DAIRY INDUSTRY IN PAKISTAN AND WORLD DAIRY INDUSTRY BY YEAR 2000*

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God has mentioned in Holy Quran *"And in the cattle too, there is a lesson for you. We give you to drink of what is in their bellies from betwixt the faeces and the blood. Milk pure and pleasant for those who drink it."*

Ladies and Gentlemen! Of course no food is better than milk for providing the body, in particular of young and elderly people, with calcium in sufficient quantities and in a form suitable for assimilation. It provides all the necessary fat, protein and vitamins to human body.

Pakistan, with an area of 803,940 Km, with a population of 110 million is considered to be 9th biggest country in the world population-wise. The annual production of milk has been recorded as 12.5 million tons. Out of this, 71 per cent is produced by buffaloes, 24 per cent by cows and 5 per cent by sheep and goat. Milk and milk products supply about 66% of protein and 26 per cent of calories consumed through animal products. It is strange that of the present world production of above 500 million tons per year, we are producing hardly 2.5 per cent. It seems that our per capita availability stays in grammage and yet being basically an agricultural country we are not able to provide a glass of milk daily to each person.

The demand of milk has increased due to high growth rate. We can see if no proper attention is paid to this sector, we will have acute shortage of milk in the country. It is strange to note that a farmer having more area rears less number of cows or buffaloes and farmers with less area rear more number of milch animals. Out of more than 25 dairy plants in the country, few are in operation and the rest have closed down due, among other factors, to unavailability of raw milk. We are importing dry skimmed milk powder worth 120-130 million rupees per year.

The dairy industry faces a particularly daunting task of attempting to industrialise the milk sector without the benefit of a coordinated and organised raw milk supply. This industry is with obvious consequences regarding quality and reliability. At the same time, it is estimated that by the year 2000 the urban population of Pakistan will increase from 25 to 47 per cent of the total population, which is estimated to be in excess of 110 million today and will be 150 million by year 2000. At present, 45 per cent of the population is under 14 years of age. The urbanisation will increase the distance between cow/buffalo and the consumer which together with further congestion in the cities will result in critical shortages and further reduction in quality of raw milk. This will result in further deterioration in public health standards.

Infact, we need to have organised farming with proper facilities of breeding, artificial insemination and embryo transfer techniques later on. In some cases, we have plenty of milk like two of the world's largest buffalo colonies have now emerged in Karachi from where one million litres of milk flows into the city everyday. The Sahiwal area is very rich in milk quantities but this all is still not enough for regular functioning of dairy plants. So, what the basic thing we need is, more organised farms and crossbreeding to achieve higher levels of production. Our milking animals under present unhygienic conditions and unhealthy atmosphere with nutritionally unbalanced feed are not producing upto the standard. The sector should be treated on industrial basis.

Now, we come to the processing industry position. This industry is already in competition with the local *"Gowalas"*. The industry cannot afford to beat the terms and conditions of *Gowalas,* as they supply milk at house door with credit facility of one month, while the industry has to put cost of production, packing, transportation, distribution, publicity and have to sell it at credit facility. The cost is also almost double of the raw milk supplied by *Gowalas.* Most of the dairy processing plants which were imported through ADBP under ADB financing have been shut down due to the fact that the raw milk is not easily available. The one which is being procured by dairy plants is of 'C' grade if compared with international standards. Bacterial load is very high since milking has been done under unhygienic conditions, antibiotics have been used due to which cultured products are of substandard quality.

On the other hand, comparing our industry with the world situation, as mentioned earlier we are far behind in milk production, milk storage, processing techniques, milk products and quality control parameters. Worldwide, Europeans and Americans are at a stage of over production. Worldwide forecasts are being made on what the dairy industry will look like in the year 2000. The exact forecast is difficult especially when it concerns the future. The value of predicting future trends lies in exposing probabilities to critical analysis, but unknown and

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outside factors, e.g. energy pricing policies, make technical forecasting most difficult.

As regards the industrialised countries, it is observed that, in the coming years, the present low industry profitability must be increased and investment reduced or directed to ventures where there are potential production cost savings, or where future modifications and profits are possible.

It has been analysed and computed that by the year 2000:

1. Amongst new technologies, membrane processes will have significant influence in the industry.

2. Genetic engineering of microorganisms will lead to more reliable acid production, higher phage resistance or new enzymatic properties of starters.

3. The trend on shelf stable dairy products using UHT technology and aseptic packing will continue to reduce dependence on refrigerated distribution and storage.

4. Computer use in dairy plants will continue to expand. Energy and water use will be minimised and their reuse will be facilitated.

5. The dairy industry of the future might also be influenced by low cost fat and protein from vegetable sources suitable for substitution in milk products.

6. A further growth of milk production in Eastern Europe and developing countries to respective levels of 30 per cent and 37.5 per cent of world milk out put will be observed.

