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Food Ethics, Traceability and the Regulatory State: Private Governance and Civil Society Trajectories

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Introduction

The agri-food sector has undergone both rapid public regulation and private standards setting in the past two decades engendering new forms of governance of food supply chains. Food safety has been at the forefront of these reforms, but increasingly food standards reflect a range of ethical concerns about food production and supply. The communication of standards with ethical implications to consumers relies upon labelling and marketing but is underpinned by schemes of certification and audit, which in turn entail effective systems of traceability of food products. Traceability reaches from food production and movement through the supply chain to the form of the food's consumption. A feature of contemporary governing has been the development of the regulatory state, where the state seeks to widen and lengthen its governing reach through steering and utilising private forms of governance. The regulatory state directs the private sector to effectively self-regulate food supply chains within legally required standards; but this process of governance can be a contest of differing values. At the European level, the revision of European Union (EU) food law (EC 178/2002) has put traceability at the centre of its reform of the governance of supply chains.

The promotion of ethical concerns around food standards has emerged from private governance sources – notably civil society based organisations who have sought to promote both particularistic and broader concerns around food production from animal welfare to fair trade. In the corporate sector both manufacturers and retailers, have taken up a wide range of standards and certification schemes which cover ethical as well as other concerns: from integrated farming processes to food assurance schemes to local food provenance schemes. The unfolding scope and nature of ethical concerns around food are explained below. The role of civil society organisations in promoting new standards for food incorporating ethical criteria points to the inter-relationships of the state (including the EU) with the corporate sector and civil society organisations in the unfolding regulation and governance of food supply chains. These regulatory and governance trajectories are examined in more detail to illustrate the different roles that food traceability is being asked to underpin. Amongst these roles, the EU's sustainability goals for the agri-food sector inter-relate with ethically informed regulations. Yet such is the dynamic and unfolding nature of these trajectories that public regulation can lag behind the private governance initiatives. The different roles that traceability as a policy and governance instrument is being called upon to deliver are dynamic and unfolding. There is an increasing traceability burden and so challenges for both public regulators and private managers of food supply chains.

The regulatory state and agri-food governance

The concept of governing depicts a command and control approach to law making and enforcement from the national state which in modern times has been underpinned by the state's successful claim to political legitimacy. In the past three decades, at least in the countries of Western Europe and other advanced (or post) industrial democracies, the state has lessened its control and command over economic sectors on the one hand, while on the other, it has sought to extend its regulatory and strategic reach, partly achieved through new governance forms (Pierre, 2000; Pierre and Peters, 2000). In this context governance implies more indirect and softer forms of direction from the state than command and control, and reflects collaborative outcomes, involving a wide range of actors often from the private sector as well as from government bureaucracy. The evolution of such governance forms reflects the spread of the new public management credo of government and public administration focusing more effort on steering rather than rowing the ship of state and public policy; in turn, diversifying the range of service providers and the criteria for efficient public services. The growth of this state direction has been witnessed also at the European Union level, and has been characterised as the development of the regulatory state (Majone, 1996; Moran, 2003). Regulatory policies, unlike the other types, potentially transfer the bulk of the economic costs to the regulated, while extending and enhancing the reach and influence of the state and its officials (Majone, 1996; Moran, 2003). The alternative types of policy are distributive or redistributive policies (Lowi 1972). Distributive policies allocate resources to actors or groups in society, such as subsidies for farmers; redistributive policies that take resources away form some sectors and re-allocate them to others, such as with taxation and social welfare. The governance forms associated with the regulatory state illustrate the extent to which policy is conducted away from the more immediate environment of the state or is emerging beyond the state.

Michael Power (1997) in his examination of the audit society identified some of the governance forms that have emerged: "Instead of regulation seeking to penetrate organizational culture from the outside, the image proffered is more that of a form of self control embodied in quality control systems" (Power 1997: 62). For Power, the delegation of regulatory control helps solve legitimacy problems for the state and enhances compliance "but the state remains an important sponsor of private interest regulation" (Power 1997: 67). In this way, there is a bridging or indeed a virtual dissolution of the public-private governance divide. The state is able to devolve responsibility and the bulk of the work of governance to industry, or other non governmental actors, including much of the auditing task. This does raise questions as to how well such arrangements address the public interest as opposed to the needs of private sector interests. The concept of private interest government (Streeck & Schmitter 1985) has been applied to the agrifood sector (Grant 1995) and applied to the new forms of

