Vanderbilt Law Review

Volume 38
Issue 3 *Issue 3 - April 1985*

Article 2

4-1985

Truth in Judging: Supreme Court Opinions As Legislative Drafting

Ray Forrester

The Importance of Analytical Chemistry to Food and Drug Regulation

*Peter Burton Hutt**

I. INTRODUCTION

The past year represents the centennial anniversary of the founding of a scientific organization whose major purpose, from its origin, has been to provide the analytical underpinning essential for enforcement of food and drug laws: The Association of Official Analytical Chemists (AOAC).[1] In the century that has passed since AOAC was founded, there has been extraordinary progress in the field of analytical chemistry and, as a direct result, corresponding improvement in public health and safety. Celebration of this centennial anniversary thus provides an opportunity to observe the relationship between science and regulation. This relationship is reflected in the importance of analytical chemistry to the field of food and drug regulation and to the protection of public health and safety.

The first thesis this Article postulates is that the history of food and drug regulation during the past twenty centuries has been the history of the development of analytical chemistry, not the history of the development of law and regulation. Statutory law during this period has remained relatively static, while general understanding of analytical chemistry has leapt ahead with unparalleled achievement. Increased scientific enlightenment, largely achieved

---

*Mr. Hutt is a partner in the Washington D.C. law firm of Covington & Burling. This Article is adapted from the Keynote Address he delivered at the General Session of the Centennial Meeting of the Association of Official Analytical Chemists in Washington, D.C. on October 29, 1984.

1. *See generally* K. HELRICH, THE GREAT COLLABORATION: THE FIRST 100 YEARS OF THE ASSOCIATION OF OFFICIAL ANALYTICAL CHEMISTS (1984); B. Adelman, *AOAC: Why FDA Analyses Stick*, 25 FOOD DRUG COSM. L.J. 407 (1970); Lepper, *A Bit of AOAC History*, 15 FOOD DRUG COSM. L.J. 407 (1960); White, *A.O.A.C. Methods of Analysis*, 1 FOOD DRUG COSM. L.J., 442 (1946). The name of AOAC was changed from "The Association of Official Agricultural Chemists" to "The Association of Official Analytical Chemists" in 1965.

through analytical chemistry, has produced every important advance in food and drug regulation. Indeed, the overwhelming success of the field of analytical chemistry has created entire scientific disciplines as well as improvement in government regulation of food and drugs.

The second thesis this Article presents is that the very nature of food and drug regulation requires that analytical chemistry will retain its central regulatory significance for the foreseeable future. The task that must be accomplished by analytical chemistry, in short, is far from completed, and stretches into the indefinite future.

Before pursuing these two theses, it is necessary to dispose of one subsidiary matter. The past few years has witnessed intense debate concerning the scope of the term "analytical chemistry." AOAC has, for example, discussed changing its name because of concern that the present title is not sufficiently broad to reflect the comprehensive purposes of the scientific field it represents.[2] The plain meaning of the words themselves, however, quite adequately describes the scope of scientific inquiry represented by this field. Chemistry is defined as "[t]he science of the composition, structure, properties, and reactions of matter."[3] Analysis, as it relates to chemistry, is defined as "[s]eparation of a substance into constituents or the determination of its composition."[4] This Article approaches the subject of analytical chemistry in this comprehensive context.

II. An Historical Perspective

The purpose of this Article is not to trace the development of analytical chemistry[5] or the parallel development of food and drug regulation[6] over 2000 years; adequate historical treatments of both are readily available. Instead, this Article briefiy reviews landmark developments occurring at significant moments in time. Six vignettes are sufficient to illustrate the first thesis—that the progress of knowledge for analytical chemistry has been the determining force in the evolution of food and drug regulation throughout history. These viguettes cover the three basic categories of food and

2. *See* Helrich, *supra* note 1, at 102-04.
3. The American Heritage Dictionary of the English Language 230-31 (1969 ed.).
4. *Id.* at 47.
5. *See, e.g.*, J. Partington, A Short History of Chemistry (3d ed. 1957).
6. *See, e.g.*, Hutt & Hutt, *A History of Government Regulation of Adulteration and Misbranding of Food*, 39 Food Drug Cosm. L.J. 2 (1984).

