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Environmental Performance of Agricultural Chemistry: The Role of FIFRA

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**Environmental Performance of Agricultural Chemistry:
The Role of FIFRA**

Introduction

By any definition, regulation of economic activity constrains and directs that activity toward chosen goals. As an alternative, tinkering with market incentives can also redirect economic activity by redefining what is profitable. Either approach incurs indirect costs in both the short- and long-run. As has become increasingly apparent in many of the world's economies, these costs may be substantial. As profitability is redefined, the mix of the supply of goods from current technologies will shift, redefining employment of labor and other resources as well as the incomes and returns to those inputs and technologies. Of equal import, as expectations of profitability in the longer term are redefined, the incentives and opportunities for innovation are directly altered and the economy is set off onto a fundamentally different course. Going one step further, in a world of multiple, competing economies, the competitiveness of the regulated or controlled economy is altered.

These general principles are well understood by many people today, in a way which was beyond our collective experience three decades ago. The evolution of this understanding is illustrated to by the case of regulation of environmental performance of agricultural chemistry. As a major force affecting both private and public sector research activity, this regulation has fundamentally reshaped the level of effort and directions of basic as well as applied research, the nature and scale of innovations pursued, and the profitability of research management decisions. The objective of this paper is to present an economist's view of FIFRA, the corner stone of regulation of ag chemistry and its environmental

performance. In the process, the paper will reassess the need for and means for redirecting research activity to achieve goals defined through social and political processes.

Incentives for Innovation in a Market Economy

To begin, most economists would argue that the role for any regulation must follow from a consideration of the performance of decentralized market forces. By understanding how and why those market forces fail to satisfy social and political goals, a rationale is established for a government role. Historically, the need has been recognized for some form of government action to ensure and protect incentives for innovation. In market oriented economies, patents have been adopted to establish property rights for innovations to the inventor. Given this right, the inventor can effectively require payment in exchange for access to the benefits of the invention. Importantly, patents establish a market for the benefits of the innovation. In abstract, a patent grants an exclusive right to supply the invention to the market. In practice, all inventions face competition from a multitude of existing and future substitutes. As in any market, competing supplies and demands in the market for the invention's benefits determine the price or value of those benefits and this defines the profit generated by the invention and the value of the patent. Similar results occur where other forms of protecting the right of access to the benefits of an invention are used. Maintenance of trade secrets or market saturation have proven viable strategies. Economists find patents a good example of an effective role for government that strengthens and catalyzes market processes rather than stifling or crowding them out.

The role for government in ensuring environmental performance of ag chemistry must be based on an understanding of why market forces fail to generate adequate incentives to achieve social and political goals. A basic requirement for the existence of a market for any good or characteristic of a product is that rights to consumption can be defined and consumption can be controlled. It is within this realm that the environmental performance characteristics of ag chemistry fail to provide the basis needed for market forces to stimulate their supply.

Consider the case of field crop chemistry. Two general types of effects can be defined to result from the field application of an agricultural chemical: 1) the direct agricultural productivity effects and 2) environmental effects possibly occurring both on and off the user's farm. As an input into a crop production process, an ag chemical contributes to increased output and enhances the productivity of other inputs. These direct or product oriented effects generate benefits which can be appropriated or realized by the farmer using the chemical. In addition to such direct effects, the environmental performance of an ag chemical involves many effects that are realized by non-users or off site on non-targeted species or physical systems. These external effects may include soil, water, wildlife, and human health effects. This type of environmental effect can be thought of as external to the original use since it typically occurs at sites that lie beyond the scope of the direct effects of use. By definition, the user's production process is not affected by these external effects, implying the effects should be ignored by the user in any profit oriented decision to use the chemical. For this reason, the user's consideration of personal profitability of ag chemistry

use can not be expected to result in a demand for environmental performance of a product.¹ Since no margin of profit is generated for the user by enhanced environmental performance, no budget is generated from which the user could pay for environmental performance of a product. In the absence of willingness to pay for environmental performance by users, no margin of revenue is available to finance the supply of environmental performance.

Despite the farmer's unwillingness to pay for environmental performance, substantial social value for such characteristics of ag chemicals is implicit in political support for FIFRA. The divergence that exists between this social value and the private return to R&D focused on environmental performance represents a key rationale for government intervention. The divergence means that market processes will fail to generate levels of environmental performance that are demanded by society. It is this failure of market forces that motivates a role for government. Intervention to stimulate R&D on environmental performance to achieve levels that reflect its social value can take many forms, one of which is regulation through standards and market gatekeeping.

