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GENERAL PRINCIPLES
GOVERNING THE USE
OF FOOD ADDITIVES

First Report
of the Joint FAO/WHO Expert Committee
on Food Additives

WORLD HEALTH ORGANIZATION
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INTRODUCTION

In 1954, the Joint FAO/WHO Expert Committee on Nutrition, at its Fourth Session,¹ briefly reviewed the problem of food additives and proposed that a special conference concerned with the problem should be convened by WHO and FAO. It further suggested that this conference should consider, as a step toward international agreement and action in this field, the desirability of convening an expert committee to lay down acceptable broad general principles governing the use of food additives.

In accordance with this proposal, a joint FAO/WHO Conference on Food Additives took place in September 1955.² This Conference was an exploratory one and gave special attention to the contribution which FAO and WHO could make in this field along lines suggested by the Joint FAO/WHO Expert Committee on Nutrition. Following the interpretation of the term "food additives" adopted by the Joint Expert Committee, the Conference confined its discussions to "non-nutritive substances which are added intentionally to food."

The Conference further recommended that an expert committee concerned with the technical and administrative aspects of the problem should be convened as soon as feasible to formulate general principles. The present Committee is the result of this recommendation.³

¹ Joint FAO/WHO Expert Committee on Nutrition, Fourth Report (*FAO Nutrition Meetings Report Series No. 9*) (*Wld Hlth Org. techn. Rep. Ser.* 1955, 97).

² Joint FAO/WHO Conference on Food Additives, Geneva, 19-22 September 1955, Report (*FAO Nutrition Meetings Report Series No. 11*) (*Wld Hlth Org. techn. Rep. Ser.* 1956, 107).

³ The WHO Executive Board, at its nineteenth session, adopted the following resolution:

The Executive Board:

1. *Notes* the first report of the Joint FAO/WHO Expert Committee on Food Additives;
2. *Thanks* the members of the Committee for their work;
3. *Expresses* its appreciation to the Food and Agriculture Organization for its collaboration; and
4. *Authorizes* publication of the report.

(Resolution EB19.R16, *Off. Rec Wld Hlth Org.*, 1957, 76,5).

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ORGANIZATION OF THE COMMITTEE

The Committee was attended by eight members and also by observers from the International Union of Pure and Applied Chemistry, the International Committee of Agricultural Industries, and the Permanent International Commission on Canned Foods. It was opened by the Director-General of FAO, Mr B. R. Sen, on behalf of both FAO and WHO. Dr William J. Darby and Dr B. Mukerji were elected Chairman and Vice-Chairman respectively of the Committee. Members of the staff of FAO and WHO acted as technical secretaries.

TERMS OF REFERENCE

The Committee was requested to formulate general principles governing the use of food additives. It restricted its discussions to "non-nutritive substances added intentionally to food, generally in small quantities, to improve its appearance, flavor, texture or storage properties," as proposed by the Joint FAO/WHO Conference on Food Additives in 1955. Substances which are added primarily for their nutritive value, such as vitamins and minerals, were not considered, though it was recognized that in certain instances chemicals added to food to impart a desired quality or for some other functional purpose may also be of nutritional value.

CIRCUMSTANCES GOVERNING THE USE OF FOOD ADDITIVES

The increase in the number of chemicals used or proposed for use in or on foods has imposed upon public health authorities and other governmental agencies the responsibility for deciding whether or not such substances should be employed. The socio-economic position of a country is an important factor in arriving at such decisions. Additives can contribute greatly to the preservation of food; for example, they can help prevent the wastage of seasonal surpluses. In economically underdeveloped countries, lack of modern storage facilities and the inadequacy of transport and communications may increase the necessity of using certain food additives for purposes of food preservation. Again, in tropical regions, where high temperature or humidity favor microbial attack and increase the rate of development of oxidative rancidity, a wider use of antimicrobial agents and antioxidants may be justified than in more temperate climates. In these regions possible risks associated with the increased use of food additives must be weighed against the benefits in the form of preventing wastage and making more food available in areas in which it is needed. In these circumstances, however, food additives should be used to supplement the effectiveness of traditional methods of food preservation rather than to replace these methods.

In countries which are technically and economically highly developed, the availability of adequate facilities for refrigerated

transport and storage reduces, even if it does not eliminate, the need for antimicrobial agents. In these countries, however, there is an increasing demand for more attractive foods, for uniformity of quality and for a wide choice at all seasons of the year. Moreover, large quantities of many of the foods consumed have to be transported from distant producing areas, a fact which may create special transport and storage problems. For such purposes the variety of useful food additives is great and their employment promotes the better utilization of the available foods.