drug regulation that have existed from ancient times: economic regulation (standards and labeling), aesthetic regulation (sanitation), and safety regulation (pathogenic contamination and toxicity).[7]

A. *Ancient Greece and Rome*

Adulteration of the food and drug supply was rampant in the ancient world. Numerous Greek and Roman writers documented this adulteration over several centuries. Pliny the Elder (23-79 A.D.) described several specific adulterations of particular foods and drugs. He mentioned the addition of "noxious herbs and drugs" to wine[8] and noted that "[p]epper is adulterated with juniper berries."[9] He criticized "the fashionable druggists' shops which spoil everything with fraudulent adulterations,"[10] and complained that "mankind wants nothing to be as nature likes to have it."[11] Dioscorides (*circa* 40-90 A.D.), who produced the earliest surviving treatise on the *material medica*, also mentioned many examples of food and drug adulteration.[12] Galen (131-201 A.D.), whose writings dominated medicine even through the eighteenth century, found such widespread adulteration that he distrusted the entire commercial drug supply.[13]

Even in those early days, laws protected the public against adulterated food and drugs. Roman law broadly prohibited any form of fraud, including the adulteration of food and drugs.[14] The Theodosian Code (438 A.D.) established standards for different grades of bread and prohibited the sale of one grade for another or any other form of fraud.[15] Knowledge of extensive adulteration of food and drugs, and laws to prohibit adulteration, however, are useless unless enforceable. The question thus arises whether the ancient scientists had developed analytical methods sufficient to

---

7. *See* Hutt, *The Basis and Purpose of Government Regulation of Adulteration and Misbranding of Food*, 33 FOOD DRUG COSM. L.J. 505, 514-15 (1978).

8. PLINY, NATURAL HISTORY 233 (H. Rackham trans. 1945).

9. *Id.* at 23.

10. 9 *id.* at 207.

11. 5 *id.* at 457.

12. *See* R. GUNTHER, THE GREEK HEREAL OF DIOSCORIDES (1934).

13. E. STIEB, DRUG ALTERNATION 7-8 (1966).

14. *See* 3 S. SCOTT, THE CIVIL LAW 67 (1932) (Scott's translation is available in a 1973 reprint which presents the 17 volumes of the original edition in only 7 bound volumes); *see also* 11 *id.* at 8.

15. C. PHARR, THE THEODOSIAN CODE AND NOVELS AND THE SIRMONDIAN CONSTITUTIONS 418 (1952).

detect such adulteration.

The ancient treatises that have survived through the centuries reveal substantial discussion of analytical methodology. Cato (234-149 B.C.) suggested a method "to determine whether wine had been watered."[16] After his description of widespread adulteration, Pliny contended that "these adulterations can be detected . . . by smell, colour, weight, taste and the action of fire."[17] Together, Pliny and Dioscorides described several dozen methods of detecting adulteration, all of which depended solely or partly upon the qualitative judgment of the individual conducting the analysis. Galen suggested methods for determining whether such common food articles as pepper were adulterated.[18]

To dismiss these ancient beginnings of analytical chemistry as sheer speculation is all too easy, in this day of scientific sophistication. Dr. C.A. Browne, President of AOAC in 1925 and Commissioner of Food and Drugs during 1923-1927, stated in 1909 that those in the ancient world who relied upon "sense perceptions" to determine adulteration "were unquestionably better judges of the purity of many articles of food than we are today."[19] Dr. Browne also concluded that the flame test, ring test, color reactions, and other physical detection methods identified by Pliny and Dioscorides had clear scientific underpinnings and reflected "a large amount of reliable chemical knowledge."[20] Archimedes, at an even earlier date, (*circa* 287-212 B.C.), applied the principle of specific gravity to determine whether the gold in King Hieron's crown was adulterated.[21] Thus, the field of analytical chemistry began at a very early date, with the most renowned scientists in the ancient world—a truly auspicious beginning for a productive relationship between science and regulation.

