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Changes in FIFRA environmental testing regulations and corresponding effects on Analytical Bio-Chemistry Laboratories Inc.

Lan Wang

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CHANGES IN FIFRA ENVIRONMENTAL TESTING REGULATIONS AND CORRESPONDING EFFECTS ON ANALYTICAL BIO-CHEMISTRY LABORATORIES, INC.

by

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CHAPTER ONE
INTRODUCTION

The government regulations and private sector requirements for environmental testing services are rapidly changing in the United States. In addition, regulations are becoming increasingly complex, and the business problems faced by various environmental testing companies also become more and more complicated. New methods, new plans, new requirements and new rules are constantly being devised to comply with the rapid changes in the government regulations. Every environmental testing company tries to track current regulation development and to predict future changes in the regulations as these changes might affect their business. This tracking and predicting phenomena are on the increase, especially among the advanced competitive companies, and the Analytical Bio-Chemistry Laboratories (ABC Labs) is no exception.

Before tracing the history and evolution of the ABC Laboratories, it is necessary to have an overview of the evolution of the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA") because the growth and success of the ABC Laboratories is heavily dependent upon this particular regulation.

Federal regulation of pesticides started with the Insecticide Act of 1910, which was designed to protect consumers from substandard or fraudulent insecticide and
fungicides. It provided for inspections, seizure of adulterated or misbranded products, and prosecution of violations as misdemeanors. The Insecticide Act, however, was essentially a labeling statute; it did not require registration or establish significant safety standards for pesticides. Even so, it remained the federal law regulating pesticides for thirty-seven years.

In 1947, Congress replaced the Insecticide Act with the more comprehensive FIFRA. FIFRA regulated "economic poisons" which included not only insecticides and fungicides, but also rodenticides, herbicides, and preparations intended to control other forms of pests which were not subject to the Insecticide Act. For the first time, FIFRA required registration of economic poisons prior to their sale or distribution in interstate or foreign commerce. States were left to regulate intrastate sales of pesticides. The 1947 Act required warnings on the labels of highly toxic pesticides, instructions for their safe use to protect the public against poisoning, and coloration of pesticides which might be mistaken for flour, sugar, salt, etc.

In 1959, Congress added nematocide, plant regulators, defoliants, and desiccants to FIFRA's definition of "economic poison". These new types of agricultural chemicals had been developed commercially and applied widely since the enactment of FIFRA in 1947.
In 1961, Congress further amended FIFPA to give the U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA) more time to complete the process of registering and establishing the requisite tolerances for new pesticides. Congress ended the practice of protest registration in 1964, and authorized the Secretary of Agriculture to deny or cancel a registration. As a check against an abuse of this enhanced authority, the Amendment assured applicants and registrants procedural rights to an administrative appeal of the Secretary’s decision denying, canceling, or suspending a registration.

During the early 1970s, the environmental movement brought about two major changes in federal pesticide regulation. First, Reorganization Plan Number 3 of 1970 created the Environmental Protection Agency (EPA) as an independent agency of the Executive Branch charged with full responsibility for pesticide regulation. Second, the Federal Environmental Pesticide Control Act of 1972 ("FEPCA") completely overhauled FIFRA and significantly increased the authority of EPA to regulate pesticides.

FEPCA is the backbone of the current FIFRA. FEPCA retained the basic provisions of the 1947 FIFRA. Registration is still the centerpiece of regulation; label and labeling are defined broadly; and adulterated and misbranded products are unlawful. But FEPCA added a new statutory standard for registration: a pesticide could be
registered only if it did not cause "unreasonable adverse effects" on human health or the environment. Under FEPCA, EPA also obtained new powers to classify pesticides into general and/or restricted use categories; to regulate pesticide use; to require federal registration of pesticides sold intrastate; to register establishments which produce pesticides; to impose regulations requiring pesticide producers to maintain records necessary for EPA's effective enforcement of FIFRA; to conduct inspections of those who produce or hold pesticides for sale; to issue "stop sale, use, or removal" orders condemning and seizing illegal pesticides; and to enlist the cooperation of the states in enforcing FIFRA.

Since the 1972 passage of FEPCA, Congress has amended FIFRA several times, and the latest amended version of FIFRA was passed in October 1988. This legislation requires all registrants to register their pesticide products over the next nine years. In its present form FIFRA deals primarily with pesticides, requiring that each be registered with the EPA before it may be distributed. The registration procedures require filing of detailed labeling for each pesticide, a full description of the tests made on the pesticide and the results thereof, and other information in the EPA guidelines.

The establishment of EPA and the development of FIFRA regulation created such a tremendous need by various
companies in the United States to get their products tested and many contract laboratories were founded. Among these, the Analytical Bio-Chemistry Laboratories, INC. (ABC Labs) situated in Columbia, Missouri, is a well-known contract lab that developed during this time.

ABC Labs is an independent environmental research services and instrument manufacturing company founded in 1968 which has charted a "course of action" to compete and advance as a profitable enterprise in today's environmental and technology markets. The mission of the company is to provide scientific, biological, and analytical services and products to support programs that respond to global environmental and health concerns of the regulatory agencies, industry, and society. The basic philosophy of the company is to create a working atmosphere which will provide careers and professional growth for employees, and at the same time, achieve a substantial return on investment.

ABC Labs consists of five divisions, the Instrumentation Division, the Environmental Biology Division (EBD), the Environmental Chemistry Division (ECD), Administration, and the Research and Development Division which was established for new business development and research in 1988. ABC Laboratories employs 268 people, 75% of whom are experienced, degreed professionals. The Instrumentation Division designs and manufactures automated
instruments used in the sample preparation and clean-up steps of typical laboratory analytical procedures. The service divisions provide a variety of environmental biology and chemistry testing services of industrial chemical products, primarily to agricultural chemical industries and animal veterinary product manufacturers.

The service divisions provide testing capabilities in the following areas:

1. **Environmental Biology Division:**
   - Aquatic Toxicology
   - Aquatic Analytical Support
   - Field Studies
   - Field Analytical Support
   - Biodegradation
   - Environmental Programs Development

2. **Environmental Chemistry Division:**
   - Environmental Fate
   - Metabolism Chemistry
   - Metabolism Biology
   - Analytical Services

3. **The Instrumentation Division:**
   - Focuses on complementing the laboratory divisions in the design and manufacture of automated gel-permeation chromatographs and
evaporation/concentration systems. These products aid in increasing the precision and productivity for laboratories around the world.

4. **The Research and Development Division:**

   Has as its purpose is to be centered on new technology, acquisition of new products, and new instrument development.

   Major clients for the Instrumentation Division are pesticide residue labs and environmental labs that provide contract services to the EPA under the Superfund program.

   The studies performed on agricultural chemical products by various industries generate data to support product registration and re-registration under EPA's FIFRA regulation. This re-registration is the main focus of service groups which accounts for 90% of the services or business of the company.

   The management is optimistic at present, expecting significant sales growth of the company over the next few years, as it continues to develop new technology and a complementary diversity of chemical and biological services. Meanwhile, the Research and Development Division will help develop and aggressively pursue new programs and business opportunities for market share.
The rapid changes of government regulations and private sector requirements for environmental testing services, challenge ABC Labs to adjust their management and service emphases to continue to maintain its market and expand its clients who are faced with changing situations and needs. The majority of the services of the ABC Labs are used by clients to comply with government regulations in order to get products approved for marketing. Consequently, ABC Labs management must maintain current knowledge of regulations and agency guidelines.

Most studies performed by the ABC Labs are conducted under the auspices of the responsible regulatory agency. Put simply, ABC Labs today is affected by changing regulations that have caused the following business opportunities:

1. Government regulations regarding environmental testing services are changing.

2. Accordingly, the kinds of services offered by ABC Laboratories are changing.

Therefore, in order to meet these changes, it is necessary to first understand what regulation changes are occurring, and how this affects the growth and direction of the company.

ABC Laboratories is a highly successful, growing company that mainly evolved as a result of the FIFRA regulation. In order to keep growing, ABC Labs must
constantly adjust their management or business to changing government regulations so as to achieve effective approaches suitable under the changeable client requirements. Based on a brief description of the evolution of the FIFRA regulation, and ABC Laboratories in its current state of development, the focus of this study will concentrate on the discussion of the changes of the FIFRA regulation regarding environmental testing and how these changes have affected the growth and direction of ABC Laboratories.

The purpose of this research is to develop an understanding of the evolution of pesticide regulation in the United States, the policies and procedures that are used to insure conformance to the regulations, including testing and analysis, and to determine whether such regulations, policies, procedures, and analytical protocols have application in China.

I have visited the ABC Labs twice since December 1989. I was officially invited to do this study from June through September of 1990. I was assigned to study the problems with the assistance of the company.

The primary sources of information for this study were government documents, marketing research reports, and personal interviews and telephone calls with managers, supervisors, employees and major clients of the company.

