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Food safety legislation and regulations have long been impacted by a variety of factors, including socioeconomic, consumer, political, and legal issues. With regard to food safety issues and concerns, certain parallels can be drawn between the beginning and close of the 20th century. At the start of the 20th century, several food safety issues were brought to the public’s attention. Atrocious sanitation problems in the meat industry, highlighted in Upton Sinclair’s novel *The Jungle*, had a major influence on the passage of the landmark legislation, the *Federal Meat Inspection Act* (1906). Likewise, fairly wide-spread food adulteration with the addition of inappropriate chemical substances, and the marketing of a variety of fraudulent and potentially dangerous elixirs, concoctions, and other formulations, led to passage of the *Pure Food and Drug Act* (1906).

We are now in the 21st century and, food safety issues have as high a priority and significance as they did over 100 years ago. Public concerns have arisen regarding high-profile food-borne illness outbreaks due to contamination of food with certain pathogens (e.g., *Salmonella*, *Escherichia coli* O157:H7, *Listeria monocytogenes*, and others) which have serious acute impact and potential chronic long-term complications in the ever-increasing high-risk population segment (e.g., elderly, children, immuno-compromised). In addition, food-borne illness outbreaks are occurring in foods previously not considered high risk (e.g., fruit juices, fresh produce, deli meats). In response to these food-borne pathogen issues, a presidential budgetary initiative was instituted in 1997 to put a multi-agency food safety strategy in place. This National Food Safety Initiative includes a nationwide early warning system for food-borne illness, expanded food safety research, risk assessment, training and education pro-
grams, and enhanced food establishment inspection systems. Pathogen issues have also resulted in endorsement and implementation of comprehensive prevention and intervention strategies, such as the Hazard Analysis Critical Control Point (HACCP) system, by the regulatory and industrial communities.

Another parallel can be drawn to earlier times. Society today, like that of the early 1900s, is strongly interested in attaining certain therapeutic and health benefits through special foods (e.g., nutraceuticals and functional foods), and, once again, the line between foods and pharmaceuticals has become blurred. The trend to market these products has created certain labeling concerns with regard to health claims, as well as safety and efficacy concerns.

As the world has gotten smaller through increased communication, travel, immigration, and trade, there are current concerns regarding the safety of food products throughout the world. Global consumer concerns regarding genetically modified foods and ingredients, as well as potential chemical residues in foods, have had a major impact on current and future legislation, as well as world trade.

The intent of this book is to define and categorize the real and perceived safety issues surrounding food, to provide scientifically non-biased perspectives on these issues, and to provide assistance to the reader in understanding these issues. While the primary professional audience for the book includes food technologists and scientists in the industry and regulatory sector, the book should provide useful information for many other audiences.

Part I focuses on general descriptions of potential food safety hazards and provides in-depth background into risk assessment and epidemiology. Potential food hazards are characterized in Part II, where biological hazards are discussed, and in Part III, which addresses chemical and physical hazards.

Control systems and intervention strategies for reducing risk or preventing food hazards are presented in Part IV, V and VI. The emphasis of Part IV is on regulatory surveillance and industry programs including Hazard Analysis Critical Control Point (HACCP) systems. Food safety intervention in food processing, handling and distribution are addressed in Part V, while the focus of Part VI is on the retail foods sector. Diet, health and safety issues are characterized in Part VII, with emphasis on food fortification, dietary supplements, and functional foods.

Finally, Part VIII addresses world-wide food safety issues through discussion of Codex Alimentarius Commission (CAC), the European Union perspectives on genetic modification, and other globally accepted food standards.

The topics within each chapter are divided into sections called units. To provide continuity across the book, these units have been generally organized according to the following structure: Introduction and Definition of Issues, Background and Historical Significance, Scientific Basis and Implications, Regulatory, Industrial, and International Implications, and Current and Future Implications.

This project was a highly ambitious project and the co-editors would like to acknowledge the many people who provided valuable input and assistance and
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RONALD H. SCHMIDT and GARY E. RODRICK
CHAPTER 1

DEFINITION OF FOOD SAFETY

ROBERT (SKIP) A. SEWARD II

INTRODUCTION AND DEFINITION OF ISSUES

The term "safe food" represents different ideals to different audiences. Consumers, special interest groups, regulators, industry, and academia will have their unique descriptions based on their perspectives. Much of the information the general public receives about food safety comes through the media. For this reason, media perspectives on the safety of the food supply can influence those of the general public.

