

Food fortification: Safety and legislation

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Abstract

The Food and Agriculture Organization/World Health Organization (FAO/WHO) International Conference on Nutrition (ICN), held in Rome in December 1992, recognized the widespread occurrence of micronutrient deficiencies, particularly in developing countries. The conference recognized food-based approaches as the most effective way to address existing micronutrient deficiencies. These approaches must include appropriate strategies to assure dietary diversification, improved food availability, food preservation, nutrition education, and food fortification.

The final report of the conference included strategies and actions for preventing and controlling specific micronutrient deficiencies. It was proposed to ensure and legislate the fortification of foods or water with necessary micronutrients, where possible, when existing supplies fail to provide adequate levels in the diet. Food fortification has been successfully used in both developed and developing countries as one strategy to address micronutrient deficiencies.

The primary purposes of food legislation are to protect the health of the consumer, protect the consumer from fraud, and facilitate trade. In the case of fortified foods, the target population must be protected from receiving either toxic or nutritionally ineffective levels of micronutrients. Legislation may be necessary to require adequate control over this fortification process by the food processors to ensure that levels of micronutrients are consistently within acceptable limits. Legislation may also be required to prohibit the addition of nutrients to commodities where it is nutritionally unnecessary or unsafe or where fortification may create an erroneous impression as to the nutritional value of the food.

Any legislation regarding food fortification should incorporate the standards, recommendations, and guide-

lines of the Codex Alimentarius. The World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement) and the WTO Agreement on Technical Barriers to Trade (the TBT Agreement) have placed new importance on Codex standards, guidelines, codes, and recommendations.

Introduction

FAO/WHO International Conference on Nutrition

The Food and Agriculture Organization/World Health Organization (FAO/WHO) International Conference on Nutrition (ICN), held in Rome in December 1992, recognized the widespread occurrence of micronutrient deficiencies [1]. The conference's World Declaration and Plan of Action for Nutrition recommended steps to eliminate iodine and vitamin A deficiencies before the end of this decade and to reduce substantially other important micronutrient deficiencies, including iron deficiency.

The ICN recognized food-based approaches as the most sustainable way to address existing micronutrient deficiencies. These approaches must include strategies to assure dietary diversification, improved food availability, food preservation, nutrition education, and food fortification. Existing constraints in many developing countries include agricultural, economic, environmental, sociocultural, political, health-related, and infrastructural issues. In every case, the most appropriate combination of the above-mentioned nutrition strategies must be employed to overcome local constraints and achieve the desired results. It was widely recognized that the long-term solution to micronutrient deficiencies must rest on the provision of adequate quantities of all micronutrients from a well-balanced diet.

The ICN Strategies and Actions related to the prevention and control of micronutrient deficiencies included the following strategy for food fortification: "Ensure and legislate for the fortification of foods or water with necessary micronutrients when feasible, when

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existing food supplies fail to provide adequate levels in the diet.”

World Food Summit

The World Food Summit, held in Rome 13-17 November 1996, adopted the Rome Declaration on World Food Security and the World Food Summit Plan of Action [2], which laid the foundations for diverse paths to a common objective of food security at the individual, household, national, regional, and global levels. Food security exists when people, at all times, have physical and economic access to meet their dietary needs and food preferences for a healthy lifestyle.

Objective 2.3 of the World Food Summit Plan of Action is “to ensure that food supplies are safe, physically and economically accessible: appropriate and adequate to meet the energy and micronutrients needs of the population.” This objective includes the provision that governments, in partnership with all sectors of civil society, as appropriate, will “implement the goals of preventing and controlling specific micronutrient deficiencies as agreed by the ICN.”

