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Regulatory Procedures in Securing Approval for New Sweeteners

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ABSTRACT

The introduction of new ingredients into the UK food supply is controlled by various means, largely under the umbrella of the Food & Drugs Act, 1955. Regulations made under the Act cover most categories of food additives by means of positive lists and, in the case of artificial sweeteners, saccharin was until recently the only permitted additive. This situation was changed as a result of recommendations made by the Food Additives & Contaminants Committee (FACC) after a four-year review of sweeteners. In common with other new additives, all sweeteners submitted to the FACC were evaluated first for case of need, and only if this was demonstrated was safety in use considered, all largely on the basis of data submitted by companies or consortia with a commercial interest in the sweeteners. In late 1983, regulations came into operation permitting the use of three new intense sweeteners and three new bulk sweeteners.

Companies developing new sweeteners must look to overseas markets in order to help recoup their investment, and this requires a global approval and regulatory strategy, and involvement with international committees such as the FAO/WHO Joint Expert Committee on Food Additives (JECFA) and the EEC Scientific Committee for Food (SCF). Although the legal systems, attitudes to food additives and approval procedures in other countries may be different from those in the UK, the petition data requirements for sweeteners are remarkably similar. However, the interpretation of the data and ideas about the rôle of non-sugar sweeteners may vary widely, leading to a heterogeneous pattern of sweetener approvals throughout the world.

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We in the UK, consumers and food industry alike, must consider ourselves fortunate that our expert-committee-based approval system is efficient, effective and objective, and generally free from political pressures.

INTRODUCTION

Non-sugar sweeteners are used extensively in most developed countries, not only in foodstuffs but also in many pharmaceutical and cosmetic products. The major food applications are in table-top sweeteners and in diet soft drinks, although in the UK such sweeteners may be used in regular soft drinks so long as a specified minimum concentration of sugar is also present.

In its 1982 Review, the Food Additives and Contaminants Committee (FACC) distinguished two types of non-sugar sweeteners: 'intense sweeteners' and 'bulk sweeteners'. In regulations that followed the review, no such distinction was drawn, and in terms of labelling food ingredients, the only sweetener designation permitted is 'artificial sweetener'. In the USA, the term 'non-nutritive sweetener' is applied to substances which may have up to the same caloric value as sucrose (i.e. $3{\cdot}75\,\mathrm{Cal\,g^{-1}}$) but must be at least 50 times sweeter (US Code of Federal Regulations, 1979). Ironically, the popular sweet dipeptide ester aspartame is regulated as a 'multipurpose additive', presumably because it functions to some extent as a flavour enhancer. Bearing in mind this array of terminology, to avoid confusion only 'sweetener' will be used in this paper and, unless otherwise stated, will cover both intense and bulk (sugar alcohol) sweeteners.

Saccharin was discovered over a century ago and has been used in food either as a preservative or a sweetener since the early 1900s. Since that time, food laws and regulations to control the introduction of new substances into the food supply have advanced to such an extent that, with saccharin and many other common ingredients, it would be by no means certain that approval would be secured under present-day criteria.

FOOD LAWS

Food laws lay down general principles covering virtually all aspects of our food supply. In England and Wales the key piece of legislation is the

Food and Drugs Act, 1955,* with parallel acts operating in Scotland and Northern Ireland. The Act contains some 137 sections, and the basic provisions are:

(i) no food shall be sold for human consumption that is injurious to health (Section 1);
(ii) all food sold shall be of the nature, substance and quality demanded by the purchaser (Section 2);
(iii) food should be properly described and the purchaser should not be misled as to its nature, substance or quality (Section 6);
(iv) food should be fit for human consumption, i.e. not infested and microbiologically sound (Section 8);
(v) ministers may make regulations covering such things as food composition, labelling, additives, contaminants, hygiene, etc. (various sections).