The extent to which food additives are likely to be needed and their nature will therefore vary considerably from region to region and even from country to country. In decisions concerning the use of an additive, attention should be given to its technological usefulness, protection of the consumer against deception, the use of inferior techniques in processing and, above all, to the evidence bearing on the safety for use of the substance. These points are discussed in the following sections in this order.

A. Technical Purposes for which Food Additives are Used

There are a number of circumstances in which there is technological justification for the use of acceptable food additives to the advantage of the consumer.

i) Maintenance of the nutritional quality of a food

It is desirable in all circumstances to maintain the nutritional quality of foods, but this is of special importance in countries in which the supply of essential nutrients in the usual diet is marginal or deficient. Any losses may then become serious and it is particularly necessary to avoid losses of the less stable vitamins. A typical example of the use of an additive in checking such losses is the addition of an antioxidant to edible

fats which contain substantial amounts of *beta*-carotene or vitamin A, destruction of which may be accelerated by the onset of rancidity during storage. In certain circumstances the nutritional value of a food may incidentally be enhanced by the use of additives. Thus, ascorbic acid, when employed as an antioxidant will increase the antiscorbutic value of foods, such as fruit products, to which it is added, while the coloring of margarine with *beta*-carotene will enhance its vitamin A activity.

ii) *Enhancement of keeping quality or stability, with resulting reduction in food wastage*

Advantage should be taken of the many achievements of chemists and food technologists in making available a wide range of acceptable additives which can materially reduce loss of food. These food additives include a great number of agents which retard the onset of deterioration. Among these are the antioxidants, various types of antimicrobial agents, inert gases, curing agents for meats, and many spices.

iii) *Making foods attractive to the consumer*

Non-nutritive additives used to increase the appeal of a food to the consumer are, chiefly, colors, flavoring agents, emulsifying, stabilizing and thickening agents, bleaching agents and clarifiers. The value of color in food products lies mainly in the fact that the interest of consumers in a food may decrease if it does not have the color to which they have become accustomed. Typical instances are manufactured dairy products, such as butter and cheese, the natural color of which may vary from season to season, canned and pulped fruits and vegetables, which have lost some of their original

color during the processing necessary for their preservation, sugar confectionery and beverages. Flavoring agents are likewise useful in increasing acceptability. In some countries emulsifying and stabilizing agents are used to improve the texture of bakery products, to impart smoothness to ice cream, and to give uniform consistency to processed fats such as shortening and margarine. In many cases the product would not be widely acceptable unless such agents are used in manufacture. The desire that certain foods should be without color, and the preference for a certain consistency in a food or beverage, for a clear beverage, or for other special properties in their foods, has led to the use of other additives such as bleaching agents, thickeners and clarifiers.

Certain plant, fish and animal products formerly used largely as animal food are being increasingly used as human food. In several instances this has been made possible through the application of food additives such as flavors, colors and agents which improve texture.

Attention must be drawn to the fact that processing practices made possible by the use of additives which increase the appeal of food to consumers should not lead to their deception. Adequate labelling of food products will help to prevent such deception (p. 17).

iv) Providing essential aids in food processing

Some modern manufacturing processes require the use of stabilizing, clarifying, oxidizing and sequestering agents, acids, alkalis, buffer salts and other processing materials. Many of these substances are used seasonally and by only a segment of a given food industry. Their use, however, often permits the economical large-scale manufacture of foods of constant composition and quality throughout the year.

B. Situations in which Food Additives should not be Used

Apart from questions of acute and chronic toxicity which will be dealt with later, there are a number of situations in which the use of certain food additives is not in the best interest of the consumer and, therefore, should not be permitted.

i) To disguise the use of faulty processing and handling techniques

In some classes of foods the use of food additives may lead to abuses which are difficult to detect and thus encourage faulty or careless processing methods, such as lack of proper hygienic precautions.

ii) To deceive the consumer

The use of an additive should not lead the consumer to believe that he is purchasing food of quality higher than it really is. Typical examples include the use of strong flavoring substances to disguise incipient putrefaction, or the use of artificial colors to disguise stale or inferior raw materials. However, the use of additives in foods of high quality, the appearance, texture and attractiveness of which have been adversely affected by the use of good manufacturing processes, may be justified. There is a greater risk of deception in the use of food additives with foods sold in the raw state than with processed foods. In the case of the former, labelling is largely impracticable, and distributors may be tempted to use additives to give inferior products the appearance of more expensive varieties. Moreover, the consumer does not usually expect that raw foods will contain intentional additives.

iii) When the result is a substantial reduction of the nutritive value of the food

The use of certain additives may result in the destruction of nutrients. Thus, an additive which possesses oxidizing properties may cause a reduction in the content of a labile vitamin. Again, a nutrient thickening agent such as sugar or gelatine, normally used in substantial quantities, may be replaced by a non-nutrient agent. While in some instances there may be no objection to this practice, in others the resulting decrease in nutrient content may be significant.