governance arising out of food safety regulation in the UK (Flynn et al 1999). In the case of food safety the state has triggered the private sector response by making the supply chain responsible for food safety through the 'due diligence' requirement – first introduced by the UK under the 1990 Food Safety Act. This stimulated a range of private governance initiatives from different parts of the supply chain – in the form of producer led and retailer led food assurance schemes and new food safety standards. Retailer led standards reached back down along the supply chains and some have became international in scope reflecting the diversity of food sourcing. A prime UK led example of an international standards scheme included the British Retail Consortium's Global Food Standard which was a comprehensive set of standards covering hygiene in food factories which met the basic requirements of all the major retailers. Another was the European Retail Retailer Produce Working Group (EUREP) and their Good Agricultural Practice

(GAP) scheme subsequently renamed GLOBALGAP. Probably, the most significant of the retailer led bodies in terms of recognising audit systems is the Global Food Safety Initiative (GFSI). Similarly the food manufacturers have become responsive to their own sourcing of food commodities and set up schemes such the Sustainable Agricultural Initiative (SAI) under Unilever, Danone and Nestle in 2002.

In the case of the UK, the introduction of due diligence stimulated industry collaboration along commodity supply chains in animal meat products and combinable crops in the form of assurance schemes. The schemes were designed to ensure that the farming and food and related industries (such as transportation) could exhibit the existence of systems of due diligence over food safety and hygiene (including HACCP protocols). Many of these schemes were producer led. The National Farmers Union (NFU), the main farming employer organisation, developed a common system and a label for farmer-producer led assurance schemes which the UK government endorsed. The scheme evolved into the Assured Food Standards (AFS) when it was required on a recommendation of a Government sponsored Commission to incorporate a wider range of stakeholder organisations from along the food supply chain. The scheme came to embrace over 78,000 farmers under its little red tractor label and a large majority of the main commodities produced in the UK. Further recognition from the state for the AFS came from the UK Food Standards Agency (FSA), who conferred further legitimacy under the implementation arrangements of the EU General Hygiene Regulations in 2007 which took food hygiene requirements right back onto the farm. Under the agreed terms of implementation only 2% of farms would be audited by local government inspectors as against 25% of non scheme farms a process of "earned recognition" (Kirk-Wilson 2008). In effect the AFS is providing a private based form of co-regulation for the UK State.

However, the AFS underwent a long period of examination and review before it reached this co-regulation status. Critiques of the scheme came from government bodies and from NGOs. These include criticisms of the lack of consumer consultation in setting standards, lack of robust environmental criteria, insufficient standards of animal welfare, lack of clarity around national origin of produce and lack of ownership by the wider supply chain (this last aspect was addressed by the scheme). The challenges to the workings of the AFS illustrate a contested process based upon on both a widening and more demanding levels of the criteria upon which assurance schemes should be based. The demands go beyond food safety and hygiene and reflect the wider sets of values emerging from both governmental, industry and civil society stakeholders in relation to food standards.

The European Union, the regulation of food standards and public confidence

The EU embarked on a major reform of its regulation of food safety and its food law from the mid to late 1990s, in an effort to ensure a safer and more trustworthy food supply after the political fall-out from the spread of BSE and infected products across the continent. The EU's regulation of food has been driven to varying degrees by the need to integrate the European market, from agricultural production subsidy and production management controls, to the harmonization of food standards around the principle of mutual recognition, to food safety and hygiene standards. In the case of BSE, the management of the single market was seen to have failed. The European Parliament found the Commission guilty of serious maladministration and threatened to censure the Commission should it fail to act. Responding in 1997 the European Commissioner Jacques Santer acknowledged shortcomings in the protection of consumer health and promised radical reform of the Commission's machinery. He called for "nothing short of a revolution in our way of looking at food and agriculture" (Santer, 1997).

