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The safety and social acceptance of novel foods

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Abstract

The regulatory processes employed in the UK and the European Union to assess the safety of novel foods and novel food ingredients, including those resulting from the application of recombinant DNA technology (genetically modified foods), are described. Examples are given of yeasts that have been genetically modified and can be used in food and drink manufacture and food enzymes derived from genetically modified microorganisms that have been deemed safe for use by the UK regulatory system. Social acceptance of such novel foods or food ingredients is not uniform in countries of the developed world. Consumer concerns can be based on ethical considerations (scientists ''playing God'') or safety worries (''more testing needs to be done''). The general acceptance of such foods and food ingredients in Europe is still unclear.

Keywords: Novel foods; Food irradiation; Genetically modified microorganisms

1. Introduction

Most developed countries have over the last 10 years or so developed mechanisms for adjudicating on the safety of novel foods prior to their being marketed. The author's experience has been that of the UK and European regulatory systems through the activities of the UK Advisory Committee on Novel Foods and Processes and the EU Scientific Committee on Food. Other regulatory systems operate in Australia, Canada, China, Japan, New Zealand and the USA. All of them have been reviewed by Tomlinson (1998).

A large number of novel foods or novel food ingredients have been derived from genetically modified plants e.g., soya, maize, oilseed rape and cotton, made tolerant to herbicide action or resistant to insect damage via the incorporation of bacterial genes, and have been, or are currently being, considered by regulatory authorities. In view of the well-developed genetics of yeast and some bacteria when recombinant DNA technology became available, it is surprising that so few genetically modified micro-organisms have been constructed and presented to national regulatory authorities for marketing consent. However, there have been some and these will be described.

2. The regulatory system in the UK

As a result of an understanding reached with the Ministry of Agriculture, Fisheries & Food (MAFF) in 1980, the then Food and Drink Industries Council recommended that members of its association should

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notify MAFF before marketing a novel food, so that the nutritional and safety aspects of the food might be evaluated, in strict confidence, by independent experts. In 1982, the Advisory Committee on Irradiated and Novel Foods (ACINF) was set up, with a remit to advise Ministers both on the irradiation of food and on food produced by means of novel processes. Most of its work related to the evaluation of food irradiation, but the Committee also issued a memorandum which included guidelines for testing the safety of novel foods (Ministry of Agriculture, Fisheries and Food, 1984).

Following completion of the review of food irradiation by ACINF, and bearing in mind the significant advances that had been made in recent years in food biotechnology and, in particular, techniques for genetic modification, the Committee was reconstituted as the Advisory Committee on Novel Foods and Processes (ACNFP) in 1988. The Committee's new name better reflected its work, which included the assessment of the safety of foods which are themselves genetically-modified organisms, or which are produced in processes involving such organisms, although the Committee continues to advise as necessary on food irradiation and the safety of novel foods which are not the result of genetic modification. Membership of the Committee is made up of 15 scientists with expertise in human nutrition, toxicology, food science, genetics, microbiology, genetic engineering, radiation biology and ethics plus one consumer representative.

The remit of the Committee is ''to advise Health and Agriculture Ministers of Great Britain and the Heads of the Departments of Health and Social Services and Agriculture for Northern Ireland on any matters relating to the irradiation of food or to the manufacture of novel foods or foods produced by novel processes having regard where appropriate to the views of relevant expert bodies''.

As well as giving advice to ministers concerning novel foods and processes being submitted for evaluation, the work of ACNFP includes giving guidance to the food industry on the information related to safety that the Committee would wish to see in any such submission. In order to fulfil this aspect of the work, the ACNFP updated and revised the Guidelines issued by ACINF to take account of the wider range of novel food products being submitted for assessment and the newer techniques of genetic modification (Department of Health, 1991).

