

chapter seventeen

Basic requirements of risk evaluation and standard setting

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17.1 Introduction

Early man, in pre-Neolithic times, hunted for meat and gathered what food he could. Just like modern man, he had to balance his requirements of energy, protein, and other essential nutrients. He also tried to avoid consumption of toxic factors naturally present in certain foods, presumably achieved by careful observation and, of course, by trial and error. Clearly, it was possible for the fit to survive such a lifestyle. The population increased and eventually agricultural methods were adopted. As society developed, undergoing the industrial revolution, there was a further change in lifestyle to an urban existence, and the ensuing need for a variety of stable, nutritious and attractive foods.

The safety of the food supply is a topic of continual interest to the media and the public at large. There are many issues involved which include concerns about environmental contaminants, use of food additives, pesticide residues, microbial contamination, and nutritional quality. New developments in the food supply prompt discussions about the scientific evidence for safety and the use of suitable control measures. Governments fulfill their responsibilities for safeguarding the food supply through a variety of laws and

regulations. These responsibilities include both the nutritional and the safety aspects of the food supply.

A distinction can be made between nutritional and toxicological mechanisms underlying adverse health effects from foods, although the endpoints, or outcomes may be similar, for example, illness, poor development, and possibly death. Nutritional changes can result from unbalanced intakes of the required nutrients, i.e., surplus or deficiency. They manifest themselves primarily as physiological changes.

Toxicological mechanisms depend on interaction of toxic substances with biochemical processes, primarily leading to definite disturbance of homeostases and ultimately to adverse effects.

Safety of the food supply can be defined in practical terms as the absence of toxicity following food consumption. However, from this chapter it will become clear that absolute safety is an unattainable goal for the food supply (and any other activity associated with human endeavor). Safety must therefore be defined in relative terms such that any dangers associated with food consumption are limited to an acceptable level. The dangers must also be weighed against the need for the consumption of a range of foods that supply nutrients sufficient for survival and good health. Toxicology is therefore more than just the study of poisonous chemicals, providing a method to assess the safety of the components which make up food. The application of modern toxicological methods improves the purely empirical observation of our ancestors and allows prediction of the possible toxicity of any new food or food component.

This chapter discusses the principles involved in the safety assessment of food components and how the information obtained is used by governments to ensure a safe and varied food supply. The nutritional evaluation of food and the mechanisms whereby governments can influence the quality and quantity of the consumed food is also covered.

17.2 *Nutritional value of the food supply*

Also in modern society, it is still necessary to balance the intake of nutrients to the requirements of growth and body maintenance. However, unlike in the times of our ancestors, at least in a large part of the Western world, there is the possibility of overnutrition from an abundant food supply. This, together with a sedentary lifestyle can lead to obesity and a number of associated diseases.

17.2.1 *Nutritional considerations*

As far as food intake is concerned, developed countries usually employ two types of recommendations: *dietary standards* and *dietary guidelines*. Dietary standards help to answer the question how much of a particular nutrient is adequate for the majority of the population. In 1943, the US Food and Nutrition Board of the National Research Council published a list of Recommended Dietary Allowances (RDAs). The list has been reviewed and reissued at regular intervals (the 10th edition was published in 1989) to incorporate new nutritional knowledge. The recommended allowances represented the quantities of certain nutrients believed to be adequate to meet the known physiological needs of practically all healthy persons in the US (see also [Section 12.1](#)). Their original use was as a guide for advising on nutritional problems in connection with the recruitment of healthy young people into the armed services.

Dietary standards are also used for:

- planning food supplies to subgroups in the population;
- interpreting food consumption records of individuals and populations;

