FOOD ADDITIVE REGULATIONS: THE AUSTRALIAN EXPERIENCE*

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ABSTRACT

In 1876, analyses in Melbourne, Victoria, revealed the use of lead chromate as a colorant in confectionery, the use of termeric and ultramarine to color spent tea leaves for resale, the watering of milk and the use of alum to whiten bread. Public opinion eliminated lead chromate, legislation controlled the facing of tea, and regular analyses for the authorities gradually stopped the watering of milk and the use of alum. More adverse publicity led in 1905 to the Victorian Pure Food Act and associated regulations. The other states adopted similar laws but additives were restricted to specific lists of colors and preservatives, and heavy metals were limited. These regulations served well until, in the late 1940's, rapid changes in food technology, food analysis and the organization of the Australian food industry led to industry moves for the unification of the various Australian state food regulations. One result was the establishment in 1953 of a Federal Food Additives Committee. The principles adopted by this committee and the work carried out by it are described. Over the succeeding years a system of consultation and co-operation between government and industry has been developed. This is also described and its effectiveness assessed.

Food additives have been defined in several different ways; this paper will not discuss them. Rather, let it be said that in the treatment of the subject by the Australian and many other authorities, and thus for the purposes of this paper, the term includes contaminants, and the definitions for both additives and contaminants are those used already by the author (Farrer 1983) as follows:

"A food additive is a substance deliberately added to food by the manufacturer to facilitate processing or to improve appearance, texture, flavour, keeping quality or nutritional value".

"A chemical contaminant in a food is a substance which is not normally present in that food in its natural form, or which is present in concentrations not normally found, or which is not permitted under the food regulations to be present or, being an additive as defined under the regulations, exceeds the concentration permitted".

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Concern over additives and contaminants has grown in the last thirty to forty years. It was there a hundred years ago but has increased as public attention has been focused on possible long term effects and governments have been forced to take a closer look at what may or may not be permitted in which food and at what concentration. The Australian experience with this problem is presented, not as a model for ASEAN countries in which conditions are so different, but as a record from which others may select and adapt, or not, according to their needs.

In 1860 the British parliament passed **An Act to Prevent the Adulteration of Food and Drink**. This followed the revelation of gross irregularities and a campaign for action. In 1863 the parliament of the Australian colony of Victoria passed similar legislation which was welcomed by the local press (Anon, 1863) by cataloguing adulterations which, it claimed, were practised in Melbourne. Some of these adulterations concerned additives: red paint to colour anchovy paste, quassia to make beer bitter.

There were already, both in England and in the various Australian colonies, ordinances purporting in one way or another to protect food but they were not applied, partly because of apathy and partly because chemical analysis and, even more importantly, chemical analysts were lacking. The position improved greatly in the 1870s.

Twenty years earlier, Dr A. H. Hassall (1855) had shown that much could be done microscopically but Dr John Muter published in **The Food Journal**, which appeared in the years 1870-74, a series of thirteen articles on Popular Food Analysis. In them ten commodities were discussed but there were many other articles on the adulteration and analysis of food, including milk, and it has been suggested (Farrer 1980a) that the work and methods described in this journal may have stimulated J. Cosmo Newbery and Frederic Dunn in the mid-seventies to analyse samples of milk, tea and confectionery offered for sale on the Melbourne market.

They found that milk was being skimmed and watered; illegal and reprehensible but not an additive problem. They also found that many samples of tea were spent tea leaves "faced", i.e. coloured for re-use, with a mixture of turmeric and ultramarine, and that sixty-four out of sixty-nine samples of yellow or orange coloured sweets contained lead chromate. Both of these latter revelations involved additives. The tea was being coloured to deceive and the confectioners were using a hazardous substance in a highly dangerous way. A press-led publicity campaign eliminated the lead salts. Legislation did away with "faced" tea.