The rise of public concerns over food safety resulted in a period of 'contested governance', signaling 'a pervasive sense of distrust that challenges the legitimacy of existing institutional arrangements' (Ansell and Vogel, 2006: 10). This distrust went beyond policy disagreement to embrace deeper concerns about the ability of the prevailing institutions and processes to manage risk in the food supply. This contested governance over food safety coincided with a more general review by the EU of its governance arrangements, and the reform efforts around food safety became tied up in the EU's political efforts to renew its legitimacy in the eyes of the European publics (Arienzo et al 2008). The food safety focus led to a reform of the EU's risk analysis institutions for food safety and the European Commission's responsibilities around food law, with a revision of the general principles of food law. In short, the reforms for food safety were part of a wider political management effort to rebuild both consumer and citizen trust in the European institutions and processes for the longer term.

After the collapse of the Santer Commission in 1999, due to another political scandal, the new Prodi Commission kept food safety as a priority and furthered the reform process, including a reorganization of the Commission's Directorates General (DGs). The Consumer Protection DG was renamed the Health and Consumer Protection DG (SANCO), taking over food safety and food law policy-making responsibilities, which had been previously housed in the DGs for Industry and Agriculture respectively. In other words, the DGs responsible for promoting the agricultural and food industries lost their regulatory responsibilities in these areas; these responsibilities were moved to a new DG oriented towards consumer safety and public health. This was a potentially important departure in policy-making focus. The White Paper on Food Safety released early in 2000 spelled out more clearly a wide-ranging consolidation and revision of European food law (CEC, 2000). It also proposed the creation of new European Food Authority which became the European Food Safety Authority (EFSA), established by a further regulation in January 2002, heralding the birth of the Authority in 2003. The importance given by the Prodi Commission to food safety reform was underpinned by continuing food scandals and controversies (e.g. dioxin contamination and GM foods). This institutional reorganization and renewed legislative agenda can be seen more broadly as part of a strategy by the Commission to restore citizens' confidence in the safety of the food supply in the EU, and to retain the legitimacy of the EU and the single market through the provision of safe food. As the European Commissioners Fischler (Agriculture) and Byrne (Health and Consumer Protection) stressed in a joint statement: "The real issue here is one of consumer confidence in the ability of the whole food chain, including public regulators, to satisfy public demand for safe quality food" (European Commission, 2002).

The linking of the regulation of agriculture and food production (regulatory policy) to the distribution of supports (distributive policy) for farming was made with the 2003 reforms of the Common Agricultural Policy (CAP) with the introduction of cross compliance (EU Regulation 1782/2003). In order to receive the Single Payment Scheme (SPS) recipients have to keep their agricultural land in 'Good Agricultural and Environmental Condition' which are broadly defined standards which are developed at Member State level. Also, importantly, farmers have to observe certain standards in the areas of the environment, public, animal and plant health and animal welfare as laid out in nineteen Statutory Management Requirements based on existing EU legislative requirements. Under the 2008 Health Check of the CAP, the European Commission stated that cross compliance is, and will remain, an essential element of the CAP with "two stated objectives: firstly, to contribute to the development of sustainable agriculture; and, secondly, to make the CAP more compatible with the expectations of society at large" (Defra 2008).

The European Commission's ambitions to use regulatory compliance to enhance both the public approval of farm supports and to contribute to sustainability policy goals are also depicted in terms of market value. Addressing a meeting on Food Ethics and Traceability the Agriculture Commissioner Mariann Fischer Boel (2008) incorporated the concerns around food ethics under the aims of quality food production.

"When applied to food and drink, the term 'quality' means different things to different people. It can certainly carry 'ethical' connotations - telling consumers about production methods and a product's relationship to animal welfare and the environment. It can refer to geographical origin. And of course, it can refer to that specific tang of a good cheese, or the way in which a good red wine goes down so smoothly. It's essential for us to know what qualities consumers are looking for in food, and which ones will persuade them to pay higher prices..."

Furthermore she made it clear that the in order to receive the Single Farm Payment under the 2003 CAP reforms:

"farmers do not have to farm a given product. Instead, they must meet high standards of environmentally friendly land management, animal welfare and public health. ... Obviously, this is a very strong incentive for more 'ethical' farming. Another effect of the new system is that farmers have much greater freedom to focus on product quality." According to the Agriculture Commissioner's assessment, consumers' desires for food quality incorporate a range of ethical concerns. This raises questions about what is meant by ethics and the scope and nature of ethical concerns around food.

