

## **Regulatory aspects of new technologies**

BY JOHN G. WOOD AND LYNN M. INSALL

*Scientific and Regulatory Affairs, The Food and Drink Federation, 6 Catherine Street, London WC2B 5JJ*

Food and drink manufacturing is a highly regulated industry. Legislation has been in force since Henry III's Assize of Bread and Ale in 1266 when legislative policy was directed at particular commodities, essentially staple foods, initially focusing on quantity rather than quality. Later, as public health implications of a safe and unadulterated food supply became better understood, legislation was directed at food composition and safety. The first law against adulterated food generally was the Adulteration of Food or Drink Act 1860 followed in 1875 by the Sale of Food and Drugs Act in which the Food and Drugs Act 1955, the Food Act 1984 and the Food Safety Act 1990 (Act of Parliament, 1990) all have their roots. The 1860 and 1875 Acts owed much to scientific development and technical ability to enforce standards of purity and quality. Moreover, the industrial revolution and shift of population from rural to urban habitation distanced many consumers from the immediacy of food production and created many opportunities for fraudulent trading. Despite the advances since that time, these factors established principles which still have relevance and bearing on the development of food technology and food legislation today (Harvey, 1978; Fallows, 1988).

The Food Safety Act 1990 (Act of Parliament, 1990) is an exemplary piece of consumer protection legislation which provides the framework for all UK food legislation, much of which is now initiated in Brussels. The principal requirements of the Act are that, throughout the food chain, food must not:

have been rendered injurious to health;

be unfit;

be so contaminated, whether by extraneous methods or otherwise, that it would be unreasonable to expect it to be eaten.

The Act also requires that food must not be falsely or misleadingly described or presented either in statements about the product or in pictorial illustrations.

The Act is enforced by both central and local government with enforcement officers being given wide powers:

to enter food premises to investigate possible offences;

to inspect food to see if it is safe;

to detain suspect food or seize it and refer it to a Justice of the Peace, or in Scotland a magistrate or The Sheriff, to condemn it.

Penalties can include imprisonment for up to 2 years or the imposition of unlimited fines. The Act also enables Ministers to make emergency control orders prohibiting commercial operations in relation to food when there is an imminent risk of such food causing injury to health.

The Act, which is an example of primary legislation, also enables Ministers to make Regulations, or Orders, known as secondary legislation, to implement more detailed legislative provisions, most of which are now derived from European legislation. For example, it foresaw the requirement to deal with new technologies such as irradiation and

novel foods by providing Ministers with the power to make specific Regulations in these areas, including the licensing of premises where food is irradiated.

The Food Safety Act 1990 (Act of Parliament, 1990) places the burden of responsibility for consumer protection on the food industry. As with other laws intended to safeguard the public interest, the Act is part of criminal law and offences are absolute. However, the Act establishes the defence of due diligence, where the person charged can prove 'that he took all reasonable precautions and exercised all due diligence to avoid the commission of the offence himself or by a person under his control' (Food Safety Act 1990, section 21; Act of Parliament, 1990). This and other statutory defences enshrined in the Act offer protection under a regime of strict liability for the person held to have committed an offence for which he had no responsibility or because of an accident or some cause completely beyond his control. This creates a balance of fairness and is common in consumer protection statutes which contain such offences (Food and Drink Federation (FDF) *et al.* 1991; Painter, 1992).

#### CRITERIA FOR LEGISLATION

The Food Safety Act 1990 (Act of Parliament, 1990) provides a sound framework of primary legislation for ensuring the safety of foods and the protection of the consumer. Within the past 5 years or so we have seen the development of a wide raft of secondary legislation, some of it very detailed and prescriptive, and most of it emanating from Brussels.

The food and drink manufacturing industry is constantly monitoring scientific, technical and marketing developments and assessing the need for regulation, and from years of experience has developed criteria which are applied whenever there is any suggestion that additional legislation is needed. These are that legislation should be:

necessary;  
based on achieving safety, clear communication, free movement of goods, fair trade;  
technically sound;  
clear and unambiguous;  
applicable to large and small companies;  
subject to uniform EU implementation;  
subject to equitable EU enforcement.

#### CURRENT REGULATORY DEVELOPMENTS

In examining the new technologies and how they are being dealt with by the regulatory process, it is helpful to examine two areas of importance both to consumers and the food industry, novel and 'functional' foods, and the regulatory procedures that have been adopted, or are proposed.