Innovation in environmental performance requires expanding the scope of research and development to consider what must be interpreted as a new set of product characteristics. However, if users can not typically be expected to be willing to pay for environmental performance, how can that expanded scope of R&D be financed? Unfortunately, the solution of patent protection is not viable for the product characteristics

such as environmental performance. The protection of patents relies upon tangibility of the invention in a form that allows the use of it to be controlled. While it could be argued that environmental performance characteristics are linked directly to tangible ag chemical products, the correspondence is not one-to-one. The benefits of environmental performance may go well beyond one product and typically would go well beyond the initial user. At a tangible level, the only solid footing that can be found for environmental performance is, in fact, the knowledge of that performance, or equivalently the data, or research results that establish its nature.

In the sum, the problem of catalyzing research and development, or innovation in environmental performance goes beyond establishing intellectual property rights over the knowledge of that performance. For the case of environmental performance, existence of such rights can not be expected to stimulate R&D in the absence of a means of financing the R&D. For most innovations, the appeal of patents and the property rights they establish is that they result in a basis for control of access and establish the feasibility of financing from sale of use rights. In the case of environmental performance, the intellectual property is data or research results. Importantly, these tangible characteristics are not consumed by the user and users must be expected to be unwilling to pay for such data.

FIFRA as a Regulatory Strategy to Achievement of Environmental Performance

In a market economy, the demand for inputs follows from users that find their use to be profitable. The supply of inputs is likewise governed by profitability of their provision

given the cost of manufacture and potential sales revenue. By design, a market mechanism effectively ensures that the right amount of such tangible inputs are exchanged at a price which approximates the unit cost of manufacture. Market economies are not adept at managing such intangibles as environmental performance. FIFRA follows the precedent of many regulatory bills by establishing standards for certain external effects of ag chemical use such as environmental performance.

Beginning in 1972, FIFRA formally recognized the value of environmental performance data. The 1972 legislation prohibited use of trade secret or confidential data by post-patent imitators. Non-trade secret data could be cited if an offer of reasonable compensation were offered by the imitator. In 1975, the duty to pay for citation of data was amended to apply only to data submitted after January 1970. In 1978, the right of exclusive use of trade secret data was withdrawn and arbitration responsibility was transferred from EPA to private arbitration. In place of unlimited exclusive use, duty to pay for 15 years after submittal was established for data submitted between January 1970 and September 1978. For data submitted after September 1978, all data was granted exclusive use for 10 years and a duty to pay for citation was established for 5 years after the exclusive use period. For data developed in response to call-ins, joint financing by registrants was required.

Operationally, FIFRA remains the federal solution to achieving environmental performance of ag chemistry. Interpretation of FIFRA's operational role hinges on the recognition of the change in social standards which it reflects. Prior to FIFRA, R&D led

to new chemistry which was marketable only if farmers were convinced its use was profitable. The feasibility of marketing a new product was, therefore, based almost entirely on the product oriented effects of the new chemistry, that is its contribution to farm productivity and value. In contrast, FIFRA focuses on the external effects of the use a new product. FIFRA represents a mechanism for ensuring that the external effects of ag chemicals meet certain standards. The implication for R&D is that the scope of effort required to market was expanded from that which would be necessary to establish farm productivity to that necessary to establish environmental performance as well.

From an economic perspective, FIFRA plays two significant roles in the agricultural chemical market. The primary economic function of FIFRA is to establish a gatekeeping process over the right to market new ag chemicals or to continue marketing of chemicals that have been recalled under FIFRA 3c2B. The second role played by FIFRA follows from its regulation of environmental performance data that constitutes evidence that a product meets environmental performance standards.

The registration process established by FIFRA represents a market permitting process that grants rights to market products when environmental performance data supports the conclusion that they meet standards. In the absence of regulations such as FIFRA, the right to market would be determined by markets for internal effects such as farm productivity and profitability. The farmer must be convinced that profit added by use of a new product exceeds the product's cost. When the farmer is convinced added profit will

exceed cost, the farmer is willing to pay for the new product and a market demand is established. The right to market product oriented effects is monitored by competitive forces and the scrutiny of users.

The second role of FIFRA represents a radical departure from the tradition of patent law. Specifically, FIFRA establishes mandatory licensing of environmental performance data that supports claims that external effects fall within standards. Patents may be viewed as a voluntary mechanism through which the innovator may establish protection for an invention, in return for revealing information concerning the invention. In contrast, FIFRA currently mandates that results of environmental performance R&D be released by the innovating firm after ten years of exclusive use. In simple terms, this amounts to mandatory licensing of trade secret information. While for five years following the exclusive use period a duty to pay (a license fee) is established, thereafter FIFRA establishes the license fee to be zero. This implicitly suggests that environmental performance R&D can be financed from the profits earned from the product's patent. The effects of such a financing mechanism on the level and direction of R&D effort depends ultimately on the R&D processes focused on marketable product characteristics and the relationship among those processes and R&D processes dedicated to environmental performance.