In the USA, the primary instrument of food law is the *Federal Food, Drug and Cosmetic Act*, as amended by the Food Additive Amendment. The latter includes the three 'Delaney Clauses' applying to food additives, colour additives and animal drug residues. As well as focusing on the carcinogenicity of additives via the Delaney Clauses, the 1958 Amendment gave the responsible agency, the Food and Drug Administration (FDA), for the first time, the authority to require a sponsor to demonstrate the safety of an additive *before* marketing could commence.

Although food laws in other countries may have evolved and may operate in different ways, the primary objectives of the legislation will be to ensure of a supply of food that it is safe, correctly described and labelled, and hygienically produced and handled.

FOOD REGULATIONS

Virtually all operations in the food industry are subject to specific regulations. The use of additives may be controlled in several ways.

Regulations on individual groups of additives (e.g. preservatives, antioxidants, colouring matters), containing a list of the only substances permitted to fulfil the particular function (Positive List), and often an indication of the commodities in which they may or may not be used.

* In England and Wales this act is no longer operative, all of the provisions on food having been incorporated intact into the *Food Act, 1984*.

Compositional regulations, often specifying the maximum concentration of a particular additive allowed (though this may be covered in additive regulations).

Labelling regulations, indicating how the presence of an additive shall be declared in or on foods offered for sale.

Standards of purity, specified either in additive regulations or in a codex or pharmacopoeia.

In England and Wales, the use of sweeteners is controlled by *The Sweeteners in Food Regulations, 1983* and only those substances listed therein are permitted for food use. *The Soft Drinks Regulations, 1964* (as amended) give maximum concentrations of saccharin (but not of other sweeteners) that may be used in different types of drinks, and *The Food Labelling Regulations, 1980* require the presence of any sweetener in a food product to be indicated by its name and/or E number and, if appropriate, by the prefix 'artificial sweetener'.

Sweeteners permitted in the USA and in Canada are described in Chapter 21 of the *US Code of Federal Regulations* and in the *Canadian Food and Drug Regulations*, respectively. Table 1 shows a comparison of the positively listed sweeteners in the UK, USA and Canada, although it

TABLE 1
Positive Lists for Food Sweeteners in Three Countries

	UK	*USA*	*Canada*
Saccharin	/	(/)[a]	(/)[c]
Aspartame	/	/	/
Acesulfame-K	/	X	X
Thaumatin	/	(X)[b]	X
Cyclamate	X	X	(/)[c]
Mannitol	/	/	/
Sorbitol	/	/	/
Xylitol	/	/	(/)+
Hydrogenated glucose syrup	/	X	X
Isomalt	/	X	X

/ = permitted; X = not permitted; [a] = prohibition deferred by SSLA (Saccharin Study and Labeling Act); [b] = FEMA GRAS (Flavour Extract Manufacturers Association, generally recognised as safe) approval in chewing gum; [c] = table-top only, restricted distribution; + = sugarless chewing gum only.

should be realised that the permitted categories of use are not necessarily equivalent in the three countries.

Where use of an additive, like cyclamate, is prohibited in one country (e.g. UK) and deemed to be safe in another (e.g. Switzerland), the scientific arguments concerning the safety and utility of the material may be finely balanced. However, in legal terms, the matter is quite simple, since additive regulations would make a non-positively-listed additive *ipso facto* injurious to health.

APPROVAL OF NEW ADDITIVES

Basically, two types of systems exist: those involving independent expert committees and those operated solely by government employees. The UK system is of the former type, the bodies involved being:

(i) Food Advisory Committee (FAC);
(ii) Committee on the Toxicity of Chemicals in Food, Consumer Products and the Environment (COT).

Any member who serves on one of these advisory committees acts in an individual capacity, and is likely to be drawn from a research institute, university, local government enforcement authority, consumer organisation or from industry. All information considered is confidential under the Official Secrets Act, though companies are encouraged to publish relevant data in scientific journals. The Committees are administered jointly by staff from the Ministry of Agriculture, Fisheries and Food (MAFF) and the Department of Health and Social Security (DHSS). About a year ago the FAC was formed from an amalgamation of the FACC and the FSC (Food Standards Committee), and the following discussion is based upon the reasonable assumption that the FAC will operate in a similar manner to that of the FACC.