It is not the purpose of the present paper to review the technologies in detail, but it is worth considering a few historical milestones such as the development of pasteurization, canning, margarine manufacture, fermentation, freezing and chilled foods. Most of these are now taken for granted, but all, in their time, have revolutionized the food supply in terms of availability and choice. More recent developments are irradiation, fat substitutes, and modern biotechnology which uses a range of techniques including modern fermentation methods, cell culture, enzyme technology and molecular biology as well as genetic modification (Institute of Food Science and Technology, 1996). There is no consumer consensus as yet on the need for these technologies and their endproducts, but

unlike the historical approach to food legislation in the form of compositional legislation, focus has now turned towards the technology itself rather than the endproduct. This was particularly well illustrated in the development of the recently-adopted EU Novel Foods and Food Ingredients Regulation (Novel Foods Regulation; EU, 1997a).

### *Novel Foods Regulation 1997*

The Novel Foods Regulation (EU, 1997a) was finally ratified in January, 1997 after a process of negotiation and consultation which had lasted more than 5 years, and was published in the European Commission's *Official Journal of the European Communities* on 14 February 1997.

The highly emotive issue of genetic modification of food and the massive research and development investment in biotechnology are the opposite poles from which respective interest groups have sought to influence the legislation, with many other commentators at various points in between. So strong has been the focus on technology, specifically with respect to genetic modification, that the resulting endproduct has almost been lost sight of. So first, what are novel foods?

Article 1 of The European Parliament and Council Regulation on Novel Foods and Novel Food Ingredients (EU, 1997a) defines as 'novel' foods and food ingredients those which have not hitherto been used for human consumption to a significant degree within the Community and which fall under the following categories:

- (a) foods and food ingredients containing or consisting of genetically modified organisms within the meaning of Directive 90/220/EEC;
- (b) foods and food ingredients produced from, but not containing genetically modified organisms;
- (c) foods and food ingredients with a new or intentionally modified primary molecular structure;
- (d) foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae;
- (e) foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and which have a history of safe food use;
- (f) foods and food ingredients to which has been applied a production process not currently used where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances.

These might roughly be translated as follows:

- (a) a viable genetically modified organism (GMO), e.g. the Flavr Savr<sup>TM</sup> tomato introduced onto the US market in 1995;
- (b) a food produced from, but not containing, a GMO, e.g. the tomato purée already on sale in the UK produced from tomatoes similar to the Flavr Savr<sup>TM</sup>, i.e. modified to ripen without softening and, therefore, firmer and drier in texture and requiring less processing;
- (c) a food of which the chemical structure has been changed, such as the fat substitute 'olestra' recently authorized for use in snack products in the USA and currently under review by the UK advisory bodies;
- (d) an example would be mycoprotein, available in the UK for several years and marketed as Quorn<sup>TM</sup>, a vegetarian substitute for meat;

(e) an example of a plant-derived food might be the Kiwi fruit, familiar now but novel in its time;

(f) an example of the last category could be a product processed by ohmic heating, a process in which an object is heated as a result of passing an electric current through it and assessed as a very effective way of sterilizing particulate-containing foods such as chilli-con-carne (Ministry of Agriculture, Fisheries and Food, 1991a).

*The case of need.* To examine why it was deemed necessary to bring forward specific legislation in respect of novel foods, the focus falls firmly onto the criteria of consumer protection, consumer confidence and fair trade. Consumers may be suspicious of new technology when applied to what they eat, and if novel foods and processes are to be introduced successfully, consumers must be convinced that they are safe and that they are being informed about the product. Both these criteria are already enshrined in the Food Safety Act 1990 (Act of Parliament, 1990), with labelling and information requirements being further enforced by the Food Labelling Regulations 1996 (S.I. 1499, 1996) a consolidated and updated version of the 1984 Regulations, which in turn are based on the 1979 EU Labelling Directive, 79/112/EEC (EEC, 1979). So why the need for an additional Regulation? First, there is no pan-European General Food Safety Act. Although consumer protection has become an increasingly important aspect of European regulatory interest, the much vaunted Green Paper on Food Law has not yet emerged and the only all-embracing product protection at European level falls under the General Product Safety Directive (EEC, 1992). Second, membership of the EU dictates that where no Community-wide legislation exists, national laws shall apply. This risked leading to a divergent approach to both the safety evaluation and marketing of novel foods in all twelve (subsequently fifteen) Member States if legislation was not negotiated at European level. Third, the emphasis on safety required that the novelty of the potential products be specially assessed and proved to be safe. And finally, a regulatory vacuum caused uncertainties in the market-place and regulation to ensure the two primary criteria of consumer protection and consumer confidence were deemed to be the most effective means of ensuring that the European biotechnology industry would not be forced to move wholesale to the USA or the Far East where regulation tends to be product-based rather than technology-based, i.e. the focus is on the endproduct and its safety and suitability, not how it was produced. This particular technology embraces far more than food production and processing, but the latter represents a substantial amount of research and development investment.