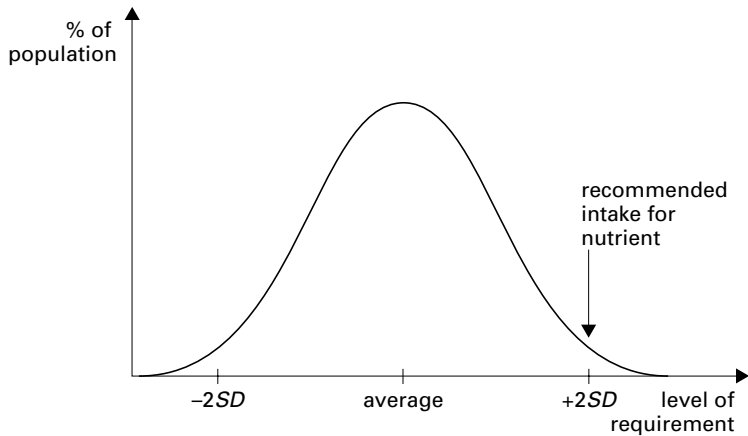


Figure 17.1 Distribution of the actual requirement of a given nutrient in a subpopulation. *SD* = standard deviation. Source: Beaton, 1985.

- evaluating the adequacy of food supplies to meet the national nutritional needs;
- designing nutrition education programs;
- developing new products in industry;
- establishing guidelines for the nutritional labeling of foods.

The recommendations are not meant to suggest that specific quantities of nutrients should be consumed every day. They are intended as a guide for intake levels averaged over a period of time (typically several days for most nutrients but over longer periods for others). This is necessary to take account of the day-to-day fluctuations in nutrient intake from the various foods consumed.

Intermezzo

RDA setting

The actual requirement of a given nutrient varies from one individual to another. If the requirements for all individuals in a given subpopulation are assumed to be normally distributed, the requirement for one particular person will be found on the characteristic bell-shaped curve (see [Figure 17.1](#)). If the RDA was set at the average requirement it would only satisfy 50% of the population. Therefore, the RDA is set slightly above the average requirement, typically by two standard deviations which, in a normal distribution, covers 98% of the chosen age or sex category. Special allowances are made for pregnant and lactating women whose requirements are unique in order to supply the fetus and suckling infant with the correct balance of nutrients.

An exception to the above is nutrient *energy* for which the RDA is set at the average requirement. The energy need varies from person to person. However, an additional allowance to cover this variation would be inappropriate because it could lead to obesity in the person with average requirements.

RDAs have been established by scientific committees in many countries but none of these can be applied globally as one single standard because of differences in diet and culture in the various countries. The task of setting RDAs is not an easy one, mainly due to a lack of basic information. As a consequence, different committees reach different conclusions, resulting in RDAs differing between countries.

It is important to understand the appropriate application of RDAs and the limitations of their use as stated in the 10th edition of the US RDAs:

- recommended allowances for nutrients are amounts intended to be consumed as part of a normal diet. Therefore, the RDAs are best met in diets composed of a variety of foods from a wide range of food groups rather than by *supplementation* or *fortification**. Such varied diets should also meet the requirements of other nutrients for which RDAs cannot currently be established;
- RDAs are safe and adequate levels of nutrient intake but are neither minimal requirements nor optimal levels of intake;
- RDAs are the amounts of nutrients which should be provided to particular groups of people. If the intake achieved by an individual is averaged over a sufficient length of time (to prevent an estimate being based on daily fluctuations of intake) and compared with the RDA, it will be possible to assess the risk of deficiency for that individual.

Dietary guidelines are recommendations for reaching an optimum nutrient balance in the diet. They aim to change the dietary pattern and thereby reduce the chance of chronic disease in a population. Such an approach is based on the results of studies on illnesses in populations or epidemiology, to enable the identification of dietary patterns associated with a low incidence of disease. The hypotheses developed from such studies may then be tested in animal models, assuming that a suitable model exists for man.

To date, dietary guidelines have not been very successful in so far that both the consumers' food choice and the industries' food supply are modified. The problem therefore appears to lie in the translation of qualitative recommendations into quantitative targets which may vary from country to country. In other words, the communication of these issues to the consumer and the food industry has not been very effective to date. The situation would be greatly improved if the European Union were to produce one set of quantitative recommendations for the whole of Europe. However, there is already a general consensus on dietary guidelines for the achievement of a healthy diet.

During the last half century, Western food supplies have become unbalanced. They now contain too much fat, too much sugar and salt, and not enough fiber. A healthy diet should be rich in vegetables and fruit, bread, cereals and other carbohydrate-rich foods, and may include fish and moderate amounts of lean meat and low-fat dairy produce. Such a diet is best to promote not only general good health but also to protect against the risk of heart and circulation problems, obesity, diabetes, some common cancers, and other Western physical disorders.