In a review of a particular class of additives such as sweeteners, four stages are involved (Table 2) (Denner, 1982). The first stage occurs when ministers decide upon a review in order to update existing regulations or to investigate regulation of a new class of additives for the first time. Submissions are invited for consideration by the FAC, and on the basis of data submitted, the FAC decides upon the *need* of the various substances

TABLE 2
Additive Review Process

Stage 1	Submissions requested in additive class review FAC evaluates 'case of need' COT evaluates 'safety in use' if 'case of need' accepted FAC makes recommendations
Stage 2	Comments on FAC report New data submitted to FAC
Stage 3	Proposals for new (or amended) regulations Comments on proposals
Stage 4	New (or amended) regulations enacted

under review, in order to judge whether each one is definitely required, bearing in mind that:

the additive may be unnecessary if manufacturing processes are improved;

existing additives, either singly or in combination, may adequately perform the function in question;

a monopoly may be created (or broken);

the consumer should benefit through lowered cost and/or better choice and quality of food.

In coming to its decisions, the FAC will look particularly to potential users of an additive for documented support for its introduction. Those substances for which a case of need has been accepted by the FAC are referred to the COT for an evaluation of toxicological data. The COT reports its findings to the FAC categorising each additive in one of five classes: one fully acceptable, one temporarily acceptable, and three unacceptable classes. The FAC then writes and publishes a report containing its recommendations.

The second stage of the review is the consideration of comments and representations made by consumers, industry and other groups. Complex issues are referred to the FAC, but many minor matters are dealt with by MAFF and DHSS officials. Additional data, usually of a toxicological nature, are often submitted by industry at this stage. The review may not progress beyond this stage for various reasons, such as the impracticalities of enforcement of any proposed legislation (as with flavours), or the existence of an EEC Directive on the particular group of additives (as with solvents).

Assuming that no insurmountable difficulties have been encountered, stage three occurs when all responses have been evaluated and proposals for new regulations are made. These proposals reflect official policy but are still subject to a comment period, after which stage four is reached, when final regulations are made by Parliament and become law. The whole process can take some considerable time. For example, the review of sweeteners, from inception to enactment of new regulations, took around $5\frac{1}{2}$ years, though there were specific reasons for the delay and other additive groups have been evaluated in a shorter time. Submissions on individual new additives can be made at any time and, if successful, will lead to insertion of the additive in the positive list by amendment of the regulations.

Virtually all European countries, and many others, operate the concept of 'need' in connection with new additives. The equivalent committee in the European Economic Community (EEC) to the FAC and COT combined (called the Scientific Committee for Food (SCF)) recognises several components of 'need', such as 'technological need' (e.g. indispensable additive in manufacturing), 'economic need' (e.g. additive reduces waste, extends shelf-life, etc.), and other considerations such as appearance and texture of food (Scientific Committee for Food, 1980).

In both the USA and Canada, independent expert committees are not normally involved, and in the USA it is not necessary to demonstrate 'need' for a new additive. However, the FDA requires extensive functionality data on the applications requested so that it may be established 'that the food additive will have the intended physical or other technical effect or that it may reasonably be expected to become a component, or to affect the characteristics, directly or indirectly, of food'. Such a requirement is effective in preventing unnecessary substances reaching the food supply, since the rigour of efficacy-testing required will most probably be provided only by potential food manufacturer users of the additive, who are most likely to be large food manufacturing companies.

FOOD ADDITIVE PETITION DATA REQUIREMENTS

In order to ensure that sufficient appropriate data are submitted by companies developing new food additives, petition guidelines have been issued by governments in various countries. For example, part 171.1 of