Consumers are the end users and thus are at the last link of the food supply chain from production, through processing and distribution, to retail and food service businesses. Consumers are multidimensional and multifaceted. Populations differ in age, life experiences, health, knowledge, culture, sex, political views, nutritional needs, purchasing power, media inputs, family status, occupation, and education. The effect of the interrelationships of these factors on an individual's description of "safe food" has not been established.

When educated consumers were asked by the author to define safe food, their descriptions included some key elements. Safe food means food that has been handled properly, including thorough washing of fish and poultry that will be cooked and anything to be eaten raw. Safe food means food prepared on clean and sanitized surfaces with utensils and dishes that also are cleaned and sanitized. These consumers mention the importance of hand washing by those involved in food preparation and the importance of not reusing cloths or sponges that become soiled. Common sense is a guiding principle for the educated, informed consumer.

Other consumers want safe food that retains vitamins and minerals but does not have harmful pesticides. They describe safe food as food that is within its shelf life and has been stored and distributed under proper temperature control. Some consumers know the word "contamination" and will define safe food as food that is not contaminated.

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For other consumers, the descriptions of safe food are more practical, like food that does not make a person ill. For these consumers, safe food means purchasing fresh chicken and not having the package leak or drip juice, making them wonder about the integrity of the initial seal. Consumers use their senses in their descriptions of safe food, and they feel that food that looks or smells bad should not be eaten. Surprisingly, not many consumers refer to labeling as a key component of safe food. Consumers believe they know what to do with food after it is purchased, and they assume that the safety of the food is primarily determined before it reaches their hands. Published data suggest otherwise.

McDowell (1998) reported the results of on-site inspections of 106 households in 81 U.S. cities by professional auditors. A college degree was held by 73% of the participants. Inspection of meal preparation, cleanup, temperatures, sanitation, the environment, and personal hygiene resulted in at least one critical violation being cited in 96% of households. The most common critical violations were cross-contamination (76% of households with this violation), neglected hand washing (57%), improper leftover cooling (29%), improper chemical storage (28%), insufficient cooking (24%), and refrigeration above 45°F (23%).

Similarly, Jay et al. (1999) used video recording to study food handling practices in 40 home kitchens in Melbourne, Australia. Households of various types were video monitored for up to two weeks during 1997 and 1998. There was a significant variance between what people said they would do and what they actually practiced with respect to food safety in the home. The most common unhygienic practices included infrequent and inadequate hand washing, inadequate cleaning of food contact surfaces, presence of pets in the kitchen, and cross-contamination between dirty and clean surfaces and food.

A national telephone survey was done by Altekruse et al. (1995) to estimate U.S. consumer knowledge about food safety. The 1,620 participants were at least 18 years old and had kitchens in their homes. One-third of those surveyed admitted to using unsafe food hygiene practices, such as not washing hands or preventing cross-contamination. There was a disparity between the level of knowledge and corresponding safe hygiene practices. This suggested that decisions to practice safe food handling likely are based on various factors including knowledge, risk tolerance, and experience.

Jay et al. (1999) conducted a telephone survey of 1,203 Australian households and found significant gaps in food safety knowledge. The most important were incorrect thawing of frozen food, poor cooling of cooked food, undercooking of hazardous food, lack of knowledge about safe refrigeration temperatures and cross-contamination, and lack of knowledge about frequency and techniques of hand washing. The authors found the participants receptive to educational information regarding the preparation of safe food. Knowledge and compliance regarding the preparation of safe food increased with the age of the participants.
Special interest groups represent a focused view on safe food. These groups study the issues that they believe are most relevant to food safety and then express their concerns to consumers, regulatory authorities, industry, and academia. They typically define safe food by more specific limits for hazards than those used in the food supply chain. The special interest groups define safe foods through more stringent control limits for microbial pathogens and chemical hazards. They seek a higher level of food safety through requirements for more interventions to control hazards and elimination of chemicals used in food production, over fears of adverse health effects.