Following the English lead Victoria made provision for local government authorities to sample food and to submit it for analysis to authorized public analysts. However, a clear definition of adulteration was lacking and this weakness in the law coupled with public concern expressed through the newspapers and even the exasperation of magistrates (Farrer 1980b) led eventually to action.

The problem was that there was a legitimate case to be made for additives, especially preservatives, but that as the law stood all such substances were adulterants, and, early in 1903 the Chairman of the Victorian Board of Health, Dr G. A. Gresswell, said, "It may be that when a proper law is in force we may be able to authorize the use of certain preservations — of course in minute quantity — for certain specified cases". Nearly three years later, on 12 December 1905, the **Pure Food Act** became law. It was a world first.

It is only the additive implications of that Act which concern this paper but in passing it is worth noting that adulteration, which was defined, included reduction in nutritive value and commercial value. The Act itself reduced the lead content of vessels for food contact and prohibited the use of certain substances in beer, but it also provided for the

appointment of a Food Standards Committee with power to make regulations thus setting the pattern which persists.

The first regulation related to food additives. It called for the declaration on the label of the nature and amount of any preservative and the nature of any colour added. So, right at the beginning, food additives were being regulated, but the regulation recognized the need and legitimacy of preservatives properly used. In so doing it fulfilled Dr. Gresswell's prediction and gave magistrates a firm base on which to administer the law.

This Act and these regulations were Victorian only, not Australia wide, and the reason for this is historical. In the last quarter of the nineteenth century the six Australian colonies moved slowly towards federation. This was accomplished on 1 January 1901 but only at the cost of compromise by which each of the colonies yielded to the new federal government certain specified powers. Those not specified were reserved to the separate colonies shortly to become states of the new Commonwealth. Certain health matters such as quarantine became federal responsibilities but health in general was **not** passed over, hence all six of the states continued to be responsible *inter alia* for the supervision of the food supply within their own borders.

Victoria's initiative in passing a Pure Food Act with concomitant regulations was quickly followed by all the other states but, while the thrust was the same in each of them, the Acts themselves and the regulations which derived from them differed in detail. At that time this did not greatly matter because the major centres of population were separated by hundreds of miles, transport was poor and interstate trade in processed foods was low.

What was important was the philosophical approach to food additives. It was Australia wide and it was exclusive, i.e. lists of additives, specifically at that time colours and preservatives, were included in the regulations and only those included in those lists were permitted to be added to foods and only, as time went by, to certain foods. This was in direct contrast to United Kingdom philosophy in which only those additives specified could **not** be added, and to the American development of the GRAS list from which manufacturers may select additives for general use.

Before regulations were adopted some eighty textile dyes were being used in Australian foods (Madgwick 1974). Regulation was obviously necessary but there was no rational basis on which to select dyes for food use. There was not in the early days of food regulation, and there is not now, an Australian dyestuffs industry so that in practice the early regulations included by name colours which had been developed in England by chemical companies primarily for other purposes but then purified especially for food use. Most were water soluble but there were some fat-soluble dyes, too, and up to the Second World War food colours were limited essentially to what the market supplied.

Preservatives, similarly, were selected on the basis of known effectiveness, not on toxicological considerations for there were none. The value of the regulations lay in the limitation of the concentrations permitted and the range of food to which they could be added.

So also for contaminants. There was a general exclusion of harmful substances and a list of limits for arsenic and a few heavy metals such as lead, but overall metals were covered in a "catch-all" clause limiting them to not more than 5 ppm. Pesticides, of course, were not even mentioned.

Food additive control in Australia until after the Second World War was not too dissimilar from control elsewhere. There was lack of concern because knowledge of long term effects was lacking, and control was relatively coarse because analytical chemistry was far less sophisticated, and therefore less sensitive, than it is now.

Though almost untouched physically by the war, Australia changed dramatically. Communications improved to the extent that the physical distribution of manufactured goods, especially processed foods, became routine. Suddenly, the differing state food regulations became a major impediment to the free flow of such goods throughout the continent and one result was that from 1947 in rapid succession there were formed in each state Food Technology Associations (FTAs) in which food manufacturers joined together to foster common aims.

