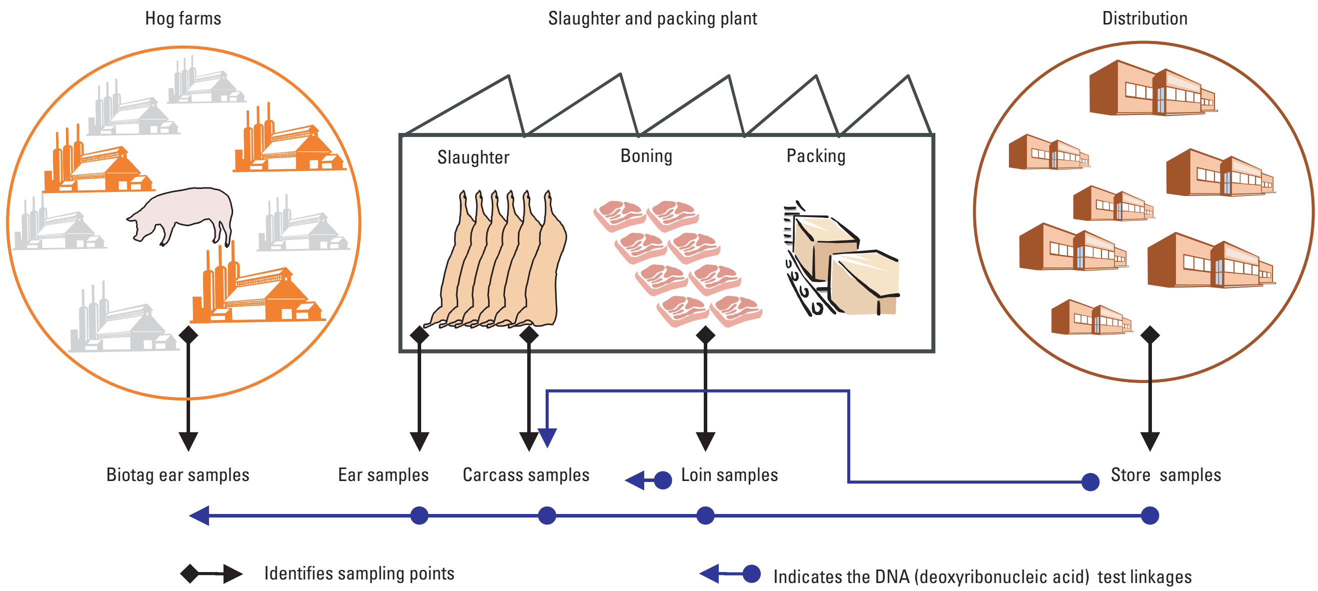

Fig. 1
Description of sampling and product tracing system for hog production

Both reference and verification samples are DNA profiled and compared to determine the source of a particular cut of meat. Figure 1 outlines a multi-stage sampling approach within the hog industry. Here samples were collected at different stages along the chain as part of a pilot supply-chain audit carried out by the Canadian Food Inspection Agency in conjunction with IdentiGEN (37). Such a structured approach can be used to trace products between pre-determined points in the chain and helps identify the source of any breakdowns in product traceability. Once problems are identified and resolved, a less intensive sampling programme can be used to act as the basis for ongoing monitoring of the chain.

The ability of DNA-based systems to span the full supply chain, the absence of associated capital infrastructure, and the capacity of these systems to trace products only when required, are leading to the broader uptake of this technology approach. A food processing company in Canada recently announced its intention to implement a DNA traceability system for its fresh pork (35). The Japanese government have also indicated that they intend to use DNA technology as a means of monitoring the efficacy of beef labelling (4). The Japanese meat industry suffered a serious crisis of confidence following revelations of widespread meat mis-labelling (3).