17.2.2 *Nutritional evaluation of foods*

A new or existing food can be characterized by its chemical composition. This can be achieved using chemical methods to analyze for:

macrocomponents: protein, fat, carbohydrate, and dietary fiber. These analyses can be further subdivided to include the profile of amino acids, fatty acids, and fiber types;
microcomponents: vitamins and minerals, including trace elements.

Chemical analysis will establish the presence of a particular nutrient but will provide little information on its availability when consumed in food. Measurements of the

* Supplementation results from the consumption of nutritional supplements such as vitamin and mineral tablets. Fortification is the addition of nutrients to standard foods (e.g., breakfast cereals) particularly those which may have lost some nutrient content as a result of processing.

bioavailability of the nutrient demands testing in whole-animal or other biological assays. However, the results of the chemical analysis should indicate the types of biological testing required.

17.2.3 Strategy for nutritional testing

There are three aspects to be reckoned with when testing for nutritional values:

- (a) Foods with a specific nutritional function require evidence that it actually fulfills its intended function both in experimental models and ultimately in man.
- (b) Foods predicted to cause nutritional disturbance will need to be assessed to determine the qualitative and quantitative nature of the disturbance. For example, a fat replacer designed to provide the technical functions of fat without providing fat calories may lead to a reduction in the amount of essential fatty acids in the diet of certain consumer groups. Also, if a traditional food is produced by a new process it may be altered nutritionally. The nutritional equivalence of the food as produced by the old and the new process should be established.
- (c) The nutritional properties of the food should be understood before toxicology testing is carried out so that nutritional disturbances can be distinguished from toxic effects.

17.2.4 Design of nutritional studies

The methods of nutritional research have not been standardized in the same way as toxicological studies, which are bound to internationally agreed protocols.

The following are some examples of study types to assess the nutritional properties of foods, carried out *in vitro*, in animals and, where appropriate, in man:

- on digestibility: *in vitro* and *in vivo* enzyme studies;
- on bioavailability: balance studies on intake and excretion of nutrients, growth, and carcass composition studies;
- on nutrient interaction: radioisotope and stable-isotope techniques;
- on physiological and biochemical effects: monitoring of blood and urinary composition, function tests; modification of the gastrointestinal microflora;
- on tolerance/adaptation: dose–response studies.

17.3 Toxicological factors affecting food safety

The presence of natural toxins and contaminants should be avoided whenever possible. Food production and processing should be carried out in such a way that their occurrence is minimized. Additives not only help to ensure maximum utilization and minimum deterioration of processed foods, but also facilitate the production of an attractive and wide range of food products.

To ensure a safe food supply it is first necessary to identify the *hazards* associated with the chemicals naturally present in food, i.e., the nutrients and any toxins of natural origin, and those chemicals added to food, either by accident (contaminants) or intentionally (food additives).

The next step is to assess the toxicological *risks* from the substances lacking nutrient properties, and thereby food safety. Although the terms hazard and risk will be defined elsewhere in this book ([Sections 8.4](#) and [21.2](#)), for a good understanding of food safety in the present context, it is crucial to recognize the difference between these terms and to ensure that some associated terms are used consistently.

Hazard can be defined as the intrinsic property of a substance that could lead to an adverse effect (e.g., cell toxicity or carcinogenicity). In other words, it is the toxic potential of the substance. *Risk* is a measure of the probability that a food component will cause an adverse effect as a result of human exposure. Therefore, risk is created by a hazard, but risk is not a necessary consequence of hazard. For example, a toxic chemical does not constitute a risk to man if, under the conditions of use, the target tissues are not exposed to the toxin. This may occur, for example if the toxicokinetic profile of the chemical in man is very different to that of the test species used to assess the toxicity of the chemical.

Hazard identification asks the questions: does a hazard exist?, and if so, what is it? A complex program of experimental techniques is often needed to answer these questions. Such a program could include analytical studies, *in vivo* animal studies, short-term *in vitro* cell culture tests and possibly epidemiological studies. *Risk assessment* is used to estimate the severity and likelihood of harm to human health (or the environment) from exposure to a toxic chemical. It must include an assessment of the source of that chemical and the characteristics of exposure (duration, dose, and dose response). The various factors are then integrated to give a measure of the risk. *Risk management* uses the information obtained from hazard identification and risk assessment. It also includes an assessment of the feasibility of taking action (together with a consideration of the political and economic impact) to determine the best course of action for reducing or eliminating the risk.