International environment affecting trade in food

Agreement on Sanitary and Phytosanitary Measures

The Uruguay Round of Multilateral Trade Negotiations, which began in Punta del Este in September 1986, concluded in Marrakech in April 1994 [3]. The Marrakech Agreement established a new World Trade Organization (WTO) to succeed the General Agreement on Tariffs and Trade (GATT). The Uruguay Round negotiations were the first to deal with the liberalization of trade in agricultural products, an area excluded from previous Rounds of negotiations. The Uruguay Round also included negotiations on reducing non-tariff barriers to international trade in agricultural products and concluded with two binding Agreements: the Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement) and the Agreement on Technical Barriers to Trade (the TBT Agreement). The Agreements will be applied by members of the WTO.

The SPS Agreement confirms the right of WTO member countries to apply measures necessary to protect human, animal, and plant life and health. This right was included in the original 1947 General Agreement on Tariffs and Trade as a general exclusion from the other provisions of the Agreement, provided that “such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade.” Despite this general condition for the application of

national measures to protect human, animal, and plant life and health, it had become apparent by the time of the Punta del Este Declaration that national sanitary and phytosanitary measures had become, whether by design or accident, effective trade barriers.

The SPS Agreement, therefore, sets new rules in an area previously excluded from GATT disciplines. The purpose of the SPS Agreement is to ensure that measures established by governments to protect human, animal, and plant life and health in the agricultural sector only are consistent with obligations prohibiting arbitrary or unjustifiable discrimination on trade between countries where the same conditions prevail, or which are a disguised restriction on international trade. It requires that, with regard to food-safety measures, WTO members base their national measures on international standards, guidelines, and other recommendations adopted by the FAO/WHO Codex Alimentarius Commission where they exist, except that they may adopt stricter measures if there is a scientific justification for doing so or if the level of protection afforded by the Codex standard is inconsistent with the level of protection generally applied and deemed appropriate by the country concerned. The SPS Agreement covers all food-hygiene measures and food-safety measures, such as the control of residues of veterinary drugs, pesticides, or other chemicals used in meat production.

The SPS Agreement states that any measures taken that conform to international Codex standards, guidelines, or other recommendations are deemed to be appropriate, necessary, and non-discriminatory. Furthermore, the SPS Agreement calls for a programme of harmonization of national requirements based on international standards. This work is guided by a WTO Committee on Sanitary and Phytosanitary Measures to which representatives of Codex Alimentarius, the Office International des Epizooties (OIE), and the International Plant Protection Convention (IPPC) are invited.

Agreement on Technical Barriers to Trade

The TBT Agreement is a revision of the Agreement of the same name first developed under the Tokyo Round of GATT Negotiations in the 1970s. Examples given in the TBT Agreement of legitimate TBT measures are those the objectives of which are national security and the prevention of deceptive practices. The objective of the Agreement is to prevent the use of national or regional technical requirements, or standards in general, as unjustified technical barriers to trade. It covers all types of standards, including quality requirements for foods, *except requirements related to sanitary and phytosanitary measures*, and includes a very large number of measures designed to protect the consumer against deception and economic fraud. The Agreement basically provides that all technical standards and regula-

tions must have a legitimate purpose and that the impact or cost of implementing the standard must be proportional to the purpose of the standard. It also states that if there are two or more ways of achieving the same objective, the least trade-restrictive alternative should be followed. The TBT Agreement also places emphasis on international standards, WTO members being obliged to use international standards or parts thereof except where the international standard would be ineffective or inappropriate in the national situation. The TBT Agreement does not include a programme of harmonizing national standards.

Codex Alimentarius Commission

The Codex Alimentarius Commission was established by FAO in 1961. Since 1962 it has been responsible for implementing the Joint FAO/WHO Food Standards Programme, the primary aims of which are protecting the health of the consumer and ensuring fair practices in the food trade. The Codex Alimentarius Commission is an intergovernmental body, with 154 member governments. The Codex Alimentarius itself is a collection of food standards, codes of practice, and other recommendations presented in a uniform way [4]. Codex Alimentarius means "Food Code" or "Food Law" in Latin. Codex standards, guidelines, and other recommendations ensure that food products are not harmful to the consumer and can be traded safely between countries.