Special interest groups often question the approvals by governmental agencies of practices designed to increase the productivity and efficiency associated with agriculture and animal husbandry, for example, the use of antibiotics and hormones. Furthermore, the definition of safe food by selected special interest groups would exclude foods made through enhanced technology, such as genetic engineering. Again, they would view with suspicion, the science that established the safety of these new foods for the regulatory authorities responsible for their approval.

Special interest groups such as the U.S.-based Center for Science in the Public Interest (CSPI) do provide guidance for consumers and recommendations for government. CSPI and the Safe Food Coalition have outlined their recipe for safe food by calling for funding for the U.S. National Food Safety Initiative proposed in 1997, more authority for the U.S. Department of Agriculture (USDA) to enforce food safety laws, more power for the U.S. Food and Drug Administration (FDA) to keep contaminated products off the market, and a single agency responsible for food safety.

The CSPI has noted that consumers need to understand the broader range of products involved as vehicles of foodborne illnesses. The CSPI has stated that, although the effort is underfunded and not well-coordinated, government has improved the safety of the nation’s food supply through legislation and regulation.

**BACKGROUND AND HISTORICAL SIGNIFICANCE**

Over his distinguished career, E.M. Foster has provided a unique perspective on the history of safe food (Foster, 1997). He has described how, for many, food production and consumption were tied to daily life on a farm. Through experience, time control became the means by which safe food was ensured, because for many people refrigeration was not available. According to Foster, examples of botulism, salmonellosis, and *Clostridium perfringens* food poisoning from new food vehicles have shown how our perceptions and understanding of safe food change with new knowledge about the capacities of microbial pathogens to adapt and proliferate in selected environments.
DEFINITION OF FOOD SAFETY

SCIENTIFIC BASIS AND IMPLICATIONS

Because academicians are some of the most educated consumers, they generally have the greatest understanding regarding the safety of foods, balancing the science with the practical application of the science in the food supply chain. Academicians can be the most knowledgeable about the science-based research used in defining safe food. However, the specifics of research, and the innumerable questions that are generated through research, lead to inevitably variable viewpoints on the science. The academic questions surrounding safe food are often multidimensional, involving scientific disciplines including biochemistry, microbiology, genetics, medicine, plant and animal physiology, and food science, to name only a few. Because academicians generally are narrowly focused in particular research disciplines, their definitions include details surrounded by boundaries and assumptions.

One of the common scientific measures used to define safe food is the number of illnesses associated with food. In the U.S., data sources for this measure include the Foodborne Diseases Active Surveillance Network (FoodNet), the National Notifiable Disease Surveillance System, the Public Health Laboratory Information System, the Foodborne Disease Outbreak Surveillance System, and the Gulf Coast States Vibrio Surveillance System. Similar surveillance systems are in use in other countries to gather foodborne disease statistics. Mead et al. (1999) used these data sources, and others, to estimate that foodborne diseases cause ~76 million illnesses and 5,000 deaths in the U.S. annually. Viruses, predominantly Norwalk-like viruses, accounted for nearly 80% of the estimated total cases caused by known foodborne pathogens.

REGULATORY, INDUSTRIAL, AND INTERNATIONAL IMPLICATIONS

Regulatory authorities are also consumers and thus carry many of the biases and perceptions held by consumers in general. However, regulatory authorities typically have a higher level of training in food safety. They differ in the scope of their responsibilities and influence, working at local, state, federal, or global levels. They also differ in their experiences with food along the food chain, from farming and animal production through manufacturing, distribution, and testing, to retail and food service. These experiences will affect their definitions of safe food.

Regulatory authorities that oversee food production are more aware of the impact of agricultural chemicals, animal hormones, feed contaminants, and antibiotics and would include details of these factors in their description of safe food. In processing environments, regulators would be more apt to describe safe food in terms of the microbiological, chemical, and physical hazards associated with manufacturing. Regulatory authorities overseeing retail and food
service would include the human factors such as cross-contamination by food handlers and personal hygiene behaviors.

Regulatory authorities also describe safe food according to regulations established by authorities such as the World Health Organization (WHO), the European Commission, and the U.S. FDA. The standards and laws set for international trade become part of the regulatory definitions of safe food. For example, the food safety standards adopted by the Joint Food Agricultural Organization/WHO Codex Alimentarius Commission (CAC) have become the international reference used to resolve international trade issues. Some regulatory authorities are using quantitative risk assessment to help define food safety, as well as to determine optimal intervention strategies. Scientific risk assessments have reportedly become the foundation for food safety worldwide with the issuance of the Sanitary and Phytosanitary Agreement by the World Trade Organization (WTO) (Smith et al., 1999).

