IV The Influence of Legislation on Research in Flavour Chemistry

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The proposition that the sale of adulterated food should not be allowed appears to be a statement of the obvious. However, it is apparent that one man's adulteration is another's amelioration and that which some consider to be a garden pest others prize as an edible snail. It is necessary, therefore, to elaborate on the sentiment, defining the meaning of the words used; in short it is necessary to draft laws and initiate legislation.

The Chemical Society too has it's rules. Few chemists know them well but despite their ignorance they usually conform to the rules because they match the common interests of chemists. In many ways societies like this model the state, *e.g.*, the rules are devised and perfected by a select few who, on behalf of the majority, take great pains to match the words to the sentiments.

In the United Kingdom, in the European Community and elsewhere, the members of these macro societies employ professional law writers—the civil servants. Although the authority for the law of the land derives solely from our democratically elected parliaments and hence from us, the structure of our states is such that in the writing of law relating to food, the effective power is in the hands of the men from the Ministry.

Although the Ministries are not without some effect on academic research, the following remarks are confined to the effect of some postulated legislation on flavour research which is commercially funded. The ultimate source of those funds is the purchaser of the end product, the consumer. The consumer is not a special variety of *Homo sapiens*; everyone is a consumer and each time a person chooses to buy or not to buy he very effectively criticizes the goods on offer. Hence research into flavour chemistry is undertaken with the firm intention of providing an incentive to the purchaser to choose the product which has benefited from the results of that research. Research, therefore, is also an investment made in the expectation of achieving a counter balancing financial reward. This is the most critical area where legislation may affect research into flavour chemistry.

In order to depict the consequences of legislative action it is necessary to examine the financial description of a research project and a model situation is shown in Figure 5. Imagine that an idea, a product concept, has been tabled. Research estimates that two years work at £10,000 a year is needed and Marketing calculate that if the idea can work then sales can be such that the net income shown in the table will be realized. The solid lines show these basic facts. The accountants

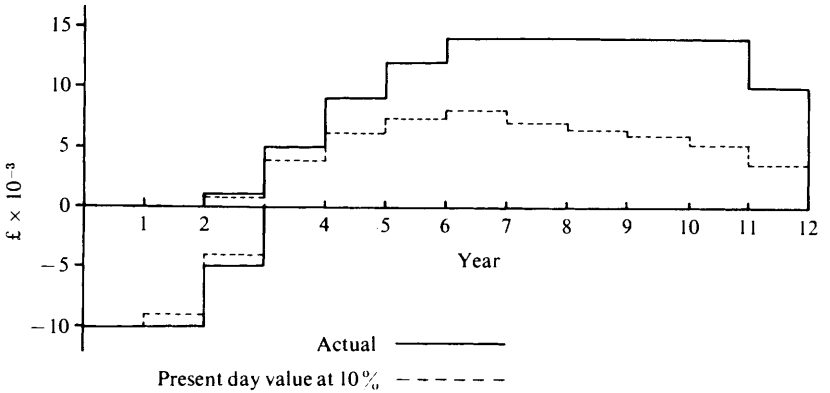

Figure 5 *Model research project*

then rightly point out that a promise of £14,000 in year eight is not the same as £14,000 in the bank today. They teach the necessity of working in present day values and the dotted line in Figure 5 shows the value today of the expectations discounted at 10%.

A research project in these terms is indeed a projection. This is not an historical record but a prediction. One further factor has to be tabled. Research is the exploration of the unknown. It can, therefore, fail. For this simple model it is assumed there are only two possible results, total success and total failure. At this point the relative probabilities of the outcomes must be weighed. Assume that the probability of success decided on is 0.7. The project is now completely described in financial terms; an investment of £23,000 at today's values for a 70% chance of receiving £55,000, again at present value. In fact one looks at the converse, the 30% chance of investing £23,000 with no return at all. The project has a mean expected income of £55,000 × 0.7, that is £38,500 but this is *not* one of the two possible outcomes. It is vital to reduce the chance of loss.

This is achieved by having more than one project, in fact by having a research programme. Consider a very simple model programme consisting of five projects each with the financial description which has just been detailed. Table 12 shows the possible results of such a programme and the probability of each result. There is a 1/500 chance of no success at all. There is only a 3% risk that £5,000 or more will be lost. This might be an acceptable situation. However, these are very simplified models put up solely to illustrate what can go wrong if an unfortunate legislative act is committed or indeed threatened. The following can go wrong: (*a*), Research and Development costs can be increased; (*b*), the chances of success can be reduced; (*c*), the timing of sales can be put back; (*d*), the magnitude of sales can be diminished.