The Novel Foods Regulation (EU, 1997a) as finally adopted was not ideal from an industry perspective; like so much legislation to emanate from Brussels it was a political compromise, but was nevertheless welcomed by the food industry as offering a degree of legal certainty in the market-place.

*The requirements of the Novel Foods Regulation.* The Regulation provides for the notification and safety assessment of a novel food or food ingredient as defined via one of two procedures, depending on the degree of 'novelty':

1. In cases where the novel food is deemed to be substantially equivalent to an existing food and falls within categories (b), (d) or (e) of Article 1, the applicant must notify the Commission of the intention to place the product on the market and provide evidence of its 'substantial equivalence'. The Commission must advise the Member States within 60 d;
2. In other cases the applicant submits a request to the Member State in which the product is to be marketed first, copying the request to the Commission. This request must contain

all necessary information, including a copy of the studies which have been carried out and any other material available to demonstrate that the food or food ingredient complies with the three important criteria laid down in Article 3.1 of the Regulation, i.e. that the food or food ingredient must not:

present a danger for the consumer;

mislead the consumer;

differ from foods or food ingredients which they are intended to replace to such an extent that their normal consumption would be nutritionally disadvantageous for the consumer. The request must also contain an 'appropriate proposal' for the presentation and labelling of the novel food or ingredient.

3. The next stage is that the Member State must carry out an initial assessment via 'a competent food assessment body' or request the Commission to arrange for another Member State to do so. At this point the Commission notifies all other Member States of the application and provides a summary of the dossier which will have been provided by the applicant.

4. The initial assessment must be completed within 3 months following which the applicant will be advised that;

(a) further assessment is required;

(b) objections have been raised; or

(c) no objections and the product can be marketed.

5. Where an additional assessment is required or an objection is raised, the application is referred to the Standing Committee for Foodstuffs, established in 1969 and consisting of Government experts (EEC, 1969), which is required to define the scope of the authorization or establish:

the conditions of use of the food or food ingredient;

the designation of the food or food ingredient, and its specification;

specific labelling requirements as laid down in Article 8 of the Regulation.

The 'fast track' procedure might apply, for example, to soyabean products akin to those derived from the Monsanto Roundup Ready<sup>TM</sup> soyabeans which have been genetically-modified to be resistant to the herbicide glyphosate, but where the endproduct is indistinguishable from that derived from conventional crops (Ministry of Agriculture, Fisheries and Food, 1994). In cases where the full approvals procedure is required, the 'competent food assessment body' which in the UK would be the Advisory Committee on Novel Foods and Processes (ACNFP), already in existence since 1989 to provide assessments on a voluntary basis and whose guidelines for the safety evaluation of novel foods and processes (Ministry of Agriculture, Fisheries and Food, 1991*b*) have provided the template for the guidelines to be adopted under the Novel Foods Regulation (EU, 1997*a*).

In addition to the safety assessment, Article 6 of the Regulation requires that an application includes 'an appropriate proposal for the presentation and labelling, in accordance with the requirements of Article 8, of the food or food ingredient'.

Article 8 lays down the following requirements for the labelling of novel foods or food ingredients, in addition to the general requirements of food labelling, where there is a:

change in composition;

change in nutritional value or effects;

change in intended use of the food;

presence of material which may have health implications for sections of the population (allergens);  
presence of material which may give rise to ethical concerns;  
presence of an organism genetically modified by techniques of genetic modification, the non-exhaustive list of which is laid down in Annex IA, Part I of Directive 90/220/EEC (EEC, 1990).

The labelling provisions were the most controversial part of the negotiation of the Regulation. On opposite sides of the spectrum, some elements of industry wanted minimum labelling requirements, believing that they would soon become irrelevant, whilst consumer and environmentalist groups wanted comprehensive labelling of anything touched by genetic modification. Final agreement between the Council of Ministers and the European Parliament was reached only after a drawn-out debate in the Conciliation Committee.

The first three requirements were relatively uncontroversial and there was no dispute over the need to label a novel food or ingredient where there had been a change in composition, a change in nutritional value or effect or a change in intended use of the food. The other three requirements were agreed only after lengthy political negotiations in the Conciliation Committee.

One of the principles of labelling legislation is that it should meet the needs of the majority of consumers by providing them with meaningful information about the content of the product, instructions for storing and cooking, and in some cases nutrition information.