Ethical concerns and food production and supply

Ethical concerns around food arise about the morality of the workings of food production and food supply systems through to consumption and their after-effects. Any human intervention has the potential to give rise to ethical concerns; to impact upon others which may include humans but also other living things and so food ethics can cover a wide range of issues. Ethics involve subjective as well as objective judgements as they can reflect differing combinations of values when applied to practical situations. The focus here is upon the types of ethical concerns that have arisen over the food production and supply chain systems. A recent comparative European study of ethical dimensions which sought to identify the extent and forms in which they arose in different commodity to food supply chains drew up a potential range of ethical concerns (Coff et al 2008). Table 1 identifies and categorises ten broad potential ethical concerns relevant to food production. This was not a closed list, indeed it remained open to include any new or unforeseen concerns that arose from the supply chains studied. Food ethics are dynamic in their nature and new ethical concerns may arise. Certainly the list would have been both different and shorter had it been drawn up twenty years or thirty years previously.

Table 1. 10 ethical concerns relevant to food production and supply (source: Coff et al 2008)

Substantive based concerns:

- 1. Animal welfare
- 2. Human health (impact of products upon human health link to food safety and hygiene animal disease working conditions etc.)
- 3. Methods of production and processing and their impact (e.g., environmental and natural resource impacts, conservation impacts landscape, links to animal

welfare)

- 4. Terms of trade (fair price for producers; fair trade etc.)
- 5. Working conditions (e.g. labour standards)
- 6. Quality (intrinsic qualities of products such as taste, composition, etc.)
- 7. Origin and place

Procedural based concerns:

- 8. Trust
- 9. Voice (participation)
- 10. Transparency

The ten identified concerns can be divided into broad two categories. The first seven ethical concerns can be categorised as substantive concerns. These are concerns that relate directly to the consequences of production practices or to the consequences or impacts of food consumption, for instance human health and food quality. They are specific to the particular food product. Inevitably, in any such attempt at typology there are some possible overlaps and clear interrelationships between these concerns as table 1 indicates. For example, 'working conditions' can relate to 'terms of trade'. Equally, 'origin and place' may be linked to concerns around 'working conditions', such as with food from developing countries. Similarly, taste can relate to methods of production, as can animal welfare. Methods of production can relate to 'origin and place' as with the Protected Designation of Origin(PDO). Furthermore, each concern may embody more than ethics. For instance, 'origin and place' may not necessarily be an ethical parameter, but people make a lot of associations with origin and place that involve ethical judgements.

In the second category are the procedural concerns - the last three ethical issues listed. These concerns involve processes of participation and responsiveness in imparting and informing about the characteristics of food products and the ways in which they have been produced and traded and their potential impacts. The procedural concerns cut across the various substantive concerns, or are of a horizontal nature. They are about access to and availability of information, the reliability of information, and the opportunity for both consumers and citizens to have a voice on the substantive concerns. Certification schemes and the standards that they validate underpin these narratives and information around labelling and marketing. Also, trust is a complex concern that seems to be interlinked with the other procedural concerns of transparency, voice and participation. The public's trust in food may be conditioned by combinations of the substantive concerns being addressed but may also rely upon one or more of the other procedural concerns being met, such as transparency. In turn, trust may be engendered through the interplay of the procedural dimensions with the bearers or choice editors of the messages around

food (Kjaernes et al., 2007; Sustainable Consumption Roundtable, 2007). Consequently, trust may embrace both substantive and procedural concerns.

The ethical concerns identified above were depicted as covering consumers' concerns about food production and supply. However, the depiction of the public's ethical concerns about food is also a reflection of their concerns as citizens as well consumers. As a result civil society organisations have sought to promote their issue concerns through market based schemes of certification and labelling. The concept of moral economy, as opposed to more purely commercial economy, has been applied to public orientations to food and its production (e.g. Morgan et al 2006). Such concerns also link to the public as citizens and the use of political voice. Civil Society organisations act as agents for public concerns to be voiced and to be translated into standards, in turn allowing the citizen to use their voice as a consumer to respond (Barnett et al 2005). The insertion into the market place of food standards derived from civil society organisations' prompting has lead to the development of some high profile schemes based upon ethical concerns. These have included: environmental and integrated farming systems (Organic Farming), working and labour conditions (the Ethical Trading Initiative), animal welfare (Freedom Foods), terms of trade (Fair Trade), and conservation of natural resources (Marine Stewardship Council).