The first goal was the establishment of common food regulations in each state. The federal government was approached but said it could only advise the states and that it lacked the staff to harmonize the various state regulations.

So industry through the newly formed Council of Australian Food Technology Associations (CAFTA) offered to do the work. The offer was accepted and so began the fruitful collaboration in which industry expertise is made available to the federal government whose officers gradually developed a system of co-operation with state health departments by which officers of those departments act as moderators of industry proposals, develop their own inputs and become thoroughly familiar and in agreement with proposed new or amended regulations before their adoption is formally recommended.

The machinery to cope with this general food regulatory work has been refined by the Australian Commonwealth government over a number of years but in 1953, in response to the increasing number of questions being asked about food additives, a Food Additives Committee was established. This committee was chaired by an officer of the Commonwealth Department of Health and included officers of state and federal Departments of Health, academics and two scientists from the food industry. It continues today as the Food Science and Technology (Reference) Sub-committee (FST) of the Food Standards Committee (FSC) of the Commonwealth Department of Health and has the same general composition. It is not representational but is an expert committee assessing matters before it on the scientific evidence. It does not put items to the vote but arrives at consensus or seeks more information before passing its findings to the Food Standards Committee for incorporation into existing or proposed regulations.

In 1953 at its second meeting the Food Additives Committee adopted a set of principles which has guided it ever since. They were:

- (1) an article offered for sale as a food must be wholesome and as far as possible of itself safe from deterioration without the assistance of any addition;
- (2) additions when necessary must not detract from food value by substituting inert or less nutritious matter for a significant portion of the food;
- (3) subject to the foregoing there is little objection to the addition to food of other substances which are themselves wholesome foodstuffs;
- (4) where it is necessary to add a substance to a food for any purpose, the purpose must be specific and in the best interests of the consumer and it must be established that there is no alternative means of achieving the purpose more consistent with the best interests of the consumer;

- (5) the substance added must be –
 - (a) pure;
 - (b) itself harmless;
 - (c) in the minimum amount necessary to effect the purpose;
- (6) approval for the addition of any substance to foodstuffs should not be general but must be limited to specific foods for specific purposes under specific condition
- (7) substances may be approved to be added to specific articles of food for the following purposes –
 - (a) to improve nutritive value
 - (b) to a thoroughly wholesome but otherwise unattractive food to improve its palatability or its appearance or to render it more appetizing provided that –
 - (i) this purpose is not attainable by any improved method of processing; and
 - (ii) the artificial improvement is not a device to disguise an inferior product;
 - (c) as a preservative only when necessary because there is no alternative practicable means of preservation of the pure article;
- (8) the label must give a true description of the contents of the food including a statement of any additive other than a foodstuff.

These are good principles and are similar to those enunciated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) (WHO 1957). Essentially they acknowledge technological need for the use of food additives, public health responsibility by those who use them, and protection of the consumer from deception.

The last of these is always foremost in committee thinking but, in dealing with submissions for new additives, the two matters on which it requires evidence are technological need and toxicological safety. We shall return to these.

The adoption of these principles was the first statement of regulatory intent in the post-war approach to food additives. The second was the decision of the committee on 28 February 1957 to recommend that each state government adopt a regulation to prohibit the addition of any additive to any food unless the additive, the food in which it could be used and the maximum concentration to which it could be added were specifically stated in the regulations. This was adopted quickly in all states and emphasized Australia's exclusive philosophy which still applies. It means that each additive and every application of it in relation both to food types to which it may be added and the maximum concentrations allowable must be specifically approved. And that means that the extension of an additive from one food to another must be the subject of another submission. Australia has no GRAS list.