The study will be divided into five chapters and a summary and conclusions. Chapter Two will define and
discuss the major regulatory changes of the FIFRA regulation regarding environmental testing. Chapter Three will describe how these regulatory changes have affected the growth and direction of the company. Chapter Four outlines the programs of research and development and European environmental program plans, Chapter Five will discuss pesticide practices in China, and the final section presents a summary and conclusions.
CHAPTER TWO

MAJOR CHANGES OF THE FIFRA Regulation

The evolution of FIFRA, the 1947 basic pesticide law in the United States, created an environmental services industry to support regulation because environmental legislation is constantly being revised and updated along with the rapid development of technology. To further discuss and understand how FIFRA has affected the growth and business of ABC Laboratories, it is important to first explore, analyze, and understand the major changes of FIFRA that have affected the contract testing services provided by ABC Laboratories. For simplicity, this chapter will address the four major FIFRA changes:

1. Shifting of its central purpose from consumer protection to health and environmental safety;
2. The establishment of the Environmental Protection Agency (EPA);
3. The development of the Pesticide Assessment Guidelines and Registration Standards program;
4. 1988 Amendment to FIFRA - FIFRA Light.

1. Shifting of Its Central Purpose from Consumer Protection to Health and Environmental Safety

The United States abundantly feeds its own growing population, now nearly
230 million people, and still exports enough food and feed to supply millions of people in the rest of the world. With high technology, American farmers use the latest farm machinery, follow modern management practices, and utilize a variety of crop protection chemicals and programs. With these modern tools, American farmers have successfully doubled production per acre since 1950.

Agricultural chemicals, agrichemicals and crop protection chemicals are some of the names used to describe chemical and biological products which, when applied in accordance with label instructions, control pests. In laws and regulations they are called pesticides.

Pesticides are naturally-occurring or man-made substances intended to kill or control target plants or animal pests.

"Pesticides have made a great impact," said the President’s Science Advisory Committee in 1963," by facilitating the production and protection of food, feed, and fiber in greater quantity and quality; by improving health; and by keeping in check many kinds of nuisance insects and unwanted plants". For the very reason that pesticides "are designed to kill or metabolically upset some living target organism," however, the President’s Committee also recognized that pesticides "are potentially dangerous to other living organisms". Since 1910, when federal pesticide legislation was first enacted, Congress has tried to strike the proper regulatory balance between the benefits and risks of pesticides.

Agrichemicals are very strictly regulated in the United States. The basic U.S. law regulating agrichemicals is the Federal Insecticide, Fungicide, and Rodenticide
Act, (FIFRA) first enacted in 1947, FIFRA put regulation of these chemicals under control of the U.S. Department of Agriculture (USDA). In 1970, this responsibility was transferred to the Environmental Protection Agency (EPA).\(^1\)

The initial use of agricultural chemicals coincided with the mid-nineteenth century trend towards intensive, specialized, crop farming. Farm specialization favored insects and fungi which lived on local plants; the agricultural chemical industry responded with insecticides and fungicides. In the early twentieth century, these products contained inorganic compounds as their active ingredients, principally arsenicals such as lead arsenate and Paris green (copper aceto-arsenite).

By World War II, synthetic organic pesticides had emerged, demonstrated great effectiveness, and received rapid market acceptance. Among them, DDT was extremely effective in controlling insects at very low dosages. Until the late 1960s, DDT was the most widely-used pesticide. Credited with saving millions of lives and preventing vastly more serious illness due to insect-borne diseases such as typhus, dysentery, and malaria, DDT was considered truly extraordinary.

The use of chemicals in agriculture has steadily increased. Modern farming techniques, including increased automation and new cultivation practices, have evolved to accommodate pesticide use as an integral part of agriculture. Farmers find that pesticides are a very effective way to deal with pest problems; also, they feel that pesticides are the most economical and efficient way to keep crop yields up.

Unfortunately, the state-of-the-art in science was still too unsophisticated to predict chemicals' long-term impact on the environment or human health. With the
growing awareness that DDT residues were widespread throughout the environment, however, the environmental movement in the late 1960s and early 1970s targeted DDT as its number one enemy.

While the persistence of organochlorine pesticides was well-known and residue information was reported in the scientific literature during the 1950s, publication in 1962 of Rachel Carson's *Silent Spring* focused national attention on the environmental hazards of persistent pesticides and raised public concern. Responding to this concern in its 1963 report, the President's Scientific Advisory Committee recommended monitoring programs on pesticide residues, federal research on pesticides, and public educational programs on hazards in the use of pesticides.

In 1969, following a large seizure of Lake Michigan coho salmon with DDT residues exceeding established tolerance levels, the Secretary of Health, Education and Welfare formed a Commission on Pesticides and Their Relation to Environmental Health. The Mrak Commission, named for its chairman, Dr. Emil Mrak, recommended various remedial measures, such as imposing greater controls over pesticide registration, restricting certain persistent pesticides to essential uses, and minimizing public exposure to pesticides which pose a potential health hazard to man. A year later, President Nixon proposed reorganization of the three federal agencies regulating pesticides. Since then, technology has advanced to the point where chemicals can be detected in environmental media down to parts per billion and, in some cases, parts per trillion. As a result, FIFRA, which was developed from the Federal Insecticide Act of 1910, primarily serving as a consumer protection law, for
the first time shifted its regulatory emphasis to public health and environmental protection. This pluses the environmental movement during the early 1970s, led to the establishment of the Environmental Protection Agency (EPA).

The emphasis of today's FIFRA is quite different from when it was first enacted. It has become more systematic, comprehensive, and complex in terms of serving as a public health and environmental protection law.

2. The Establishment of the Environmental Protection Agency (EPA)

On December 2, 1970, President Nixon's Reorganization Plan No.3 created EPA, which acquired the pesticide and pure food regulatory staffs of the U.S. Departments of Agriculture, Interior, and Health, Education and Welfare and assumed responsibility for federal registration and regulation of pesticides.

EPA is headed by an Administrator and Deputy Administrator who are appointed by the President with the consent of the Senate. They supervise the Regional Administrators for EPA's ten offices located in various parts of the country and Assistant Administrators for EPA's six operational offices located at EPA's headquarters in Washington, D.C. The Assistant Administrators also are presidential appointees approved by the Senate. The Assistant Administrator in charge of the Office of Pesticides and Toxic Substances (OPTS) oversees strategies for implementing and integrating EPA's pesticides and toxic substances programs and has overall responsibility for the Office of Pesticide Program (OPP), which is responsible for EPA's pesticide activities.
EPA's regulation of pesticides is mandated by Congress. Through OPP, EPA administers two statutes:

i) FIFRA, which governs the licensing or "registration" of pesticide products, and

ii) The Federal Food, Drug and Cosmetic Act (FFDCA), which governs pesticide residue levels in food or feed crops.

FIFRA prohibits the distribution and sale of any pesticide not registered with the Administrator and gives the Administrator broad enforcement authority to prescribe standards for registration; to cancel or suspend registrations; to register and inspect establishments which produce pesticides; to regulate use and disposal of pesticides; and otherwise to enforce FIFRA's provisions through stop sale orders, seizures, and civil penalty proceedings.

Under the FFDCA, EPA's Administrator also establishes and monitors compliance with tolerance limits for pesticide residues on raw agricultural commodities and processed foods. The Food and Drug Administration retains jurisdiction under FFDCA to enforce compliance with the pesticide tolerances promulgated by EPA.

Within OPTS, OPP has the overall responsibility for the following activities under FIFRA and FFDCA: registering and re-registering pesticides; undertaking special review of pesticides which may pose an unreasonable risk to human health or the environment; monitoring pesticide residue levels in man, food, and non-target fish and wildlife; drafting registration guidelines and standards for registration and re-registration; and establishing tolerance levels for pesticide residues in foods.
Throughout the 1970s, EPA systematically challenged the registrations of the most important organochlorine pesticides. Following lengthy administrative hearings, EPA banned virtually all uses of DDT.

The early concerns with pesticides centered around their effectiveness in controlling insects, weeds, and plant pathogens, and their possible acute hazards to the user. With the increased sensitivity of analytical equipment and its detection of trace pesticide residues, the focus shifted to the environmental and human health significance of long-term, low-level exposure. Today, EPA rarely considers data on pesticidal effectiveness, but leaves judgments of efficacy primarily to the marketplace. Instead, the Agency looks at pesticide exposures to the applicator and to the public, either directly during use or indirectly from environmental levels in food, air, and water. EPA analyzes data on the acute, and chronic hazards (such as carcinogenicity, mutagenicity, and teratogenicity), and assesses the risks to man and the environment from each use pattern of a pesticide.