Under current UK food law, companies must be satisfied as to the safety of their products and must themselves evaluate whether foods or processes should be referred to the Committee for consideration. Such submissions remained as a voluntary procedure until May, 1997. In order to provide guidance for those producing such foods and wishing to market them, the Committee devised a decision-tree scheme which, by posing a series of questions requiring yes/no answers, indicated the kinds of information likely to be required in individual cases (Fig. 1). Examples of questions are: Is the source organism a strain that has been developed using genetic modification as defined in Directive 90/220/EEC?; Is the product a purified chemical not containing any genetic material? Is there a history of human consumption of the parent strain of the GMO?; Does the product contain viable seeds or potentially live organisms? Working through the decision-tree scheme results in a novel food or process falling into one of 19 categories (A to S) (Advisory Committee on Novel Foods and Processes, 1994).

The information requirements in the scheme are shown in Table 1. Foods that are, or contain the products of genetic engineering fall into categories L to S. Each of these categories has an information requirement of 11–12 items of information. For example, chymosin from a genetically modified microorganism would exit from the decision-tree at point L and so the information required from the company by ACNFP in order to assess its safety in food would be I–VIII, X, XI and XV.

A genetically modified lactic acid bacterium intended as a probiotic and consumed as a live product would exit the decision-tree at point S and would require information related to II, VI–XV.

Traditionally, the safety of the human food supply is based on the concept that there should be a reasonable certainty that no harm will result from its consumption. The fact that the new techniques of genetic modification can now be applied to some foods does not affect this concept, nor does it require a different standard of safety. Thus, food or food ingredients derived from genetically modified organisms must be considered to be as safe as, or safer