B. The Dark Ages and Middle Ages

After the fall of Rome, nontheological scholarship was discontinued and the scientific progress begun in Greece and Rome was lost for centuries. The adulteration of food and drugs continued, however, and attempts to contain it required the application of an-

16. M. CATO, ON AGRICULTURE 101-02 (W. Hooper trans. 1936).
17. 4 PLINY, *supra* note 8, at 27.
18. GALEN'S HYGIENE 162-163 (R.M. Green trans. 1951).
19. Browne, *Adulteration and the Condition of Analytical Chemistry Among the Ancients*, 29 SCI. 455, 457 (1909).
20. *Id.* at 458.
21. 1 ENCYCLOPAEDIA BRITANNICA MACROPEDIA ARCHIMEDES 1087-88 (15th ed. 1978).

alytical methods and regulatory controls.

Throughout the Dark Ages and Middle Ages, a thriving spice trade existed, originating among the Mediterranean countries and ultimately reaching England. During that period, even more than today, spices were extraordinarily valuable and presented an irresistable opportunity for fraudulent profit. Government inspectors—called "garblers"—were employed to remove both natural and artificial adulterants from spices. Although the origin of garbeling is lost in history, records from the very early 1300s reveal that the practice was already established in England.[22] Thus, from early times, England was concerned about food adulteration. In 1266, Parliament enacted laws prohibiting the sale of staple food products that were "corrupted" or "not wholesome for Man's Body."[23] These laws, with periodic amendments, continued in effect throughout England for almost 600 years, until they were repealed in 1844.[24] The medieval guilds also had independent authority to inspect the food and drugs purveyed by their members, and to punish any adulteration.[25] These laws and regulatory controls, however, like their Greek and Roman counterparts, depended upon available analytical methods for their enforcement. The works of Pliny and Dioscorides, moreover, had not yet been rediscovered. Thus, throughout this period, garbeling was based entirely upon physical inspection of the spice supply. Protection against other forms of food adulteration similarly was limited to determinations by sight, smell, and taste.

As the centuries passed, adulteration became more sophisticated and even more difficult to detect. Because of the lack of detection methods only gross contamination could be prevented, such as the inclusion of stones, charcoal, dust, and straw in particular products or the putrefaction of fish, meat and bread.[26] Lack of effective detection methodology and the resulting poor enforcement of the laws prohibiting food and drug adulteration were sources of continuing public problems and complaints. Although the records of London reflect a number of actions to enforce these early regulatory laws,[27] they also reflect widespread dissatisfaction by legiti-

22. F.A. FILBY, A HISTORY OF FOOD ADULTERATION AND ANALYSIS 24-27 (1934).
23. A Statute of the Pillory and Tumbrel, 51 Hen. 3, stat. 6, §§ 2-3 (1266).
24. 7 & 8 Vict., ch. 24, § 2 (1844).
25. W.C. HAZLITT, THE LIVERY COMPANIES OF THE CITY OF LONDON (1892).
26. *See, e.g.*, H. RILEY, MEMORIALS OF LONDON AND LONDON LIFE 90, 121, 132, 332 (London 1868).
27. *See id.*

mate retailers and the public. In 1592 the Grocers of London, complaining that the garbelers were doing an inadequate job of enforcement, submitted a petition suggesting specific and detailed standards and procedures that should be followed to improve regulatory efforts.[28]

C. *The Emergence of Chemistry from Alchemy*

In its purely technological, as contrasted with philosophical and theological, aspects, alchemy was the origin of the field of chemistry, but to break away from the mysticism of alchemy and establish the foundations of modern experimental chemistry took the work of Paracelsus in the sixteenth century and Robert Boyle in the seventeenth century.