Through major revisions to FIFRA in 1972, 1975 and 1978, Congress provided an increasingly comprehensive regulatory system. All the data required for each pesticide must be thoroughly evaluated by EPA scientists and staff before a label registration is granted to the applicant. Only then can the product be marketed legally.

Today, EPA is actively involved in the enforcement of rule 40, Code of federal regulations (CFR), Part 15812 which specifies the kinds of data and information that must be submitted to EPA to support the registration of each pesticide under the FIFRA. EPA uses the submitted data and information to make regulatory judgments
with respect to the safety of each pesticide proposed for registration or experimental use. By enforcement Part 158, EPA provides pesticide registrants with explicit instructions concerning the data requirements, which will enable more efficient pesticide development and registration.

3. The Development of the Pesticide Assessment Guidelines and Registration Standards Program

Under the FIFRA, all pesticides that are sold or distributed in commerce must be registered. In order to obtain such registration, data must be available to EPA to allow the Agency to evaluate chemical risks and benefits. EPA will register a product only if the Agency has sufficient information about a pesticide product to make the statutory risk/benefit determinations.

On July 3, 1975, the Agency promulgated final registration regulations, 40 CFR Part 162, Subpart A. These regulations established the basic requirements for registration of pesticide products.

From 1975 to 1981, EPA issued several subparts of the Guidelines for Registering Pesticides in the United States which described, with more specificity, the kinds of data that must be submitted to satisfy the requirements of the registration regulations. These guidelines included sections detailing what data are required and when, the standards for conducting acceptable tests, guidance on evaluation and reporting of data, and examples of acceptable protocols.

In October 1981, EPA decided that it was impractical and unnecessary to
include in a regulation most of the detailed technical and scientific information contained in the guidelines. EPA recognized that it was inappropriate to set forth most of the guidelines material (e.g., test protocols and provisions for evaluating and reporting data) as regulations since there may be several acceptable or even preferable protocols and provisions in addition to those in the regulation. Moreover, due to the vast diversity of pesticide products subject to regulation and due to the rapidly advancing state of the science in chemical testing and evaluation, it is impractical to attempt to specify detailed testing regulations that will adequately address each situation.

Therefore, in 1981 EPA decided to reorganize the guidelines and limit the regulation to a concise presentation of the data requirements and when they must be fulfilled; thus, the data requirements for pesticide registration pertaining to all former subparts of the guidelines are now specified in Part 158, which were split away from the regulation.

On November 24, 1982, the Pesticide Registration Guidelines were re-proposed as Part 158, 40 CFR, in 47 Federal Register 53192, and presented in the Federal Register of January 18, 1983, which proposed to amend Title 40, Chapter 1 by adding Part 158-Data Requirements for Registration.

On October 24, 1984, a final rule, 40 CFR Part 158 which specifies the kinds of data and information that must be submitted to EPA to support the registration of each pesticide under the FIFRA, was officially published. The purpose of Part 158 is to specify the types of data and information the Agency requires to make regulatory
judgments with respect to the safety of each pesticide proposed for registration or experimental use. This Part also specifies the test substance to be used in testing conducted to fulfill the data requirements. Part 158 consists of two Subparts, A and B. Subpart A contains the general provisions and policies pertaining to the registration data requirements. Subpart B contains the data requirements for registration.

The development of the Pesticide Assessment Guidelines by the EPA has provided the testing industry for the first time in its history a good guide document on how to do proper testing and for the development of testing protocols. Today, by promulgating Part 158, EPA will provide pesticide registrants with explicit instructions concerning the data requirements and therefore will enable more efficient pesticide development and registration.

From 1980-1984, to ensure the implementation of the Pesticide Assessment Guidelines, EPA established the Registration Standards and Standard Evaluation Procedures (SEPs). The Agency produced a set of guidance documents which explained the procedures used to evaluate environmental and human health effects data submitted to the Office of Pesticide Programs.

The Registration Standards program is EPA's approach to the reassessment and re-registration of pesticide products as mandated by Congress in FIFRA Section 3 (g). The reassessment involves a thorough review of the scientific data base underlying pesticide registrations and an identification of essential but missing scientific studies which may not have been required when the product was initially registered. It may also require new testing or retesting to ensure the safety of the
compound by contemporary scientific standards.

The goal of the registration standards program is to develop 600 standards on a variety of pesticide active ingredient and inert applicable to approximately 50,000 currently registered pesticide formulations. EPA estimates that this process will take ten to fifteen years to complete. It has developed a scheme, commonly referred to as the "cluster concept," for giving priority to certain chemicals in developing standards.

The 600 active ingredient/inert chemicals subject to re-registration have been grouped into 48 clusters. Each cluster contains chemicals closely related in use and site of application. For example, EPA has clustered ten herbicides used in corn production. Every generic chemical is assigned to one cluster, usually based on its largest use.

EPA follows a four-step process in developing standards for each chemical in a cluster. These steps include i) gathering data, ii) evaluating the data, iii) developing a regulatory position, and iv) issuing a standard.

Once the data have been gathered, they are reviewed to identify data gaps. EPA has established a regulatory position by identifying the uses that are supported by adequate data and any additional regulatory requirements that will be imposed.

A typical standard includes an overview that discusses the regulatory justification for the standard, the re-registration requirements, and the types of data evaluated by EPA in developing the standard. The final standard contains the Agency’s regulatory position, including a tabulation of data requirements for re-registration, the availability of previously submitted data, the need for additional
data, and time permitted for submitting additional data. Finally, it usually includes a detailed discussion of the existing data base pertaining to the products involved.

In addition to registration standards, the Standard Evaluation Procedures (SEPs) are designed to ensure comprehensive and consistent treatment of major scientific topics and to provide interpretive policy guidance where appropriate. They are used in conjunction with the appropriate Pesticide Assessment Guidelines and other Agency Guidelines. The SEPs also serve as valuable internal reference documents and inform the public and regulated community of important considerations in the evaluation of test data for determining chemical hazards. The development of SEPs has improved both the quality of science within the EPA and, in conjunction with the Pesticide Assessment Guidelines, has led to more effective use of both public and private resources.

4. **1988 Amendment to FIFRA - FIFRA Light**

On October 25, 1988, the President signed into law the FIFRA Amendments of 1988. The 1988 amendments to FIFRA, which is administered by the EPA, strengthen the Agency’s authority in several major areas of pesticide regulation. Among other things, the amendments require a substantial acceleration of the re-registration process for previously registered (licensed) pesticides and authorize the collection of fees to support re-registration activities. The law also changes EPA's responsibilities and funding requirements for the storage and disposal of suspended and canceled pesticides and the indemnification of holders of remaining stocks of such
canceled pesticides.

Under FIFRA, all pesticides must be registered with EPA before they may be sold or distributed in commerce. FIFRA sets an overall risk/benefit standard for pesticide registration, requiring that pesticides perform their intended function, when used according to labeling directions, without posing unreasonable risks of adverse effects on human health or the environment. In making pesticide registration decisions, EPA is required by law to take into account the economic, social, and environmental costs and benefits of pesticide uses.

FIFRA was first enacted in 1947. Thousands of pesticide products have been registered since then. However, the standards for pesticide registration have not remained the same since 1947 but have evolved in tandem with science and public policy. In particular, test data requirements for pesticides have become increasingly stringent in light of advances in such areas as toxicology and analytical chemistry.

Under FIFRA, pesticide registrants (companies that hold pesticide registrations) are responsible for providing all test data necessary to satisfy EPA’s registration requirements.

To ensure that previously registered pesticides measure up to current scientific and regulatory standards, FIFRA requires the review and "re-registration" of all existing pesticides. This has proved to be a massive undertaking. A combination of factors has impeded the Agency’s progress in carrying out the re-registration mandate. Of the approximately 600 pesticide active ingredients that require re-registration under FIFRA, EPA has issued "Re-registration Standards" for about
A Re-registration Standard includes a comprehensive review of all the available data on an existing chemical, a list of additional data needed for full re-registration, and the Agency's current regulatory position on the pesticide.

In addition, the amended version of FIFRA requires all registrants to re-register their pesticide products over the next nine years. EPA estimates that today 35,000-40,000 pesticide products are sold in the United States, which are based on approximately 1,300 active ingredients. In order to successfully re-register existing pesticides, manufacturers have to meet all the requirements specified in the EPA's pesticide assessment guidelines. These include nine guidelines that spell out the specific requirements for aquatic toxicology, residue chemistry, product chemistry, environmental fate studies, biodegradation, etc. Chemical manufacturers have to submit data along these lines to receive approval. According to one EPA official, "Everyone is scrambling for capacity and searching for laboratories with these capabilities." Fully accredited laboratories having broad service capabilities in these areas are not very common, and thus the manufacturer sometimes must contract with multiple facilities to get the total job done on time. These amendments appear to be a major factor in driving the market for environmental fate and effects testing.