It is desirable to restrict as far as possible the use of non-nutritive substances to replace ingredients which have nutritive value. This is of special importance with general purpose foods. However, the use of certain non-nutritive additives is justified in making possible the preparation of foods designed for medical or other special purposes.

iv) When the desired effect can be obtained by good manufacturing practices which are economically feasible

New and improved processing procedures can often eliminate the need for an additive. For example, in some situations color may be retained in a processed food by improvement in processing conditions or the need for a preservative may be eliminated by refrigeration or other means during storage or transport. Where feasible, these improvements are to be preferred to the use of an additive. Attention should be drawn to the possibility of certain antimicrobial agents losing their effectiveness by the production of resistant strains of food spoilage organisms after a period of use.

C. Safety for Use of Food Additives

Safety for use is an all-important consideration. While it is impossible to establish absolute proof of the non-toxicity of a specified use of an additive for all human beings under all conditions, critically designed animal tests of the physiological, pharmacological and biochemical behavior of a proposed additive can provide a reasonable basis for evaluating the safety of use of a food additive at a specified level of intake. The Committee was informed that a further technical committee would be convened to deal specifically with such toxicological procedures. For this reason, no attempt has been made in this report to deal with the problem of toxicity in detail.

The Committee stresses the principle, however, that any decision to use an intentional additive must be based on the considered judgment of properly qualified scientists that the intake of the additive will be substantially below any level which could be harmful to consumers. The decision as to a safe level should be based on knowledge of the maximum dietary level that produces no unfavorable response in test animals, of the severity and type of response in animals above that level, and of the estimated potential intake of the additive.

Toxicological considerations should include not only the food additive as such, but also substances produced in the food by the action of the additive and the possibility of the formation of toxic substances from the additive during processing, storage and household preparation. The possible interaction of additives should also be borne in mind.

Judgment as to safety must recognize that there may be groups within a population which, because of physiological state or organic disease, may be specially sensitive to the additive concerned. These groups include those suffering from a variety of chronic diseases, for example, malnutrition, parasitosis and certain degenerative conditions. In this connection, it must

be emphasized that while easily identifiable foods are readily avoided, this is not so with some food additives.

It is therefore clear that the study and laboratory testing of a substance, and the scientific advice given concerning its use, may well differ from country to country.

Permitted additives should be subjected to continuing observation for possible deleterious effects under changing conditions of use. They should be reappraised whenever indicated by advances in knowledge. Special recognition in such reappraisals should be given to improvements in toxicological methodology. In some countries additives are employed without the safeguard provided by appropriate study. The limited facilities for toxicological work in many countries should be expanded in order to meet the needs for these investigations. There should likewise be a continuing increase in the international co-operation and exchange of information in this area.

OTHER FACTORS TO BE TAKEN INTO ACCOUNT IN FOOD ADDITIVES CONTROL

A. Bearing of the Usefulness on the Decision to Permit a Food Additive

When a new food additive is proposed for use, clear evidence must be available to show that benefits to the consumer will ensue. In comparison with additives already in use, it should either be equal or more effective in producing an acceptable product, or should confer on that product acceptable qualities not produced by other additives, or should be cheaper and thus tend to reduce the price of the food to the consumer. The potential health hazard should be no greater and preferably lower than that of comparable approved additives.

B. Classes of Food in which the Use of Food Additives should be Limited

In principle, the use of intentional additives should be limited in those classes of foods which constitute a considerable proportion of the diet, and particular care should be exercised in granting permission for such use. Since the greater portion of the diet of infants and young children may be derived from a few foods, the limitation of additives in these foods is especially to be desired.

C. Need of Specifications of Identity of Food Additives

The presence of harmful impurities in food additives can be excluded most effectively by the establishment of specifications of purity. Food legislation should make provision for

limits in foods of inorganic impurities such as arsenic and heavy metals. These requirements not only provide protection from the harmful effects of such contaminants, but also have a beneficial effect on the general level of food processing. On the other hand, some food additives may contain organic impurities which are particularly dangerous, the detection of which is difficult or impossible after admixture with food. In such instances it is most important that the specifications for the food additives should exclude or limit these substances.