Food-safety standards are defined in the SPS Agreement as those relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice. As mentioned above, Codex food-safety standards are to be used as the reference point for the WTO in this area. Over the years, the Codex Alimentarius Commission has established maximum residue limits for 182 agricultural and veterinary chemicals, 39 codes of hygienic and good manufacturing practice, and 227 Codex standards. It has evaluated over 700 chemicals proposed for food-additive uses and established guideline levels for a number of environmental and industrial contaminants in foods, including radionuclides.

Food hygiene has been a major activity of the Codex since its establishment. The Codex Committee on Food Hygiene is hosted by the government of the United States and has held 27 sessions since 1963. Because food hygiene is best regulated at the production and processing stage in the exporting country, the Committee's main outputs have been Codes of Hygienic Practice rather than end-product microbiological standards. The Codex Alimentarius Commission has been actively revising much of its work in recent years to stress the so-called horizontal aspects of food regulation, including food hygiene. New considerations, such as risk analysis and the determination of equivalence in different

food-control systems, have an impact on the new approach to international food-hygiene regulations.

Codex and food fortification

The following standards, guidelines, and codes of practice adopted by the Codex Alimentarius Commission should specifically be considered in the development of national legislation regarding food fortification [4]:

- » Codex General Principles for the Addition of Essential Nutrients to Foods (GL 9-1987)
- » Codex General Standard for the Labelling of Pre-packaged Foods [Codex Stan 1-1985 (Rev. 1-1991)]
- » Codex General Standard for the Labelling and Claims for Pre-packaged Foods for Special Dietary Uses (Codex Stan 146-1985)
- » Codex General Guidelines on Claims (CAC/GL 1-1979 Rev. 1-1991)
- » Codex Guidelines on Nutritional Labelling (CAC/GL 2-1985)
- » Recommended International Code of Practice: General Principles of Food Hygiene [CAC/RCP 1 (Rev. 2-1985)]
- » Guidelines on the Application of the Hazard Analysis Critical Control Point (HACCP) System (CAC/GL 18-1993)

Trends in food-hygiene regulation

Hazard Analysis Critical Control Point system

The need for a more formal approach to the process of controlling hazards has been recognized by the Codex. In adopting the Codex Guidelines on the Application of the Hazard Analysis Critical Control Point (HACCP) system in 1993, the Codex Alimentarius Commission acknowledged that the HACCP system was the most cost-effective method devised to date for controlling food-borne hazards (GL-1993)[4].

HACCP is a system that identifies specific hazards as well as preventive measures for their control. The seven principles of HACCP, as adopted by the Codex, establish the framework for developing specific HACCP plans for each combination of food product and production line. When a specific HACCP plan is being developed, the identification of all potential hazards which are "of such a nature that their elimination or reduction to acceptable levels is essential to the production of a safe food" is required. However, the determination of which potential hazards are "essential" to control will involve a risk-based hazard assessment. This hazard assessment will result in a list of the significant hazards that should be addressed within the HACCP plan. In the specific area of food hygiene, the Codex Alimentarius Commission is revising its main document "Recommended International Code of Prac-

tice: General Principles of Food Hygiene” to incorporate risk-assessment principles and to include specific references to the HACCP system.

The application of HACCP as public policy requires defining the role of governments in the use of the HACCP process. Recent moves by some importing countries to require application by exporting countries of HACCP principles to food produced for export will result in significant trade barriers for countries unable to meet these requirements.

Other quality assurance systems

HACCP is a quality assurance system directed to the control of hazards in foods. A wider quality control system is available through the use of the ISO 9000 series of quality control. The ISO 9000 system can be used to assure the quality of both goods (products) and services.

The ISO 9000 systems are used to transfer the assurance of quality to different partners in the sequence of food processing. For example, food-packaging materials can be purchased by the food processor on the basis of quality assurance certification from the supplier. However, the use of the ISO 9000 system in the food industry is generally controversial, as it is frequently too costly for small-scale food processors to implement effectively. Also, because the ISO 9000 series provides quality assurance for the totality of the quality attributes of a food product, it goes beyond the basic regulatory requirements of ensuring that food is safe and properly labelled and presented to the consumer. Regulators are, therefore, content to insist on the application of the HACCP system to meet national and international food regulations.