In some European markets, a routine programme of verification sampling and DNA analysis/matching is used to continuously monitor the ability of a supply chain to provide traceable products. This approach has been used in Ireland and the UK since the late 1990s and is marketed as a means of reassuring consumers as to the safety and quality of fresh beef (41). The graph in Figure 2 describes a data set that has been generated through the implementation of DNA-based traceability within the beef industry in the EU (courtesy IdentiGEN Ltd). It describes the proportion of meat products that were successfully linked back to a source carcass through a comparison of DNA profiles of the products with the DNA profiles of animals from their stated batch of origin, as determined by the batch code on the retail meat pack (within the EU, regulation 1760/00 stipulates that all meat sold at retail must have a batch code which indicates the animal or group of animals from which it came) (12). The data clearly show that in the early stages of implementation of DNA tracing, significant levels of error are apparent in the labelling system; in other words, it is not possible in all cases to correctly match meat cuts with their animal of origin as specified by their batch code. However, once the system is fully implemented, errors become transparent and can be quite quickly corrected and removed to yield good correlation between label and product (DNA) traceability. A further feature of the data indicates that continuous monitoring over time can reveal occasional breakdowns in the labelling system, breakdowns that would not be apparent in the absence of a DNA tracing system.

The precision of a traceability system is a function of the tracking units used and an acceptable error rate (23). The data presented in Figure 2 indicate that conventional labelling systems operating in an industrial environment can harbour significant levels of error. Since the risks posed by the unauthorised use or release of biotech-derived animals are arguably significant, only a low error rate should or would be acceptable, especially in the early stages of commercialisation. This view is supported by Kok and Jones (32), who propose that in specific cases it may be necessary to 'include in the label the unique identifier code specific for a single founder animal and its offspring'. Implementation of a DNA traceability system for biotech-derived animals, in addition to providing a very precise system, would act as the foundation for product traceback to the individual animal of origin. Furthermore, as DNA can be found in many – if not most – animal-derived products, the system could also be used to trace many of the by-products of animal biotechnology through the full life-cycles of the products. Species-specific DNA marker panels for individual identification could easily be developed and made available in the public domain for such purposes. The nomination of marker sets for pedigree analysis by the International Society for Animal Genetics represents an example of this approach.

As well as providing a method of individual animal identification, developing a DNA traceability infrastructure would also offer the possibility of checking for the presence of specific genetic modifications in animals or their by-products, offering a means of product authentication. Unlike the DNA traceability systems described above, this would require a knowledge of the DNA sequences engineered into a transgenic animal in order to design tests to detect the modified DNA. This approach has been well documented as a means of detecting GM plants and is reviewed in detail elsewhere (5). While some commentators have described the approach as a DNA traceability system, the author would like to distinguish it from the DNA traceability concept described above in which individual animals are traced, irrespective of the way in which they have been engineered or modified. When the 'tracking unit' used is the actual genetic modification rather than the animal, little or no information is provided on the individual animal of origin, and this type of approach, therefore, provides less precise

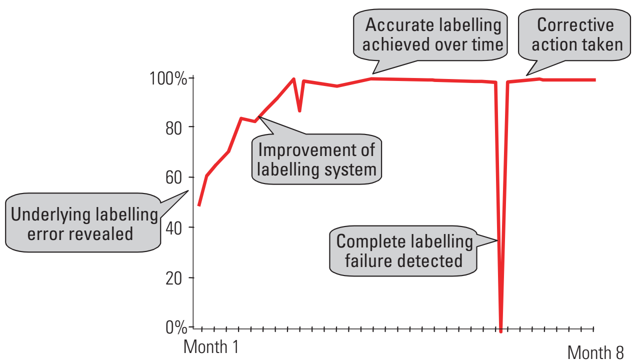

Fig. 2
Sample data from the implementation of a deoxyribonucleic acid traceability system within the European Union (EU)
The graph line indicates the proportion of meat cuts correctly matched with an animal of origin using the batch code data required for retail meat cuts within the EU

traceability. The added precision of the methods that trace individual animals rather than a genetic modification could be important where concerns arise relating to a particular population or strain of transgenic animals, or when a transformation event is licensed to a number of different developers. Such a system would enable tracing back to individuals or groups of individuals rather than all animals engineered with the transformation event.