17.3.1 Safety assessment of new food components

Reviewing the process of safety assessment is useful from the point of view of a food company developing a new food or new food additive with a promising commercial application.

In the case of a new food, a detailed knowledge of its nutrient content is necessary for labeling on the packed food to inform the consumer. Such labelling enables the consumer to make a deliberate choice for the nutritional balance of his diet. If a traditional food is produced by a new process or a new variety is produced by selective breeding, analysis of the nutrient profile and the nutrients' bioavailability will indicate whether the novel food is equivalent to its traditional predecessor.

The new food may also contain natural toxins and it may be possible to detect and measure the levels of those that are known. In addition, the nutrient bioavailability studies and toxicological evaluation would indicate the presence of these natural toxins.

The possibility of contamination of the new food must also be considered by reviewing the processes used in its production, transport, and storage. If new contaminants are detected it will be necessary to assess the risk they pose and, as is also the case for known contaminants, to make sure they do not exceed the acceptable levels in the food.

The technical necessity of new food additives must be established to ensure that consumers are not exposed unnecessarily to the additional risk of a new chemical if it is of no particular benefit. Many people question the need for the many types of food additives presently available, but in practice, these additives are needed to ensure the availability of a range of attractive food products with a long shelf life. One only needs to look at the range of food products available in the supermarkets and consider how few would be possible without the use of some additives.

For the new preservative the support for its need should be based on its unique activity which will permit a new range of food products with an acceptably long storage life, which would not be possible with the existing preservatives. The next consideration is the safety of the new additive. It is the companies' responsibility to carry out the hazard identification. This information should be supplied to the regulatory authority which will, in conjunction with the company, carry out the risk assessment. If the risk associated with its

use is deemed acceptable, the company will be granted permission to use the new additive. This approval will probably restrict the use to particular levels in certain food products or food categories. The regulatory authority can then incorporate the new chemical into its risk management programs to monitor its levels in food products and its intake by the population in general, and by certain high-risk groups in particular. This may take the form of post-marketing surveillance in which the occurrence of any unexpected effects may be monitored in certain groups. However, the approval for the use of any new food component is based on information currently available at the time of the safety review. If new information about the safety of a chemical emerges, its use must be reviewed. For this reason, the safety of food components is continually monitored by industry and government.

17.3.2 Methods of hazard identification

The type of toxic effect and the dose level at which it occurs are important issues in hazard identification (see [Figure 17.2](#)).

The test requirements are not necessarily the same for all food components. They will be influenced by properties of the substance such as:

- expected toxicity
- human exposure levels and pattern of use
- natural occurrence of the component in foods
- occurrence as a normal body constituent
- use in traditional foods
- knowledge of effects in man

It is impossible to give a detailed review of all the requirements for the safety assessment of a new food component here. Only a general outline of the approach will be presented.

The first step is to track the existing literature to find out whether the new chemical, or one which is structurally related, has been tested in the past. Once such information is collected, it is possible to design a program for safety testing to cover the pattern in which

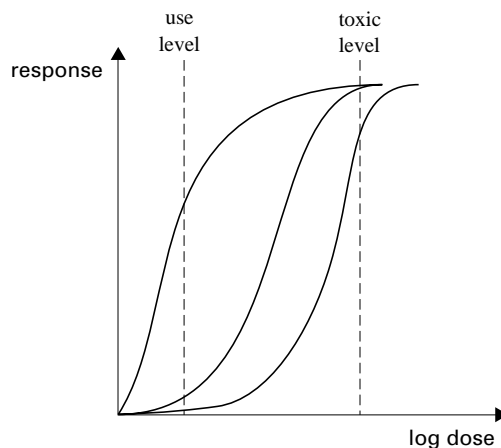


Figure 17.2 Dose–response curve. The steepness and shape of the dose–response curve indicate the size of the hazard as the dose or exposure is increased. Substances showing a steep curve with a low threshold before any toxic effect is detected, are of the greatest concern because their safety margin is very narrow.