Sampling and analysis at import

Risk-based inspection

When a consignment of food arrives at the point of import, national food authorities are normally required to verify that the food is in conformity with national food regulations before the consignment receives customs clearance and is released to the importer. The inspector is faced with several options, which range from the inspection of all consignments to the use of a random inspection system. It is generally recognized that the inspection of all food consignments is too costly (especially in terms of laboratory resources) and can result in loss if the food is perishable. Random inspection procedures, even if soundly based on statistics, will result in directing efforts too diffusely, with the result that foods known to be the source of risks will escape inspection.

More attention is being paid internationally to risk-based inspection systems (targeting certain foods or

hazards on the basis of the likelihood of risk). Some countries have formalized this approach and categorize imported foods as having high, medium, or low risk, assigning their inspection resources accordingly. In these systems, exporters are also categorized on the basis of their ability to conform to the importing country's requirements.

The idea of risk-based import inspection systems is incorporated into the Codex Principles for Import and Export Inspection and Certification, adopted by the Codex Alimentarius Commission in July 1995. More precise guidelines for practical application are in the course of development by the Codex Committee on Food Import and Export Inspection and Certification Systems.

Equivalence of inspection systems

The Uruguay Round SPS Agreement calls for the recognition of “equivalence” in the application of sanitary and phytosanitary measures. At a basic level, this means that the exporting country need not apply the same regulations for processing and production as are required in the importing country, provided that the outcome of the regulatory process is the same in terms of assuring the safety of the food product. The same concept applies to the inspection systems used by the two countries. The impact of this decision has special relevance for food hygiene, in which inspectors are required to exercise a high degree of judgement and for which countries have frequently adopted quite diverse systems for the selection, education, and training of inspectors.

The SPS Agreement places the responsibility for demonstrating equivalence on the exporting country, and the WTO Committee on SPS Measures is currently considering how such “equivalence” should be determined. Equivalence of inspection systems is also incorporated into the Codex Principles for Import and Export Inspection and Certification, and the concept will be developed further by the Codex Committee.

Certification control and bilateral agreements

Risk-based inspection and the recognition of equivalence in inspection systems lead to a consideration of certification procedures and the acceptability of certificates issued by national export authorities. If an exporting country is recognized as being able to provide an equivalent inspection system, then goods accompanied by a certificate issued by the exporting authorities should be subject to less frequent inspections than would otherwise be the case. This has the multiple benefit for the importer of releasing resources for inspection of other, higher-risk consignments and providing a better assurance of safety, especially if the certificate indicates that a full in-process safety-control system, such

as HACCP, has been used. For the exporter, it means better and quicker access to the importing country's market. The same objectives can be achieved through bilateral agreements that establish mutually acceptable inspection procedures (providing equivalent health protection) but do not require the individual certification of consignments.

Hygiene certificates have been in use for some time, but their acceptability is highly variable, depending on the issuing authority. The Codex Committee on Food Import and Export Certification and Inspection Systems is preparing guidance for governments in developing certification systems that should meet the requirements of importers. It is also considering guidelines for the overall scope and content of bilateral agreements covering the same area.

Methods of analysis

Analytical procedures used in food inspection have undergone changes similar to those effected in the inspection process itself. The Codex Committee on Methods of Analysis and Sampling, working in close cooperation with the International Organization for Standardization (ISO), AOAC International, and the International Union for Pure and Applied Chemistry (IUPAC), is recommending protocols for determining the reliability of analytical test methods and the results of laboratory analyses. Here, also, there is a trend towards recognizing the equivalence of different test methods that obtain reliable results, thus allowing laboratories to use the method of their choice, depending on local considerations.

FAO technical consultation on food fortification: Technology and quality control

The Food and Agriculture Organization (FAO) of the United Nations convened a Technical Consultation on Food Fortification: Technology and Quality Control in Rome, 20-23 November 1995 [5]. The following practical problems were discussed.