In short, pesticide registration proceeded under FIFRA throughout the 1950s and 60s with little apparent concern about possible adverse effects of pesticides on human health and environment. The regulatory emphasis shifted abruptly with the onslaught of the environmental movement in the early 1970s. President Nixon created EPA, and cancellation of DDT soon followed, which has paved the way for more...
drastic changes of FIFRA, especially during 1980s.

Of the four major changes of the FIFRA regulation discussed in this chapter, the establishment of the EPA is the most important of all. It is the EPA that has further developed FIFRA, and initiated and published a series of pesticides guidelines, Standard Evaluation Procedures, and registration/re-registration standards. These, in turn, have made great impact on the rapid development of the contract laboratory industry in the United States in the 1980s, and ABC Laboratories is a typical example of a contract testing laboratory that has successfully grown as a result of the drastic changes of the FIFRA regulation during this specific period, which will be further discussed in Chapter Three.
CHAPTER THREE

THE EFFECTS OF FIFRA REGULATORY
CHANGES ON THE CHEMICAL SERVICES OF ABC LABS

In Chapter Two, through a detailed discussion of the major changes of the FIFRA regulation, we have had a better understanding of the major changes in FIFRA that have occurred regarding environmental testing since it was first enacted in 1947, and how these changes have taken place and why. This chapter will focus on the discussion of corresponding effects of regulatory changes on the chemical service business of ABC Labs, which will include the following four major effects.

1. Effects on ABC’s early direction and growth (1968-1978)
2. Effects on ABC’s rapid growth and diversification (1979-1987)

1. Effects on ABC’s Early Direction and Growth (1968-1978)

ABC Labs was established at a time when the use of chemicals in agriculture had steadily increased in the United States, and pesticide registration proceeded under FIFRA with little apparent concern about possible adverse
effects of pesticides on human health and environment. The need to offer chemical and biological testing support to industry and the government for the betterment of man was one of the original concepts of ABC, which led to the founding of ABC Labs in 1968.

ABC Laboratories started basically with five people: Dr. Charles Gehrke, Professor of Biochemistry and Manager of the Experiment Station Chemical Laboratories at the University of Missouri Columbia, a recipient of numerous awards in chemistry and biochemistry and the Co-Founder of ABC Laboratories, who serves as Chairman of the Board of Directors (the BOD) since the establishment of the company; Dr. David Stalling, Chief Scientist at the National Fisheries Research Laboratories, and 1967 doctoral student and graduate under Professor Gehrke; Dr. Stalling is now senior research scientist at the National Fisheries Contaminant Research Center, Columbia, Missouri, and Co-Founder and Board Secretary; and Mr. James Ussary, Supervisory Chemist at the Experiment Station Chemical Laboratories, who was the first president of ABC Laboratories, and is presently Manager of Quality Assurance with Imperial Food Company in Goldsboro, North Carolina. Charles Fetterman, President of Research Assistants Corp Inc., and Guy Hardin, Accountant and Al Tidland lawyer of St. Louis, Missouri, were also members of the founding group.
In 1970, Professor of Organic Chemistry Norman Rabjohn, Chairman of the Department of Chemistry, University of Missouri Columbia, and Dr. Raymond Lansford, Professor of Finance and Management, and Associate Dean at the University of Missouri School of Business joined the Board of Directors. Dr. Rabjohn is Treasurer of the Corporation to July 1990.

In 1973, Ralph Waltz replaced James Ussary as President. Mr. Waltz, graduate in Agricultural Chemistry of Purdue University in 1949, was formerly associated with Hewlett Packard, Searle Analytic Company as Product Support Manager, Publications Manager, and Application Manager. He served as President/CEO from 1973 to May 1, 1990 and now is in the position of Executive Consultant to BOD and Management. Mr. Larry Stambaugh has become President/CEO on May 1, 1990.

Among them, Dr. Gehrke played a most important role during the early development of ABC Labs. With his knowledge of the industry, his contacts, his awareness of emerging technology and his abilities, new testing services were gradually introduced, programs strengthened and innovative methods developed. As a result, efficiency of many chemical analyses was increased significantly in a short period of time, which paved the way for the rapid growth of the company later on.

The first step is always the most difficult. Just as
Floyd Kaiser, a senior specialist expressed: "The first year was a struggle, very slow and very tough." The Analytical Service Group, which is a part of the Environmental Chemistry Division now, was the only service group started at the founding of ABC Laboratories. The initial work of the company was concentrated on the nutritional type of analyses and amino acid analyses, which were carried out on a rather small scale. The total working area was 4,000 square feet. The company was involved with poultry companies analyzing chicken fat and chicken feed, which was called "soap stock." It was the remaining portion of soybeans after they had been extracted—a dirty type material. Along with the expansion of the nutritional analyses, the company worked and developed new methodology and new instrumentation, which paved the way for the establishment of the Instrument Manufacturing Division in 1973. Utilizing the new instrumentation, gel permeation chromatography, helped a great deal in the recoveries of "soap stock." This also helped the early growth of the company.

In 1973 and 1974, the company had 12 to 15 employees and gradually involved a relatively larger clientele. The annual sales were $250,000 to $350,000.

With the establishment of the EPA in 1970, the public concern for environmental contamination, primarily pesticides, was getting stronger, especially, there was a
large concern about the use of DDT. The FIFRA regulatory climate made it more important for the pesticide industry to get their products tested to meet the FIFRA registration requirements. This tracing regulatory trend affected the early direction of the ABC Labs. In order to grow more rapidly, the company began to shift its initial direction from offering nutritional types of analyses more toward the residue type of analyses to meet the basic pesticide residue needs. Samples were received, prepared and analyzed for specific chemical entities on a relatively low level of concentration. The kind of analysis done by the company at that time, was almost exclusively what people called "chlorinated pesticides." The purpose of doing those analyses was for the protection of agrichemical users.

From 1976 to 1978, ABC Labs developed more rapidly in capabilities of analyses as a result of constant revision of FIFRA and new requirement of pesticide registration for the EPA. The company became involved in a lot of survey type of analyses on fish to see what contamination fish contained, and gradually moved into aquatic toxicology analysis. In December 1976, a new building to house this service was equipped and occupied. Since then, the company became more known for its analytical capabilities and the quality of its work. In 1976, ABC's Aquatic Toxicology Group was established to supply aquatic bioassay and analytical support for product registration and regulatory compliance.
While expanding its analytical services, the company was also developing new techniques and the trust of its clients. The company has been a leader in aquatic toxicology testing since 1976.

Along with the increased regulatory needs of FIFRA in the late 1970s, the direction of the company was focused more on the residue analysis, environmental analytical services and instrument manufacturing, aquatic toxicology and chromatographic repair services, while nutritional analyses became less of the objective of the company.

In order to meet the changing regulatory climate and to offer sufficient services to its clients to grow as quickly as possible, in December 1977, ABC Labs adopted the following major corporate objectives as part of the 5 year plan:

a) Achieve a 20% growth/annum over inflation.

b) Retain present programs and enter into related new ventures.

c) Provide a 10% dividend return on stockholders investment.

d) Achieve and maintain a minimum of 20% net profit before taxes.

e) Provide our employees with security, and opportunity for growth, and a feeling of satisfaction and pride in being a part of ABC’s contribution to society^{15}.

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As a part of ABC's 5 year plan, it was projected that a conservative estimate of 10,000 square feet of new space was needed. In January 1978, structural steel for 16,000 square feet of new building was purchased. The company had approved the construction to be undertaken in the summer of 1978. In addition, the company had 32 employees, an increase of 27 since 1970\textsuperscript{15}.

The 5 year plan not only ensured ABC Labs would speed up its development, but also guaranteed it would develop in a well-planned way. The company's net sales growth from $5,940 in 1969 increased to the 1978 fiscal year level of $850,000\textsuperscript{15}.

Effects of FIFRA regulatory changes on the early direction and growth of ABC were relatively small. This is mainly because that FIFRA just started to shift its central purpose from consumer protection to health and environmental protection. Further EPA was still in its early stage in terms of making drastic and systematic changes in pesticide regulations. Therefore, both the FIFRA regulatory climate and the whole environmental industry were in a transitional period. As a result, markets for environmental contract services and instrumentation were relatively less competitive. In addition, ABC Labs was in its early development stage and had limited resources and capabilities to provide the more complicated science services. It was not financially strong enough to grow aggressively in sales.
and in the development of new services. Nevertheless, effects of FIFRA regulatory changes on the early direction and growth of ABC has played a very important role in the later rapid growth of the company during the 1980s.

2. Effects on ABC's Rapid Growth and Diversification (1979-1987)

As stated above, the establishment of the EPA in 1970 was the major event that happened as far as contract testing services were concerned. As an enforcement regulatory group, the EPA represents the highest authority responsible for pesticide regulations in the United States, which made it possible for the FIFRA regulation to be more intensified in the testing area. As a result, all environmental testing was well regulated, organized and controlled by the EPA.