However, where modern biotechnology is involved, and particularly genetic modification, it was recognized that certain minority interests would need to be addressed. First there was concern that the ability to move genetic material between unrelated species might lead to the introduction of allergens in products not normally allergenic. A study was conducted in which Brazil (*Bertolletia excelsa*)-nut protein was introduced into a soyabean line, aimed at enhancing the methionine content of the beans to enhance the nutrient value for livestock. The programme was discontinued in response to preliminary findings that the Brazil-nut gene transferred a potential for nut allergenicity to the soyabeans. There was never any intention of using this particular variety of modified soyabean in the human food supply (Pioneer Hi-bred International Incorporation, 1996).

Soyabean is known to give rise to adverse reactions in sensitive individuals and the recently introduced Monsanto Roundup Ready™ variety was tested for allergenicity by the ACNFP and found to be no more or less allergenic than traditional varieties (Ministry of Agriculture, Fisheries and Food, 1994). The safety assessment procedure, therefore, addresses this issue and the Regulation requires an indication on the label if a modified product is likely to have an allergic effect on some sectors of the population when the conventional product would not. In practice the introduction of any such food or food ingredient is most unlikely.

There are also the ethical concerns, for example if copy genes from animal species not consumed by certain religious groups are introduced, or if animal genes are introduced into plant products, or if human copy genes are used. The 'Polkinghorne Committee' set up by the UK Government to review the ethical implications of genetic modification in food made recommendations with regard to labelling which were subsequently adopted by the Food Advisory Committee (FAC) and accepted by Ministers (Ministry of Agriculture, Fisheries and Food, 1993). This Report and the May 1995 recommendations of the Group of Advisors on the Ethical Implications of Biotechnology of the European Commission (1995) were influential in securing this particular labelling requirement which had kept the draft Regulation in a political bloc within the Council of Ministers for several months.



The final labelling requirement was agreed only after negotiations in the Conciliation Committee and was introduced by the European Parliament. The original intention of the Council of Ministers was that only viable genetic material should be labelled. However, the European Parliament wanted more extensive labelling and sought to introduce the requirement to anticipate techniques of genetic modification which are not yet in use and were therefore not covered by the Deliberate Release Directive, 90/220/EEC (EEC, 1990). Precise interpretation is likely to be established by precedent.

The European Parliament also introduced two new Recitals which allow for 'negative' labelling of products which have not been produced by or using genetic modification and for the use of 'may contain' type statements where commodity crops such as genetically-modified (GM) soya or maize have been co-mingled with conventional varieties and the presence or absence of GM material cannot be definitely established.

*Impact of the regulation.* To return to our principles for legislation and the practical application of the legislation as drafted, we might consider our experience to date and whether or not it might have been different had the Novel Foods Regulation (EU, 1997a) been in place.

First, will the single market operate effectively in respect of novel foods? The ink was scarcely dry on the agreed text before two Member States had put forward additional labelling requirements in respect of products produced using Monsanto's GM soyabean.

Even after the Regulation was agreed the Council of Ministers and European Parliament appeared to have different ideas as to what the labelling provisions meant and the Member States are likely to add their own particular gloss. This illustrates our two final criteria for legislation: the need for uniform implementation and equitable enforcement throughout the EU.

Accusations of failure to offer choice following the introduction of non-segregated GM commodity crops has caused the food industry to review the supply chain carefully and may well result in the need to seek more expensive segregated non-GM supplies to satisfy certain markets. Some retailers are requesting reformulation of certain products to remove all soyabean protein derivatives, a potentially retrograde step when no safety issue is involved and a good source of protein may be lost. This is ultimately likely to benefit no-one and indeed has adverse implications, both nutritionally and economically, and negates two of the potential benefits of the technology, those of a cheaper food supply and reduction in use of herbicides, both a health and an environmental benefit.

Whether or not the introduction of the new Regulation will redress the balance following the introduction of GM commodity crops remains to be seen. Provided confidence can be gained in modern biotechnology it offers benefits throughout the food chain, from primary producers to consumers. Whilst the recently approved modifications have involved agronomic differences, many compositional modifications are already at an advanced research stage and offer nutritional benefits such as change in fatty acid composition of oil seeds and higher starch content in potatoes.

It is also important not to lose sight of the potential benefits to the developing countries where tolerance to drought or saline conditions and pest resistance have the potential to make an enormous impact on food security. Regulatory and consumer acceptance barriers in Europe risk prejudicing future investment and could isolate us from future benefits.

Finally, the impact of scientific and technical advance on the development of legislation, with particular reference to analytical methods, is important. In this case, regulation has anticipated such advances by providing for genetic modification techniques not yet invented and presumption of labelling requirements for changes in DNA structure not yet detectable, a challenge both to industry and to the enforcement authorities.