With the expanding range of fortificant compounds available and the need to use various vehicles according to the designated target groups, it is necessary to consider the technologies best suited to achieve a fortified product with the desired properties. The Consultation agreed that, ideally, a fortified food should:

- » be commonly consumed by the target population;
- » have a constant consumption pattern with a low risk of excess consumption;
- » have good stability during storage;
- » be relatively low in cost;
- » be centrally processed, with minimal stratification of the fortificant;

- » have no interaction between the fortificant and the carrier food;
- » be contained in most meals, with the availability unrelated to socio-economic status;
- » be linked to energy intake.

Selection of an appropriate vehicle is a critical step in successful fortification. In many cases, identification of suitable vehicles is made difficult by the absence of reliable information on dietary habits.

The desirability of providing detailed methodologies for the fortification of foods to countries with limited resources interested in carrying out such activity was recognized. In recognition of the fact that the need for information on technical procedures in the fortification of foods still exists, the consultation recommended that a database documenting fortification practices and new developments be established and maintained. This should facilitate ready access to such information internationally, thus reducing wastage of resources and improving efficiency in the establishment of food fortification.

Important lessons learned in the technical research and development work carried out for food fortification processes include the following:

- » The long time and high cost required for the development of new combinations of fortificants and vehicles must be considered in planning fortification activity;
- » Fortificants must meet quality criteria specifications explicitly established for each application, including chemical stability, appearance, bioavailability, and homogeneity;
- » Field testing of fortified food must be done at several locations in the country of intended fortification use, due to differing environmental conditions, and consideration should be given to problems potentiated by scaling up production activities from pilot to industrial scale;
- » In certain situations, promotion of the production and consumption of fortified foods has proven to be a critical factor influencing the acceptability of the food.

Active participation must be maintained by all partners involved in fortification programmes. These should include relevant governmental organizations, food industry, trade organizations, consumer organizations, academic and research facilities, and marketing and interested international organizations and agencies.

General principles for addition of nutrients to foods

At the present stage of world trade development, international provisions pertaining to the addition of nutrients to foods are necessary in order to facilitate trade in such products. Within the FAO/WHO Food

Standards Programme, the Codex Alimentarius Commission has adopted "General Principles for the Addition of Essential Nutrients to Foods" (GL09-1991) [4]. According to these general principles, essential nutrients may be added to food in order to achieve any of the following: restoration of nutrients lost during processing, nutritional equivalence of substitute foods, fortification, and ensuring the appropriate nutrient composition for a special-purpose food. The following are the basic principles for the addition of essential nutrients to foods, as stated by the Codex Alimentarius Commission:

- » The essential nutrient should be present at a level which will not result in either an excessive or an insignificant intake of the added essential nutrient considering amounts from other sources in the diet;
- » The addition of an essential nutrient to a food should not result in an adverse effect on the metabolism of any other nutrient;
- » The essential nutrient should be sufficiently stable in the food under customary conditions of packaging, storage, distribution, and use;
- » The essential nutrient should be biologically available from the food;
- » The essential nutrient should not impart undesirable characteristics to the food and should not unduly shorten the food's shelf life;
- » Technology and processing facilities should be available to permit the addition of the essential nutrient in a satisfactory manner;
- » Addition of essential nutrients should not be used to mislead or deceive the consumer as to the nutritional merit of the food;
- » The additional cost should be reasonable for the intended consumer;
- » Methods of measuring, controlling, and/or enforcing the levels of added essential nutrients in the foods should be available;
- » When provision is made in food standards, regulations, or guidelines, for the addition of essential nutrients to foods, specific provisions should be included identifying the essential nutrients which are to be considered or required and the levels at which they should be present in the food to achieve their intended purposes.