Some of the proposed legislation can achieve all of these changes in the financial picture at one stroke. However, for the present the gross effects of these distortions are considered. Essentially they diminish the incentive to commit

Table 12 *Model research programme*

Five financially identical projects

Research costs	£23,000
Projected net income if successful	£55,000
Probability of success	0.7

Probability of outcome equal to or not worse than result shown	*Possible results*
1.000	Lose £115,000
0.998	Lose < £60,000
0.97	Lose £5,000
0.84	Gain £50,000
0.53	Gain £105,000
0.17	Gain £160,000

Programme mean expectation: Gain £77,500

resources to Research and Development. It may become more profitable to improve the distribution system or to indulge in more advertizing than to engage another flavour chemist. Successful businesses are successful because they adapt rapidly to their environment. Very successful businesses anticipate the environmental changes and plan their adaptation in advance. However, the major victim will as usual be the consumer. The gross effect of ill-considered legislation must be to deny to the consumer the improvements which he might otherwise have enjoyed. One of the most extraordinary distortions of the truth is put about by those who relentlessly insist on doing good for us. They claim that all their efforts are aimed at restraining the wicked manufacturer or the trader. This claim does not sustain close examination since usually the restraints do not apply to manufacture for export. The restrictions bear entirely on the domestic consumer. In effect the legislators and the do-gooders are saying to the consumer, we will tell you what you may eat and what you may not eat, in what unit quantities you will be permitted to buy it, and so on. The analogy with the censorship of the written word is obvious. The offence is committed by the publisher but the objective is to prevent public access to kinds of literature which authority deems to be harmful. The *Codex Alimentarius* and the *Codex Expurgatorius* have a great deal in common.

Another analogy is relevant in this connection. In the seventeenth century the witches of Salem were hung. This particular set of trials is well recorded but there were many more victims in Europe at that time. The important factor is that, at that time, throughout the world there was universal belief in witchcraft. Everyone concerned, accused as well as accusers, the judges, the people and their leaders, sincerely and honestly believed that they dealt with a very real problem—witchcraft.

Today, thanks to the activists of the consumerist movement, to the delight of the media in predicting doom, and of course to authority which converts all

things to its own sustenance, the people at large are persuaded that they are in peril from food additives and flavours. It is ironic that the *Codex Alimentarius* draft code of ethics for the Internation Trade in Food is graced by a remarkably appropriate quotation, dating back some 3,500 years. It reads: 'Thou shalt not bewitch thy neighbours fat' (FAO/WHO CY/GEN 77/1 June 1977). Little has changed in thirty-five centuries except that the flavour chemists are now cast in the role of the witches.

It is in this context of almost superstitious fear that legislation is being formulated. It is not a context that admits rational argument and always one is finally confronted with the two ultimate absurdities; prove that it is safe and prove that regulatory action is unnecessary.

In this context the possibility of the legal control of the use of flavourings by total positive listing cannot be ignored. Suppose one of the research projects was aimed at establishing the identity of the more important substances contributing to the delightful aroma of butter fried mushrooms and assume that this work leads to the identification of just one novel compound and its synthesis. The R & D money has now been spent but the discovery cannot be exploited since the substance is not on the positive list! Presumably there will be some mechanism for petitioning the authorities for it to be added to the list. One has to make a guess about the delay this will entail: assume, for example, that it is one year. Immediately this diminishes the present day value of the predicted income by 10%. This is the most optimistic view. A more likely result of such a petition will be a demand for biological work costing, for a modest programme, perhaps another £10,000 and a further delay of one year. An additional factor to take account of is that biological work can, on an innocuous substance, incur a risk of an adverse verdict arising by chance. The original picture of a R & D investment at present day values of £23,000 with a 0.7 probability of a return income of £55,000 has now altered to an investment of around £31,000 and a 0.60 probability of an income of £44,550. That becomes a mean expectation of an income of about £27,000 and that is a mean expectation of a loss of £4,000. If the expectation of success had been left at a probability of 0.7 it would have meant a mean expectation of just about breaking even. Why does the probability of success fall even though it has been assumed that our substance is quite innocuous?