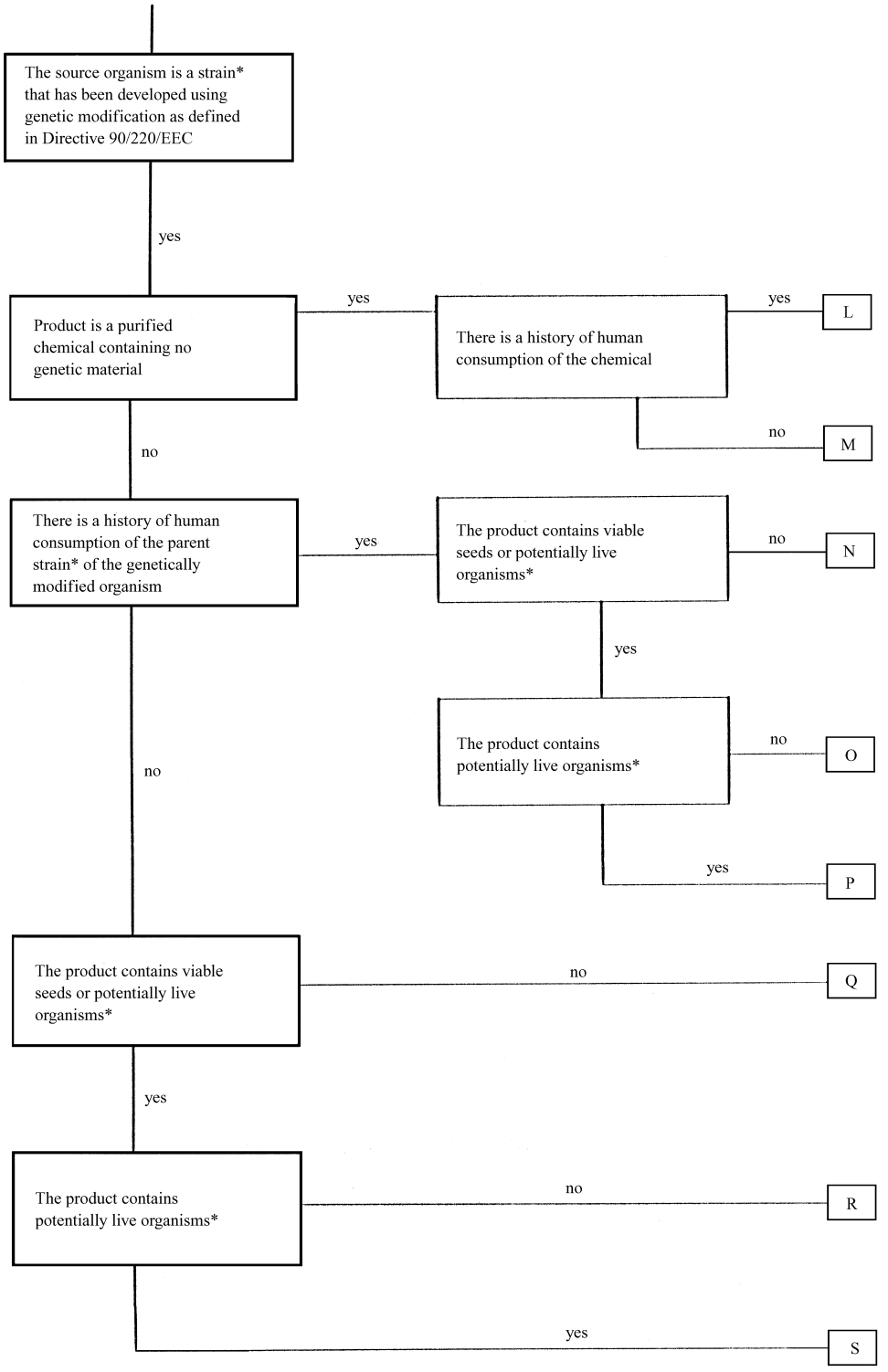

Fig. 1. Part of the decision tree scheme developed by the UK ACNFP for its safety assessment of novel foods. This part covers those foods that are produced from genetically modified organisms.

Table 1
Information requirements for novel foods and processes

I	Evidence of previous human exposure
II	Intake and extent of use
III	Technical details of process
IV	Product specification
V	Nutritional assessment
VI	History of the organism
VII	Characterisation of derived strain in comparison with the parent strain
VIII	Toxicological assessment
IX	Human data
X	Effect of the genetic modification on the known properties of the parent organism
XI	Genetic stability of the modified organism
XII	Site of expression of any novel genetic material
XIII	Transfer of the novel genetic material
XIV	Assessment of the modified organism for survivability, replication and colonisation/amplification in the human gut
XV	Safety information

than, their traditional counterparts before being recommended as safe by the ACNFP. It is the Minister's prerogative, on the basis of the advice given by ACNFP, to advise companies of his/her decision, and all clearances are announced by press release.

The ACNFP has now issued 10 Annual Reports covering its activities from the first meeting in October 1988 to the end of 1998.

The Committee is of the view that the advice it gives to Ministers and the reasoning behind that advice should be available to the general public. Consumers have the right to be given all relevant information about radically new technologies and to be able to see that all reasonable safeguards have been taken. Thus, in addition to publication of the Annual Reports, Agendas of the Committee are published in advance of meetings, summaries of the meetings published afterwards and copies of the Committee's reports to Ministers are made available on request. Additionally, the Committee has instituted a procedure for the deposition, to the British Library, of data from toxicological and other safety evaluation studies in support of an application.

The ACNFP is, of course, only one of a number of independent Committees advising the UK Government on food or biotechnology matters. Some issues require consideration by more than one of these Committees and the ACNFP frequently refers to other Committees for input into particular cases. For example, the Committee on Toxicity provides expert advice on toxicological issues; the Advisory Committees on Genetic Modifications and Releases to the Environment advise on safety at work and environmental protection, respectively, with regard to genetically modified organisms; the Food Advisory Committee (FAC) is responsible for the labelling, composition and chemical safety of food, including food additives.