the *US Code of Federal Regulations* (1979) outlines the FDA requirements, and the Red Book (*Toxicological Principles for the Safety Assessment of Direct Food Additives*) delves into considerably more detail on the rationale and methodology of toxicological testing. Canadian requirements are summarised in the Food and Drug Regulations, more information being supplied in a 'guidance note' (Food and Drug Directorate, 1970), although the toxicology section of the latter is now somewhat outdated. In the UK, there is no up-to-date document on petition requirements, though it is clear from recent additive reviews that these are much the same as those specified by the USA and Canada. However, the DHSS has published guidelines on toxicity, mutagenicity and carcinogenicity (DHSS, 1981, 1982*a*, *b*). Detailed petition guidelines are available for many other countries including France (*Journal Officiel de la République Française*, 1980), Belgium (*Moniteur Belge*, 1978), Holland (Food and Nutrition Council, 1973), Denmark (National Food Institute, 1981), Sweden (Swedish National Food Administration, 1977), Norway (Health Services of Norway, 1980), Australia (National Health and Medical Research Council, 1981), New Zealand (Food Standards Committee) and Japan (Federation of Food Additives Associations in Japan, 1981). International bodies such as the World Health Organization (WHO, 1978), the EEC (Scientific Committee for Food, 1980) and the Organization for Economic Co-operation and Development (OECD, 1981) offer guidance on testing methodology for food additives (and other chemicals).

Confusion can often be generated by differing concepts and interpretations of toxicological testing guidelines by regulators in different parts of the world. Some regulators use the check-list approach, requiring all listed tests, often irrespective of their relevance, on all additives, whilst others, as in the UK (DHSS, 1982*a*), are willing to take a more flexible approach and agree to a package of tests appropriate to the particular additive. Over the last few years, progress has been made, both in respect of harmonisation of testing requirements and of flexibility, though there does seem to be an inbuilt contradiction in the concept of a harmonised flexible approach!

In a typical food additive petition, three major areas would need to be covered:

additive identification and characterisation;
need, applications and projected intake;
toxicological test data.

TABLE 3
Typical Petition Data Requirements for a Major Sweetener

Identification and characterisation
(1) Name, structure, formula
(2) Specification, impurity profile, analytical procedures
(3) Chemical and physical properties
(4) Method of manufacture and quality control checks
(5) Storage stability

Use/intake profile
(1) Functionality in petitioned applications
(2) Advantages to consumer and to manufacturer
(3) Use levels, stability, interactions, residues, analysis
(4) Possible abuse conditions; nutritional considerations
(5) Per capita intake, mean and extreme values
(6) Intake in special subgroups, e.g. children, diabetics

Toxicological test (species)
(1) Acute (rat, mouse)
(2) Genetic toxicology
(3) Metabolism and pharmacokinetics (rat, dog, man)
(4) Sub-acute (rat, dog)
(5) Reproductive toxicology, including teratology (rat, rabbit)
(6) Chronic toxicity/carcinogenicity (rat)
(7) Carcinogenicity (mouse)
(8) Special studies, e.g. biochemistry, immunology, and possible studies on impurities and/or breakdown products
(9) Ecotoxicology, biodegradability, environmental impact

For a sweetener with an extensive usage pattern and significant projected intake, at least all of the topics shown in Table 3 would have to be addressed in a petition. Data are not developed by companies, or evaluated by government agencies, in water-tight compartments. For example, information on manufacturing, product specification, analysis, use pattern, etc., all impact upon safety evaluation. For a new sweetener, it would be common practice for the company involved to discuss plans and progress with the major regulatory agencies periodically throughout the development programme. This is of particular relevance in toxicology which, past and present, has been an area of major controversy for several sweeteners, for example, cyclamate, saccharin and aspartame.

TOXICOLOGICAL TESTING

In the 1940s, safety testing of food chemicals was conducted on small numbers of rats, mice and rabbits for short periods; a one-month study

was normally referred to as a chronic study (Coulston, 1966). The science of toxicology developed, and by the late 1950s the foundations for today's empirically based testing had been laid, particularly by the WHO (WHO, 1958) and FDA (FDA, 1959) with acute, sub-acute (usually 90 days) and chronic tests (12–18 months). During the 1960s and 1970s, teratogenicity, embryotoxicity and mutagenicity were added, existing tests refined and more attention paid to metabolic studies. So far in the present decade, there has been great interest in short-term tests with a view to reducing the number of animals used, but validation against standard tests will not occur overnight. The need for observations on man following either accidental or deliberate exposure has been revitalised, particularly in the UK; authorities in other countries, like the USA, do not follow this lead, primarily due to different perceptions of legal and ethical constraints.