In addition to the establishment of EPA, a series of environmental testing guidelines were published since 1982, especially the development of various Standard Evaluation Procedures by the EPA in 1984, 1985, and up to mid-1987 which were released by a subvision of FIFRA and are considered as the teeth of FIFRA. These were also a facilitator for the environmental services industry during the 1980s. The constant revision of the environmental legislation and rapid development of technology had a great impact on the pesticide industry and the testing industry as well. This is because for the first time industries were
given guidelines and specific standards to comply with in their testing programs. Besides, testing facilities for the first time had a real protocol guidance that was standard across the country. All of these rapid regulatory changes throughout the 1980s had paved the way for the further growth of ABC Laboratories.

ABC's rapid growth and diversification from 1979 to 1987 came at a time when the environmental testing emphasis under FIFRA came about and drastic regulatory changes in FIFRA took place. Many registration rules, new requirements, testing guidelines and standards revised by the EPA were made more strict in terms of biological type of studies or aquatic toxicology type of studies. Since then, the direction and business of the company has diversified into separate operating divisions which offered specialized testing services demanded by the increased regulatory climate of the EPA, FIFRA, and FDA. Many new services were added as the company grew. For instance, in addition to pesticide residue analyses and aquatic bioassay testing services started in the 1970s, the Environmental Fate Group was started in 1980 to respond to client needs created by the EPA's pesticide registration program.

From 1984 to 1987, more and more comprehensive publications of various Pesticide Assessment Guidelines and Standard Evaluation Procedures by the EPA were issued which provided pesticide registrants with more explicit
instructions concerning the data requirements. Chemical manufacturers must submit data along those lines and standards to receive approval. They had to search for laboratories with multiple facilities and broad service capabilities that could offer comprehensive testing services for them on time. Again, this was in turn a big challenge to the environmental testing services industry, and played an important role in accelerating the rapid development of this industry.

It was under such a kind of regulatory changing situation that ABC Labs was driven aggressively and became stronger, and more capable.

In 1984, domestic animal residue and metabolism studies, and human clinical studies and biopharmaceutical analyses were added in response to the environmental regulatory changing situations.

In 1987, according to the new requirements of guidelines and standards established by the EPA for the purpose of regulatory approval of different chemical compounds, new services were added to include metabolism chemistry and field studies on agricultural products. The company also started to introduce metabolism studies in rats and limited large animal investigations.

All of the service operating divisions were structured to assist industry to meet regulatory compliance for FIFRA, TSCA, FDA and the Organization for Economic Cooperation and
Development (OECD). They all provided services for regulatory compliance for federal and state agencies as well as private industry. Approximately 80 percent of ABC’s work then was in contract research services and most of the services business was connected with FIFRA. The well-known major companies that the company was offering services to totalled thirty, which included American Cyanamid, Monsanto, Dupont, DowElanco and so forth. In addition, such services resulted in the delivery of a study report to the customer. Therefore, ABC’s reports were all structured to comply with reporting requirements of the EPA Pesticide Assessment Guidelines so as to meet the needs of its clients.

In order to meet rigorous quality control standards, which were essential to ensure that eight service divisions met the requirements of clients and the appropriate regulatory agencies, each division had its own service emphasis and addressed a specific testing or equipment need for its clients in providing high-quality services. The major characteristics of each service division in the 1980s were as follows:

Analytical Services Division - Providing the essential analytical support to analyze samples generated by the other laboratory and bioassay groups. Accomplishing pesticide residue and metals analysis for its clients. Samples were received, prepared and analyzed for specific chemical entities. Method development and validation services were
also provided. Instruments techniques were used to analyze a wide variety of sample matrices for many different types of compounds in water, soil, plants, tissue and processed foods.

Aquatic Toxicology Division - Carrying out investigations of the toxicological properties of chemicals to fish and invertebrate organisms under EPA's Wildlife and Environmental Effects Testing Guidelines, EPA Toxic Substances Control Act, and for abroad, the Organization of Economic Cooperation and Development. Both acute and chronic studies were accomplished for submission to regulatory agencies by the clients for registration purposes. The Aquatic Toxicology Division has been nationally recognized as one of the best contract facilities qualified to generate acceptable data in the United States.

The Analytical Support Division - Supplying chemical analysis support for the Aquatic Toxicology Division. Residue and metabolism studies were accomplished to supplement and verify the findings of the other division's studies.

The Environmental Fate Division - Doing exactly as its name implies: determines the fate of chemicals in the environment, generally through laboratory simulations of environmental conditions. Through standardized test methods and protocols, evaluation of a chemicals' mobility, degradation, and ultimate dispersal into the "real world"
could be accomplished. This division provides studies to satisfy the guidelines of subpart N of EPA’s FIFRA regulation.

The Pharmaceutical Division - Was split into three areas at that time. The Clinical Analysis section analyzes human serum and urine samples for trace levels of drug compounds. These samples were generally the result of a clinical study which had been conducted by the client. The Clinical Studies section, in conjunction with Columbia Regional Hospital, conducted clinical trials on human subjects. The demand for this type of service was generally to register a "generic" form of a drug by providing bioequivalence to a previously FDA-registered drug. These studies were conducted under the direction of a medical doctor and must comply with FDA regulations for Clinical Trials. The Pharmacy Section assays finished dosage form samples from stability studies, and conducted drug stability, purity, and dissolution rate studies. The data generated in the Pharmacy Section were used to derive the expiration date which appeared on all "over-the-counter" and prescription drugs. This group provided analytical support and human clinical trials for pharmaceutical clients. Target animal studies were also performed for data supporting new animal drug applications for veterinary products.

The Field Study Division - Was the newest venture to
expand the services of the company. This division conducted field investigations at remote sites to generate the samples that the Analytical Services Division received. Selection of field sites and collaborators, protocol design, sampling, labeling, shipping samples to ABC and completion of the study report were the basic functions of this division.

Metabolism Chemistry Division - Providing isolation, characterization, identification and quantitation of metabolites from rat, goat, poultry, plant and soil metabolism studies and aquatic bioconcentration studies.

The Large Animal Investigations Division - Providing services including residue and metabolism studies of domestic livestock species such as dairy cows, goats, sheep, and poultry. The investigations are designed to meet clients' needs for data to support product registration, animal health care efficacy, safety evaluation and product development. These "meat, milk, and egg" studies are important to EPA's risk assessment prior to the registration of a chemical for use on food crops.

The Instruments Division - Specializes in the design, manufacture, and marketing of automated, scientific equipment. The mainstay of the instrument line was the AutoPrep Gel Permeation Chromatograph which was required for many methods of analysis used by the chemical industry and federal agencies. It was accepted as an official method of analysis for certain chlorinated hydrocarbon pesticides in
animal fats by the Association of Official Analytical Chemists.

The newest instrument, the Autovap, was the result of three years of research and development of the company. It was patented in the United States and patents were applied for overseas by ABC Laboratories. The company was represented overseas by an organization of equipment representatives who had accounted for approximately twenty-five percent of the total instrument sales since 1979.

The eight operating divisions at that time were supported by the general and administrative group which included Senior Management, Marketing, Regulatory Affairs, Quality Assurance, Maintenance and the Office Staff.

From 1979 to 1987, the company was able to expand by providing timely and quality services to clients, as well as diversifying. The total working area doubled from 32,000 square feet to 64,000 square feet. The company employed 134 persons of which 34 were technicians, 66 were professionals and 34 were administrative, sales and support personnel. Besides, the company sold its services and products to more than 700 customers who represented a majority of the leading corporations and federal agencies in the United States and Canada. The major marketing strategies and approaches adopted by the company were direct client contact through a technical sales force, personal contacts by company employees, direct mail, advertising in trade journals and
participation in trade exhibitions.

By 1987, the service sales totalled $6,181,135\textsuperscript{17}. The 41.46% increase was the largest growth the company achieved in the last ten years which averaged 25.9% growth in sales per year\textsuperscript{18}. Since 1984 the company's net sales has grown 77\%\textsuperscript{19}.

The rapid growth and diversification of ABC Labs from 1979 to 1987 discussed above has reflected that many regulatory changes of FIFRA during that period had a significant impact on the rapid growth and diversification of the company. By 1987, the regulatory emphasis of FIFRA had changed greatly versus the intent when it was first enacted forty years earlier. Likewise, ABC Laboratories had taken on an entirely new look from that of twenty years earlier. The testing services provided by the company were not only for chemical manufacturers in the United States, but also for many of the world's largest chemical manufactures. Over the years, the reputation of the company had grown as the company had shown itself capable to provide complex scientific testing services required by regulatory groups such as the EPA, FDA, and USDA. The favorable regulatory climate and economic situation of ABC Laboratories from 1979 to 1987 has provided a solid foundation for the further expansion and accelerated growth of the company today.
3. Effects on ABC’s Accelerated Growth (1988-1990)

The 1988 amendments to FIFRA-FIFRA Light was the biggest event in the late 1980s. The amended version of FIFRA requires all registrants to re-register their pesticide products over the next nine years. Pesticide registrants are responsible for providing all test data necessary to satisfy EPA’s registration requirements. In order to successfully re-register existing pesticides, manufacturers have to meet all the requirements specified in the EPA’s pesticide assessment guidelines. These include nine guidelines that spell out the specific requirements for residue chemistry, product chemistry, environmental fate studies, biodegradation, etc. Chemical manufacturers have to submit data along these lines to receive approval.