In the latter case, the Marine Stewardship Council was an idea instigated by Unilever and developed as a certification scheme by the international conservation body WWF in partnership with the company. The Ethical Trading Initiative arose form NGO pressure on retailers and was taken up very quickly by a selection of retail corporations and after ten years sees itself as a tripartite alliance of labour organisations, NGOs and companies. In the case of civil society based initiatives such as ethical trading, marine stewardship and animal welfare - the NGOs are holding corporations to account in the absence of any state action or as an attempt to raise standards above minimal state based interventions - acting as what has "accountability entrepreneurs" (Koenig-Archibugi 2005). In turn, such civil society instigated standards may see the state intervene as with the organic movement which has had its standards recognised and taken over by state and EU regulation reflecting its growing market presence. The corporate sector has led the way in the private development and governance of food standards, as explained above. However, the ethical concerns around food have had their origins more clearly in civil society based organisations. What is clear is that these ethical concerns add to the load upon the market based systems of certification and labelling. Similarly, they add to the roles that traceability must fulfil as a policy and governance instrument.

Food Traceability: regulatory responses and demands

Four main objectives of food and feed traceability can be identified. Firstly, supply chain efficiency and management as reflected in just in time systems of stock ordering and delivery. Secondly, product verification and control such as through identity presentation. Thirdly, the risk management of food safety and to aid public health recalls. Finally, traceability enables the verification of systems for quality assurance and provenance of food. Traceability has come to the fore as a key requirement for realising the evolving EU regulatory goals around food. Within the EU, traceability was defined in Regulation 178/2002 on the General Principles and requirements of Food Law regulation: 'means the ability to trace and follow a food, feed, food producing animal or substance intended to be or expected to be incorporated into a food or feed, through all stages of production, processing and distribution' (Article 3 (15)) (OJL, 2002). There is a full food and animal feed chain approach, as the stages are defined as originating with primary production, and the regulation includes imports, and extends 'up to the final consumer'

(Article 3 (16)). However, in terms of its operation and implementation it is a one-step-back and one-step-forward approach to record keeping (Article 18). Nonetheless, this effectively transfers responsibility to each stage of the food chain back as far as the farm. The priority of traceability in the general principles regulation was to enhance risk management procedures around food (Arienzo et al 2008). However, there are a range of other demands upon traceability within EU regulation. Food provenance schemes around Geographical Indicators demand forms of traceability and verification as does organic food. The traceability of beef and veal products stemmed from the BSE crisis and the need for risk management. The traceability for fish stemmed from both risk management as well as conservation demands to reduce the risk of further depletion of fisheries. In the case of GMOs, the European Commission made it clear that traceability and associated labelling was also to allow for consumer choice, as only those GM products that had been deemed safe through the EU's risk assessment processes would be allowed on to the market. Table 2 outlines these different regulatory requirements for traceability.

At the international level of private governance agreements, the International Standards Organisation (ISO) has a general definition for traceability that covers industrial products, drawing in particular from existing definitions pertinent to comparable national standards for measurement instrumentation: "Traceability: ability to trace the history, application or location of that

Table 2. EU regulations and directives including food traceability (source Arienzo et al 2008)

1. Food provenance, place of origin and production methods:

PGI – Protected Geographical Indications. This labelling scheme is for individual products that have a specific characteristic or reputation associating them with a given geographical area. At least one stage in the production, processing and preparation process is carried out in that area.

PDO – Protected Designations of Origin. The product has proven characteristics which can only result from the natural environment and abilities of producers in the region of production it is associated with.

TSG – Traditional Speciality Guaranteed. TSG implies that the product has distinctive features, which either have traditional ingredients or are made by traditional methods.

Organic food. In the traceability system of organic foods, each link in the food production chain (farm to fork) must be documented to show compliance with approved organic methods.