GOOD LABORATORY PRACTICE (GLP)

In the mid-1970s, FDA scientists noticed discrepancies in toxicological reports submitted on a drug called Flagyl. A widening of the inquiries to other substances submitted by the same Company (Searle) and to the laboratory conducting a significant number of the tests led to, amongst other things: the withdrawal of aspartame from the market (before any was sold); the closure of the testing laboratory, and the establishment by FDA of Good Laboratory Practice (GLP) (US Code of Federal Regulations, 1982). The purpose of GLP is to ensure that safety testing is conducted to a high standard, the data produced are reliable and results and procedures are sufficiently well documented to enable independent checks to be readily carried out. Table 4 shows the major components of GLP as applied to non-clinical safety testing of a food additive. Clearly, all studies in animals should be conducted to GLP, but what about all of the other laboratory activities such as analysis and storage tests which may also impact upon the safety of the additive? A common-sense approach, but erring on the side of caution, appears to be taken by most companies. GLP studies require more resources than non-GLP ones and, if too much emphasis is placed on GLP, the consequence is fewer resources for research! Incidentally, FDA validated the safety data on aspartame, but this and other issues delayed the reintroduction of the sweetener for seven years.

TABLE 4
Good Laboratory Practice (GLP): Main Components

(1) *Organisation and personnel*
e.g. Management, study director, Q.A. unit
(2) *Facilities*
e.g. Animal care, specimen and data storage
(3) *Equipment*
e.g. Maintenance and calibration
(4) *Testing facilities operation*
e.g. Standard operating procedures (SOP)
(5) *Test and control articles*
e.g. Characterisation, stability, homogeneity and achieved concentration in test mixes
(6) *Protocols*
e.g. Protocol design and study conduct
(7) *Records and reports*
e.g. Study reporting requirements, storage and retrieval of records
(8) *Disqualification of testing facilities*

RISK ASSESSMENT AND RISK MANAGEMENT

Ensuring that a food additive is safe for human consumption is not a once-and-for-all exercise conducted during petition review. Certainly, it is a major decision to allow a new sweetener into the food supply and the attendant risks have to be evaluated on the basis of the available data, but strategies and options for *managing* the risk will depend primarily upon the regulatory and enforcement practices in the particular country.

For example, cyclamate was given a provisional safety clearance by the COT in the 1982 FACC Sweeteners Review, but the FACC declined to give cyclamate a positive listing because its requested use in soft drinks could have led to high consumption by children. In the USA, the existence of the Delaney Clauses places severe constraints upon the ability of the FDA to manage the risk of substances, like saccharin, which have been found to be carcinogenic (though only in one animal species and/or sex, under conditions of 'heroic' dosing). It now appears to be a growing practice for some governments to survey the pattern of use, intake and alleged adverse effects of some groups of additives, which can be thought of as a post-approval phase of risk management.

Table 5 shows just one scheme of the processes leading to, and contributing to, risk management. The scheme is somewhat arbitrary,

TABLE 5
Risk Evaluation and Risk Management

Process	*Possible procedures*
Hazard evaluation	Structure, intake; assessment of significant toxic effects
Risk estimation	Dose-response; no-effect levels Extrapolation and relevance of data to man
Risk evaluation	Acceptable daily intake (ADI) calculations Mathematical risk probability models; risk/benefit analysis; special high risk groups
Risk management	Review options available under laws and regulations Accept/reject for positive list; set specification Allow in selected products with maximum level of use Survey use pattern, intakes, idiosyncratic effects

and is not based upon practices in any particular country, but does serve to illustrate the intertwining of science, law and regulation in the risk management process (Miller, 1984).