*Industry's role in communicating with the consumer.* FDF has developed a **foodfuture** programme which aims to improve public understanding of modern biotechnology through transparent and objective dialogue with all sectors of society, both opinion-forming groups and consumers. The programme was established by FDF in 1995 on behalf of the UK food and drink manufacturing industry, and developed from the findings of the first National Consensus Conference on Plant Biotechnology organized by the Science Museum in association with the Biotechnology and Biological Sciences Research Council (BBSRC). The issues highlighted in the Consensus Conference report (The Lay Panel of the UK National Consensus Conference on Plant Biotechnology, 1994) provided the basis for FDF's detailed quantitative consumer research, carried out by National Opinion Poll (NOP), on perceptions and understanding of modern biotechnology. The NOP survey findings confirmed the conclusions of the Consensus Conference: consumers wanted more information; open discussion should be facilitated; and a wide range of interested groups should work together. These conclusions were used as a guide in the development of the **foodfuture** communications programme and supported FDF's way of working with a wide range of interested parties to ensure that all voices are heard in the debate.

The **Foodfuture** programme comprises a wide range of activities including: a series of booklets explaining, objectively, the technology and its applications to food (*Food for Our Future: Food and Biotechnology, Modern Biotechnology – Towards Greater Understanding, Food for Our Future: A Guide to Modern Biotechnology – Cheese, Tomato, Soya and Maize; FDF, 1995a,b,c*); Forum events representing all perspectives including research, science, legislation and enforcement, farming, manufacturing, retailing, ethical and consumers; a National Review Conference co-hosted by FDF, BBSRC and the Science Museum which aimed to draw together the main themes which had emerged from the preceding Forum events; a Media Programme; School-based Consensus Conference; and an Interactive exhibition.

FDF's **foodfuture** programme has initiated wider discussion in the community of the science, perceived benefits and disadvantages of modern biotechnology as well as the ethical and moral concerns raised by some groups. The programme aims to help consumers achieve the level of awareness they need to make informed decisions about the food they eat. The programme has reinforced the need for continuing consumer information.

Some groups may consider labelling to be the obvious solution to meeting this need but the label cannot provide all the facts consumers may need to understand this complex technology and the related issues, and not all products have the convenience of packaging as a vehicle for such labelling. Labelling can never be a substitute for education. It is essential that the process of informing consumers about the new technology continues to enable consumers to understand the information provided and, therefore, help them make more informed choices. If public confidence in food biotechnology is to be gained, it is vital that all relevant interest groups (researchers, regulators, farmers, manufacturers, retailers, consumers and others) engage in constructive dialogue.

### *Functional foods*

Moving to the other area of current consumer interest, the term 'functional foods' has become common currency in the wealth of media coverage these foods have received but in food science terms is utterly meaningless. Some of these so-called functional foods or their ingredients may be novel, or they may fall within the so-called PARNUTS legislation, i.e. foods for particular nutritional uses, Directive 89/398/EEC (EEC, 1989), or they may



be both or they may be neither. This potential for overlap and the inability to define such foods precisely has led to some confusion, and perhaps undue concern, as to possible regulatory requirements for marketing them (Brander, on behalf of the MAFF Consumer Panel, 1995). The only common categorization for these foods is that they make a health claim and this is the issue on which the industry has concentrated in considering whether or not they should be regulated.

In trying to define or categorize these foods, industry found it easier to define what they are not: they are not medicines, capsules, pills or potions which we would expect to be medicinal products and therefore licensed under the Medicines Act 1968 (Act of Parliament, 1968); they are not supplements of the type taken for an extra boost of, for example, a particular vitamin or mineral; they are not remedies of the herbalist-type which, since they are not licensed as medicines, are deemed within UK law to be foods. Although they make a health claim, they are not foods used under medical supervision, a specific category governed by PARNUTS legislation (EEC, 1989); and they are not foods which claim to 'not contain' ingredients or additives which some consumers may consider to be 'unhealthy'.

In discussing so-called functional foods and considering technology in its broadest context, what functional foods are chiefly seeking to achieve is the application of state-of-the-art nutrition research which indicates that consumption of a particular ingredient or substances at a certain level could have beneficial effects on health in terms of disease-risk reduction, enhanced metabolic functions or healthy-eating patterns. They have been developed in response to a market increasingly conscious of the links between diet and health and focus on 'positive' nutrition, i.e. they contain specific substances or ingredients claimed to have additional physiological benefits beyond satisfying nutrient requirements (Brady, 1996a; Richardson, 1996).