In addition to FIFRA Light, concern for the preservation and protection of the planet has focused attention on the impact of chemicals introduced into the environment. Increasing regulations worldwide require additional, more intensive testing of specific chemicals. This has greatly accelerated the development of the testing services industry. Indeed, more opportunities were created for testing during that time. ABC Laboratories, a well-known testing company both at home and abroad, responded to the challenge of the new regulatory situation and met the opportunity to accelerate its growth.

To meet the challenge of the new regulatory climate
and to provide services to its clients more efficiently and effectively, the company has reorganized its operating divisions to re-emphasize its major service areas.

Today, ABC Laboratories is made up of five divisions: Environmental Chemistry, Environmental Biology, Instrument Manufacturing, Research and Development, and Administration. The first two divisions provide scientific research services to chemical companies and other laboratories around the world. Professionals in these divisions perform environmental fate and effect tests to enable clients to comply with regulatory requirements for registering and re-registering chemical compounds. Included in these divisions are aquatic toxicology testing services, pesticide residue analysis, field studies, environmental fate studies, and metabolism services. In 1990, Biodegradation studies and a mesocosm testing program were added. The third division is responsible for the manufacture of scientific testing equipment for leading laboratories around the world. In addition, on May 1, 1988, the Research and Development Division, a program for new business development and research, was established.

The five operating Divisions are supported by the General and Administrative Group which includes Senior Management, Marketing, Regulatory Affairs, Finance, Human Resources, Quality Assurance, Data Processing, Maintenance, Custodial and Office Staff.
The service divisions of the company such as Analytical Services, Aquatic Toxicology, Environmental Fate, Instrumentation are more developed and more capable. For instance, the Analytical Services group from a small team of chemists analyzing a few samples per week, has grown to become one of the premier pesticide residue laboratories in the world, analyzing thousands of samples for pesticide residue in diverse matrices.

The Aquatic Toxicology group, a leader in aquatic toxicology testing since 1976, has grown to become more capable to consistently meet clients needs for aquatic bioassay and analytical support for product registration in compliance with environmental effects testing regulations.

The Environmental Fate group has grown to become one of the most active work centers of the company since its establishment in 1980. Services are provided to domestic and world wide chemical manufacturers, enabling them to comply with national and international testing regulations.

The Instrumentation Division has grown to become more innovative and advanced. In 1973, an automated Gel-Permeation Chromatograph was first introduced. In 1986, the AUTOVAP, the first automated solvent evaporation system was invented. Today, these instruments are used by laboratories around the world. Innovations continue as plans are being made to unveil new laboratory instruments that will further automate labor intensive laboratories.
procedures to meet the need of the rapid technological development in the environmental testing services industry.

In addition, to meet growth challenges, employee recruiting efforts have been enhanced. Superior scientists and support personnel are recruited to satisfy market demand and to help accelerate the growth of ABC Laboratories. In 1990, the company has 268 employees. The working area now totals 91,000 square feet. The company's total sales have topped $10 million for the first time, at $12.7 million in 1990--almost double the sales figure of two years ago. Net income was $1.1 million.

In July of 1990, the Environmental Biology Research Center was built at a cost of 2.2 million. This modern laboratory will be dedicated on September 5, 1990. Also a new company wide Digital Equipment Corporation (DEC) business computer was approved with beginning installation to improve and correlate all business activities. In addition, a VG Laboratory System, Ltd. scientific computer was put in place to handle all high performance liquid chromatography (HPLC), gas chromatography (GC), and other scientific data. These additions will position ABC Laboratories into the 1990s as a highly sophisticated environmental laboratory with a broad range of program services.

The accelerated growth of ABC Labs from 1988-1990 discussed above involves many important factors. However,
the many new regulatory changes of FIFRA, especially the new amendment to FIFRA in 1988, might be the most important factor of all. This is because the re-registration program established by the EPA for all of the pesticides in the United States has created tremendous needs for the pesticide industry to get their products tested for regulatory approval. This has greatly accelerated the expansion of the testing services industry, and ABC's accelerated growth is a typical example among the contract testing companies in the United States during that specific period.


From 1991 to 1995, the EPA will continue to add more pesticide and toxicity compounds to be tested under FIFRA. This means that there will be more testing services opportunities for ABC Laboratories to expand. However, according to the scientific analysis made by the experts and managers of the company, Dr. Paul Mehrle, Associate Vice-President Bill Foristal, and Vice President Carl Thompson, etc., three or five years later, the testing services generated from FIFRA would reach a plateau because the new amendments to FIFRA in 1988, will be implemented for the next nine years and data requirements by the EPA would meet a relatively standstill situation. Therefore, the FIFRA regulatory changes on the direction and growth of ABC Labs from 1991 to 1995 might lead to two different effects: a
positive impact which would further accelerate the growth of the company; a negative impact which may cause the company to diversify and open up new markets other than FIFRA to keep growing.

To ensure the future growth of the company, ABC Laboratories has currently taken two important strategic actions. One is to strengthen the academic leading function of the Research and Development Division, a program for new business development and research, which was initiated by the Chairman of the BOD, Professor Charles W. Gehrke, on May 1, 1988. The other is to invite and hire experts specialized in government environmental testing regulations to help develop future new business plans for the company. Among them, Dr. Paul Mehrle is a well-known leading expert in this new biological research field. This will be further discussed in Chapter Four.

In conclusion, changes in FIFRA environmental testing regulations and corresponding effects on ABC Laboratories discussed throughout the above two chapters have explained: 1) why the increasingly stringent regulatory situation is the predominant factor that has driven the environmental testing services industry in this country; and 2) how ABC Laboratories has continuously adjusted their management and services emphases to meet the changing regulatory situation in order to continue and maintain its market share and expand its client base since it was founded in 1968. It
has also reflected a close correlation between regulatory changes in FIFRA and the growth of a company; as Vice President Carl Thompson expressed: "FIFRA certainly means a lot to us. We are definitely affected by FIFRA."

As above stated, the effects of FIFRA on ABC's direction and growth in the near future will tend to diminish. However, the impact of other environmental testing regulations on the company might become stronger. Therefore, a discussion of the effects of FIFRA on ABC Laboratories in this chapter might be very helpful and useful in analyzing where ABC is today, and in predicting the direction and growth of ABC in the near future.
Chapter Three addressed the major effects of FIFRA regulatory changes on ABC Laboratories over the last 20 years. A major question before the company presently is: how will ABC Laboratories proceed in the near future, particularly after testing services generated by FIFRA reach an expected plateau in 1995? The answer clearly is to continually diversify its services and product offerings. Facing this diversification effort will be a rapidly changing regulatory climate, both domestically and internationally.

To help explore and understand the future diversification and business development of the company, this chapter will outline and address the following two important strategic actions that ABC Laboratories has recently taken: strengthening the function of the Research and Development Division (R&D program), and developing new business plans for service expansions.

1. The Research and Development Program

The Research and Development Division, a program for new product development and research was initiated on May 1, 1988. The ultimate goal of the program is to establish ABC Laboratories as a technology leader in the area of environmental analytical instrument technology. The main
focus of this division is to be centered on new technology, acquisition of new products, more emphasis on new instruments development, and new ventures. The major functions and responsibilities are: keeping abreast of new regulations and changes in existing ones in order to assess their impact on ABC's instrument business and internal analytical capabilities, identifying and capitalizing on new opportunities arising from changes in regulations, maintaining close contact with academia, government laboratories, and the instrumentation industry, and further developing existing analytical methodologies applied in ABC's present and future service businesses. To aid the evaluations of program options, a management committee was established to review proposed or existing R&D programs. This management committee will review and develop Research and Development programs prior to reporting projects to the BOD Committee, which has the final responsibility for evaluating and approving research related issues such as new concepts, ideas and programs for project initiation.

In addition, on December 18, 1988, the BOD authorized the expenditure of 5% of annual sales so that the R&D programs were sufficiently supported\(^2\).

The R&D division is headed by an internationally-known expert in environmental research, and a Co-Founder of ABC Laboratories, Dr. David Stalling. He interacts with all ABC Vice Presidents, and works closely with the Managers of the
various ABC divisions to evaluate ideas and concepts for research projects.