An application for the use of a food additive must follow an established format which calls for details of the substance including its chemical nature, likely impurities, stability or otherwise in food systems, and analytical methods for the determination of the additive itself and of any substance likely to be formed in food as a result of its use. The types of foods in which the additive is to be used must be stated with the proposed maximum and minimum concentrations of use and the likely daily intake from the total diet. The

committee also wants to know whether the additive has been approved or rejected elsewhere. Finally, the applicant must establish the technological need and describe the likely benefits accruing to the consumer.

In describing technological need the applicant must show what the additive does and why its use is necessary at all. Sometimes it can be seen that a particular product cannot be made without it. In other cases improvements in shelf-life, texture or appearance can be demonstrated; or, perhaps, improvements in packaging of particular relevance to storage, transport or presentation will be apparent. But technological need is not seen to be established if the committee thinks that an additive is being proposed for an end result which it believes could be achieved by good or better manufacturing practice. There are examples of refusal to accept for a particular purpose an additive which is toxicologically safe but for which, in the opinion of the committee, there was no technological justification.

Toxicological safety takes account of the general approach used by JECFA in relation to acute and chronic toxicity, short and long term studies in two species, biochemical effects, special information concerning mutagenicity, carcinogenicity, teratogenicity, and effects on reproduction, behaviour etc. Evidence before the committee includes original results of toxicological studies, findings of JECFA, Codex Alimentarius and the Council of Europe, and other information derived from governments, research institutes and other sources in Europe, North America and elsewhere, and from the scientific literature. Food safety is apolitical and information, perceptions and action pending are generally shared throughout the world.

When a submission is received the food technologists on the committee advise on technological need and the toxicologists/pharmacologists assess the toxicological evidence. By common consent each usually accepts the others' conclusions but, naturally, each group may and frequently does ask questions of the other. From the resulting discussion in which government members of the committee join a consensus is reached.

No-one makes a submission for a contaminant provided that processing aids such as paraffin oil, waxes, talc, etc. used in confectionery are classified as incidental additives and not contaminants and allowance is made for boiler water treatment agents which may by accident get into food products. There is a technological need for such things but the question of the control of contaminants is essentially one for the toxicologists who draw on information available and the experience of others to establish maximum permissible concentrations for specific contaminants in specific food groups, say, shell-fish, or, sometimes, in specific foods, e.g. aflatoxin in peanuts. A zero tolerance is never set because today's analytical method which shows zero may be superseded tomorrow by a more sensitive one which shows a measurable amount of the contaminant to be present.

The FST does not prepare draft regulations. It passes its findings to the FSC which is responsible for incorporating them into draft regulations and following through any consequential changes which may be necessary to existing regulations. These proposals go to all state Departments of Health, to industry and to consumer organizations all of which may comment. Any comments are similarly circulated and the whole procedure is thus a long one. But it works.

Proposals regarding additives and contaminants are usually accepted because it is understood that they are based on the best scientific evidence available. When adopted by the states, parliamentary draftsmen incorporate them into the relevant regulations and it is only at that stage that lawyers become involved. In Australia there is no place for lawyers in discussions leading to the setting of food regulations.

SOME EXAMPLES

Colours

In 1953 the committee began its work with a review of the list of permitted food colours. These substances are additives which are natural targets for control. Their use is less sustainable than that of, say, emulsifiers or even preservatives and there were papers in the literature which suggested that some, especially fat-soluble dyes, were carcinogenic. It was therefore recommended that the latter be deleted forthwith. This decision took industry by surprise with turned to consternation when it was proposed to delete certain water soluble colours as well.

At that time the committee lacked pathological and toxicological expertise and the two industry scientists were chemists. Concern was expressed that deletion was being proposed on insufficient evidence, but in hindsight the events of this period were part of the process of learning to work together. There was only grudging acceptance of technological need, especially for the cosmetic role of colours in certain foods, and there was lack of recognition that **any** physiological change induced by an additive is a warning sign.

