12 Regulatory requirements in the USA

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12.1 Introduction

According to the American Crop Protection Association, pesticide chemical development, testing and US Environmental Protection Agency (EPA) approval takes 8–10 years and costs manufacturers between $35 million and $50 million for each new pesticide [1]. Achieving EPA registration is costly and time consuming, requiring a working knowledge of the many federal regulations, policies and guidelines that control the process.

This chapter provides a review of the key features of the federal registration process with discussion of state requirements as well. It can serve as a general guide to those developing, testing, marketing or registering pesticides in the USA. A comprehensive review of reference sources is provided and includes many that are available on the World Wide Web of the Internet.

Throughout this chapter the term ‘pesticide’ is used to mean the biologically active ingredient in a product which produces an effect on a target pest. The terms ‘pesticide’ and ‘active ingredient’ are used interchangeably. The terms ‘product’ and ‘formulation’ are used interchangeably to refer to the combination of active ingredient, diluents and adjuvants as a packaged mixture.

Regulatory requirements in the USA are continually changing and evolving. Each year EPA issues new or revised regulations or policies that affect the pesticide industry. To the extent possible, the most relevant and up-to-date sources of information and references available at the time of this writing have been used. When considering registration decisions, one must be sure to consult the most current version of any EPA regulation.

12.2 Federal pesticide laws

In the USA there are two laws which must be considered when seeking a federal license to sell, also known as a pesticide registration. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) regulates the manufacture, distribution and sale of pesticides, whether in high-strength technical grade products or in formulations. The Federal Food, Drug, and
Cosmetic Act (FFDCA) regulates the distribution and sale of crops and food items containing residues of pesticides and of inert ingredients used in pesticide formulations. The FIFRA is contained in Title 7 of the US Code of Laws [2]. That portion of the FFDCA which regulates pesticide and inert ingredient residues in or on food and crops is contained in Title 21 of the US Code, Sections 321–409 [2]. FIFRA in its entirety and the previously mentioned portion of the FFDCA are administered by the US Environmental Protection Agency (EPA). It is EPA’s responsibility to provide detailed guidance to the regulated community on how to comply with both laws. This guidance is provided principally in Title 40 of the Federal Code of Regulations (CFR), Parts 150–189. One must have an in-depth knowledge and understanding of the these regulations and how EPA interprets and applies them to be successful in obtaining pesticide registration approvals.

### 12.2.1 Federal Insecticide, Fungicide, and Rodenticide Act

The Federal Insecticide, Fungicide, and Rodenticide Act was established as US law in 1947 to regulate pesticides, defined in the law as substances ‘intended for preventing, destroying, repelling, or mitigating any pest or intended for use as a plant regulator, nitrogen stabilizer, defoliant, or desiccant.’ Intent is determined by claims on the product label and/or composition or mode of action of the product as distributed or sold. In 1947 FIFRA was primarily a law which set standards for product labeling. Since then FIFRA has been amended and its scope broadened many times. The 1972 amendment expanded the standards for product labeling and required that pesticide manufacturing sites should be licensed. The 1974 amendment established standards, based on dermal toxicity, to protect agricultural workers who enter pesticide-treated crops. The 1975 amendment created the Scientific Advisory Panel, an independent body of scientists selected by EPA, to assist in deciding critical scientific issues.

The 1978 amendment was especially important to the agrochemical industry, adding several key components to form today’s modern law. It gave EPA authorization to grant ‘conditional’ registrations, thereby allowing the possibility of earlier market entry with an earlier financial return on investment. It also granted manufacturers 10 years of exclusive-use protection of their registration data. This amendment also created a formalized process for revoking registrations of products where the risks exceed the benefits of use.

The next amendment in 1988 required EPA to accelerate the rate of product reregistration. This required industry to replace older safety studies which did not satisfy current requirements with studies conducted to modern standards. For many agrochemical companies this process placed a financial strain on research and development resources in order to comply with EPA deadlines for submitting these new studies. This amendment