7. Milk output in EEC will undergo only a modest increase, and in relative terms it will fall to about 22.5 per cent, while that of relative remaining industrialised countries will fall to 20 per cent of world milk production.

8. In the developing countries, an increase of 3.2 per cent milk production will represent a source of job creation because of the greater labour intensity of milk and dairy production.

9. World milk output will be increased by about 1.9 per cent per annum.

10. Cheese production in the year 2000 will account for about 30 per cent of world milk output. Production of whole milk powder and condensed milk will also rise.

11. Sales of butter and liquid milk will remain almost stable in Western countries.

12. In the developing countries, sales of liquid milk will rise sharply and at the same time, demand will increase for skimmed milk powder and butter oil (for the recombining industry).

The targets which the world dairy industry aim at in coming years are to:

1. reduce hunger in the world,

2. increase the number of employment opportunities, especially in developing countries,

3. improve income of milk producers,

4. ensure better supply management in Western countries,

5. achieve better international cooperation, and

6. increase dairy food aid, above all for the sake of very poor.

In conclusion, it will be clear that the dairy industry will be faced with enormous challenges, and this industry will have to bear it's share to restrain the bogey of famine and shortages of food.

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Government Regulation of Food Safety: Interaction of Scientific and Societal Forces

A Scientific Status Summary by the Institute of Food Technologists' Expert Panel on Food Safety and Nutrition

☐ The safety of the food supply continues to command public attention. The issues are many and varied, including but not limited to environmental contaminants, pesticide residues, product tampering, nutritional quality, and microbial contamination. New situations and issues prompt discussions about the scientific evidence, public perceptions, necessary control measures, and appropriate claims and labeling. The interplay of legislative, regulatory, scientific, social, and political forces is evident with every issue.

Government plays a major role in guarding the safety of the food supply through a variety of laws, regulations, standards, guidelines, and control measures. In addition, the food industry plays a critical role in controlling food hazards. Producers, processors, manufacturers, distributors, retailers, and foodservice establishments adopt quality control and quality assurance programs that reflect industry standards, company standards, consumer expectations, and government regulations.

Decisions about any one food safety issue are complicated by the fact that many issues and public policies are interrelated, as expressed in legislation such as that focusing on environmental protection, nutrition, international trade, child welfare, product labeling, agricultural production, and farm policies. The positions of various interest groups and the policy decisions of legislators and regulators are made within the context of many competing and influencing forces.

This summary reviews the roles of federal, state, and local governments in safeguarding consumers against hazards associated with the food supply. Through selected issues, the summary illustrates the interplay of science and societal considerations that legislators and regulators confront as they strive to adopt food safety policies that will address today's food safety concerns.

Evolution of Food Laws

Current policies that safeguard the food supply are the product of a long evolution, linked to issues of trade as well as to consumer health. During the colonial days, states enacted various laws and regulations, many of which were intended to protect trade advantages. In 1883, Congress acted to "prevent the importation of adulterated and spurious teas" (Schultz, 1981). But until the 20th century, federal lawmakers paid little attention to the safety of the nation's food supply, considering it to be a matter best left to local control.

In 1906, Upton Sinclair stirred public opinion with his novel *The Jungle*, which prompted Congress to enact the Federal Meat Inspection Act as an amendment to the 1906 USDA appropriations bill. That same year, Congress enacted the first comprehensive food and drug law, but only after lengthy debate and many failed attempts. In the 27 years before 1906, nearly 200 food and drug bills had been introduced (Schultz, 1981).

The 1906 laws focused attention on the manufacture and sale of *adulterated* and *misbranded* foods. The health hazards resulted from unsanitary conditions and added chemicals that posed immediate hazards, primarily acute poisoning. Dissatisfaction with the 1906 law prompted continued debate and attempts to amend the law to expand its coverage. In 1938, the 1906 law was replaced with the Federal Food, Drug, and Cosmetic Act (FDCA) which remains a cornerstone of U.S. food safety policies.

Current laws continue to address the issues of adulterated and misbranded foods, but the areas of concern have shifted as perceptions and scientific understanding of risks have changed. By the 1950s, cancer was recognized as a major health problem and widely feared. The idea that cancer-causing substances could enter the food supply was considered by some people to be a major public health threat requiring special regulatory controls. As a result, the Delaney clause stating that "no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal" has been added to the FDCA three times [Sections 409(c)(3)(A), 512(d)(1)(H), and 706(b)(5)(B)].