One year before his death Boyle wrote the first modern tract on the use of analytical chemistry to detect the adulteration of food and drugs.[29] This work, published in 1690, used the principle of specific gravity to determine "[h]ow by the Weight that divers Bodies, us'd in Physick, have in Water; one may discover Whether they be Genuine or Adulterate." In effect, Boyle did no more than apply the principle of specific gravity, used centuries earlier by Archimedes, for the purpose of determining the adulteration of food and drugs. In so doing, however, he established a scientific foundation for food and drug regulation. Boyle's test for adulteration utilizing the specific gravity of a substance no longer depended on individual opinion, as did most of the earlier tests identified by Pliny and Dioscorides. Based upon Boyle's work, other chemists soon made substantial progress in chemical analysis.

D. *The Accum Treatise*

Fredrick Accum, a German-trained scientist working in England,[30] published a landmark treatise on chemical methods of analyzing adulteration of food and drugs in 1820.[31] Accum not only documented extensive adulteration of the food and drug supply, but offered detailed chemical methods for detection. Perhaps his

---

28. GROCERS OF LONDON, A PROFITABLE AND NECESSARIE DISCOURSE, FOR THE MEETING WITH THE BAD GARBELLING OF SPICES, USED IN THESE DAIES (London 1592).

29. R. BOYLE, MEDICINA HYDROSTATICA: OR, HYDROSTATICS APPLIED TO THE MATERIA MEDICA (London 1690).

30. *See generally* Browne, *The Life and Chemical Services of Fredrick Accum* (pts. 1-3), 2 J. CHEMICAL EDUC. 829, 1008, 1140 (1925).

31. F. ACCUM, A TREATISE ON ADULTERATION OF FOOD AND CULINARY POISONS (2d ed. London 1820) (1st ed. London 1820).

most important achievement was to bring the field of analytical chemistry directly to the public, publicizing that adulteration had important health as well as economic consequences.[32] Accum's treatise had an overnight effect, both in the United States and in England, stimulating the enactment and enforcement of regulatory laws and the public awareness of adulterated products. Lemuel Shattuck published his important treatise on public health in the United States in 1850, recommending government regulation of the food and drug supply as an important element in protection of the public health.[33] Following this report, food and drug laws were enacted in numerous states throughout the country.

Shortly after Shattuck's work, Arthur Hassall began his extensive investigations of food and drug adulteration in England.[34] By introducing use of the microscope, which had been invented two centuries earlier, to food and drug analysis, Hassall led food and drug regulation into a new era. Forms of adulteration that could not be detected in any other way were found easily. In England, Hassall's research led to Parliament's enactment of three major new statutes to protect against food and drug adulteration, in 1860,[35] 1872,[36] and 1875.[37] The Government established public analysts to prevent the adulteration of food and drugs.[38] English analysts established Society of Public Analysts in 1874,[39] only ten years before the founding of AOAC.

E. Wiley and the 1906 Act

Harvey W. Wiley and the Division (later Bureau) of Chemistry in the United States Department of Agriculture mirrored the work undertaken by Hassall in England. Congress enacted a statute to establish the Department of Agriculture in 1862 and specifically

---

32. *See id.* at 3-4.

33. L. SHATTUCK, REPORT OF THE SANITARY COMMISSION OF MASSACHUSETTS 1850 220 (1948).

34. *See* A. HASSALL, ADULTERATIONS DETECTED; OR PLAIN INSTRUCTIONS FOR THE DISCOVERY OF FRAUDS IN FOOD AND MEDICINE (London 1857); A. HASSALL, FOOD AND ITS ADULTERATIONS (London 1855).

35. 23 & 24 Vict., ch. 84 (1860).

36. 35 & 36 Vict., ch. 74 (1872).

37. 38 & 39 Vict., ch. 63 (1875).

38. Curran, *British Food and Drug Law—A History*, 6 FOOD DRUG. COSM. L.J. 247, 251 (1951).

39. Taylor, *The Society of Public Analysts and Other Analytical Chemists*, 9 FOOD DRUG COSM. L.J. 133, 136 (1954); B. DYER, THE SOCIETY OF PUBLIC ANALYSTS AND OTHER ANALYTICAL CHEMISTS: SOME REMINISCENCES OF ITS FIRST FIFTY YEARS (1932).

authorized the Commissioner of Agriculture to employ chemists:[40] The initial appropriations for the new Department included money "for the purpose of establishing a laboratory, with the necessary apparatus for practical and scientific experiments in agricultural chemistry."[41] From its very inception, therefore, the Department included a Division of Chemistry that was to determine the entire future course of national protection against food and drug adulteration in the United States.