The uncertainties of this period gave way over a few months to mutual understanding and when in 1959 doubts were cast on Rhodamine B it was recognised by all that even though this colour, because of its stability in processed foods, was a most valuable one, it had to go. Its deletion was recommended in March 1960 and acted on at once. It is inevitable that deletions from permitted lists happen quickly while additions take a long time. Caution and conservatism favour both.

From very early in its history the Food Additives Committee, as it then was, established a sub-committee to maintain a watching brief on food colours. This sub-committee had recommended the deletion of Rhodamine B and other colours but it also recommended the inclusion of some and, although the committee had no funds with which to support research, one of the academic members of the sub-committee became so interested in the problems of colour metabolism as to initiate some work himself on the elimination of tartrazine via the bile. This lead has since been followed by others and government and industry as well as academic laboratories have from time to time contributed without financial reward to the work of the committee on subjects other than food colours.

Vitamins and Minerals

In the 1950s several products on the Australian market were reinforced with vitamins and minerals to levels far in excess of those one would normally expect to find in them and these concentrations were then used by advertising men to promote the products.

In 1959, therefore, the committee initiated a review which resulted in a recommendation that the addition of vitamins and minerals should be permitted only to specified foods to certain specified concentrations, and that any claims made should be made only in a specified way. In arriving at the various concentrations recommended the committee did not rely on its own resources but drew on the expertise of government nutrition advisers. This regulation, which did not apply to normal claims for natural foods, put a stop to the ever increasing claims being made for competing products. It was seen to be a sensible regulation and was non-controversial. Most of the people involved welcomed it.

This vitamins and minerals regulation, which was adopted throughout Australia very quickly, did two things. First, it recognized that substances of perceived nutritional

significance were, if used in this way, additives. Secondly, as a corollary, that additives so defined could, in fact, be beneficial.

Aflatoxin

The story of the recognition, identification and carcinogenic potency of aflatoxin is well known; it began in 1960. In 1963 Australian regulatory authorities noted the possibility of the contamination of peanuts and oil-seed cake with aflatoxin but noted also that there was no indication of a public health problem in Australia. Late in 1965, however, Kraft Foods Limited reported to the committee that its R&D Laboratories had found aflatoxin in Australian peanuts. No recommendation was made at that time but the attention of state health departments was drawn to the potential problem and the Food Research Laboratories of the Commonwealth Scientific and Industrial Research Organization developed a simple kiln drier for use in the peanut production areas.

After this one outbreak, if such it could be called, the levels in Australian peanuts fell to the limits of detection and remained so for years, but late in 1972 one state Department of Health pointed out that Australia had no maximum level for aflatoxin and that there should be one. Consideration of methods and results obtained by government and industry laboratories led eventually to a recommendation in February 1975 that aflatoxin in foods should be limited to not more than 5µg/kg. In the meantime one state had begun to work to a limit of 10µg/kg. Both were lower than maxima being set overseas but both seemed to be well within the capacity of Australian industry even for peanuts.

Then, in 1977, when the Australian regulatory processes had arrived at general agreement on a maximum of 5µg/kg, the Kraft laboratories suddenly found Australian peanuts with up to 100µg/kg and reported the results immediately to the committee secretariat in Canberra. By the evening of the same day all the Health Departments in Australia had been informed, the toxicologists on the committee consulted by telephone and an absolute limit of 15µg/kg accepted for peanuts and peanut products only; all other foods to remain at 5.

The peanut industry were thrown into chaos and urgent meetings were held with government officers and scientists. The Peanut Marketing Board urgently updated its handling, sorting and testing methods. A large proportion of the crop was diverted to crushing and, as a matter of urgency, peanuts were sought from the United States.

Consignments of peanuts with United States Department of Agriculture certificates for "Nil Aflatoxin" were available, but there was consternation in Australia when it was found that a-USDA NIL certificate meant "less than 25µg/kg".