Throughout the late 1960s and the '70s, the concept of zero risk for cancer was debated. The proposal by the Food and Drug Administra-

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tion to ban saccharin, on the basis of the Delaney clause provision, prompted Congress to pass the Saccharin Study and Labeling Act of 1977; the act allowed this potential carcinogen to be added to food but required a health warning on the label. Congress has renewed the saccharin law each time it was scheduled to expire. The marketing of saccharin violates the Delaney clause, and saccharin is available to consumers only as a result of continued Congressional action. The public debate over saccharin stimulated several unsuccessful legislative attempts to modify federal food safety laws. Throughout the 1970s and '80s, many issues and actions have focused attention on regulation of the health and safety of the food supply (Table 1).

Scientific Advances and Public Perceptions

The terms *hazard, risk,* and *safety* are common vocabulary in discussions about food safety issues, but the differing meanings are not always appreciated.

A hazard is a source of danger. Some hazards such as microbial food poisoning or allergic reactions elicit relatively immediate effects, while others such as cancer may not be realized until many years after damage begins. Genetic changes, birth defects, behavioral effects, and reduced nutrient availability are other potential hazards that have been associated with substances in food.

A risk is a measure of the probability and severity of harm to human health. To determine risk from exposure to a substance, scientists (1) identify a hazard, (2) determine the relationship between the dose or amount of a substance and the likelihood of the hazard's occurring, and (3) determine the quantity of the substance to which humans are or could be exposed (Hotchkiss, 1989a).

Safety is a judgment of the acceptability of risk. A substance in food is considered *safe* if its risks are judged to be acceptable. Because individuals make differing judgments about which risks are acceptable, effective discussions about food safety issues require that conflicting viewpoints be recognized and mediated.

The ability of scientists to identify potential risks in the food supply far outstrips the ability, even of scientists, to interpret the importance of these risks to public health. Advances in analytical techniques allow scientists to detect substances present at parts-per-trillion or even lower levels. The scientific tools for predicting levels of risk to humans are much less precise. Extrapolation of health risks from animal studies to humans entails many assumptions and uncertainties, creating scientific debate about risks associated with a specific compound (Hotchkiss, 1989b). The climate of scientific uncertainty makes for difficult policy decisions and fuels discontent among those consumers who are risk-aversive and mistrustful.

Determining the safety of a substance requires both a scientific assessment of risk and a judgment as to the social acceptability of the risk (Lowrance, 1976). The difficulties in meshing these two tasks may explain why surveys consistently show great disparity in the perceptions of risk by scientists and the lay public. Scientists—who tend to rank risks according to the numbers and probabilities of illness and death—rank microbiological foodborne illnesses and nutritional imbalances as major food-related risks to health (Roberts, 1981; Hotchkiss, 1989b; IFT, 1990). But consumers generally perceive environmental contamination, pesticide residues, and drugs or hormones used in animal production as greater health risks than either microbial contamination or nutritional imbalances, although few surveys compare all of the issues (FMI, 1990; van Ravenswaay, 1988; Kramer and Penner, 1986; Smallwood, 1989).

A recent attempt by the Environmental Protection Agency to rank environmental risks was described as "a methodological nightmare, given the paltry data, uncertain techniques, and value-laden questions" (Roberts, 1990). Differing scientific philosophies finally led EPA's Scientific Advisory Board to list, but not rank, 11 environmental problems as the ecological and health risks of greatest environmental concern. While SAB endorsed the use of comparative risk assessment as the best way for a regulatory agency to set priorities, the task undertaken at EPA underscores the difficulties of meshing scientific rigor with policy making.

Public perceptions strongly influence judgments about the acceptability of a risk. A situation that is involuntary, uncontrollable, or unfamiliar often is considered risky by the public, regardless of the scientific evidence of risk or the magnitude of the risk (Sandman, 1986; Kraus and Slovic, 1988). Values, needs, and priorities of affected groups—producers, processors, distributors, retailers, and regulators—often clash. Media professionals influence the flow and exchange of information, thus influencing public perceptions and policy actions.

Public perceptions shape both individual choices and policy decisions. As stated by Burger (1988), "To the extent that disparity exists between perception and true risk, we are in danger of embracing in a wholesale fashion inappropriate, expensive, or unproductive public policy choices." The growing field of risk communication is becoming increasingly important as a means of decreasing this disparity so the safety of the food supply can be effectively managed. This task is complicated "by a public mood which fluctuates, a public perception which is not consistent throughout the population, and a public view which is difficult to measure" (Middlekauff, 1989). Public acceptance and support for policy decisions require more explicit communication of assumptions, uncertainties, and judgments within the decision-making process (Smith, 1984; Hutt, 1982).

Technological Change

Technology has transformed the production, storage, and preparation of food from a relatively simple system of local farming and home preparation into a complex system involving producers, processors, distributors, and retailers. Technological changes have affected all facets of the food system from production to retail sales. Commercial canning, refrigeration, and freezing are examples of early technological developments in food processing that strongly influenced the price, availability, convenience, and safety of foods. Microwave ovens, aseptic packaging, and vacuum packaging are examples of fairly recent innovations that continue the trend of change within the food system.