the new food component is used. This would typically include studies of some or all of the following aspects:

- potential to cause mutagenesis in bacteria and mammalian cells
- absorption, distribution, metabolism, and excretion
- toxicity on repeated exposure for 4, 13, or 52 weeks in rodents
- effects on the reproductive systems and fetal development
- carcinogenic potential (e.g., 2-year feeding study in rodents)
- effect on the immune system
- effect on the nervous system
- effect on the endocrine system
- special studies on underlying mechanisms

The purpose of such tests is to build up a toxicological profile of the test material and to understand the dose–response relationship for any toxic response. A key determination is the assessment of the no-effect level from the feeding studies. Determination of the no-effect level depends primarily on the proper selection of doses for the study. Ideally, the highest dose should exert a toxic effect, whereas the lowest dose (a multiple of the human exposure level) should not show the effect. Additional dose groups are spaced between the top and bottom dose to define the dose–response curve further.

The risk assessment is carried out by determining the no-observed-adverse-affect-level (NOAEL) which is the highest dose in the most sensitive animal species which causes no toxic effects. The NOAEL is then divided by a safety factor to set an acceptable daily intake (ADI) level. The ADI is an estimate of the amount of a food additive, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable health risk. Substances that accumulate in the body are not suitable for use as additive. ADIs are only allocated to those additives that are substantially cleared from the body within 24 hours.

17.3.3 Safety factors

Safety factors are used to set an ADI that provides an adequate safety margin for the consumer by assuming that man is 10 times more sensitive than the test animal. A further factor of 10 is included which assumes that the variation in sensitivity within the human population is within a 10-fold range. The no-effect level, determined in an appropriate animal study, is traditionally divided by a safety factor of 100 (i.e., 10×10) to set the ADI. A food additive is considered safe for its intended use if the human intake figure is less than or equivalent to ADI. ADI is usually derived from the results of lifetime studies in animals and therefore relates to lifetime use in man. This provides a sufficient safety margin so that no particular concern is felt if man is exposed to levels higher than the ADI in the short term, provided that the average intake over longer periods does not exceed it. Higher safety factors may be used if the nature of the chemical's toxicity is of particular concern (e.g., if the substance is a carcinogen through a secondary mechanism, as is the case for bladder tumors following the formation of bladder stones caused by mineral imbalance), or if the chemical's toxicological profile is incomplete. Occasionally, lower safety factors may be used if there are human data to indicate that human sensitivity varies by less than 10-fold.

If a similar approach were applied to some essential nutrients (e.g., vitamin A, vitamin D, certain essential amino acids, and iron) it would become apparent that they may cause toxic effects at levels less than 10 times higher than those needed to satisfy the nutritional requirements for good health. This can be summarized as shown in the diagram below (Figure 17.3).

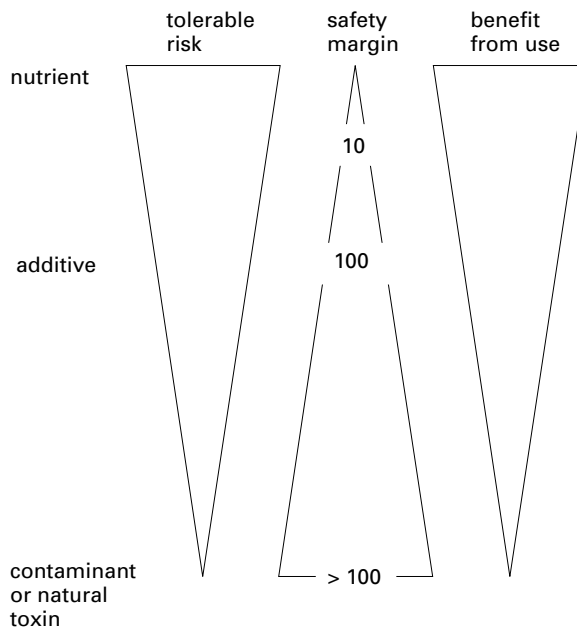


Figure 17.3 Use of safety factors. Small safety margins (2–10) are acceptable for essential nutrients e.g., selenium and vitamin A. Conversely, large safety margins (>100) should be set for contaminants. Additives will fall in-between (usually ~100). Source: ILSI Europe.