Data Compensation as a Mechanism for Financing Environmental Performance

The salient characteristics of the R&D process determine the feasible means of both management and financing of the process. If the process were project focused, linear, and subject to little uncertainty of success, simple time and cost accounting for each project would accurately describe the effort preceding marketing of a new product. Management of each stage could be pursued independently of future stages and the economics of the process would differ little from a standard construction project. For each project, returns could be compared with costs to assess the profitability of project investment.

If, instead, the process is more general in focus, if progress is not continuously related to time and effort, and if substantial uncertainty persists throughout the process, then the conduct of R&D is more accurately perceived of as the operation of a complex engine that generates opportunity. The value of this opportunity requires expert insight and continuous investigation if it is to be recognized and appropriated. Within this context, the R&D organization is not one which simply implements a set of distinct projects each of which may be financed independently. Instead, the R&D organization is a highly tuned engine composed of interacting teams of human and physical resources that participate in highly interrelated projects.

In this case, analysis of profitability must be more broadly focused. Over time, the organization generates a stream of effort and expense which may result in a periodic set of

commercially valuable discoveries. In this sense, the revenue flow from commercialized discoveries represents returns to the organization's stream of effort and expense. Financing of product oriented R&D requires a stream of funds capable of financing the R&D organization's on-going activity. Successful commercialization requires a high level of secrecy during the discovery and development phases. This imperative limits the nature and extent of external financing that is available and attractive to the R&D organization. Revenues from commercialized products are heavily relied on to provide funding for on-going R&D. In combination with exigencies to maintain stable levels of growth and return to equity, finances available for R&D are necessarily limited.

Standards for the environmental performance of ag chemicals leads to two important effects on R&D: 1) expansion of the scope of R&D and 2) reduction in the probability of marketable discovery and increase in the cost of marketable discovery.

Expansion of the Scope of R&D

The environmental performance standards established by FIFRA are not simply warranty standards requiring proof of particular product performance claims. Instead, FIFRA's regulation of environmental performance requires an expansion of the scope of R&D objectives to include achievement of the standards for external effect performance. In the absence of concern for external effects, the discovery phase of R&D involves a search for biological activity for which a profitable market demand can be predicted. Product oriented R&D focuses on identification of potential candidate compounds and screening of

the biological performance of those compounds. Concern for external effects requires that the identification and screening process be expanded in scope to include consideration of both internal effects of value to the farmer as well as environmental and other external effects of potential concern. How this expanded scope of enquiry in the R&D process is operationalized varies by corporation. Environmental performance R&D activities ultimately interact with product oriented R&D focused on biological activity valued by the farmer. At a scientific level, considerable interaction may result from joint use of basic knowledge of chemical properties and performance of biological systems.

Time, Expense, and Uncertainty of R&D under FIFRA

Statements such as "On average it takes 8 years and 10 million dollars to produce a new agricultural product" suggest that the R&D process underlying new products is 1) product specific in focus, 2) linear and 3) highly predictable. This conceptualization also suggests that the R&D process is demand driven, starting with a specific unfilled need. In fact, this conceptualization of the R&D process is misleading. Though R&D progresses through time, the rate of effort and expenditure may be variable and discontinuous. Further, progress is highly variable, uncertain, and it is not continuously related to time, effort, or expenditure. While R&D is typically responsive to demand, new discoveries may open unexpected opportunities for which demand is not clearly articulated.

In the absence of comprehensive theories of biological performance, R&D typically begins in a discovery phase where objectives are only given general focus to determine

general forms of biological activity. Potentially active chemistry is identified, acquired, and its biological activity assessed. Feedback to chemical identification continues. During the process, numerous forms of biological activity may be identified and pursued, only some of which may be related to initial general research objectives. The biological activity of specific compounds are further explored in a development phase. Here, investigation and development of the precise form and extent of commercial viability of the compound becomes an objective. However, discovery of a basis for non-viability may have equal ultimate value for R&D or as a basis for an entirely different product.

From this perspective, the focus of R&D processes in the ag chemical industry is not accurately described as involving a set of product specific projects. Instead, the R&D process involves a sequence of effort and expense that is more generally directed at increasing the probability of discovery. When a narrowing of the extent of uncertainty is achieved, progress is made.

The effect of environmental performance standards is to force innovators to establish not only the biological performance of an active ingredient in controlling a particular target pest on the farm but also the external biological and physical performance of the new product. Commercially successful R&D under FIFRA requires that environmental performance R&D is not simply an activity added-on to product oriented R&D, but rather is an integral part of the both discovery and development phases.