At the turn of the century, steps were taken to address an escalating public concern in this country about food and drug adulteration. In December 1879 the National Board of Trade adopted a resolution establishing a "$1000 Competition for the Draft of a Food Adulteration Act." The three top submissions selected by the award committee were printed in full in a special supplement to the December 1880 issue of *The Sanitary Engineer*. G.W. Wigner, a public analyst in England, submitted the prize-winning essay, which proposed a law for the United States that was based upon the law enacted in England in 1875. Although twenty-six years passed before Congress enacted the Food and Drugs Act of 1906,[42] the final law remained very similar to the original Wigner draft. Thus, an analytical chemist served as the principal draftsman of the first national food and drug legislation enacted in this country. The 1906 Act was the result largely of the development of extensive documentation of the adulteration of the American food and drug supply.[43] This evidence, which ultimately overwhelmed congressional reluctance to enact the legislation, resulted from the painstaking and persistent work of the Division of Chemistry and AOAC.[44]

F. The Past 35 Years

There has been more progress in the field of analytical chemistry in the past thirty-five years than in the prior twenty centuries. More detailed understanding of the chemical composition of the food and drug supply has compelled major changes in the regulation of food and drugs. New statutes have been enacted to require industry to prove the safety of food and drug substances before

40. Act of May 15, 1862, ch. 72, § 4, 12 Stat. 387, 388.
41. Act of Feb. 25, 1863, ch. 59, 12 Stat. 682, 691.
42. Act of June 30, 1906, ch. 3915, 34 Stat. 768.
43. *See* HELRICH, *supra* note 1, at 23-26; Hutt & Hutt, *supra* note 6, at 50-53.
44. *See generally* Horwitz, *The Role of the A.O.A.C. in the Passage of the Federal Food and Drugs Act of 1906*, 11 FOOD DRUG COSM. L.J. 77 (1956).

they are marketed, and to require the Food and Drug Administration to approve those substances as safe.[45] Without the advances achieved by modern analytical chemistry, new regulatory approaches would not have been feasible and could never have occurred.

G. *Summary*

This brief historical perspective readily demonstrates that laws and regulations to protect the public against adulteration of the food and drug supply have not changed significantly throughout history. Fraud has been prohibited since the days of Greece and Rome. Filth has been prohibited since the Dark Ages. Unsafe substances have been prohibited since at least 1266. The only element that has changed is the ability of analytical chemists to detect, identify, and understand the substances that comprise our food and drug supply. Progress in the field on analytical chemistry thus has led, and indeed forced, progress in consumer protection. This truly breathtaking story should instill every analytical chemist with pride in his profession and in the remarkable contribution it has made to public health and safety.

The question that now faces, however, is whether the preeminence of the profession of analytical chemists in the regulation of food and drugs has come to an end. Has the past leadership of analytical chemistry now been passed on to toxicologists, pharmacologists, and molecular biologists?

III. A Promising Future

The field of analytical chemistry has spawned entire new scientific disciplines over the centuries including toxicology, pharmacology, pedemiology, and the new emerging field of risk assessment. None of these disciplines can function without analytical chemistry, which is the sole basis for all exposure calculations. Regulatory decisions are as dependent upon sound analytical determinations today as they have been in the past. Thus, the field of analytical chemistry remains secure as the central focus of food

45. *See, e.g.*, Food Additives Amendment of 1958, Pub. L. No. 85-929, 72 Stat. 1784 (codified as amended in scattered sections of 21 U.S.C. and 42 U.S.C. § 210); Color Additive Amendments of 1960, Pub. L. No. 86-618, 74 Stat. 397 (codified in scattered sections of 21 U.S.C.); Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (codified in scattered sections of 21 U.S.C.); Animal Drug Amendments of 1968, Pub. L. No. 90-399, 82 Stat. 342 (codified in scattered sections of 21 U.S.C.); Miller Act, Pub. L. No. 83-518, 68 Stat. 511 (1954).

and drug regulation for the foreseeable future.