As part of the risk evaluation process, many agencies use the concept of acceptable daily intake, originated by the FAO/WHO Joint Expert Committee on Food Additives (JECFA). The ADI is calculated by dividing the no-effect level expressed in $mg\,kg^{-1}\,day^{-1}$, usually taken from a chronic toxicity test, by a safety factor which is normally 100 (but can be higher or lower according to circumstances, such as availability of data in man).

JECFA ADI values in $mg\,kg^{-1}\,day^{-1}$ for major sweeteners are as follows: saccharin, 2·5; aspartame, 40; cyclamate, 11; acesulfame-K, 9. ADI values can be used in advance of approval in deciding which applications are permissible (the total anticipated intake not to exceed the ADI even in high consuming groups), and after approval in evaluating the significance of current intakes obtained through food surveillance.

SCIENTIFIC AND REGULATORY DECISIONS

In their data evaluations, some authorities pay a great deal of attention to the metabolic and pharmacokinetic profile of a substance, whilst others may relegate such data to a less important category. Different conclusions may be drawn upon the carcinogenicity of a compound depending upon,

for example, the tumour classification, statistical techniques and/or mathematical models applied. Differing scientific decisions on risk evaluation can be made by different agencies, following which varying types of risk management strategies may be applied. Thus, the eventual outcome of an additive submission is governed by a regulatory decision which represents the sum total of scientific assessments, risk management policies and, occasionally, other factors like public opinion.

The situation in Europe is further complicated because, in some countries e.g. France, Italy, sweeteners are regulated as drugs and so tend to be available only from pharmacies. It is possible that the current evaluation of sweeteners by the SCF may pave the way to a more uniform pattern of availability within EEC countries, but progress will undoubtedly be slow.

REGULATORY STRATEGIES

Companies developing sweeteners or other food additives must clearly be aware of the different regulatory climates prevailing in the countries which are expected to provide their major markets. The more developed countries have the resources to evaluate the enormous data package that a new sweetener generates and, for this and other reasons, will be willing to take decisions on approval or rejection. Government authorities in some other countries are often reluctant to grant an approval until either JECFA has successfully evaluated the sweetener and/or several major countries have already approved it. For such reasons, sweetener companies need to develop regulatory strategies in order to secure a succession of approvals in the most effective and expeditious manner.

Developing a new sweetener is an enormously costly and time-consuming process. A period of 8–10 years from invention to first major petition is about the minimum feasible time to accommodate all of the developmental activities in the interlocking areas of manufacturing, marketing, technology and safety. On the cost side, the current £1–2 million for toxicological tests is only a very small part of the expenditure. Upgrading a bench-scale process, first to pilot- and then to manufacturing-scale, requires a major financial outlay, and skilled personnel are required in all areas. Delays in regulatory approvals can, therefore, be extremely frustrating since, once this stage has been reached, there are unlikely to be many years of patent protection remaining, after which time any other company is free to manufacture and market the sweetener.

DISCUSSION

Uncertainties over commercial success and regulatory approvals make the development of new sweeteners a high-risk business. On the approval side, the issue of safety evaluation is undoubtedly the major contributor to regulatory uncertainty. In the USA, strong public interest in sweeteners, combined with high awareness of health issues, the openness of the regulatory system, the media polarization of consumer and industrial interests, and the propensity to turn readily to legal action, create an extremely confusing environment for the introduction of new sweeteners. In the past, it has sometimes been difficult to tell whether the true entrepreneurs are represented by companies developing sweeteners or by those attacking them on alleged health concerns! For example, a proponent of the risks associated with consumption of degraded aspartame in soft drinks took out stock market options through which he would have profited if Searle's stock price had dropped significantly as a result of his attacks. Unfortunately for him, the stock price did not fall to a great extent and details of his financial dealings were made public. However, to be fair, the majority of attacks on sweeteners and many other additives come from earnest and highly motivated individuals and groups, who are genuinely concerned about the safety and nutritional implications of the move from natural foodstuffs to the consumption of more processed, additive-containing foods. Incidentally, this kind of stance allows both sugar and non-sugar sweeteners to be denounced but apparently without a dramatic impact, since in most developed countries sales of the former have been steady, and sales of the latter have been increasing following the introduction of aspartame.