At the same time, adoption of new technologies has in many respects made consumers less familiar with what they eat. Many consumers have a limited understanding of science, food production, food processing, and food marketing. Lack of knowledge and control is likely to make consumers more anxious about safety, particularly if they do not trust the system responsible for pro-

ducing, processing, and safeguarding the food supply.

Government Policies

Governments at all levels—federal, state, and local—form an extensive and complex network for safeguarding the safety of the U.S. food supply. The federal level functions with laws enacted by Congress and with agencies responsible for interpreting and enforcing them (Table 2). Regulations established by federal agencies add specificity to the laws and provide enforcement procedures. Agencies can add, withdraw, or revise regulations.

Agencies of state and local governments are involved with inspection of restaurants, retail food establishments, dairies, grain mills, and other food establishments to assure safe handling of foods, proper labeling, and fair marketing practices. States "own" fishing waters within their jurisdiction. States can regulate food with laws concerning weights and measures, food labeling, consumer information, antifraud and deception, and health warnings. The departments responsible for health and safety functions vary by state and community. States usually adopt federal guidelines or policies, but often have the power to enact more stringent laws or regulations.

In addition to the U.S. infrastructure aimed at ensuring the health and safety of our food supply, the U.S. cooperates with other governments in establishing international policies. The mission of the United Nation's Codex Alimentarius Commission is to deal with international food safety and trade issues (Sachs, 1990). Codex develops "standards" and "codes" involving basic principles, technical specifications for products, and good manufacturing practices. The process for setting standards is lengthy and subject to extensive debate and political pressures, but Codex does exist as an international forum for resolving food safety issues that affect trade.

Enforcement and Monitoring Programs

To be effective, a law must be enforceable and adequate resources to support enforcement efforts must be appropriated by Congress to the regulatory agencies. Several methods for regulatory enforcement exist, including inspection at the point of production or processing, examination of products at the retail or wholesale level of distribution, and

Table 1—Selected Policy Actions

1969	White House Conference on Food, Nutrition, and Health is held
	FDA bans use of cyclamate
	GRAS Review is mandated by executive order
	Congress enacts National Environmental Policy Act (NEPA), which makes environmental protection a part of the mandate of every federal agency and department
1972	Consumer groups petition USDA to ban or greatly reduce the use of nitrite in meats
1973	FDA issues final regulation on nutrition labeling
1977	FDA announces a program for the periodic review of all food additives
	Consumer group petitions FDA to halt the use of BHT
	FDA proposes to ban use of saccharin in food
	Congress enacts the Saccharin Study and Labeling Act
1978	USDA begins monitoring bacon samples for nitrosamines
	USDA, FTC, and FDA hold public hearings on food labeling issues
1979	FDA issues final rule requiring label declaration of FD&C Yellow No. 5 in foods and drugs
	NAS/NRC recommends an overhaul of the food safety laws to give FDA a range of options for regulating substances like saccharin
	U.S. Court of Appeals rules in favor of FDA's use of the *de minimis* policy for regulating acrylonitrile, a carcinogen which might migrate from food packaging materials into a noncarcinogenic food additive
	FDA announces completion of scientific review of 415 food ingredients classified as GRAS in 1958
1980	FDA initiates a campaign to alert the public to possible adverse health effects of caffeine
	FDA issues final policy statement concerning the nutrient fortification of foods
	HHS and USDA issue *Dietary Guidelines for Americans*
1982	Food Safety Working Group, a subgroup of the president's Cabinet Council on Human Resources, releases suggested changes in food safety laws for public comment
1984	FDA issues final rule which makes sodium content a mandatory part of nutrition labeling and creates definitions for sodium claims on labels
	White House Office of Science and Technology Policy issues notice stating how products of biotechnology will be regulated
1986	Consumer group petitions FDA to prepare an environmental impact statement under NEPA regarding bovine growth hormone
	California enacts the Safe Drinking Water and Toxic Enforcement Act under Proposition 65
	NAS/NRC recommends a uniform "negligible risk" standard for regulating pesticide residues in all foods
	FDA issues final rule banning use of sulfites on raw fruits and vegetables
	Consumer groups file suits against FDA's use of the *de minimis* policy in interpreting the Delaney clause for methylene chloride and some color additives
1987	U.S. Court of Appeals rules against FDA's use of the *de minimis* policy in interpreting the Delaney clause for D&C Orange No. 17 and D&C Red No. 19
1988	Surgeon General issues report, *Nutrition and Health*
	NAS/NRC recommends revision of regulations that govern grading, labeling, and product standards to encourage the production and marketing of leaner meat and dairy products
1989	NAS/NRC issues report, *Diet and Health*
	Bureau of Alcohol, Tobacco, and Firearms requires health warnings on labels of all alcoholic beverages
1990	FDA issues final rules which ban the use of one form of FD&C Red No. 3 in food, drugs, and cosmetics
	FDA approves chymosin produced by biotechnology techniques as a GRAS food ingredient
	FDA approves use of irradiation on fresh or frozen uncooked poultry to control *Salmonella* and other bacteria
	Congress enacts the Nutrition Labeling and Education Act
1991	FDA establishes a new Office of Seafood in the Center for Food Safety and Applied Nutrition
	FDA proposes new food labeling regulations to implement the Nutrition Labeling and Education Act, and USDA proposes similar regulations for meat and poultry