It is necessary that food additives, many of which are not single chemical substances, should be identifiable in chemical and physical terms. The components of such mixtures should be described and the limits of reproducible composition defined. Such identification is essential in order to compare the results of toxicity testing and to ensure that the additive tested is the additive which is used in practice.

D. Limitation on Levels of Use

The amount of an authorized additive used in food should be the minimum necessary to produce the desired effect. Some additives are self-limiting in the amounts which may be employed, due to the quantities which are technologically useful. With others, the concentrations which are likely to be used will be strictly limited by economic considerations.

However, it may be necessary to set an upper limit on the amount of some additives to be used, either in foods in general or in specific groups of foods. Such limits should be determined primarily with regard to safety, but technological considerations designed to prevent deception or the use of faulty processing techniques should also be given attention. They should be established with due attention to:

- a) the estimated level of consumption of the food or foods for which the additive is proposed;

- b) minimal levels which in animal studies produce significant deviations from normal physiological behavior;
- c) an adequate margin of safety to reduce to a minimum any hazard to health in all groups of consumers.

E. Possible Combined Effect of Food Additives

In fixing such limits as may be necessary in regard to the levels of additives to be permitted in foods or in individual groups of foods, care should be taken to avoid a gradual and unrecognized increase in the amounts present in the total diet to a point at which an adequate margin of safety is no longer ensured. At times it may be that safeguards against the indiscriminate use of an additive should be established by limiting its use to specific foods or groups.

In addition, attention should be given to the question of whether the combined effects of a number of additives with similar toxicological properties might produce an undesirable summation of reactions. Finally, there may be substances which, because of some special biological property, may have the effect of making other additives harmful. Evidence bearing on these points deserves consideration in decisions pertaining to the use of additives.

F. Need for Legal Authorization

Experience has indicated that it is essential to maintain legal control over the use of food additives. They should be used only after authorization by the appropriate governmental body.

G. Relative Merits of Using Permitted and Prohibited Lists

The Committee considered that the legal control of food additives should be based on the principle of a permitted list. This system effectively prevents the addition of any new sub-

stances to food until an adequate basis for judgment of their freedom from health hazard has been established. The safeguarding of the public health is impossible if manufacturers are allowed to use new substances before appropriate study has established their suitability for such use. The alternative method of a prohibited list may entail a considerable risk to the community since it can allow a harmful additive to be used for several years before the accumulation of sufficient evidence to warrant placing it on the prohibited list.

The use of a permitted list eliminates such dangers. At the same time it places all those wishing to introduce an additive in the same position inasmuch as adequate toxicological data must be presented before a substance can be used. The permitted list thereby tends to place the responsibility for such investigations on those who wish to employ the additive for food. It also has the added advantage of reducing the number of substances requiring extensive investigation by regulatory agencies.

The principle of permitting only certain substances has been criticized on the basis that it tends to create vested interests. Provision must therefore be made for the admission with a minimum of delay of properly tested food additives which are considered desirable. Similarly there should be provision for the immediate withdrawal of substances from use should such action become necessary for protection of health or other reasons. The legal procedure adopted for the control of food additives should not have the effect of discouraging inventiveness through impeding progress in the improvement of food processing.

While the number of food additives required for a particular purpose should be kept as small as possible, it would not be practicable for the responsible authorities to limit any group to a specific number, i.e., to insist that the inclusion in the list of a new additive requires the elimination of one already permitted.

H. Desirability and Nature of Declaration

The Committee agreed that in principle consumers should be informed of the presence of additives in their food. Label declaration is the most effective method of achieving this result, but in some countries alternative approaches have been adopted. Thus, in the United States, standards of identity for foods have been established which are available to the public and which list the permissive ingredients. These standards require the label declaration of only certain specified classes of additives. Provided that strict legal control over the use of additives is exercised, label declaration is necessary to inform the consumer rather than for the protection of his health.

Exceptions may have to be made for certain classes of food. For example, some foods are normally sold in an unpackaged form and in such circumstances label declaration becomes impractical. In other instances, the addition of certain additives is sufficiently evident and therefore label declaration may not be necessary.

Since most consumers are uninformed as to the nature and purposes of additives, confusion and suspicion tend to be created in their minds if the manufacturer is compelled by law to state the chemical name and concentration of the additive which is used. Therefore, simple declarations of the presence of a particular class of additives such as "artificial color added" or "artificial flavor added" are sufficient.

When non-nutritive additives are deliberately employed to replace nutrients in the preparation of foods for special uses, it is clearly necessary to identify the use for which the food is intended in order to avoid deception of the consumer.