Based on a systematic scientific analysis and study, it is predicted that the R&D programs can be accomplished through four developing technologies:

A) Biotechnology methods development and an expanded service base,

B) Development of environmental and biotechnological automated separation and enrichment systems (techniques and instruments) for important molecules or classes of molecules,

C) New instruments development in biotechnology and the environmental sector; and

D) Acquisition of new products or closely related testing services, and ventures.

As stated in the previous chapter, it is expected that the environmental testing business generated by FIFRA will reach a plateau in five years. In order to expand, be profitable and competitive, ABC Laboratories will need to develop and aggressively pursue new product lines. The unique R&D program outlined above is one of the alternatives to help enhance ABC's business and mitigate ABC's declining FIFRA business in the near future.

2. European Environmental Program Plans

In addition to the establishment of the R&D Division
for new products, ABC is actively pursuing several new service lines to meet the changing regulatory climate. Of all the proposed new business plans, the European Environmental Programs plan (EEP) is perceived to be the most viable and optimistic for the company, which addresses environmental business opportunities in Europe. Based on a thorough evaluation of regulatory activities in the European Economic Community (EEC), which currently consists of twelve (12) Member States, a lucrative environmental testing market has been identified.

Based on an assessment of current and future environmental testing needs in European markets, the assumptions of the EEP Plan were developed which includes the following five points: 1) Significant implementation of European Community-1992 (EC-92) will have begun by 1992; (2) The European market will offer profitable business for ABC Laboratories; 3) EEC legislation will proceed mostly on schedule and new environmental regulations will enhance environmental testing business in Europe; 4) The demand for environmental compliance testing in Europe will exceed the supply of laboratory testing capability in Europe in 1991 and for at least the following three years; and 5) The environmental testing and regulatory compliance business in Europe will grow significantly throughout the decade of the 1990s.

The objectives of the EEP plan are: 1) To establish
ABC Laboratories as a major international environmental contract services, consulting and scientific instrument producing organization; 2) To initially expand the program of ABC Laboratories by establishing marketing and regulatory consulting offices in the European Economic Community; and 3) To evaluate the opportunities and need for experimental testing facilities in Europe, including the evaluation of economic, cultural, political and social attributes of this decision.

The unique EEP business plan addressed above is one option for ABC Laboratories to diversify and grow in order to meet the declining regulatory trend of FIFRA. In addition, the same efforts have been made to explore the potential for ABC Laboratories to develop a pesticide technology interchange and testing facilities in collaboration with the government of China. Obviously, the long-term success of expanded operations and future business of ABC Laboratories is dependent on domestic and international environmental regulations. It is indeed exciting to see that ABC Laboratories, which has already established itself well in the U.S. marketplace, can now enter global environmental testing markets and thereby ensure its continued growth and prosperity for the years to come.
CHAPTER FIVE
PESTICIDE PRACTICES IN CHINA

In the preceding chapters, emphases were given on the discussion of changes in FIFRA environmental testing regulations and the corresponding effects on ABC Laboratories. In this section, I will address pesticide practices and status of the testing industry in China. Particular emphasis has been given to:

1. Pesticide industry in China
2. Pesticide regulations and testing approach in China

1. Pesticide Industry in China

China is similar to the United States in size and latitude. It has a population of 1.08 billion (about 5 times that of the U.S.) and a cultivated area of 100 million hectares (about 80% of that of the U.S.). China’s major crop is rice, which comprises nearly half of the national grain production in the southern provinces. In the northern provinces, wheat, corn, millet and sorghum are produced. The nation-wide irrigation practices, use of high-yield varieties of fertilizers, pesticides, and intensive cultivation, have permitted China to have made great strides in providing adequate food for her large population. China’s pesticide industry has contributed greatly in this
achievement.

The demands of a rapidly expanding agriculture in China encouraged the development of the pesticide industry which has grown from virtually nothing before the founding of the People's Republic of China in 1949 into a current large-scale production. Pesticide production in China in 1977 was about 500,000 tons (in gross weight)\textsuperscript{24}. Though many pesticides are produced in large quantities, the present supply can only meet about 60% of the demand.

Since the fifties, many research institutions in China have screened about 10,000 synthetic compounds and new antibiotics in bioassay. Many candidate pesticides have been processed through screening tests, which are China's first efforts at originating her own pesticides to adapt to her peculiar needs. In recent years, certain research groups in China have also been active in the fields of insect pheromone development, and natural bio-active products\textsuperscript{24}. Nevertheless, most efforts in this direction are still in the stage of research and development, rather than large-scale production. At present, 90% of all pesticides produced in China are insecticides; however, recent emphasis has been placed on the research and development of fungicides, herbicides, and rodenticides. China also imports new pesticides from abroad to supplement some of her special needs.

Since the publication of Rachel Carson's "Silent
In 1963, many environmentalists have become concerned about environmental pollution arising from the widespread use of pesticides. As a result, many countries, including China, have strengthened the control and regulation of pesticides. Today, research on pesticide testing not only involves the collaborative efforts of chemists and biologists, but also that of biochemists, pharmacologists, toxicologists, and environmentalists.

The pesticide industry has experienced several developmental stages. In the mid-fifties, when highly active organo-phosphorus insecticides were first introduced to the market, their large-scale production was encouraged, and many "highly active, highly toxic" pesticides actually went into production. Only acute toxicity data was required at that time, and potential chronic effects were unknown. In the sixties, due to the growing awareness of some serious accidents that occurred during the mishandling of these highly toxic substances, the emphasis was shifted gradually to produce new "highly active, low toxic" pesticides. At this time, "acute toxicity data", and subchronic data emerged as important information on the potential toxicity of such compounds. Thus, some relatively low-toxicity pesticides came into production to replace older, more toxic ones. Starting in the seventies, due to the rapid advances in the field of toxicology, several national pesticide conferences were held in China to discuss guidelines for the
future development of pesticides. New pesticides have been required to be "highly active, highly selective, low residual, less expensive". Checking residual problems with nontarget organisms has been greatly stressed. Currently, comprehensive carcinogenic, mutagenic, and teratogenic data must be submitted before production for each new pesticide. An Integrated Pest Management (IPM) policy has been officially announced and is greatly encouraged. All kinds of cultural and biological control methods have also been popularized nation-wide. Production, storage and application of mercury-containing pesticides have been strictly prohibited. Tin and arsenic-containing pesticides have been eliminated. Organo-chlorine pesticides have been greatly restricted and are gradually being phased out.

2. Pesticide Regulations and Testing Approach in China

As mentioned above, China's early efforts at pesticide regulation concentrated on acute toxicity efforts. Pesticide regulations became complicated when chronic toxicological problems arose. In 1974, when the National Pesticide Information Conference was held in China, Wuhan Medical College presented its own toxicological data about an imported low-toxicity fungicide, dichlozoline. In their chronic tests, they confirmed that dichlozoline could cause cataracts and induce malignant tumors in experimental mice.
At that time, Chinese scientists were trying to use the "low-toxicity" chlordimeform. Reports from abroad that chlordimeform was possibly carcinogenic surprised everyone and the application of chlordimeform was abruptly stopped. These events spurred the Chinese workers to start their own toxicological research. Later, a series of national conferences were held to address this problem. In 1976, the National Forum on Pesticide Toxicology and Residues was held. In 1978, the Ministry of Chemical Engineering (MCE), the Ministry of Agriculture (MA) and the Ministry of Public Health (MPH) called for a national meeting to discuss the toxicology and residue problems of pesticides and finally drafted "Proposed Regulations of Experimental Methods for Pesticide Toxicology" and "Proposed Regulations for Pesticide Toxicology and Residues". This was an attempt for the first time in China to standardize the methodology involved in the toxicological tests. In April, 1980, a decisive step was taken jointly by the MA, the MCE, the MPH, and the Environmental Protection Agency (an organization directly responsible to the State Council) to create more rigid pesticide guidelines. After consulting with the specialists and practitioners concerned, the four departments jointly drafted out the "Regulations for Pesticide Management", which consists of three parts: a) processing of applications for pesticide registrations, b) rules of quality control of pesticides, and c) rules of safe
application of pesticides\textsuperscript{30}. This provided the legal basis for regulating and monitoring the research, production and application of all pesticides in China.

According to these new regulations, the application for registration of any new pesticide in China must first be submitted to the Institute for the Controlling of Pesticides, an authoritative state organization, under the auspices of the Ministry of Agriculture. This Institute will review the submitted sections on bioactivity, phytotoxicity and residues on behalf of the Ministry of Agriculture. All the other data will be sent simultaneously to the MCE, the MPH and EPA for joint review. The MCE will scrutinize the related production technology, analytical methods, waste management, etc. The MPH will probe into toxicology aspects in detail, and the EPA will examine the potential for pesticide contamination in soil, water, and air. Only after all the minimum data are cleared by approval from these Ministries can the formal registration petition be granted by the Ministry of Agriculture.