licensing of establishments that manufacture or handle foods (Schultz, 1981). Because it is impossible to inspect every food at each site of production, processing, and distribution, the incentives to comply with regulations depend heavily on the probability of detection and the penalty for not complying.

In addition to the fines and legal proceedings that regulators can impose, there are additional economic and business incentives for complying with regulations. A processor does not want to buy something that will have to be disposed of because of safety concerns or even quality defects. Loss of customer confidence can be especially crippling to foodservice establishments that experience a highly publicized foodborne disease outbreak.

Much of the enforcement effort of regulatory agencies focuses on working with establishments to prevent problems from occurring. Examples of cooperative industry–government efforts to prevent drug residue violations include the Residue Avoidance Program, the Residue Violation Information System, and the Verified Residue Control Program (Ritchie, 1990).

An example of an industry-initiated effort to prevent contamination of food by microorganisms and/or foreign matter during production is the widespread adoption of the Hazard Analysis Critical Control Point (HACCP) system. HACCP has been successfully applied to certain food processing industries, foodservice establishments, and retail food stores (Stevenson, 1990; Bryan, 1990). In 1989, the National Advisory Committee on Microbiological Criteria for Foods endorsed HACCP as an effective, rational, and systematic approach to assure food safety (NACMCF, 1989). The National Advisory Committee was created by the Secretaries of the U.S. Depts. of Health and Human Services, Agriculture, Commerce, and Defense, on behalf of their respective agencies, after being suggested by a subcommittee of the National Academy of Sciences in 1985 (NAS/NRC, 1985).

When problems do occur, regulatory options range from product recalls to criminal prosecution. The penalty authority of a regulatory agency is defined by each food law. Agencies may share enforcement authority under separate statutes, as reflected in the efforts of USDA, FDA, and EPA to prevent illegal residues in food (USDA, 1984; FDA, 1990c). Cooperation of federal agencies with state and local agencies is critical to the success of enforcement programs, as is an effective working relationship with industry. Imported products are subject to the same legal requirements as domestic products and are subject to inspection at the point of entry by U.S. Customs Service personnel.

Federal Preemption

Challenges to federal food safety policies by state governments have become increasingly common. The ethylene dibromide (EDB) and Alar situations are just two recent examples in which states took action because they thought the actions of federal agencies were inadequate to protect consumers (Caswell, 1988). To what extent states should have the right to enact and enforce statutes for the health, safety, and welfare of its citizens is a debate that goes back to the time at which the U.S. Constitution was written.

Food regulation falls within the historic "police powers" of states, as long as state statutes are not in conflict with federal law (Janssen, 1987). Under the Supremacy Clause of the Constitution, however, Congress and the regulatory agencies can displace state authority by so stating their intent in laws or regulations. In the Federal Meat Inspection Act, Congress expressly stated its intent to preempt state authority, while acknowledging the right of states to enforce federal requirements (Taylor, 1985). Yet such a clear statement of federal and state authorities is lacking in most laws and regulations governing food safety.

Those who support the right of states to legislate food safety laws that are more stringent than federal laws feel that states have a responsibility to respond to the demands of their citizens and that they can adjust programs in response to changing needs more rapidly than can the federal government (Caswell, 1988; Silverglade, 1990). Those who support federal preemption in matters of food safety argue that without it the marketplace becomes fragmented, eroding the principles of an effective national economy. They argue that federal preemption is essential on matters of food safety "where the prevalence of scientific uncertainty means that there are often many arguably 'right' answers to a given problem" (Taylor, 1985).

Federal preemption has been discussed with respect to many food safety issues. A 1989 presidential plan, embraced but not yet adopted by EPA, USDA, and FDA, recommended that all registered pesticides be subject to federal preemption (White House, 1989). Waivers would be granted only when warranted by special local circumstances. California's Proposition 65 (the Safe Drinking Water and Toxic Enforcement Act of 1986) has opened a floodgate of litigation and debate about states' rights and federal preemption (Stone, 1989; Mitchell, 1990). It requires that the public be adequately warned about chemicals "known to the state" to cause cancer or reproductive toxic effects. In 1987, USDA refused to approve a proposed label carrying a Proposition 65 warning, stating that a label carrying such a warning would be misleading (Stone, 1989). All products regulated by USDA, unlike those regulated by FDA, are required to have premarket clearance of their labels.