The Codex definition of fortification is "the addition of one or more essential nutrients to a food, whether or not it is normally contained in the food, for the purpose of preventing or correcting a demonstrated deficiency of one or more nutrients in the population or specific population groups." Within the above general principles outlined by the Codex, nutrient addition for purposes of fortification should be the responsibility of national authorities, since the kinds and amounts of essential nutrients to be added and foods to be fortified will depend upon the particular nutritional problems to be corrected, the characteristics of the target

populations, and the food-consumption patterns in the area. Any fortification programme should, therefore, meet the following conditions:

- » There should be a demonstrated need for increasing the intake of an essential nutrient in one or more target groups. This may be in the form of actual clinical or sub-clinical evidence of deficiency, estimates indicating low levels of intake of nutrients, or possible deficiency likely to develop because of changes taking place in food habits;
- » The food selected as a vehicle for the essential nutrient should be consumed by the population at risk;
- » The food selected as a vehicle for the essential nutrient should be stable and uniform, and the lower and upper levels of intake should be known;
- » The amount of the essential nutrient added to the food should be sufficient to correct or prevent the deficiency when the food is consumed in normal amounts by the population at risk;
- » The amount of the essential nutrient added should not result in excessive intakes by individuals with a high intake of a fortified food.

Conclusions and recommendations of the consultation

Food fortification is an essential element in nutrition strategies to alleviate micronutrient deficiencies. It is a dynamic area developing in response to the needs of population groups and industry. Efforts should continue to develop new and improved systems of delivering micronutrients to target populations through appropriate fortification procedures. To facilitate this, those involved in the establishment of food-fortification programmes locally must have ready access to information concerning fortification techniques and procedures being used all over the world. A multidisciplinary approach is essential for successful fortification, with active collaboration of all sectors involved, including government, donor agencies, food industry, local academic institutions, food legislators, and consumers. Adequate monitoring of food fortification is essential and should include both monitoring of critical control points in the production and distribution of fortified food and monitoring of the micronutrient status of target populations, in establishing the need for intervention and to assess the impact of food fortification. The importance of this underlines the need for agreement on suitable clinical and analytical methods to be used; where satisfactory methods do not exist, improved procedures should be developed. Following the deliberations of the consultation, general recommendations for food fortification were agreed upon, and specific recommendations were made with respect to the technical aspects of food fortification as deemed necessary.

General recommendations

The consultation agreed upon the following general recommendations regarding food fortification:

- » Where foodstuffs cannot provide naturally occurring essential nutrients to population groups, the use of fortification, following the principles outlined in the Codex Alimentarius, should be given serious consideration as a means of achieving ICN goals;
- » A multisectoral approach must be adopted in the establishment of any food-fortification programme, encompassing the participation of relevant governmental organizations, food industry, trade organizations, consumers, academic and research facilities, marketing specialists, and any involved international organizations and agencies;
- » Efforts should continue to harmonize national legislation concerning fortified foods with the international standards of the Codex Alimentarius;
- » International guidelines to advise food-aid donors on acceptable and safe fortification practices should be developed; guidelines should not be so restrictive as to impede the provision of high-quality food-aid commodities nor to hinder communication on fortification between relevant parties;
- » There should be appropriate fortification of foods used in food-aid programmes, with donors being required to provide relevant nutritional information, particularly through adequate labelling;
- » Levels of fortification should be evaluated and adjusted according to the bioavailability of the nutrient(s) in the diets of target populations;
- » It is important to evaluate the potential of local food industries to become involved in the production of high-quality fortified food products, including those destined for use in food-aid programmes, in areas where problems of micronutrient deficiency are likely to occur;
- » Food-control systems based on HACCP principles, risk-based inspection procedures, and internationally accepted analytical methods should be developed in support of fortification programmes;
- » The impact of food fortification on the nutritional status of target populations should be monitored so that appropriate corrective action can take place as required.

Recommendations regarding legislation and international standards

The consultation recommended the following:

- » Establishment, at the international level, of an advisory list of nutrients for use in food fortification;
- » Determination of the need for additional regulations, at the national level, pertaining to fortified foods according to specific regional, national, or even local situations;

- » Further consideration of evidence indicating the undesirable effects of excessive intakes of essential micronutrients in order to establish maximum levels of fortification where necessary.