A further benefit of tracing animals through their individual DNA code is that this approach should work equally well for inter-specific hybrids, animals derived from *in vitro* cultivation and chimeras, all of which are genetically unique at the individual level but may or may not incorporate a genetic modification. With particular reference to animal clones, more research will need to be carried to ascertain if there are sufficient genetic differences among them to make an approach based on the DNA of individual animals appropriate for tracking clones (15). Also, for certain species such as insects where the numbers of individuals are likely to be relatively large, the benefits of individual over group identification would need to be weighed against costs and feasibility. For such species the use of population-based DNA markers or incorporation of a DNA tag during animal development could act as the basis for group, rather than individual, identification.

Finally, in reviewing DNA-based traceability approaches it is important to note that, like any technology, DNA has its limitations. Principal amongst these is the inability to read the DNA code in real time, a key requirement for trace-forward applications and the monitoring of product movements. Furthermore, certain product categories such as highly purified therapeutic proteins or fats derived from a transgenic animal may have all their DNA destroyed or removed, making identification by DNA impossible. Depending on the application in question, the integration of DNA with other identification technologies such as RFID could be used for both tracking and tracing applications so as to provide the most comprehensive traceability solution.

The technology

Underpinning DNA-based traceability concepts are a number of key technologies, most notably DNA sampling and DNA analysis. These are integrated through information technology (IT) infrastructures which can store product-related information (e.g. the type of modification, source herd, feeding regime and process history) and incorporate data algorithms to make possible the matching of animal products with source animals.

Samples of DNA can in theory be collected from any biological tissue. In practice the DNA sampling function should be cheap and relatively easy to perform, and should produce samples in a format suitable for laboratory analysis. There have been a number of innovations in the area of DNA sampling, most notably the combination of live animal identification (ear tagging) with sampling through DNA-sampling ear tags (6). Additionally, systems are being developed which enable the integration of low-cost DNA sampling with conventional abattoir infrastructures to facilitate sample collection in modern industrial-scale slaughter plants.

Probably the most critical technological developments leading to the uptake of DNA tracing concepts relate to DNA analysis technology; for a review of the relative merits of different DNA markers the reader is referred elsewhere (44). DNA identification or 'fingerprinting' technology was first developed in the mid-1980s, when it was discovered that DNA digested by site-specific cutting enzymes revealed DNA fragment patterns (profiles) specific to the individual (29). The DNA markers targeted for this purpose were termed mini-satellites and produced complex banding patterns that could be interpreted only by the trained eye. In the late 1980s, following the development of polymerase chain reaction (PCR) technology, a newer and simpler type of DNA marker was discovered: microsatellites. Microsatellites were found to occur more frequently in the genome and were easier to analyse and interpret, heralding a new era in DNA identification. However, both minisatellite and microsatellite markers have some drawbacks. The basis for their genetic variation – and consequently their inheritance patterns – is not fully understood, creating potential anomalies in data interpretation. More importantly though, these markers can be difficult to score and are not amenable to automation (44). Despite this, microsatellites remain in widespread use; the adoption of these markers as the basis for forensic DNA analysis in many countries and the potentially large number of genetic variants (alleles) at any particular microsatellite locus make microsatellites attractive for identification purposes.

Single nucleotide polymorphisms (SNPs) represent the simplest type of genetic marker. As their name suggests, SNPs refer to genetic variation at the lowest possible level: the single base or nucleotide. As a result, the amount of genetic variation in each such unit is limited. In contrast to microsatellites with numerous alleles, SNPs typically have only two alleles. This makes SNPs much less powerful for identification purposes but much more amenable to automation and high-throughput screening. Each of the principal livestock species has literally millions of SNPs, although in practice relatively few are required for identity purposes. Key innovations in terms of how SNPs are detected (assay chemistries) and the platforms on which they are detected are leading to significant cost reductions and capacity increases in their analysis. (For a more detailed review of developments in this field see Jenkins and Gibson, Kwok, and Vignal *et al.* [30, 33, 44].) As a consequence, SNPs are increasingly becoming the DNA markers of choice for high-throughput identity applications.