In biological testing a randomly selected group of test animals is subjected to large doses of the test substance and their responses are compared with a similar, randomly selected, control group. Two kinds of quantified observations are possible, typified on the one hand by weights of an organ and on the other hand by counts of injuries (*e.g.* tumours). It is well known that individuals of a species vary naturally one from another and in this circumstance the methods of statistics seem appropriate. The logic of the usual analyses is worth careful consideration. In effect one makes the hypothesis that the test substance is without effect. Hence the two groups are each a sample of the composite whole. The question posed is then what is the probability of getting by chance a result equal to or more disparate than that observed. If the answer is less frequent

than 1 in 20 times then, as a reflex, out comes the cry—a significant result. When the probability of success in the model project was lowered from 0.7 to 0.6 this was equivalent to assuming that only three comparisons of this nature would be made.

Thousands of pounds have been spent and animals have been sacrificed (a beautifully appropriate word) to obtain a verdict which could be as validly obtained in 30 seconds with the aid of a pair of dice, or by tossing a coin, or if one really wanted to be scientific, by using a table of random numbers!

The author might cheerfully condone this game of roulette if he were tolerably certain that a harmful substance would be detected and condemned along with the unlucky innocent. Regrettably it is not common practice to consult a statistician in advance of fixing the protocol and to ask him how many experimental animals would be necessary, say, to detect a 10% increase in the incidence of a cancer in a given strain with only a 5% risk of not detecting an increase of this magnitude. It would be convenient to state the answer in terms of kilo rats.

One more effect must be noted. The law is a public matter; hence the contents of the positive list must be published and each addition to the list will be scrutinized carefully by everyone in the flavour industry throughout the world. It follows that the breakthrough in identifying a new substance is shared with the world before it is possible for the discoverer to begin to exploit it and therefore it is doubtful if it is possible to maintain any confidence in the sales forecast on which the expected income was based. And incidentally it would be illegal to have a gentlemen's agreement with ones competitors not to take advantage of this situation.

It is a curious quirk of this positive list scenario that it favours work on substances which do not occur naturally. The patent system gives virtually no protection to the discovery of a novel naturally occurring substance of the kind that has been discussed. This is because it is extremely difficult to police a patent. The problem is essentially the same one which makes enforcement of a total positive list by analysis an impossibility. However, a truly artificial flavour substance can be usefully patented because it can be identified by analysis. Thus the sales potential can be better protected.

Clearly the control of the use of flavour by means of a positive list must seriously diminish the commercial incentive to conduct research into flavour chemistry.

Authority has recently considered other extraordinary possibilities. The first draft of an EEC directive concerning the labelling of food would have required at least the qualitative disclosure of the composition of flavours. A rather old fashioned strawberry flavour composition was tabled to show that its disclosure would require rather a lot of additional label space to list each of its thirty or so components. It was suggested that thirty components was rather excessive. This line of discussion was closed by the submission of six foolscap sheets listing the known volatile components of natural strawberry juice.

Nor must attention be confined to legislation specifically directed at chemists or at flavours. The proposed EEC directive on Product Liability must encourage

insurance companies to consider demanding higher premium for the risks associated with innovation which is again a disincentive for R & D work in any field, including flavour research. One must pause and ask does the consumer really benefit by putting progress into the deep freeze to await more enlightened authority.

There is one small ray of hope. The U.K. law will evolve in common now with the emerging patterns of E.E.C. directives. These stem from article 100 of the Treaty of Rome which reads:

> 'The Council shall, acting unanimously on a proposal from the Commission, issue directives for the approximation of such provisions laid down by law, regulation or administrative action in Member States as directly affect the establishment or functioning of the common market.
>
> The Assembly and the Economic and Social Committee shall be consulted in the case of directives whose implementation would, in one or more Member States involve the amendment of legislation.'

Thus to be legal a directive must approximate existing laws *and* the differences between national laws must be a technical barrier to community trade. There is no authority in the Treaty for a directive demanding an extrapolation of existing national laws. No member state has a total positive list system of controlling the use of flavours. Should the E.E.C. issue such a directive, action to have it voided by the European Court could be initiated within 60 days of its promulgation.

It is a sad picture of impeded progress which is evoked by the title of this paper; the effect of legislation on research in flavour chemistry. I hold that as chemists and as scientists, we have a broad duty to our fellows to press for rational legislation founded on fact and not on fostered fears, and if the law persists in being an ass, we must not cease from calling attention to its foolishness.