Government officials often speak of safe food in terms designed to appeal to public emotions about food safety. For example, on July 2, 1998, the U.S. Vice President challenged the U.S. Congress to fund a Food Safety Initiative and “give Americans peace of mind when they reach for a piece of food.” The Vice President stated the need for “new authority to seize meat that may be contaminated, to protect America’s families.” However, experts know that more recall authority does not improve food safety. The U.S. Food Safety Initiative is broad in its vision and scope. A key component of the Initiative is educating consumers on the responsibilities for food safety of everyone involved in the food supply chain.

The industry sector is broad in its constituency. Farmers and ranchers are the basis on which most of the food supply chain exists. At this level, food safety is defined by the practices of the farmers and ranchers, whether in regard to chemical treatment of the soil or use of hormones in animal production. These plant and animal producers define safe food based on the practical application of production principles, balancing economic pressures of production with demands for control of hazards. Safe food at this level means doing what is practical to ensure safety and focusing on optimal use of government-approved chemicals to maximize production. Thus far, there has not been a significant focus on controlling microbiological hazards at this level of the food chain; however, there is increasing recognition of the role of farmers and ranchers in defining safe food through their practices.

The food industry defines safe food by its specifications for raw materials and finished products. These specifications define the acceptable limits for chemical hazards such as pesticides and hormones, physical hazards such as bone and metal fragments, and microbiological hazards such as *Listeria monocytogenes* and *Salmonella*. The industry defines safe food in terms of pathogen reduction associated with processing technologies, whether well-established like pasteurization or new like pulsed, high-energy light.

The industrial sector also includes distribution, retail, and restaurant busi-
nesses, as well as related industries supporting the growth of plants and animals and the use of by-products for nonfood applications, such as for health care and clothing. Distributors, retailers, and restaurants define safe food by the expectations of their customers and the regulatory authorities.

**CURRENT AND FUTURE IMPLICATIONS**

Safe food is a composite of all of the views and descriptions held by consumers, special interest groups, academicians, regulatory authorities, and industry. Almost any single definition of safe food will be overly simplistic, because safe food is a complex, multifaceted concept. The scientific experts attending the 1998 American Academy of Microbiology Colloquium on Food Safety (AAM, 1999) described safe food as follows: Safe food, if properly handled at all steps of production through consumption, is reliably unlikely (i.e., the probability is low and the variability is small) to cause illness or injury.

Everyone wants a safe food supply. The criteria by which food is defined as safe will become more detailed and comprehensive as new steps are taken to improve safety. As capabilities rise, so will the expectations. The difficult decisions are those relating to perceived risks that drive the unnecessary use of public and private resources. If a food is perceived or reported to be unsafe, the story can be amplified in the press and then validated in the public mind by the involvement of politicians and regulators. All this can happen in the absence of scientific data that truly defines the risk (Smith et al., 1999).

Consumers have a role to play in ensuring that food is safe. They need to make informed choices about their food and how it is handled and prepared. According to Lopez (1999), consumer education about food safety must take place. Without a widely accepted definition of safe food, the public will have unrealistic misconceptions about the degree of safety that is attainable. Lopez pointed out that food safety standards have economic as well as scientific dimensions and that consumers are not likely to pay the high costs of absolutely safe food. To this end, industry and government have responsibility for improving safety as well as for educating consumers on the practical aspects of safe food. Research is needed to determine what impacts consumers' food safety practices (AAM, 1999).

The application of *Salmonella* and *Escherichia coli* performance standards for the U.S. food supply exemplifies a trend by regulators toward using microbial counts and prevalence data to define safe food. Yet there is general agreement among experts in food safety that food sampling and testing is not the sole means of ensuring safe food. The statistics of routine sampling indicate the limits of testing to define safe food. For example, *E. coli* O157:H7 in ground beef and *Listeria monocytogenes* in cooked foods are present at low levels, typically below 0.1%. Even when testing 60 samples per lot, there is a greater than 90% chance of not detecting the pathogen. Companies normally test fewer samples (3-5 per lot) to confirm that their Hazard Analysis and Critical Con-
trol Point (HACCP) system is functioning; thus the likelihood that testing will establish the safety of the food is greatly limited. Furthermore, pathogens will not be homogeneously distributed in many contaminated foods, which may also reduce the value of sampling and testing to determine safety.