With respect to the actual detection of these marker systems, a key feature of the DNA traceability application is the ability to screen relatively large numbers of individuals with a relatively small number of SNP markers – typically 30 to 50. Consequently, platforms that integrate multiple high-throughput approaches for sample handling, DNA preparation and DNA analysis are more suitable for this application than platforms with large parallel processing power, where the focus is on detecting large numbers of SNP markers from fewer individuals (24). Within the IT sector, Moore's law predicts a doubling of micro-processing power every two years. Similar rates of improvement are being seen in relation to SNP genotyping, ultimately reducing the costs of DNA traceability; current platforms are capable of conducting 500,000 analyses per day at approximately 7c to 10c for DNA traceability applications.

Concluding remarks

Traceability is increasingly recognised as a key risk mitigation and management tool, as well as a critical component of quality assurance in the agri-food industry. Within the livestock sector, animal identification – a key requirement for traceability – is becoming mandatory in many regions of the world. Such developments are not only helping to drive improvements in traceability technologies but are leading to more cost-effective solutions and ultimately to a broader uptake of traceability systems. Animal biotechnology, although still in its infancy, can readily benefit from such developments. Like any technological innovation, animal biotechnology has the potential for harm as well as for significant good. Experience with GM plants has shown that public confidence in both the technology and its regulation will be critical if animal biotechnology is to realise its potential. Furthermore, consumer surveys have indicated that greater levels of public concern are likely to be associated with the development of animals derived from biotechnology than plants. In this context, full traceability of biotech-derived animals can help assure the public that any problems that may arise can be quickly and effectively managed. The implementation of a comprehensive traceability system could also facilitate post-market surveillance programmes, ensuring the longer-term safety of animal biotech products, and support voluntary and/or mandatory labelling claims.

In evaluating alternative traceability solutions, a number of issues need to be considered. Biotech-derived animals, which are likely to cover the full range of risk profiles from the low to higher-risk animals, will be developed in a variety of different production systems and by means of widely differing methodologies. As a consequence, no 'one size fits all' traceability approach is likely to be appropriate for all such animals, or command the support of all stakeholders. The configuration of a system will inevitably represent a trade-off between costs and benefits, and will need to be matched to particular supply chain needs. Notwithstanding this diversity, a core requirement for any traceability system is an ability to identify that which is to be traced.

In this context DNA has many strengths; it is unique to the individual and creates a means of permanent identification throughout the life cycle of the animals and, in many cases, of their by-products. DNA traceability infrastructure could be used to check for the presence of a particular genetic modification. The risks posed by the unauthorised use or release of biotech-derived animals dictate that only a very accurate and precise product identifier would be appropriate. Experience with conventional or external product identifiers has demonstrated that they are prone to error and fraud, which may not always be apparent. Through tracing animals/products by their DNA code rather than an associated tag/label, this difficulty can be overcome.

The uptake of DNA-based traceability concepts in the agri-food industry is leading to improvements in the technology. There are now a variety of means to capture DNA samples within conventional agricultural systems, and the costs and turnaround times associated with DNA identification are improving. The technology exists today to DNA sample biotech-derived animals cost-effectively on a large scale, particularly for the larger livestock species, and to have individual DNA profiles stored in databanks and available for cross-checking. Such an approach would help create a unique and permanent record of these animals and create the necessary infrastructure to facilitate the rapid and precise tracing of their by-products. This capability would not only provide an unprecedented level of traceability but would undoubtly contribute towards greater levels of public confidence in animal biotechnology.