The health and safety aspects of sweetener consumption have proved a fertile ground for claim and counterclaim because concepts of safety concerns have expanded greatly over the last few years with respect to both the sources and types of hazard. Identification and quantification of chemicals (for example, sweetener impurities and/or breakdown products) are routinely possible at part per billion levels. Even if chronic studies are conducted using the sweetener with all of its impurities, and if special tests are conducted on any degradation products, eventually traces of a hitherto undetected chemical entity will be found, bringing with it actual or potential health concerns. Our spectrum of health hazards has broadened to cover new areas such as behavioural, mutagenic and allergenic effects. As we have attempted to address such

issues by increasing the depth and breadth of safety data, this in turn has multiplied uncertainty and controversy over the most appropriate ways of assessing human risk for both normal individuals and for special sub-groups. At the scientific level, discussion of this uncertainty, particularly involving assessment of carcinogenic risk, has become almost theological, often being connected with current *theories* proposed to explain the cancer process. The spilling over of such discussions into the media frequently occurs out of context, and basic provisos concerning the dose, route species, etc., of the tests in question, and the often arbitrary assumptions made in their interpretation, may well be omitted. Lifespan, high dose animal studies are feasible to a large extent because food additives are remarkably *non*-toxic, whereas there is a myriad of known and unidentified substances occurring naturally in food, whose toxicity would preclude such extensive testing. In comparison to their number, very few of these natural toxicants have been properly tested, and it is to be hoped that any extension of research in food safety will include such substances, and not follow the present over-zealous concentration on food additives.

In the approval of new sweeteners, governments bear the responsibility of safeguarding the health of the nation, but hopefully not by adopting an approach that is so unreasonable that innovation in the food industry is stifled. In the UK, we have an approval system and a general approach which seems to avoid some of the excesses occurring in the USA. Dr Sanford Miller of the FDA reflected recently (Miller, 1984) upon our two systems, as follows.

> I heard the other day many people are looking with great longing at the system Peter Bunyan described in England. They say, 'Gee, how rational this whole system looked with expert committees and industry input and all that kind of stuff,' but I would hasten to ask these individuals whether they would be willing to give up their rights of appeal to agency decisions, whether they are willing to give up their rights to go to higher and higher courts to keep the matter going, whether they are willing to give up their rights to prolong the regulatory activity as long as they want and in fact, give up their rights to open kinds of hearings of one kind or another. The fact of the matter is that decisions are made in most countries, not all certainly, but in most countries in camera. Scientific committees make their recommendations based on discussions they hold without necessarily providing complete

> records of what went on in the meeting. Members of the committee do not have to reveal all of their associations and those of their wives, grandchildren, and anybody else they have contact with, and that is fine, but if that is the system that we want then we had better make some fundamental changes in the American legal and political system, and I don't think that is going to come.

The confidential aspects of the UK system have been attacked recently (Millstone, 1984), and the complete disclosure of toxicological information is advocated. The UK authorities do in fact strongly recommend publication of safety data by companies making submissions, and this lead is often followed when scientific journals can be persuaded to publish what are overwhelmingly negative data. Additionally, toxicological data summaries on food additives are available in JECFA monographs. With the possession of toxicological data should come responsibility in its dissemination, but the media in the UK have all too often shrugged off such responsibility in the interest of a 'good story' by taking a simplistic 'black-and-white' approach to complex safety issues. It is not surprising, therefore, that the average consumer's view of food additives is one of great concern, and of suspicion of the food industry, whereas 'natural' or 'additive-free' foods are perceived as entirely safe and marvellously nutritious. Perhaps the strengthening of legislation on defamation of product, or group of products, might lead to a more balanced presentation of such issues and to a reshaping of consumer views to something nearer the truth.

In conclusion, we have seen that governments in different parts of the world acquit their responsibilities in the introduction of new sweeteners and other additives in different ways, and notwithstanding Dr Miller's remarks and the complaints of home-based critics, I feel that the UK system gives a fair deal to all interested parties.

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