Regulatory Categorization of Substances

The federal government has assumed many of its roles and organizational structures regarding food safety as a result more of historical events than of any master plan. Because of this, the system has been described as a "crazy quilt" of regulations. Portions of laws apply differently to different products and substances, depending on which agency oversees it, how it is legally classified, and what safety standard is applicable (Table 3). This may cause some confusion for industries trying to comply with such regulations and for consumers trying to understand the regulations.

In 1984, the White House Office of Science and Technology Policy issued a *Federal Register* notice in cooperation with FDA, EPA, USDA, and the National Institutes of Health concerning the regulation of products of biotechnology (OSTP, 1984). Updated in 1986 (OSTP, 1986), the notice states that existing laws are sufficient for regulating the products of genetic engineering. It indicates which agencies are responsible for which products of biotechnology and provides guidelines for regulatory coordination and review.

The Concept of Safety

The 1958 Food Additives Amendment to the FDCA marked the beginning of a new era in regulatory

actions to safeguard the food supply with inclusion of the term "safe" in the law. Congress left to FDA the task of defining "safe," except for carcinogenic substances which were to be subject to the amendment's Delaney clause.

In its food additive regulations, FDA defines "safe" or "safety" as "reasonable certainty . . . that the substance is not harmful under the intended conditions of use" (21 CFR 170.3). Similar wording appears in the color additive regulations (21 CFR 70.3).

In the regulation of pesticides, the concept of safety is found in the term "unreasonable adverse effects on the environment" which is defined as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide" (40 CFR 162). This concept of safety entails the use of risk/benefit analysis which is not permitted in the regulation of food and color additives. Suggestions to adopt the concept of risk/benefit more broadly into food safety laws have caused much debate among research scientists and those concerned with regulatory policies (IFT, 1988).

Safety evaluation includes many health considerations, but carcinogens receive special attention in food additive, color additive, and new animal drug regulations. In these regulations a "zero-risk" concept of safety is embodied in the Delaney clause. After this clause was enacted, analytical techniques for identifying substances improved dramatically, making it apparent that absolute avoidance of potential carcinogens in foods might not be reasonable public policy. Consequently, regulatory agencies in recent years have attempted to add a degree of flexibility to the strict interpretation of the Delaney clause, as noted in the following cases.

A clause known as the "DES proviso" exempts new animal drugs from the Delaney clause if no residue is found, using approved methods of testing. Through informal rulemaking, FDA has adopted a "no significant risk" interpretation of the exemption clause. FDA defines "no significant risk" for carcinogenic animal drug residues as less than a one-in-one-million risk of cancer (FDA, 1987). The administrative interpretation is based on the premise that the term "no residue" is not intended to have an absolute meaning, since Congress's primary purpose was to provide reasonable relief from the strictures of the "zero risk" concept (Geyer, 1988).

Table 2—**Cabinet-Level Departments and Independent Agencies** *important to national policies for ensuring the health and safety of the U.S. food supply, and legislation*

U.S. Dept. of Health and Human Services
- Food and Drug Administration—a unit within the Public Health Service, food labeling, safety of food and food additives, inspection of food processing plants, control of food contaminants, food standards
  - 1906 Pure Food and Drugs Act
  - 1938 Federal Food, Drug, and Cosmetic Act (FDCA)
  - 1944 Public Health Services Act
  - 1954 Pesticide Residue Amendment to FDCA
  - 1958 Food Additives Amendment to FDCA
  - 1960 Color Additive Amendments to FDCA
  - 1962 Drug Amendments to FDCA
  - 1966 Fair Packaging and Labeling Act
  - 1968 New Animal Drug Amendment to FDCA
  - 1977 Saccharin Study and Labeling Act
  - 1990 Nutrition Labeling and Education Act
- Centers for Disease Control—a unit within the Public Health Service, analyses and reporting of incidence of foodborne diseases
- National Institutes of Health—research related to diet and health

U.S. Dept. of Agriculture
- Food Safety and Inspection Service—inspection and labeling of meat, poultry, and egg products; grading of all foods
  - 1906 Federal Meat Inspection Act
  - 1946 Agriculture Marketing Act
  - 1957 Poultry Products Inspection Act
  - 1967 Wholesome Meat Act
  - 1970 Egg Products Inspection Act
- Animal and Plant Health Inspection Service
  - 1966 Animal Welfare Act
- Human Nutrition Information Service—food consumption standard tables for nutritive value of food; educational materials

U.S. Dept. of the Treasury
- Bureau of Alcohol, Tobacco, and Firearms—regulation of alcoholic beverages
  - 1935 Federal Alcohol Administration Act