Food legislation

The role of legislation

The primary purposes of food legislation are to protect the health of the consumer, to protect the consumer from fraud, and to ensure the essential quality and wholesomeness of foods. Food law must first provide the legal authority and an adequate legal framework for the food-control activities. It has been found that food law is managed most effectively in two parts: a basic food act and food regulations. The act itself should set out broad principles, whereas the regulations should contain the detailed provisions governing the different categories of products. Within the regulations should be found lists of approved fortificant compounds and food standards stating the allowed levels of nutrients in the fortified foods. This organization gives some flexibility to food laws, as it is much more difficult to have laws amended than to revise regulations. Prompt revision of regulations may become necessary because of new scientific knowledge, changes in new processing technology, or emergencies requiring quick action to protect the public health.

With respect to regulations dealing with fortified foods, changes might be prompted as a result of safety evaluations of nutrient compounds or new information regarding the roles and optimal levels of specific micronutrients in the maintenance of good health. Changes in food-processing and -packaging technologies could be shown to result in a significant reduction in processing and storage losses of micronutrients, thus requiring a revision in the allowed levels of added nutrients. In the face of demonstrated micronutrient deficiencies, regulations regarding standards for certain foods and levels of fortification may need to be revised.

Principles regarding food-fortification legislation

The following principles should be considered in the development of food-fortification legislation:

- » Fortification should always be in the best interests of the selected population;
- » There should be input from interested parties in the development of the law and regulations;
- » The provision of the law should allow flexibility;
- » The law should state clearly what is required or prohibited;
- » The law should create a device for enforcement;
- » The law should provide for quality assurance;

- » The law should provide the government with adequate inspection and sampling powers;
- » The law should contain both incentives and penalties;
- » The law should treat everyone equally and fairly.

Quality assurance and control

Quality assurance and control in food processing

The maintenance of a well-functioning quality assurance programme is essential if a consistent product is to result that meets all required standards. Good manufacturing practices based on the Codex General Principles of Food Hygiene should be established as the basis of any food quality assurance and control programme. In addition, an HACCP system should be developed to ensure that potential hazards are identified and either prevented, eliminated, or reduced to acceptable levels.

A quality assurance programme must consider all activities that have an impact on product safety and quality, from raw materials and ingredients used to product handling, through distribution channels, all the way to the final consumer. Components of a quality-assurance system include:

- » Raw material control: standard specifications must be adopted for all ingredients, which must then be inspected to ensure conformity;
- » Process control: all chemical, physical, and microbiological hazards as well as quality factors must be identified; critical control points must be established and monitored, and a record made of any action taken;
- » Finished product control: this requires that the finished product be unadulterated and properly labelled, and that the integrity of the finished product be protected from the environment.

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Quality assurance in food fortification

All food-production activities must be monitored and controlled within the framework of an effective quality assurance programme. The addition of nutrients to a food for the purpose of fortification increases the number of control points that must be considered. Poor manufacturing control leading to excessively high levels of nutrients in the finished product could have important health implications for the consumer if intake of the nutrient reaches the toxic dose. Conversely, low levels of nutrients in the finished product could render it nutritionally ineffective. This could also have serious health implications if the target population in the fortification programme is at high nutritional risk. Poor manufacturing control could also lead to other quality defects related to interactions of added nutrients with other components of the system.

Conclusions

Food fortification is an important element in nutrition strategies to alleviate micronutrient deficiencies in selected populations. Food fortification must, however, be controlled through the development of appropriate legislation. Adherence to the legislation will ensure that the objectives of the food-fortification programme are achieved and that the levels of micronutrients are controlled within safe and acceptable limits.

The standards, guidelines, and codes of practice adopted by the Codex Alimentarius Commission should be considered in the development of food legislation, including those related to food fortification as they are now recognized under the WTO Agreements on Sanitary and Phytosanitary Measures and on Technical Barriers to Trade.