Using an ADI derived from a no-effect level found in an appropriate animal study and a suitable safety factor, implies an in-built conservatism reflecting the uncertainty of the extrapolation of experimental animal data to the diverse human population. In the case of contaminants, extrapolation is difficult from high-dose animal experiments to the human situation in which lower doses are consumed (see [Section 17.4.2](#)). The ADI also makes some allowance for the possible synergistic effects humans experience when additives are consumed together in foodstuffs. The effect of the interacting additives may be different from the responses to the individual additives.

17.3.4 Harmonization of safety testing procedures

Once a company has complied with its responsibilities for hazard identification and gained approval from the appropriate regulatory agencies, it may market its new food component worldwide. It is essential that any toxicological assessment is carried out to comply with internationally acceptable standards, to avoid the need for repetition of safety studies before gaining approval for use of the component in another country. The Organization for Economic Cooperation and Development (OECD) has developed guidelines for validated study protocols which provide acceptable basic standards for all member countries.

The World Health Organization (WHO) in combination with the Food and Agriculture Organization (FAO) through their Joint Expert Committee on Food Additives (JECFA) has also developed guidelines to improve the quality and general acceptability of food safety testing. Other organizations, including the Scientific Committee for Food (SCF) as the expert body within the European Union, EU, have also produced guideline protocols based on those of the OECD. Many individual countries have developed their own guidelines which may differ slightly from those of the OECD. Fortunately, most of these differences are disappearing as harmonization in standards increases, stimulated by the activities of the OECD, EU, and WHO.

17.4 *Setting tolerable intake levels for natural toxins and food contaminants*

Toxins of natural origin and contaminants are undesirable components which serve no nutritional or technical function (as do food additives) in the marketed food product. They constitute a large and diverse group of chemicals which man may consume in sizeable amounts. It is therefore essential that the toxicological profiles of the major natural toxins and contaminants are known so that their presence in food can be limited. The setting of acceptable intakes is based on an understanding of the toxicological profile of the component in question in a way similar to that described for food additives. In the case of contaminants, the term acceptable daily intake is changed to tolerable daily intake (TDI) to reflect the levels permissible in food to maintain a safe and varied supply (see also [Section 16.3.2.1](#) and [Section 21.4.4.3](#)).

17.4.1 *Assessment of toxicological risks from contaminants*

Contaminants are often more toxic than additives. In the ideal situation, all toxic contaminants should be removed from food, but often the factors leading to their presence are difficult or impossible to control. Therefore, the unavoidable intake of contaminants should be limited to safe levels. As for food additives, limits for the presence of contaminants in food will need to be based on a no-effect level from an appropriate toxicity study. The safety factor applied to calculate the TDI of contaminants is frequently greater than the 100-fold factor used for additives.

For some contaminants that may accumulate in the body, the tolerable intakes are expressed on a weekly basis. The principle concern with respect to such contaminants is exposure for longer periods. This makes calculating intakes over a weekly interval more relevant as this eliminates daily fluctuations in intake.

In the case of genotoxic carcinogens (i.e., carcinogens which act directly by altering the genetic material), human exposure must be reduced to the lowest practically achievable level. The JECFA introduced the concept of "irreducible level," defined as "that concentration of a substance which cannot be eliminated from a food without involving the discarding of that food altogether and thereby compromising the ultimate availability of major food supplies." This level may in fact be the lowest detectable level and therefore the sensitivity of the analytical method is a key factor in defining the tolerable exposure.

Intermezzo

Sensitivity of measuring methods

The ability of analytical methods to separate and detect extremely low levels of contaminants in food has increased dramatically in recent years to the extent that detection of one part in a million (1 mg/kg) is routine. Methods for detecting 1 part per billion are commonplace and for some contaminants, additional orders of magnitude of sensitivity are achievable. However, it is very difficult to assess accurately the toxicological significance of exposure to such low levels.