Bases of Interaction between Product Oriented and Environmental Performance R&D

Interaction may occur due to common knowledge and discovery processes, i.e. as a result of technical interaction. Alternatively, interaction may be induced from financial constraints faced by the corporation. Two types of constraints are important to note. First, R&D is limited by available human and physical scientific resources. These resources are in scarce supply at the market level and are costly to assemble. Further, the productivity of these resources takes time to evolve and depends critically on management decisions which direct and hone the package of available resources into an effective and creative team. Second, financial resources limited by exigencies for internal funding place a further significant constraint on R&D activity. Within the context of these constraints, R&D concerned with environmental effects can only be achieved by reduction of product oriented R&D activities.

Financing Environmental Performance R&D from Product Patent Returns

In the absence of any regulatory standards for environmental performance of an ag chemical, the absence of a market for such performance characteristics would imply they would be ignored by the innovator. Environmental performance R&D expenditures would earn no return and would not be attractive to private finance. FIFRA introduces mandatory standards for certain external effects which must be met as a basis for securing the right to market. Nonetheless, the absence of a market for environmental performance characteristics or alternative means of financing environmental performance R&D implies that environmental performance R&D can only be financed out of patent returns earned

for product characteristics. Because R&D is financed internally from limited earnings and in the absence of any market value for the results of environmental performance R&D, internal financing of environmental performance R&D necessarily reduces funds available to finance product oriented R&D.

Mandatory Licensing under FIFRA and Financing through Data Compensation

FIFRA steps beyond the voluntary nature of patent law by requiring that after an exclusive use period firms share scientific results from environmental performance R&D with competitors. after an exclusive use period. This constitutes mandatory licensing and FIFRA's requirement for compensation can be interpreted as requiring that licensees pay for access of the environmental performance R&D results. The question of what form data compensation should take is, therefore, a question of what is the best form of compensation for a mandatory license for use of EE data. An economically sound means of financing environmental performance R&D is needed and data compensation, interpreted as a mandatory license fee, represents an important opportunity for achieving this end. Unfortunately, FIFRA and its amendments fail to define how environmental performance R&D can be financed and litigation has been an important value for determination of the venue of data.

Rules of Thumb for Catalyzing Innovation in Environmental Performance

The conclusion can be drawn that the impacts of FIFRA and data compensation on the levels and scope of R&D deserve careful consideration. While a variety of studies have been completed over the past decade (see e.g. Hatch, Conservation Foundation, or OTA), none of these studies have taken an approach based on the microeconomics of R&D or one that has recognized the fundamental and unique characteristics of environmental performance as an R&D output. Past studies have failed to grapple with the basic contradiction that is apparent from their own results that have concluded that environmental performance standards have not impacted R&D processes and the conclusion of research managers who are forced to recognize the impacts on a daily basis as they attempt to allocate scarce research resources to achieve maximum return.

This paper has presented an argument from which several testable hypotheses can be drawn. To conclude these may be summarized as:

- * The environmental performance R&D process is substantively interrelated with product oriented R&D processes.
- * Environmental performance constitutes innovation that extends product oriented R&D.
- * No margin is available in patent returns to finance environmental performance.
 - Users are not typically willing to pay for environmental performance .
 - Patent returns for product oriented performance are driven by competition to just cover the cost of product oriented R&D.

* Financing mechanisms can be designed that will catalyze environmental performance R&D while maintaining and expanding product oriented R&D.

Without question, FIFRA and its amendments have laid important groundwork in ensuring that social and political standards for environmental performance of ag chemistry are met. Private and public sector R&D efforts have adapted to this regulation and great advances have been made in identifying and bringing to market products with enhanced environmental performance. This paper has argued that such progress has occurred in the absence of an adequate and appropriate mechanism for financing environmental performance. The strategic challenge of the next decade will be to engage these hypotheses and develop stable and effective mechanisms for financing environmental performance of ag chemistry.

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Endnotes

1. The nature of the market for environmental performance or any other external effects of new agricultural chemicals is such that the simple economics of R&D for go awry. In contrast to protection offered to the results of R&D by patents for productivity effects, patents offer no protection to claims of the absence of specific types of environmental performance or other external effects. Farmers are, in general, not willing to pay for external performance characteristics. While some degree of altruism could be expected to lead farmers and research organizations to have some concern for external effects, the economic principles of market economies assume external effects will be ignored by decision-makers. Intuitively, by ignoring external effects the farmer limits his decisions to effects which he can observe. This limited consideration is desirable from both the farmer's and society's perspective since it eliminates errors in decisions based on imperfect information concerning external effects. The conclusion can be drawn that no market exists among users for external performance characteristics of new agricultural chemicals.