U.S. Dept. of Commerce
- National Marine Fisheries Service—a unit within the National Oceanic and Atmospheric Administration—inspection, standards, and quality of seafood
  - 1956 Fish and Wildlife Act
  - 1976 Fishery Conservation and Management Act

U.S. Dept. of Labor
- Occupational Safety and Health Administration—employee safety in production, processing, and distribution of food
  - 1970 Occupational Safety and Health Act

Independent Agencies
- Environmental Protection Agency—standards for drinking water and water pollution; pesticide use on food crops
  - 1947 Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
  - 1972 Federal Environmental Pesticide Control Act—the law revising FIFRA
  - 1974 Safe Drinking Water Act
- Federal Trade Commission—food advertising; competition in the food industry
  - 1914 Federal Trade Commission Act

Another administrative interpretation is that of *de minimis*. *De minimis non curat lex* means "The law does not concern itself with trifles." In a 1956 decision, the courts determined that insect and worm fragments were *de minimis* (Strauss, 1987). This judicial decision upheld regulatory actions for controlling filth in food, acknowledging that all filth cannot be eliminated and that setting acceptable levels is an economic and practical necessity.

The 1979 acrylonitrile case dealt with the *de minimis* doctrine as it applies to the migration of an indirect additive into a direct additive (Strauss, 1987). The court held that FDA could allow a carcinogenic chemical that migrates into a noncarcinogenic food additive or color additive if the amount of the chemical is so low as to present a reasonable certainty of no harm.

In a 1987 court decision, FDA was barred from using the *de minimis*

doctrine to approve permanent listing of D&C Orange No. 17 and D&C Red No. 19 (Long, 1987). The court agreed with FDA that the risks were trivial, but the court held that the language of the Delaney clause in the color additive amendments is rigid and therefore the *de minimis* exception did not apply. Although neither coloring is used in foods, this decision could limit FDA's further use of the *de minimis* doctrine in interpretations involving the Delaney clause.

Regulation of carcinogens is influenced by FDA's constituents policy, which was upheld in court in 1984 (Strauss, 1987). This policy states that if a "constituent" or nonfunctional chemical component of a food additive is found to be carcinogenic, the additive can be approved for use, provided that the additive as a whole does not induce cancer.

Regulatory Review Processes

Yet another regulatory challenge is how to achieve equitable safety judgments over time without unreasonably disrupting the continuity of the food supply. As the scientific knowledge base for assessing safety continues to expand, past decisions can become outdated. Balanced against the dynamic research environment is the fact that regulatory review processes are costly and time consuming.

Several categories of substances have been the focus of safety reviews. A 1969 presidential order mandated that FDA review the safety of all substances listed as Generally Recognized as Safe (GRAS), since the list was created in 1958 by a procedure greatly different from that required for new food additives (SCOGS, 1982). An expert panel of scientists convened by FDA completed this review, and FDA's subsequent actions resulted in most substances being affirmed as GRAS, some being reclassified, and a few being withdrawn from use. In 1972, Congress mandated that EPA review the safety of all registered pesticides. In 1988, Congress gave EPA authority to collect fees from manufacturers to expedite the pesticide reregistration process. The safety of direct food additives has been the object of FDA's Priority Based Assessment, initially called the Cyclic Review of Food Additives (Kirschman, 1983).

Instigation of broad regulatory reviews of these types should be considered carefully. Policy makers and society must determine if the review is truly needed, because such reviews are expensive, are time consuming, and result in diversion of agency efforts from other programs.

Labeling and Product Claims

Closely aligned with many food safety issues is the subject of food labeling. Nutrition labeling, ingredient labeling, health claims, and other information on the product, at the point of purchase, or in advertising can facilitate choice and informed decision making. How well the existing regulatory system is able to ensure the goal of informed choice has been the subject of much debate.

The system for regulating food labeling is complex, relying primarily on two federal agencies which operate under laws that are quite different in their histories, provisions, and modes of implementation and which sometimes have overlapping jurisdictions (IOM, 1990). USDA regulates the labeling of meat, poultry, and eggs, except that products containing relatively small proportions of meat and poultry are exempted, thus coming under the authority of FDA, which regulates all other foods. A third federal agency, the Federal Trade Commission, regulates food promotion practices that extend beyond labeling. In addition to federal regulation, state and local governments may have the authority to impose labeling requirements that are more stringent than federal actions.

Over the course of 20 years, labeling reform has represented a fundamental shift in federal regulatory philosophy toward increased consumer choice in the marketplace. Yet labeling reform has not kept pace with the advances in knowledge about the relationship between nutrition and chronic disease (HHS, 1988; NAS/NRC, 1982, 1988, 1989). While new products and label claims have made nutrition and disease avoidance a major food marketing theme, many educators believe that incomplete and misfocused label information has left shoppers confused and unable to make appropriate choices (IOM, 1990).