The development of such foods would not be possible without the existence of new technologies. For example, there are technological difficulties involved in incorporating certain vitamins and minerals into foods: advances in the synthesis of thiamin were instrumental in wartime fortification of bread and flour; adding Fe still presents problems of colour, flavour, texture and quality control (Brady, 1996b). The wholesale use of *n*-3 fatty acids in a wide range of foodstuffs would not be popular if they all tasted and smelled of fish; the consumption of fibre in liquid form would have been unthinkable until relatively recently.

*A case for regulation?* Reverting to our general principles for legislation, again there are three issues involved: consumer protection, consumer information and fair trade.

To look at the safety issue, all foods are governed by the general provisions of the Food Safety Act 1990 (Act of Parliament, 1990) so they must be safe. If there is something novel about the food or one of its constituent ingredients, it will fall within the Novel Foods Regulations (EU, 1997a) so will be evaluated for safety in accordance with the procedures laid down in that Regulation. If it is a food targeted at a specific segment of the population for a special purpose, it may fall within PARNUTS legislation and, therefore, will need to comply with these special provisions.

With regard to labelling, it must, like all other foods, comply with the Food Labelling Regulations 1996 (S.I. 1499, 1996) and provide information about the ingredients, the keeping qualities of the food, how to store and consume the food, and if a nutrition claim is made, it must also provide nutrition information. In addition, the Food Safety Act 1990 (Act of Parliament, 1990) makes it an offence to publish, or to be party to the publication of, an advertisement which falsely describes any food or which is likely to mislead as to the nature or substance or quality of the food.

Turning to the trade issue, a primary consideration is to safeguard *bona fide* manufacturers, whose product research and development costs may have been considerable, as well as the consumer. We also need to recognize that the market is not just the UK (the concept of so-called functional foods originated in Japan where they have a huge market, and markets are also developing in the USA, Asia and Australasia as well as the rest of Europe), but the regulatory issue is essentially one of consumer information and substantiation of claims rather than product safety, so what can be achieved by additional legislation?

*Health claims issue.* Functional foods are not a defined food category and the issue that has brought them to the fore is that of health claims. Does this constitute a requirement for specific legislation, given that existing legislation already requires that labelling must be accurate and not misleading and claims must be capable of substantiation? Another matter for consideration is the nature of the claims being made and whether or not they can be legislated for and, if so, how the legislation is enforced. This point is of particular importance in the case of health claims, as Trading Standards Officers cannot be expected to have an encyclopaedic knowledge of nutrition science and might not be qualified to assess scientific information that would be presented by a company asked to substantiate a claim.

In circumstances where safety is not at issue and the point in question is how to avoid the consumer being misled by claims of a new product, a voluntary approach seems appropriate in a climate where manufacturers have a record of acting responsibly and who would not find it in their interests to damage their reputations or their record for research and innovation.

Having examined the situation in some detail, and with regard to the views of consumer groups, the food and drink manufacturing industry has assessed that the existing regulatory framework is adequate but that clarification of the legislation relating to claims through the development of voluntary guidelines would be desirable and a mechanism for the scientific substantiation of health claims needs to be established. The industry believes that appropriate voluntary guidelines should be consistent with its desire to:

- promote the prudent and responsible application of scientific research and development to the promotion and marketing of new products;
- respond positively in terms of technological innovation and the application of scientific research essential to the competitive advantages of the UK manufacturing industry;
- develop a secure regulatory framework by helping to clarify existing legislation;
- accept the main burden of responsibility concerning the use of health claims.

It is important that health claims should not exaggerate the potential benefits of the product, thus should be made in such a way that it is clear that the health benefit is dependent on the consumption of the product as part of a dietary pattern; should not be made for foods which are eaten in quantities insufficient to have any beneficial effect, even if the claim is factually correct; and should conform to the same general principles as other claims, i.e. they must not be false or misleading and the manufacturer must be in a position to substantiate a claim. For this reason the industry welcomes the FAC's proposed approach to the regulation of health claims through voluntary guidelines which will place the onus on the manufacturer to substantiate any health claim made for the product.

We have yet to see if the rest of Europe will be comfortable with such an approach, but our experience of attempts to negotiate legislation in respect of nutrition claims (Commission of the European Communities, 1992) suggests that agreement would be

unlikely this side of the millennium and we have a fairly urgent requirement to secure some form of regulation to protect both consumers and *bona fide* manufacturers from unscrupulous traders. Voluntary codes of practice have their place in such circumstances and a former Director-General of Fair Trading, Professor Gordon Borrie (now Lord Borrie), once wrote: 'I believe that proposals to change the law should be made only when absolutely necessary because I have increasingly realised that extension of the law is no automatic panacea for consumer problems. It is all too easy to suggest measures for consumer protection which are either impractical or prohibitively costly'. The advantage of the voluntary or self-regulating code is that it is tailor-made for the problems that it seeks to address and can thus be more detailed and specific than is practicable in legislation and readily adaptable to new circumstances. Its disadvantage is that it lacks any direct way of enforcing it and can only be 'binding' on members of the trade body which has established it and thus cannot be imposed on imports, to the political disadvantage of domestic suppliers (Harvey, 1978). However, it is an area for consideration as part of the current consultation process of the FAC.