2. Cattle and beef products

Since September 2000 an extensive labelling and registration scheme has been obligatory for beef in the EU. Beef and veal on the market in the EU must be labelled with information on: country of origin, country of slaughter, slaughter company, country(-ies) of further processing, company(-ies) of further processing. The aim was to establish traceability between a carcass, quarter or pieces of meat to an individual animal or a group of animals, for food safety reasons. The regulation bids each member state to establish a system for identification and registration of bovine animals, comprising ear tags for the individual animal, databases, animal passports, and individual registers kept on each holding (farm records). The legislation is also connected to a more specific regulation (Commission Regulation (EC) No 1825/2000 of 25 August 2000) laying down detailed rules for the application of Regulation (EC) No 1760/2000 as regards the labelling of beef and beef products. In this regulation the sizes of batches, the demands for labelling for minced meat, control and sanctions are specified

3. Fisheries and fish products

From 1 January 2002 a new labelling scheme was put into effect for a wide range of fish products. The aim was to supply consumers with information on catch area, species and production method (caught in freshwater, or farmed). The regulation requires the information on species and catch area to be made available to the consumer through either labelling or trade documents. The regulation is Commission Regulation (EC) No 2065/2001 of 22 October 2001, laying down detailed rules for the application of Council Regulation (EC) No 104/2000 as regards informing consumers about fishery and aquaculture products.

4. GMO traceability

On 22 September 2003 the Council adopted new rules for improved traceability and labelling of GMOs (Regulation 1830/2003). According to these rules, all products (food and feed) consisting of or containing GMOs shall be labelled. This also applies to GMO products with no protein or DNA residue (e.g., GM soy oil). Traces of GMOs are allowed in unlabelled food, provided they are adventitious or technically unavoidable and in a proportion no higher than 0.9%.

5. Packaging materials

Since 27 October 2006, processors have been required to have a traceability system in place for packaging materials. This new requirement is a provision of EC Regulation 1935/2004, which deals with materials and articles that may come into contact with foods. It covers materials such as rubbers, ceramics, plastics, paper, glass, metals, inks, textiles, waxes, cork and wood. It applies to all food, animal feed, food-producing animals and all types of food chain operators.

which is under consideration". In terms of applying traceability to food, this is covered under the quality management systems standards for food and the international standard agreed in 2007 for:

Traceability in feed and food chain – General principles and basic requirements for system design and implementation (ISO 22005). The text explained that: "A Traceability system is a useful tool to assist an organization operating within a feed and food chain to achieve defined objectives in a management system" (ISO, 2007: iv).

At the international political levels, in the UN's Joint FAO/WHO Joint Food Standards' body the Codex Alimentarius, disagreement centred on what the objectives of food traceability systems that needed to be regulated should be – reflecting disagreement around the importance of food provenance as opposed to food safety demands (Barling 2008). This disagreement reached to the very use of the term, as reflected in the Codex definition: "Traceability, product tracing: the ability to follow the movement of a food through specified stage(s) of production, processing and distribution" (CCGP 2004a). Product tracing reflected the US emphasis on tracing a product back along the food chain, principally for reasons of product recall in the case of a food safety concern. That is, as a risk management procedure by governing authorities. The notion of product tracing also emphasizes a step by step process. Conversely, the term traceability implies a whole food chain perspective, which implicitly would allow a food's history to be told in full, and is the common term in Europe. The US stated that it "does not believe that information on raw materials used, on how a product was changed, or on controls which the product has been subject to are elements of all product tracing systems. Requirements of this type of information would be determined on a case-by-case basis" (CCGP, 2004b: 8). Conversely, the European regional co-ordinating committee for Codex stressed the importance of traceability to ensure the authenticity of the product to be of equal importance to food safety concerns (CCGP, 2003: paras 30-32). The European Community emphasized that the definition should take into account the need to identify specific characteristics of the product such as 'organic', 'halal' or 'kosher' (CCGP, 2004b: 2).

Conclusions

These differences over the scope and role of traceability underline the differing roles that traceability is being called on to provide. A fifth aim that is emerging which relates to the fourth heading of quality assurance and food provenance is the public's desires for information as either consumers or citizens. Civil society organisations are pressing for and, in turn, the corporate sector and public regulators are adding to, the more specific information that can be relayed and communicated to the public. Clearly, ethical concerns are part of this increasing demand. Civil society organisations act as 'accountability entrepreneurs' and spokespersons, by proxy, for public concerns for food. Their demands and promptings form the supply chain mean that the list of concerns to be addressed is not static but is dynamic and unfolding. Within the concerns over environmental impacts of food production and supply chains, carbon use and water use are appearing on the agenda. The growth of diet related non-communicable diseases has accentuated the need for reformulation of processed and manufactured foods. These are becoming pressing public policy concerns for governments and for the EU. The successful communication of this information demands effective systems of certification and audit. Traceability is an important instrument in such systems. The policy demands for such systems and for traceability are increasing.

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