Methods of hazard identification are usually based on feeding relatively high levels of the contaminant to animals to determine whether the substance has the potential to cause a toxic reaction, for example carcinogenesis. Therefore, the methods for safety assessment are frequently not as sensitive as certain analytical chemical techniques. As a consequence, it may be necessary to extrapolate the effects seen at relatively high dose levels (used in experimental animals) to the much lower exposure levels relevant to human risk. Such

extrapolations are based on certain assumptions about the shape of dose–response curves. These assumptions are difficult to validate but the extrapolation may at least give an order of magnitude for the risk. Such techniques of quantitative risk assessment (QRA) are taken up with varying enthusiasm by the various regulatory bodies.

17.4.2 *What are the toxicological challenges for effective risk assessment of foods in the future?*

The available guidelines for the design of toxicity studies (for example those provided by the OECD) should be regarded as minimum standards for studies acceptable to the regulatory authorities. Test methods must be enhanced on a case-by-case basis to reflect the chemical nature and pattern of use or exposure to the new chemical. It is essential that the safety assessment of foods is based on the application of sound scientific principles rather than a checklist of toxicity tests to be completed prior to approval.

The guideline protocols and the safety factors employed for risk assessment are based on the assumption that new additives and ingredients will be used at levels well below 1% in the food. This assumption is not applicable to many of the current developments in food technology. The pace of development of new food additives has declined, but future developments will come from the area of biotechnology and the use of novel macro-components in the diet. The methods of genetic engineering are increasingly used to develop novel food sources with desirable characteristics. In addition, following the recognition of the need to modify the balance of macronutrient intakes to achieve a more desirable diet, materials such as fat replacers are actively developed.

These new developments pose an interesting challenge to the food toxicologist to combine his skills with the nutritionist's to develop test methods which will separate the toxic effects from those caused by altered nutrition in experimental models. Only a multidisciplinary approach will assure the continuous safety of our food supply.

17.5 *Risk management*

It is obvious then, that our food supply is composed of chemicals some of which are essential to nutrition, some of which serve no useful purpose, and others that are useful to maintain a varied food supply.

What can be done to ensure a safe food supply to the consumer? In other words, the food supply must contain sufficient nutrients to maintain health, while the levels of natural toxins, contaminants, and additives do not exceed those prescribed as safe. The two main weapons in the armory of a government are surveillance and enforcement.

Surveillance is concerned with estimating average and extreme intakes of foods by the general population or of high-risk groups within it, e.g., children, pregnant women, and the elderly. The intake of food components (both nutritious and potentially harmful) can be calculated and compared with recognized safety standards. The intakes of chemicals from food are measured from total diet surveys of standard food items purchased at regular intervals in different locations in the country. Amounts of foods consumed can be measured in diary studies where a record of the type and amount of a food or foods is kept. An extension of the diary study is a duplicate diet study in which a duplicated portion of each food item consumed is prepared and analyzed. Such studies are difficult and costly to carry out effectively, and therefore priorities have to be set and decisions to be made on the food components that are of the greatest concern and that need to be surveyed. Such techniques can provide an overview of the effectiveness of food control policies and a basis for their future development.

Enforcement is concerned with the compliance by agriculture and food producers with the legal limits for chemicals in food. Such procedures complete the chain from the safety assessment of foods and their components to the legal limits of chemicals in food established from the results of the assessment, in order to ensure consumer protection.

17.6 *Summary*

The challenges to early men who hunted and gathered their food were to obtain enough food to meet their nutritional requirements while avoiding those potential food sources that were acutely toxic. The challenges in present society are composed of some of the same elements, but the nature of the food supply is much more varied and complex. Nutritional standards and the safety of the diet are protected by regulatory processes laid down by governments. In addition, societies today are generally aware that certain food components may have effects on health in the longer term, for example on our cardiovascular health and the likelihood of developing some forms of cancer.

Safeguarding our food supply cannot be perfect, and risk evaluation and standard setting both have their problems, as illustrated in this chapter. Consumption of food, like any other activity, can never be entirely risk-free. Risks must be assessed and managed to protect the public from unsafe food components. There is a balance to be struck between the nutritional benefits of a varied diet and the low risk levels associated with food consumption.

Reference and Reading List

FAO/WHO *Evaluation of certain food additives and contaminants*. 22nd report of the Joint FAO/WHO Expert Committee on Food Additives. Technical Report Series No. 631. pp 14–15, 1978.