#### THE FUTURE OF INNOVATION

To sum up, it is fair to assume that food and drink manufacturers want new technology to succeed. Too often industry blames the regulatory process for placing obstacles in the path of innovation, and there is some truth in this if regulation focuses too much on the technology rather than the safety of the endproduct, i.e. it is technology-based rather than risk-based. However, if the reasons for this are examined, the pressure does not always come from the legislators.

In a climate where the accent is placed firmly on consumer choice in an affluent market-place with a tendency to over- rather than under-supply, consumers and the politicians who claim to represent them have first to be convinced of the need for and the benefit to them of something new.

In the light of the experience of irradiation where a potentially good technology was rejected on the basis of emotive associations with nuclear radiation, not least because of the unfortunate timing of the Chernobyl melt-down, industry has endeavoured to involve the public in the debate about modern biotechnology in an effort to ensure that the potential benefits it can bring to the raw-material supply, food processing and to the end-consumer are not lost through lack of information or understanding. FDF (1995a) published a booklet *Food For Our Future – Food and Biotechnology* and in 1995 and 1996 took the debate around the country in a series of forum events. Key speakers discussed the issues of what modern biotechnology is and what it can achieve, its potential use in the food supply chain, the labelling of products produced using modern biotechnology, the science base, and ethical issues.

In 1996 the first GM product was introduced in Sainsbury's and Safeway, a tomato purée produced from GM tomatoes, labelled as such and giving an explanation as to the benefits. Consumers readily accepted the product, which also brought with it a price benefit, and demand has often outstripped supply. However, later in the same year US farmers began harvesting crops of soyabean, genetically modified to be resistant to the herbicide glyphosate, and maize, genetically modified to be resistant to the European corn-borer but also carrying a herbicide-tolerant gene and an antibiotic-resistant marker gene. Although both products were approved as safe in their processed form and received marketing consent for import into the EU under Directive 90/220/EC (EU, 1996, 1997b), both were co-mingled with the main commodity supply, are indistinguishable from

conventional varieties in every respect in their processed form and, therefore, cannot readily be labelled. Consumers are inherently distrustful of these new products, not least because they arrived on the market within months of the bovine spongiform encephalopathy débâcle which has done more than anything in recent years to undermine consumer confidence in the safety of the food supply, destroy their trust in Government, and scientists, and question all aspects of food and drink manufacture, and indeed the entire system of regulation and enforcement.

In conclusion, achieving the appropriate regulatory environment for new technologies will not necessarily guarantee their success in the market-place. The examples of irradiation, and more recently GM soya and maize, demonstrate how consumer reaction can be influenced by extraneous events affecting new and unfamiliar technology in an unexpected way. Several prosecutions have already been brought against products claiming specific health benefits, potentially prejudicing the market against further innovative products claiming similar ingredients or benefits. In an atmosphere of reduced consumer confidence, the incentive to experiment with new products is likely to be considerably reduced, unless they are perceived as an 'antidote' to a current food scare. Of the many influences, such as price, taste, quality, brand, on food purchasing habits, confidence in the safety of the product is likely to be paramount. Familiarity is both a result and a driver of trust, and in time these products of the new technologies may no longer be regarded as 'novel'. In the meantime confidence in the regulatory system will be an important aspect of trust in new technologies. That confidence will not be gained if those who negotiate the legislation, or are deemed to influence it, are themselves not trusted. Honesty and openness are therefore important factors, as is an understanding that regulatory negotiations inevitably involve partnerships and consensus between, and compromises for, all parties concerned. Only the essential of food safety is not subject to compromise and is negotiable only as a result of scientific and technological advance.