History teaches, however, that the more we learn, the less we understand. Analytical chemistry is no exception. New problems continually appear in this field just as they do in others. In order to retain the preeminent position of analytical chemistry in scientific regulation, it is important that the emerging new questions that face this field be addressed and resolved. Three areas, in particular, justify prompt review and consideration.

A. Organizational Issues

Several important issues that directly affect the professional stature of the field of analytical chemistry deserve evaluation and resolution. As in any evolving profession, retaining both the quality and the integrity of the field is critical. These attributes have been essential to this field for the past century, and must remain equally important in the years to come. As the complexity of analytical chemistry continues to increase and even accelerate, the field must increasingly be concerned with the qualifications of both the individuals who practice analytical chemistry and the laboratories in which they work.[46] The half-life of knowledge in this field grows ever shorter; the need for continuing education grows ever greater. The funds needed both to keep abreast of the latest knowledge, and, more importantly, to obtain the costly new equipment required to utilize that knowledge, is multiplying exponentially. These factors could, if left unaddressed, create a widening gap between the best and the worst of those who work in this field and the laboratories in which they work. The AOAC, therefore, must consider the subject of minimum qualifications for analytical chemists and laboratories promptly, before a crisis occurs that could raise the threat of regulation by outside authorities. This field has shown a remarkable ability to keep abreast of current developments and requirements, but that ability must not lull the profession into thinking that these issues are not real and pressing.

Similarly, AOAC must address the involvement of private sector scientists. From its origin, the AOAC membership has been comprised of "official" agricultural chemists.[47] Industrial scientists, however well-qualified, are limited to associate membership.

---

46. The National Bureau of Standards conducts a National Voluntary Laboratory Accreditation Program, which includes general criteria for facilities, equipment, and staff. *See* 49 Fed. Reg. 44,622 (1984) (to be codified at 15 C.F.R. pt. 7).

47. *See* Lepper, *supra* note 1, at 407-09; *AOAC Urged to Make Industry Members "Peers,"* Food Chem. News, Nov. 1, 1982, at 22.

Clearly, science recognizes no such boundaries. These artificial distinctions are both insulting and unnecessary. Furthermore, industrial participation in the AOAC must be undertaken without either the appearance or the actuality of compromising the integrity of the official methods. This task can be accomplished by paying the same strict attention to potential conflicts of interest as is done in other important scientific organizations. In short, recognized solutions would permit the full participation in AOAC activities by all analytical chemists, regardless of their employment status, without compromising the important work of the Association. The commitment of all analytical chemists to the work of AOAC must be a major objective if the Association is to retain its preeminent position in the field of analytical chemistry in the future. The field of analytical chemistry has been subjected to extraordinarily rapid change. Methods of analysis that formerly remained static for years now change with disconcerting speed. Cooperation in this field is needed to meet the needs of regulatory agencies for validated analytical methods in the future.

Since 1920, the AOAC has published the *Official Methods of Analysis of the Association of Official Analytical Chemists* which have been validated through collaborative testing and formally adopted by the AOAC.[48] These official AOAC methods have met with remarkable acceptance in the courts.[49] Nonetheless, the AOAC also must reconsider its process and procedures for the validation and acceptance of official methods to meet the increased pace of the regulatory developments. Suggestions for provisional or interim acceptance of methods must be reviewed and evaluated. The AOAC cannot afford to lose its traditional position as the leading authority in this field by falling far behind the accelerating pace of new methodology.[50] The AOAC, however, cannot risk its reputation for thoroughness and accuracy by adopting new procedures that threaten the integrity of the process, the validity of the methods that are accepted, or the enforcement of AOAC methods in the courts.[51] This problem presents an enormous challenge to

48. *See* White, *supra* note 1, at 446-47.