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Traçabilité des animaux issus des biotechnologies : application des technologies utilisant l'ADN

R. Loftus

Résumé

La traçabilité devient aujourd'hui une démarche courante de l'industrie agroalimentaire, en grande partie à la suite des crises alimentaires récentes et des demandes de transparence relatives à l'ensemble de la chaîne alimentaire. Cet état de fait conduit au développement d'une série de concepts et de techniques de traçabilité adaptés aux différents besoins de l'industrie. L'expérience enregistrée avec les plantes génétiquement modifiées a montré que la traçabilité peut contribuer à améliorer la confiance du public dans les biotechnologies et pourrait aussi permettre de répondre en partie aux craintes nées du développement des biotechnologies animales. La traçabilité est également une composante essentielle de toute stratégie de gestion des risques et un élément clé de la surveillance des produits commercialisés.

Compte tenu de la diversité des concepts et technologies de traçabilité disponibles, une grande attention doit être portée à l'étendue et à la précision des systèmes de traçabilité appliqués aux biotechnologies animales. L'expérience enregistrée à ce jour a montré que les systèmes classiques de marquage peuvent comporter un certain niveau d'erreurs et ne sont pas toujours suffisamment précis pour les animaux issus des biotechnologies. Les techniques reposant sur l'acide désoxyribonucléique (ADN) permettent de vaincre ces difficultés puisque les animaux et les produits sont suivis grâce à leur code ADN et non à une étiquette. Pour certains produits issus des biotechnologies, cette approche permet de remonter aux animaux tout au long de la chaîne commerciale, offrant ainsi un niveau de traçabilité sans précédent. Les développements des techniques de prélèvement et d'analyse de l'ADN rendent de plus en plus accessibles et maniables les applications à grande échelle reposant sur la traçabilité par l'ADN et pourraient conduire à une plus large utilisation de ces concepts.

Mots-clés
Gestion des risques – Identification des animaux – Identification des produits – Identification par l'ADN – Surveillance des produits commercialisés – Traçabilité – Traçage des animaux.

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Aplicación de la tecnología de ADN a la trazabilidad de animales obtenidos por medios biotecnológicos

R. Loftus

Resumen
La trazabilidad está adquiriendo carta de naturaleza en todos los sectores de la industria agroalimentaria, a resultas en gran parte de las últimas crisis ligadas a los alimentos y la consiguiente demanda de transparencia en la cadena alimentaria. De ahí que estén surgiendo una serie de técnicas y conceptos en la materia adaptados a distintas necesidades del sector. La experiencia con plantas modificadas genéticamente demuestra que la trazabilidad puede ser útil para reforzar la confianza del público en la biotecnología y quizá también, de forma análoga, para disipar las inquietudes ligadas al desarrollo de la biotecnología aplicada a los animales. Por lo demás, la trazabilidad es también un componente esencial de cualquier estrategia de gestión de riesgos y un requisito básico para la vigilancia posterior a la comercialización de un producto.

Dada la heterogeneidad de conceptos y técnicas existentes en este terreno, es preciso tener en cuenta el alcance y la precisión de los sistemas de trazabilidad que se apliquen a la biotecnología animal. La experiencia ha demostrado que los sistemas convencionales de uso de crotales y etiquetas conllevan cierto grado de error y quizá carezcan de la precisión suficiente para el caso de animales obtenidos por medios biotecnológicos. La tecnología del ácido desoxirribonucleico (ADN) puede ayudar a salvar estas dificultades porque permite identificar a los animales y sus derivados gracias a su secuencia de ADN y no a una etiqueta asociada. Ello abre la posibilidad de seguir las trazas de algunos derivados de animales obtenidos por biotecnología a lo largo de la cadena de aprovisionamiento, ascendiendo por ésta hasta llegar al animal de origen, lo que proporciona niveles sin precedentes de trazabilidad. El progreso de las técnicas de obtención de muestras y análisis de ADN hace que la aplicación a gran escala de la trazabilidad de este ácido nucleico sea cada vez más rentable y factible, y probablemente suscitará un creciente interés por los conceptos asociados a esta técnica.

Palabras clave
Gestión de riesgos – Identificación por ácido desoxirribonucleico – Identificación de animales – Identificación de productos – Rastreo de animales – Trazabilidad – Vigilancia tras la comercialización.

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