Global differences in judgments on safe food are likely to continue, such as the current disagreements over the safety of beef hormone treatments and genetically modified foods between the U.S. and the European Union. These differences exist despite mechanisms such as the dispute resolution system of the WTO. In general, the European view of safe food is fundamentally different from that in the U.S., with culture and history as important as science in some decision-making processes.

LITERATURE CITED

INTRODUCTION AND DEFINITION OF ISSUES

Hazard characterization with respect to foods began as a means to help prioritize risks and categorize hazards. Over time, hazard characterization has broadened in scope, as the criteria used to evaluate hazards have increased in number and breadth. Today, characterization of hazards is more important than ever in developing food safety control programs. The use of categorization is of lesser importance as susceptibility of the population to the hazards becomes greater. The WHO (1995) described hazard characterization as the qualitative and quantitative evaluation of the nature of the adverse effects associated with biological, chemical, and physical agents that may be present in foods.

Van Schothorst (1998) suggested that hazard characterization might be better termed “impact characterization.” The impact can vary from mild (simple acute diarrhea) to severe (chronic illness or death), depending largely on the susceptibility of the person exposed. To accommodate the many assumptions associated with impact characterizations, a worst-case scenario often is used to estimate the risk presented by a particular pathogen in a specific food. Van Schothorst points out that assumptions and uncertainties of hazard characterization ultimately can lead to an unreliable risk assessment, as well as credibility and liability problems.

The National Advisory Committee on Microbiological Criteria for Foods (NACMCF) (1997) defined a hazard as a “biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.” Microbial pathogens are the most common biological hazards, and they can cause infections (growth of the disease-causing microorganism) and intoxications (illness caused by preformed toxin produced by a micro-
organism). Scott (1999) has detailed the characteristics of numerous common microbial hazards and described the factors that affect the risk of illness from the hazards.

Chemical hazards include agricultural compounds such as pesticides, antibiotics, and growth hormones; industrial chemicals such as cleaners and sanitizers; and equipment-related compounds such as oils, gasoline, and lubricants. Other chemical hazards include naturally occurring toxicants such as mycotoxins, environmental contaminants such as lead and mercury, and chemical preservatives and allergens.

Physical hazards include glass, wood, plastic, stones, metal, and bones. The introduction of physical hazards has been characterized as inadvertent contamination from growing, harvesting, processing, and handling; intentional sabotage or tampering; and chance contamination during distribution and storage (Corlett, 1998).

BACKGROUND AND HISTORICAL SIGNIFICANCE

The language surrounding the term “hazard characterization” has referred to the food products themselves, as well as to the hazards that might be present in the food. Hazard characterization has been used in the development of Hazard Analysis and Critical Control Point (HACCP) plans and regulatory policies, as well as for risk assessments. In 1969, the National Academy of Sciences issued a report evaluating the Salmonella problem (NAS, 1969). This report described three hazard characteristics associated with food and Salmonella:

1. Products containing ingredients identified as significant potential factors in salmonellosis.
2. Manufacturing processes that do not include a control step that would destroy Salmonellae, and
3. Substantial likelihood of microbiological growth if mishandled or abused in distribution or consumer usage.

With the various combinations of these three hazard characteristics, five categories were created that reflected the potential risk to the consumer. Category I included food products intended for use by infants, the aged, and the infirm, that is, the restricted population of high risk. Category II included processed foods that were subject to all three hazard characteristics (ABC) listed above. Category III included those products subject to two of the three general hazard characteristics. These would include such products as custard-filled bakery goods (AC), cake mixes and chocolate candy (AB), and sauce mixes that do not contain a sensitive ingredient (BC). Category IV included products of relatively minor microbiological health hazard level, subject to only one of the hazard characteristics. Examples include retail baked cakes (A) and some frosting mixes (B). Category V includes foods that are subject to none of the
microbiological hazard characteristics and therefore of minimal hazard potential, for example, canned foods sterilized after packaging in the final container.