The sudden rise in the aflatoxin content of Australian peanuts was due to abnormal weather conditions in the growing areas. Unfortunately, the mould growth was so widespread as to infect the fields with *Aspergillus flavus* over a wide area and to ensure that never again will peanuts with aflatoxin as low as 5µg/kg or Not Detectable be available. The vigorous steps taken, combined with constant vigilance, ensure that the limit of 15 can be met but the run of the mill value nowadays is about 10.

This episode showed that on a *priori* grounds the committee wishes always to push the upper limits for contaminants as low as possible (in this case 5µg/kg for all foods including peanuts and peanut products) commensurate with industrial practicalities, but that it will set, if need be, a limit (15µg/kg for peanuts and peanut products) which industry **must** meet. It also demonstrated a high degree of co-operation between government officers at state and federal levels, members of the committee, the Peanut Marketing Board and individual companies to solve as rapidly as possible a nasty regulatory problem.

Vinyl Chloride Monomer

In 1973 a rare angiosarcoma was attributed to inhalation over a long period of time of vinyl chloride monomer (VCM) by workers in a factory making poly-vinyl chloride (PVC). This immediately directed attention to the possible pick-up of traces of VCM from food and drink packed in PVC containers.

In Australia the control of packaging migrants was covered by the blanket exclusion clause not by specific regulations. Food manufacturers generally were entirely in the hands of the manufacturers and converters of plastics but had to accept final responsibility for whatever found its way into their products. The committee responded to the VCM challenge by asking the Standards Association of Australia to establish standards for plastics for food contact. The Standards Association procedures involve everyone likely to be concerned with a product at any stage, and in this case government, industry, converter and consumer representatives all joined in pressing the representatives of the plastic manufacturers to tighten manufacturing procedures to ensure that plastics intended for contact with food would contain objectionable substances only at concentrations which would ensure that any migration into food would be at levels well below those to which there would be any toxicological objection.

Those substances include monomers, colours, plasticizers, etc., but in addition it was recommended that VCM be specifically limited by the food regulations as follows:

- in PVC containers for food use, not more than 10 mg/kg
- in PVC films for food contact, not more than 1 mg/kg
- in food, not more than 0.05 mg/kg.

This episode focused attention on the possible contamination of food by packaging materials, it led to the establishment in some countries of limits for substances likely to migrate from the package into the product; in Australia it initiated steps to ensure that regulations recommended for plastics for food contact could be met; and, finally, it stimulated co-operation with another body to follow up that initiative.

Non-nutritive Sweeteners

Non-nutritive Sweeteners are essentially flavouring substances and saccharin has for a long time been a permitted additive in foods, as tablets and as a table-top sweetener. Cyclamates were discovered by accident in the 1940s and introduced in the fifties as an alternative to saccharin.

In 1968 it was reported that cyclamates could cause bladder cancer in some animals under certain conditions, and an extraordinary trial by media followed. The American, Canadian and even the United Kingdom authorities were stamped into precipitate action to ban cyclamates, an action which is now seen to have been unjustified.

In Australia no action was taken. Non-nutritive sweeteners had always been closely regulated and limited to certain foods at certain concentrations. Accordingly, the committee coolly assessed the evidence in the light of the controlled community intake and decided that no change in the regulations was justified.

Saccharin is now thought to have weak carcinogenic properties but the Australian regulations deriving from Australia's exclusive philosophy, together with the dilution effect in total sweetener intake of the introduction of new sweeteners such as aspartame and thaumatin, are considered to be sufficient to control the intake of saccharin.

CONCLUSION

One may sum up the Australian experience with food additive regulation by pointing to the early awareness of the problem, to early government action and to the contribution of industry expertise and organization in harmonizing uncoordinated state regulations, in the first place, and then co-operating with government in establishing the current practices and assessing technological need.

In Australia the model has worked well if at times slowly. Perhaps, its most significant contribution has been the demonstration that scientists and technologists in industry will act responsibly, that industry organizations will temper the wilder expectations of the less responsible companies and that, under the moderation of government officers and academic scientists, these things can be seen to be happening.

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