49. *See, e.g.*, Knapp v. Callaway, 52 F.2d 470 (S.D.N.Y. 1931) (recognizing pursuant to the authority of the Department of Agriculture that a rule was adopted providing that all foods shall he analyzed by the methods prescrihed by the AOAC). No court has ever failed to enforce an official AOAC method. The FDA has for many years adopted the AOAC methods for purposes of enforcing the law. *See* 21 C.F.R. § 2.19 (1984).

50. *AOAC President Calls for Alternatives to Establishing Official Methods*, Food Chem. News, Oct. 24, 1983, at 17.

51. In United States v. *Corrao*, Crim. No. 40551 (E.D.N.Y. 1948), *reprinted in* V.A.

the leadership of the AOAC and undoubtedly represents the single most serious and pressing issue to be resolved.

B. *New Methods of Detection for Old Problems*

The power of modern analytical chemistry is not only remarkable, but undoubtedly beyond the comprehension of most laypersons. Analytical methods now exist at the level of parts per quadrillion, and perhaps lower. To most laypersons, therefore, it remains inexplicable that many problems of even gross contamination of natural food products remain unsolved.

As demonstrated, by the recitation of historical developments,[52] the field of analytical chemistry was developed largely to address the adulteration of natural food and drug products. As modern chemistry has evolved, however, the origins of this field have been forgotten and the purpose for which it was initially developed has been ignored. Modern analytical chemistry has left unattended simple food and drug adulteration, perhaps even regarding it as a scientific backwater. In some respects, analytical chemists are in no better position to detect and quantify the adulteration of natural food products like fruit juice[53] and meat[54] today than they were at the beginning of this century. No improvement has been made over the organoleptic methods used to determine the decomposition of fish and other foods since the days of Pliny.[55] No methods exist to ascertain the impact of bacterial contamination on the quality of the food supply.[56] Methods to analyze the

---

KLEINFELD & C.W. DUNN, FEDERAL FOOD, DRUG, AND COSMETIC ACT, 1938-1949 387 (1949), the trial judge in a criminal case set aside a jury verdict convicting the defendant of food adulteration because the analytical method on which FDA relied never officially had been adopted by AOAC.

52. *See supra* notes 5-46 and accompanying text.

53. M.R. Johnston, *Citrus Juices: Adulteration Detection and Actions of the FDA*, Presented at the Association of Food and Drug Officials, Workshop on the Detection of Juice Adulteration (June 16-17, 1983).

54. Need for Tests to Detect Meat-Derived, Nonmeat Proteins Emphasized, Food Chem. News, Nov. 15, 1982, at 12.

55. *See, e.g.*, United States v. 1,200 Cans, Pasteurized Eggs, 339 F. Supp. 131 (N.D. Ga. 1972); United States v. An Article of Food Consisting of 51 Cases, No. 71-35-35 (E.D. La. October 22, 1973), *reprinted in* V.A. KLEINFELD, A.H. KAPLAN & S.A. WEITZMAN, FEDERAL FOOD, DRUG, AND COSMETIC ACT, 1969-1974 145 (1976).

56. The FDA proposed general regulations and specific microbiological quality standards for two types of food products in 37 Fed. Reg. 20,038 (Sept. 23, 1972) and promulgated those regulations in 38 Fed. Reg. 20,726 (Aug. 2, 1973), but after objections were received and a further opportunity for public comment was provided in 41 Fed. Reg. 33,249 (Aug. 9, 1976), the Agency withdrew the two specific standards in 43 Fed. Reg. 9272 (Mar. 7, 1978) but confirmed its general regulations in 45 Fed. Reg. 37,422 (June 3, 1980). FDA has

interaction of added substances in food and drugs do not exist nor appear on the immediate horizon.[57] Research in these areas could have enormous practical impact. New methods to address age-old problems would represent a major advance in public protection and carry forth the tradition of public service represented by this field.