The Pillsbury Company is recognized as the first company to have developed HACCP plans. The Pillsbury approach to HACCP systems also used three hazard characteristics to categorize food products. In this instance, the hazard characteristics were generalized to include all potential microbial, physical, and chemical hazards, not only *Salmonella* (Sperber, 1991). As in the NAS report, the permutations of the hazard characteristics resulted in five product hazard classes.

The use of the three hazard characteristics to assess risks was standard in the 1970s (Bauman, 1974). In 1989, the NACMCF presented a HACCP document that used six hazard characteristics to rank microbial hazards for risk assessments (NACMCF, 1989). Chemical and physical hazards were included subsequently (Corlett and Stier, 1991). Hazard characterization at this time was made on the basis of criteria such as:

The consumers' risks associated with factors such as age and health,
- The risk associated with the ingredients used to make the food product,
- The production process and its impact on the hazard,
- The likelihood of recontamination after processing,
- The potential for abuse during distribution and consumer handling, and
- The ability of the consumer to detect, remove, or destroy the hazard during the final preparatory steps.

The hazard classification scheme (Hazard Categories A-F) described in the 1989 NACMCF document was updated in 1992 (NACMCF, 1992) and again in 1997 (NACMCF, 1998a). These revisions aligned U.S. HACCP concepts with those published by the internationally recognized Codex Alimentarius Commission (CAC) (1997). The most recent HACCP documents characterize hazards as part of the hazard analysis. The hazard characterization, or evaluation, is done after the hazards have been identified. The criteria for characterizing the hazard include:

- The severity of the hazard, to include the seriousness of the consequences of exposure, or the magnitude and duration of the illness or injury,
- The likelihood that the hazard will occur, based on published information and epidemiological data,
- The potential for both short-term and long-term effects from exposure, and
- Available risk assessment data,

as well as many of the criteria stated in earlier documents.

Ultimately, according to William H. Sperber (personal communication), "the hazard characteristics were discarded in favor of an open-ended hazard analysis in which an unlimited number of relevant questions could be asked
about the product and the process by which it is produced. The product hazard categories fell into disfavor as we recognized that a relatively large percentage of consumers are immunocompromised. All foods must be safe for all consumers. The emergence of new foodborne pathogens in relatively narrow niches, e.g., *Listeria monocytogenes* in some perishable ready-to-eat foods, further rendered the concept of product hazards categories moot."

**SCIENTIFIC BASIS AND IMPLICATIONS**

In addition to its role in the development of HACCP plans, hazard characterization has been identified as the second step of the risk assessment process (Smith et al., 1999). The characterization includes determination of risk factors, defining the site and mechanism of action, and measuring the dose-response relationship (proportion responding or severity of response). Despite large uncertainties, dose-response models are commonly used to predict human health effects and even to establish regulatory policies.

According to the WHO (1995), a dose-response assessment should be performed for chemical hazards. For biological or physical agents, a dose-response assessment should be performed if the data are obtainable. Although potentially hazardous chemicals may be present in foods at low levels, for example, parts per million or less, animal toxicological studies typically are done at higher levels to obtain a measurable effect. The significance of the adverse effects associated with high-dose animal studies for low-dose human exposure is a major topic of debate with regard to the hazard characterization of chemicals.

The extrapolation of animal exposure data to human exposure levels is uncertain both qualitatively and quantitatively. The nature of the hazard may change with dose. Not only is the equivalent dose estimate in animals and humans problematic in comparative pharmacokinetics, the metabolism of the chemical may change as the dose changes. Whereas high doses can overwhelm detoxification pathways, the effects may be unrelated to those seen at low doses (WHO, 1995).

A primary contributor to the uncertainty of the hazard characterization is the intraspecies variance in the dose response at different dosage levels. Large exposures often are used to increase the power of a study yet may be inaccurate for low-dose exposure. Variance also results from many other differences among individual animals and humans.

Toxicologists often use thresholds to quantify adverse effects from chemical exposures, except in the case of carcinogenic effects, where initiating events can occur as persistent somatic mutations that later develop into cancer. Some carcinogens may be regulated with a threshold approach, such as the "No Observed Effect Level (NOEL)-safety factor" approach. A safe level of a chemical often is derived from an experimental NOEL or No Observed Adverse Effect Level (NOAEL) by using safety factors. A safety factor of 100 has been applied when using data from long-term animal studies, but it may be adjusted