#### REFERENCES

- Act of Parliament (1968). *The Medicines Act 1968*. London: H.M. Stationery Office.
- Act of Parliament (1990). *The Food Safety Act 1990*. Statutory Instrument no. 1383. London: H.M. Stationery Office.
- Brady, M. C. (1996a). Report of an FDF Working Party: Addition of nutrients: the importance to public health. *British Food Journal* **98**, 3–11.
- Brady, M. C. (1996b). Report of an FDF Working Party: Addition of nutrients: current practice in the UK. *British Food Journal* **98**, 12–18.
- Brander, J., on behalf of the MAFF Consumer Panel (1995). *Functional Foods What Are They?* CP (95)94/3. London: MAFF.
- Commission of the European Communities (1992). *Draft Proposal for a Council Directive on the Use of Claims Relating to Foodstuffs*. Doc. SPA/62/Orig-FR/Rev.1. Brussels: Commission of the European Communities.
- Department of Health (1991). *ACNFP Guidelines on the Assessment of Novel Foods and Processes. Report on Health and Social Subjects no. 38*. London: H.M. Stationery Office.
- EEC (1969). Council of the European Communities' Decision of the Council of 13 November 1969, instituting a Standing Committee for Foodstuffs (69/414/EEC). *Official Journal of the European Communities* **L291**, 9 (English special ed. Series I, **69**, 500).
- EEC (1979). Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer. *Official Journal of the European Communities* **L033**, 1.
- EEC (1989). Council Directive 89/398/EEC of 30 June 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses. *Official Journal of the European Communities* **L186**, 27.
- EEC (1990). Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms. *Official Journal of the European Communities* **L177**, 15.
- EEC (1992). Council Directive 92/59/EEC of 29 June 1992 on General Product Safety. *Official Journal of the European Communities* **L228**, 24.

- EU (1996). Commission decision 96/281 of 30 April 1996 concerning the placing on the market of genetically modified soya beans (*Glycine max L.*) with increased tolerance to the herbicide glyphosate pursuant to Council Directive (90/220/EEC). *Official Journal of the European Communities* L107, 10.
- EU (1997a). European Union Regulation (EC) no. 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients. *Official Journal of the European Communities* L43.
- EU (1997b). Commission decision 97/98 of 22 January 1997 concerning the placing on the market of genetically modified maize (*Zea Mays L.*) with the combined modification for insecticidal properties conferred by the Bt-endotoxin gene and increased tolerance to the herbicide glufosinate ammonium pursuant to Council Directive 90/220/EEC. *Official Journal of the European Communities* L31, 69.
- Fallows, S. J. (1988). *Food Legislative Systems of the UK*. London: Butterworths.
- Food and Drink Federation (1995a). *Food for our Future – Food and Biotechnology*. London: FDF.
- Food and Drink Federation (1995b). *Modern Biotechnology – Towards Greater Understanding*. London: FDF.
- Food and Drink Federation (1995c). *Food for our Future: A Guide to Modern Biotechnology – Cheese, Tomato, Soya and Maize*. London: FDF.
- Food and Drink Federation, Institute of Environmental Health Officers, Local Authorities Co-ordinating Body on Food and Trading Standards, National Consumer Council, National Farmers Union and the British Retail Consortium (1991). *The Food Safety Act 1990. Guidelines on Statutory Defence of Due Diligence*. London: FDF.
- Group of Advisors on the Ethical Implications of Biotechnology of the European Commission (1995). *Ethical Aspects of the Labelling of Foods Derived from Modern Biotechnology*. Brussels: Commission of the European Communities.
- Harvey, B. W. (1978). *The Law of Consumer Protection and Fair Trading*. London: Butterworths.
- Institute of Food Science and Technology (1996). *Guide to Food Biotechnology*. London: IFST.
- Ministry of Agriculture, Fisheries and Food (1991a). *Advisory Committee on Novel Foods and Processes Annual Report 1991*. London: H.M. Stationery Office.
- Ministry of Agriculture, Fisheries and Food (1991b). *Advisory Committee on Novel Foods and Processes Guidelines 1991*. London: H.M. Stationery Office.
- Ministry of Agriculture, Fisheries and Food (1993). *Report of the Committee of the Ethics of Genetic Modification and Food Use*. London: H.M. Stationery Office.
- Ministry of Agriculture, Fisheries and Food (1994). *Advisory Committee on Novel Foods and Processes Report on Herbicide Tolerant Soya Beans*. In *ACNFP Annual Report 1994*, pp. 59–66. London: MAFF.
- Painter, A. A. (1992). *Butterworths Food Law*. London: Butterworths.
- Pioneer Hi-bred International Incorporation (1996). *Open Letter Regarding Transgenic Soya Beans Containing Brazil Nut Protein*. USA: Pioneer Hi-bred International Incorporation.
- Richardson, D. P. (1996). Functional foods – shades of grey. *Nutrition Reviews* 54, S174–S185.
- Statutory Instrument, no. 1499 (1996). *The Food Labelling Regulations 1996*. London: H.M. Stationery Office.
- The Lay Panel of the UK National Consensus Conference on Plant Biotechnology (1994). *Final Report*. London: Science Museum.