C. *Improvement of Existing Methods*

The third area in which analytical chemistry can contribute further to government regulation of food and drugs, and thus public protection, is in the improvement of existing analytical methodology. Without doubt, existing methods can be made more practical, less costly, more efficient, more accurate at lower levels, less variable, more rapid, and more reliable.[58] This statement, easily made, is very hard to accomplish. Accomplishment of these objectives requires not simply large sums of money, but enormous patience and determination. Above all, success requires the persistent inquiry of a committed scientist who has dedicated a life to this endeavor for the benefit of the public. These objectives represent a goal that never fully can be achieved, because, as history demonstrates, every new advance in analytical technology carries with it a new challenge for improvement in the future. The never ending search to improve official methods thus must remain the essence of the work of this field.

As a nation, we must have no fear of discovering more and more contaminants in our food and drug supply by means of lower and lower levels of detection. Nor can we fear learning that everything we ingest affects the carcinogenic process or otherwise alters our lifespan. In regulation, and indeed in all of life, knowledge can never be feared. Only ignorance, and those who would impose ignorance upon us, must be feared and distrusted. The public and the regulatory agencies that serve the public have learned to cope with

---

since issued "recommended" microbiological quality standards for certain frozen fish products in 45 Fed. Reg. 37,524 (voluntary guidelines) (proposed June 3, 1980) and 46 Fed. Reg. 31,067 (voluntary guidelines) (proposed June 12, 1981) and enforcement guidelines for microbiological contamination of another fish product in 48 Fed. Reg. 43,223 (to be codified at 21 C.F.R. pt. 110) (proposed September 22, 1983).

57. *See generally* SECOND TASK FORCE FOR RESEARCH PLANNING IN ENVIRONMENTAL HEALTH SCIENCE, HUMAN HEALTH AND THE ENVIRONMENT—SOME RESEARCH NEEDS (1976) (Docs. HE 20,3552 MB ½).

58. Horwitz, *Analytical Measurements: How Do You Know Your Results Are Right?*, in THE PESTICIDE CHEMIST AND MODERN TOXICOLOGY, ACS SYMPOSIUM SER. No. 160, ch. 24 (1981).

the expanding scientific knowledge about food and drugs, even though that experience often has been painful and disturbing.[59] For example, the public was not pleased to learn that there is unavoidable filth throughout the food supply and that the FDA has been forced to adopt informal guidelines establishing acceptable levels.[60] Nor has the public been pleased to learn that the entire food supply is contaminated with low levels of known carcinogenic substances, and that the FDA must now set acceptable levels for these substances as well.[61] This country, however, is built upon the foundation of an informed and educated public. Knowledge breeds understanding and acceptance.

The field of analytical chemistry bears a major burden, not just in announcing the bare results of these new analytical findings to the public, but also in explaining their meaning. Throughout history, simply to determine and quantify the composition of our food and drugs has never been sufficient. Understanding the relevance and explaining the significance of these findings to the public is equally important.

The field of analytical chemistry has been blessed with leaders who have exhibited an extraordinary breadth and depth of knowledge and understanding. From Pliny and Dioscorides, through Boyle, Accum, Hassall, and Wiley, to the leaders of today, analytical chemists have appreciated the social, public policy, and regulatory implications that emanate from their work. A major task is to continue to recruit, educate, and retain this remarkable, high, professional quality in the future.

IV. Conclusion

The public focuses on changes in statutes and regulations as reflecting progress in protection of health and safety. As this Article illustrates, however, advance in scientific knowledge permits, and even forces, those statutory and regulatory changes. Although the field of analytical chemistry is relatively obscure and unknown to the public, it has made the dominant, and usually the control-

59. *See generally* P.B. Hutt, Accommodating Divergent Societal and Individual Interests in Determining Regulatory Policy, in FDA, Proceedings of the Second National Conference for Food Protection 253 (1984); Hutt, *Public Participation in Toxicology Decisions*, 32 Food Drug Cosm. L.J. 275 (1977).

60. *See* 21 C.F.R. § 110.99 (1984).

61. *See generally* 47 Fed. Reg. 14,464 (1982) (advance notice of proposed rule making on regulatory caranogenic chemicals in food and color additives); *see also* Scott v. FDA, 728 F.2d 322 (6th Cir. 1984) (per curiam).

ling, contribution to regulation of food and drugs throughout history.