The Nutrition Labeling and Education Act of 1990 accelerated label reform initiatives. In November 1991, FDA and USDA proposed major changes in food labeling regulations, including mandatory nutrition labeling for most processed foods and a voluntary nutrition labeling program for raw fruits, vegetables, fish, and single-ingredient meat and poultry products (FDA, 1991; USDA, 1991). The proposed regulations would change the content of the nutrition information, require the use of consistent serving sizes, set definitions for ten descriptive terms, and establish conditions under which health claims are to be permitted. These extensive food labeling proposals aim to make label information more useful to consumers who wish to select a healthy diet, as well as unify the labeling policies of FDA and USDA.

The Future of Food Safety Policies

Food safety issues are likely to remain on public policy agendas through the 1990s. Advances in science, health, and technology will resolve some food safety concerns, but other less-recognized or previously unknown concerns will emerge. Existing laws and regulations will be challenged by new scientific understandings, new advances in technology, new developments in world food markets, and changing perceptions and expectations among the many segments of the U.S. population. Public policy makers and government officials will be responsible for reconciling scientific and social forces as well as the concerns of many different interest groups.

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Table 3—**How Substances are Regulated** *under the Federal Food, Drug, and Cosmetic Act. Adapted from Smith (1984)*

Food ingredient category	Definition and *Code of Federal Regulations* citation	Safety standard	Burden of proof	Rule-making procedure
Unavoidable contaminants	Inherent food substances which cannot be avoided by good manufacturing practices (21 CFR Part 109)	Adulterated if substance "may render food injurious to health"	Manufacturer	Informal
Food additives	Substances added to foods for specific intended effects, excluding prior-sanctioned substances, GRAS substances, color additives, new animal drugs, and pesticides (21 CFR Part 170)	"Reasonable certainty of harm" and Delaney anti-cancer clause	Manufacturer	Formal
GRAS substances	Substances that are Generally Recognized as Safe by the scientific community (21CFR Part 182)	Must be "generally recognized as safe"	FDA	Informal
Prior-sanctioned substances	Substances that received explicit approval from FDA or USDA for use in food prior to 1958 (21 CFR Part 181)	Adulterated if substance "may render food injurious to health"	FDA	Informal
Pesticides	Substances intended for preventing, destroying, repelling, or mitigating any pest, or intended for use as a plant regulator (40 CFR Part 162)	Tolerance based on whether it is "safe for use" considering its benefits	Manufacturer	Formal
New animal drugs	Substances intended for food-producing animals, excluding antibiotics (21 CFR Part 500)	"Reasonable certainty of no harm" and Delaney anti-cancer clause with DES proviso	Manufacturer	Formal
Color additives	Dyes, pigments, or other substances capable of imparting color, excluding substances that impart color but have other intended functional effects (21 CFR Part 70)	"Reasonable certainty of no harm" and Delaney anti-cancer clause	Manufacturer	Formal
Prohibited substances	Substances prohibited from use because they present a potential risk to public health or have not shown adequate scientific data to be safe for use in food (21 CFR Part 189)			

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FILM PACKAGING FOR SHELF-LIFE EXTENSION OF PERMISSION FRUIT

The agroclimatic conditions of N.W.F.P. are very suitable for profitable growing of persimmon fruit. The area and production of this fruit is increasing every year. The fruit is highly perishable and possesses a very short storage life. For marketing fruit is commonly packed in wooden crates lined with newspaper, dried straw, hay etc. which are technically unsuitable and could be source of infection as well. The newspaper and straw are not an efficient barrier to check loss in weight due to transpiration/respiration during post-harvest handling/storage. Film packaging is being successfully used for many fruits and vegetables in many countries of the world for extending their shelf life. Limited studies have been reported for enhancing marketable life of persimmon. Therefore, research was undertaken in the Food Science Division of NIFA by a group comprising of M.A. Chaudhry, Dr. A. Sattar and Mrs. N. Bibi.

For these experiments, orchard picked green but mature fruits were utilised. The fruit was packaged in fibre-board cartons lined with newspaper (control), polyethylene (PE), cellophane and wax paper prior to ambient storage. PE-lined fruit retained more weight and maintained better quality than all other packages used. However, different thickness of PE did not cause significant effect on the post-harvest life of this fruit. The PE bulk packaging was found to extend the storage life of this about 15 days over control, which normally was 20 days. The PE packaged fruits exhibited much better texture and sensory ratings. Ascorbic acid contents were almost comparable in both the cases. Further experiments revealed that unipackaging extended the shelf-life of this fruit by about 20 days over that of control. Determination of astringency causing polyphenolics showed generally a decreasing pattern during ripening at ambient storage. For marketing, bulk/unipackaging of fresh persimmon is recommended. For further details contact Dr. A. Sattar, Head Food Science Division, NIFA, P.O. Tarnab, Peshawar.

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