In applying for final registration of a candidate pesticide, there are additional steps to go through. The first step after the minimum research is completed is to file for an application for a "Preliminary Technical Appraisal Conference"\textsuperscript{30}. At this conference, organized by the appropriate national or local authorities, a technical steering appraisal committee will be set up. The committee
is composed of representatives invited from national or provincial organizations of Science and Technology, Chemical Engineering, Agriculture, Environmental Protection, agriculture research institutions, medical institutions, occupational hygiene research institutions, Academy of Science, universities and other concerned bodies. These representatives will examine carefully all the reports which must include: a) background, b) comparison of different synthetic routes, c) analytical methods, d) bioassay results of greenhouse and test plots, e) acute and subchronic toxicity data, and f) experimental waste disposal. In this review process, subchronic teratogenic and mutagenic data should be included. For organophosphorus compounds, delayed neurotoxicity testing is required. Residue analysis in food crops, forage, poultry, animals and aquatics biota is also needed.

Only after all the reports are discussed, inquiries and suggestions are made, and research work is evaluated as acceptable and satisfactory, will a "Preliminary Appraisal Certificate" be drafted and signed by every representative and the chief practitioners who are responsible for the reports. To reach this stage usually takes 1-3 years. With this formal step completed, further financial support can be sought for additional research work, which often takes 2-4 more years (field tests and chronic toxicology tests require data for 2 successive years). At this point, all reports
are submitted to the authorities concerned to request an "Intermediate Technical Appraisal Conference". A larger group of representatives from all the related fields will be invited to examine and scrutinize all the details of these reports. Such reports include the following: a) pilot plant test runs, b) industrial analytical methods, c) bioassay in large demonstration and in productive field tests, d) subchronic and chronic toxicological data (subchronic-toxicity tests, 3 months; chronic-toxicity tests 2 years. e) formulation data, f) standardization of product, and impurities and residue allowances, g) waste management test runs on pilot plant, h) standard measures for occupational hygiene, detoxification and safety, the determination of ADI, (Acceptable Daily Intake), etc., and i) calculation of production costs. Chronic-toxicity tests include carcinogenicity and reproduction tests (3 generations), residue dynamics, and metabolism and degradation data.

Many questions and requirements will be raised at this point. Another Intermediate Appraisal Certificate has to be signed in a similar manner to the earlier process. All the documents, reports, and certifications are then sent to the various Ministries for joint review and approval. Only after the formal registration is granted can the chemicals and equipments be disbursed from the MCE. The design and implementation of this project will take probably another 1-3 years before the new pesticide finally goes into
The above procedure is applied primarily to new pesticides or older pesticides with new formulations. It will gradually cover the re-registration of the older pesticides already in use. Registration for imported pesticides with reliable chronic toxicity data will be granted for field application. However, in the case of the dichlozoline example mentioned above, Chinese workers confirmed its chronic-toxicity problems with their own data and decided later to discontinue its use in China.

In short, pesticide practices in China discussed above have shown sound progress in the past ten years. There is also much room for future improvement in application and formulation of pesticides for the purpose of protecting human health and environmental safety. Any improvement in technology to simplify and advance environmental testing will certainly help improve pesticide practices in China, which will be further addressed in the following section.
SUMMARY AND CONCLUSIONS

The study of FIFRA environmental testing regulatory changes and corresponding effects on ABC Laboratories has proved very helpful in understanding the historical evolution of pesticide legislation in the U.S., the rapid development of testing guidelines, and the overall management system of the environmental testing regulations in the United States.

The regulatory changes in FIFRA regarding environmental testing are the results of the environmental movement and the rapid development of technology, and the establishment of the EPA is the most important of all in terms of regulatory changes in FIFRA.

The establishment and rapid growth of environmental testing firms like ABC Laboratories are the products of the increasingly stringent regulatory climate in the past 20 years, especially in the late 1980s in the United States. The future diversification and growth of environmental testing companies in the U.S. might be still heavily dependent on domestic and international environmental regulations such as Organization for Economic Cooperation and Development and European Economic Community addressed in the previous chapters.

The concern of human health and environmental safety
is no longer a matter for a nation, but a global one. This means that more and more environmental testing services will be needed by countries of the world. To meet these needs, firms like ABC Laboratories in the U.S. will enter many new markets abroad which include China.

Like the United States, the pesticide practices in China today are making progress. China and the United States share many similarities in their pesticide regulation and testing practices. Generally speaking, the achievement of pesticide regulatory activity in the two countries is primarily due to the environmental movement. People are more aware, more sensitive and more responsive to global environmental concerns. It is a public response to complex technological issues. The advanced environmental testing approaches and technology can now detect and analyze chemical compounds in the environment that we never knew existed there before. However, due to the geographic, economic, cultural and social differences between the two countries, the pesticide industry, pesticide regulations and the environmental testing industry of the two countries are distinctly different. In general, pesticide practices in China need to be further improved. For consideration, I would like to highlight the following two points drawn through this study that might be helpful and beneficial to China in terms of studying its future improvement in pesticide practice: 1) the scientific management of the safe
use of pesticides, and 2) the rapid development of advanced testing technology.

The increasingly stringent regulatory climate in the United States in the late 1980s described in the previous chapters has reflected that intensive regulations and testing are required for the safe use of pesticides. Pesticide regulations, registration procedures, re-registration programs, and pesticide testing guidelines and standards established by the EPA have become more scientific, systematic, efficient and effective. As a result, the adverse impact on human health and the environment caused by the use of agricultural chemicals, especially pesticides, has been greatly reduced. Pesticides are essential chemicals for modern agriculture and its production and, like all chemicals they can be used safely. Appropriate regulation and testing can produce benefits for millions of people, when pesticides are used correctly and with care. The U.S. FIFRA experiences provide excellent technological advancement and guidance for continued development of the regulations and the testing and use of pesticides in China.

In China, the regulated use of pesticides has been significantly advanced in the last 10 years. Rules, regulations, testing guidelines, standards, registration and re-registration programs have been gradually established. Yet, owing to the increasing requirements for achieving
high-yield grain output to meet the needs of her huge population, the application of agrichemicals are often over-emphasized, while the risk management of agrichemicals is de-emphasized. As a result, the adverse impact on human health, such as high residue content in agricultural products and environmental pollution caused by the inadequate use of agrichemicals, is neglected to a certain extent. In addition, the pesticide management system in China is a centralized one. Principles, policies, rules, regulations, environmental testing guidelines and standards are basically guided and made by the central government, whereas, the implementation of those rules and regulations totally depends on the local governments. A good or poor management of pesticides at the local government level can directly affect the safe use of pesticides in any geographic area. Therefore, to scientifically manage the use of pesticides by local governments at various levels is crucially important in terms of the improvement of pesticide management practice in China in the years ahead.

As mentioned above, the environmental testing industry can play a decisive role in safe regulations of pesticides. Due to the current economic situation in China, the technology regarding environmental testing is less advanced than in the United States. There are very few environmental testing laboratories in China with the advanced facilities and technology as ABC Laboratories in the United States,
which could hardly meet the testing needs of the country. To solve this problem, China will need to develop more environmental testing institutions or laboratories in order to provide adequate testing data for the purpose of protecting the human health and the environment in China in the coming decades. It would be wiser, moreover, for China to learn advanced testing technology and to collaborate in the useful approaches and experiences from western countries such as the United States that would be helpful and suitable in China. Collaborative efforts with U.S. firms, such as ABC Laboratories, could help accelerate this technology transfer.

In conclusion, this project has provided useful information for the assessment of current and future environmental testing needs and business in the United States. It has also proved equally valuable for the development of pesticide practices in China. This project may prove to be particularly helpful and valuable when considering the ultimate goal of this study: exploring the potential for ABC Laboratories to develop a pesticide technology interchange and testing facilities in collaboration with the Academia Sinica and the government of China. Although this would involve many complicated issues, it is hoped that this study can contribute to a further investigation toward this goal of collaboration and joint venture between the People's Republic of China and the ABC
Laboratories in the United States.
ENDNOTES


2"Federal Insecticide, Fungicide, and Rodenticide Act" (PL 104, June 25, 1947), United States Statutes at Large 61, pp. 163-183.

3"Nematocide, Plant Regulator, Defoliant, and Desiccant Amendment of 1959" (PL 86-139, August 7, 1959), United States Statutes at Large 73, pp. 286-288.

4"Nematocide, Plant Regulator, Defoliant, and Desiccant Amendment of 1959 Amendment" (PL 87-10, March 29, 1961), United States Statutes at Large 75, p. 18.


6"Federal Environmental Pesticide Control Act of 1972" (PL 92-516, October 21, 1972), United States Statutes at Large 86, pp. 973-999.


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