I. Regulatory Control

As in other aspects of food legislation, it is virtually useless to issue regulations governing the control of additives unless the law can be enforced. Enforcement requires the employment of trained food inspectors supported by adequately staffed and equipped food control laboratories.

It is desirable to have reliable analytical methods for the detection and, if necessary, the estimation of food additives, authorized as well as non-permitted, in each class of food. There are, however, difficulties in the development of analytical procedures for the determination of substances in certain groups, for example, flavoring agents. The concentration of some of these additives is self-limiting. However, when it is necessary to establish an upper limit of concentration within a food, a reliable quantitative method should be available before the substance is authorized for use.

In communities where only limited regulatory control can be exercised, it seems desirable that permission should be confined to a small number of additives possessing especially wide margins of safety.

RECOMMENDATIONS TO FAO AND WHO

The Committee reviewed and approved the joint FAO/WHO program on food additives, including *inter alia* the publication *Current Food Additive Legislation* and the compilation of data sheets on food colors. It recommends that FAO and WHO should:

- (1) continue and expand their activities in this field, including the compilation and publication of food additive legislation and the dissemination of physical, chemical and toxicological data on individual food additives;
- (2) extend the publication program of food additive legislation to include summary reviews of relevant legislation in individual countries;
- (3) convene as soon as practicable a second session of the Joint FAO/WHO Expert Committee on Food Additives to consider procedures for the toxicological testing of food additives;
- (4) arrange by appropriate means for a comprehensive review of analytical procedures and standards of purity and, if necessary, convene a further session of the Joint Committee to review progress in this field;
- (5) continue to consult, in their work on food additives, governmental and non-governmental organizations and groups which are active in this field.

SUMMARY

(1) The increase in the number of chemicals used or proposed for use in or on foods has imposed upon public health authorities and other governmental agencies the responsibility for deciding whether or not such substances should be employed. Food additives have a legitimate use in the food processing and distribution systems of both technologically advanced and of less well developed countries, in that they promote the better utilization of available foods.

(2) The use of food additives to the advantage of the consumer may be technologically justified when it serves the following purposes:

- a)* the maintenance of the nutritional quality of a food;
- b)* the enhancement of keeping quality or stability with resulting reduction in food wastage;
- c)* making foods attractive to the consumer in a manner which does not lead to deception;
- d)* providing essential aids in food processing.

(3) The use of food additives is not in the best interest of the consumer in the following situations and should not be permitted:

- a)* to disguise the use of faulty processing and handling techniques;
- b)* to deceive the consumer;

c) when the result is a substantial reduction of the nutritive value of the food;

d) when the desired effect can be obtained by good manufacturing practices which are economically feasible.

(4) Safety for use of an additive is an all-important consideration. While it is impossible to establish absolute proof of the non-toxicity of a specified use of an additive for all human beings under all conditions, critically designed animal tests of the physiological, pharmacological and biochemical behavior of a proposed additive can provide a reasonable basis for evaluating the safety of use of a food additive at a specified level of intake. Any decision to use an intentional additive must be based on the considered judgment of properly qualified scientists that the intake of the additive will be substantially below any level which could be harmful to consumers. Permitted additives should be subjected to continuing observation for possible deleterious effects under changing conditions of use. They should be reappraised whenever indicated by advance in knowledge. Special recognition in such reappraisals should be given to improvements in toxicological methodology.

(5) Other factors must be taken into account in food additives control. When a new food additive is proposed for use, clear evidence must be available to show that benefits to the consumer will ensue. In classes of foods which constitute a considerable proportion of the diet the use of intentional additives should, in principle, be limited. The presence of harmful impurities in food additives can be excluded most effectively by the establishment of specifications of purity. Food additives should be identifiable in chemical and physical terms.

(6) The amount of an authorized additive used in food should be the minimum necessary to produce the desired effect. The limit should be established with due attention to:

a) the estimated level of consumption of the food or foods for which the additive is proposed;

b) minimal levels which in animal studies produce significant deviations from normal physiological behavior;

c) an adequate margin of safety to reduce to a minimum any hazard to health in all groups of consumers.

(7) Legal control over the use of food additives is essential. This is best accomplished through the use of a permitted list, which effectively prevents the addition of any new substances to food until an adequate basis for judgment of their freedom from health hazard has been established. The alternative method of a prohibited list involves risk, since it may result in the use of a harmful additive before it has been adequately studied.

(8) In principle, consumers should be informed of the presence of additives in their food. Label declaration is the most effective method of achieving this result. A simple declaration of the presence of a particular class of additive is sufficient.

(9) Regulations governing the control of food additives are useless unless the law can be enforced. This requires trained food inspectors, food control laboratories, and reliable analytical methods.