3. The regulatory system in the European Union

In the EU, the safety of genetically modified food is controlled by Regulation EC No. 258/97 which concerns itself with novel foods and novel food ingredients. The regulation came into effect on 15th May 1997 and introduced a mandatory pre-market safety assessment for all novel foods. The regulation defines a novel food as a food or food ingredient which has not been used for human consumption to a significant degree within the European Community and which falls into one of the following six categories:

1. foods and food ingredients containing or consisting of genetically modified organisms within the meaning of Directive 90/220/EEC (the release directive);
2. foods and food ingredients produced from, but not containing, genetically modified organisms;

3. foods and food ingredients with a new or intentionally modified primary molecular structure;
4. foods and food ingredients consisting of or isolated from microorganisms, fungi or algae;
5. foods or 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 having a history of safe food use;
6. foods and food ingredients to which has been applied a production process not currently used where that process gives use 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.

Before a novel food can be approved under the Regulation it must satisfy three criteria; it must not present a danger to the consumer, mislead the consumer or differ from foods they are intended to replace, to such an extent that their normal consumption would be nutritionally disadvantageous to the consumer.

The assessment procedure is delegated to the Member States. A company wishing to market a novel food would apply to the Member State where it first intends to market the product. The Member State has 90 days in which to carry out a safety assessment and forward its opinion to the European Commission. In the UK, applications come before the ACNFP for safety assessment. The other Member States having received details of a favourable opinion from the Commission have 60 days to agree or disagree. If there are no objections, the product can be marketed. If there are disagreements, then the application is considered by the Standing Committee for Food (representing all 15 Member States) where a decision is made on a qualified majority vote. The Standing Committee will seek the advice of the Scientific Committee for Food on any issues relating to public health. To help Member States adopt a similar approach to the safety assessment of novel foods, the Scientific Committee for Food has produced a set of guidelines setting out the type of information expected in support of an application for approval of a novel product. The guidelines are broadly similar to those developed by the ACNFP in that a decision tree approach is used and the information items required are similar to those listed in Table 1.

4. Examples of genetically modified microorganisms assessed for safety

In 1988, a dossier on modified baker's yeast was submitted by Gist–Brocade. The producers of this strain sought to accelerate the process of natural breeding and selection by replacing the host genes responsible for the production of the enzymes maltase and maltose permease in one strain of baker's yeast with a more efficient set of genes from another strain. Apart from some short synthetic non-coding DNA sequences linking the new genes to the yeast genome, there was no DNA in the modified yeast that did not come from *Saccharomyces cerevisiae*. This application received clearance from the appropriate UK authorities in 1989. Details of the construction of the strain are described by Van Rooijen and Klaassen (1998).

In 1993, a dossier on an amylolytic yeast was submitted by Brewing Research International for safety consideration. In some beer production processes an enzyme amylase is added to the fermentation broth to break down starch and allow the yeast to make more alcohol. Attempts to develop such a strain by conventional breeding produced beers that were unpalatable. Using recombinant DNA technology, an amylase gene from *Saccharomyces diastaticus* was introduced into *S. cerevisiae* together with a selective gene for copper resistance. Approval for the use of this strain in beer manufacture was obtained. Details of the construction of this strain, its passage through the regulatory procedure and its limited use for demonstration purposes are described by Hammond (1998).

It is interesting to report that although both these yeasts were deemed safe by the ACNFP and were approved for use, neither has gone into commercial production because of the reluctance of the industries involved to risk a consumer backlash.

A number of food enzymes produced as a result of the genetic modification of microbial producer strains has also been approved for use. In the UK, the safety of enzymes used in food manufacture is considered by the Food Advisory Committee (FAC), but the safety of the genetic modification aspects of

their production was considered by the ACNFP and its advice passed to the FAC for the decision. The development of genetic approaches to the manufacture of enzymes as food processing aids is considered at length by Roller and Goodenough (1998).

Chymosin is an enzyme used in the manufacture of cheese. Traditionally, it is obtained as rennet from calves' stomachs but because of an increase in demand alternative sources have been developed. Three submissions have come before the FAC and the safety of the genetic modification to the ACNFP. The gene for chymosin has been cloned and inserted into *Kluyveromyces lactis* (1991), *Aspergillus niger* var *awamori* (1991) and *Escherichia coli* (1992). In cheese sold in the supermarket, it is normally described as having been made using vegetable chymosin.

Xylanase enzymes are used in breadmaking to increase volume and improve crumb structure. *A. niger* and *Bacillus subtilis* have been genetically modified to increase the production of xylanase enzymes (1996). This involved insertion of copies of the xylanase genes derived from the same strains to give multiple copies of genes in each microbe.

Riboflavin (vitamin B2) is not synthesised in higher animals but is obtained from consumption of peas, beans, grains, yeast, milk and eggs. Riboflavin has been made by chemical synthesis and used to fortify breakfast cereals, slimming diets and baby foods. Classical genetics has been used to deregulate the pathway leading to riboflavin biosynthesis in *B. subtilis*. Overproducers in other strains of *Bacillus* were isolated and multiple copies of the riboflavin operons introduced into the deregulated strain. The production strain has 33 copies of the operon.

The above cases were all approved for use in the UK via the appropriate authorities as described earlier. Under the European Regulation 258/97 which came into operation in May 1997, no opinions have yet been given on a novel food application involving genetic modification.

5. The social acceptance of novel foods

Novel foods resulting from the application of recombinant DNA technology have been on sale in British supermarkets since 1994. At present, it is possible to buy cheese made using chymosin from a genetically modified microorganism, tomato paste from tomatoes modified to reduce the action of an enzyme, polygalacturanase, that causes the fruit to soften, and manufactured foods containing soya and maize products from plants genetically modified to confer herbicide tolerance or insect resistance.

However, the introduction of these items has not been without its problems. The cheese and tomato paste were labelled, in the latter case with large lettering drawing attention to the fact that the paste was made from genetically modified tomatoes. There appeared to be very little hostility to the products and the labelling allowed consumers a choice between genetically modified and traditional varieties. Public concern was triggered by the introduction particularly of the soya products from genetically modified plants into about 60% of manufactured foods without appropriate labelling. As a result of this and other factors there is at the present time in the UK a huge press and public concern about the environmental safety of genetically modified crops and the safety of genetically modified foods, and it is not clear yet where this will lead.

The notion that the introduction of genetically modified foods would elicit a public backlash predates the introduction of such items into our diet. The reasons for distrusting the technology and its products operates at various levels and these have been discussed and reviewed extensively (Frewer and Shepherd, 1998; Reiss and Straughan, 1996; Straughan, 1998). At the ethical level there are concerns about scientists ''playing God'' by tinkering with the stuff of life, that genetic manipulation breaches the natural barriers and boundaries between species which Nature has set up through the process of evolution, and that genetic manipulation distorts mankind's relationship with the rest of nature. There are also concerns that the technology is an expensive one and will not be available to ''poor'' farming communities and may even distort the economies of third world countries.

At the consumer level, there are worries about the future safety of the technology, i.e., it is not a worry about the technology but rather about its consequences. The risks envisaged are often catastrophic in nature, for example the creation of superweeds from the escape of engineered genes in crop plants into wild relatives or the development of serious illness at some long time in the future. The problem

is that in theory any activity could lead to catastrophic consequences and the UK population has been sensitised by the emergence of new variant CJD by apparent consumption of meat from cows infected by BSE, in spite of assurances to the contrary.

Risks are unavoidably involved in any activity, but the question is whether irresponsible and unjustifiable risks are being taken. To counter this view it is possible to point to the fact that the possible harmful effects seem to be entirely speculative; there have been no reports of illness from the consumption of such foods. Additionally, the stringent regulations that have been described and operate across the developed world would eliminate many of the horror scenarios described for the future by opponents of the technology.

Consumer concerns across the globe are not uniform. There seems to be much less concern about the consumption of genetically modified foods in the USA than in Europe, but we live in interesting times and the resolution of these difficult issues will occupy us for some years to come.

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