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Market approval of phytosanitary active substances in Europe: An empirical duration analysis

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ABSTRACT

The aim of this paper is to analyze empirically the main determinants of delays to market approval of active substances in Europe. An interesting feature of this regulation is that it is based on both a decentralized examination by the rapporteur country and a centralized examination by the European Food Safety Authority (EFSA). Our econometric analysis is based on standard survival and competing risks models. The data cover 393 active substances reviewed between 1993 and 2013.

We show that the review process is affected by regulatory factors, the characteristics of the active substances and the characteristics of agri-chemical firms. Log-logistic and log-normal survival models are the preferred parametric specifications, and the results suggest that the hazard function is non-monotonic over time.

1. Introduction

Prior to its introduction to the market, agri-chemical firms must seek an official approval of a new patented plant protection product. The market approval procedure is aimed at ensuring that the pesticide will not have unacceptable toxic effects on human health and environment, and establishing the conditions under which the product is deemed efficient. In Europe, the approval procedure is conducted the European and national levels. Specifically, the active ingredients are reviewed by European authorities and the pesticide formulation is reviewed by a national regulatory agency, as part of a mutual recognition system within a geographic area (European Commission Regulation, 2009).

The present paper focuses on the market approval of active substances in Europe. Note that, the administrative procedure related to approval for these products involves delays which can range between 20 to 32 months days (European Commission Regulation, 2009). According to data collected from the European Food Safety Authority (EFSA) website, these can range from 38 to 215 months, much longer than indicated in the administrative procedure. It seems that submitters are responsible for much of these delays since reviewers have relatively stringent time limits.[1] Of course, it may be that the reviewers request additional data, which might be one of the causes of delays. This highlights the importance of uncovering the main determinants of examination delays related to approval of active substances in Europe. We conduct an empirical investigation based on econometric duration analysis.

Understanding what determines examination delays is essential for three reasons. Firstly, in the empirical literature on examination delays, review time is used as a measure of regulatory stringency (see e.g. Ollinger and Fernandez-Cornejo (1998) for the case of U. S. Environmental Protection Agency (EPA) registration). The basic intuition is that the review time becomes longer when regulation becomes more stringent. Indeed, since registration time depends on the number of tests which regulators must scrutinize, an increase on this number will increase the review time. In addition, there may be a great deal of interaction between the firm and the reviewer. This interaction might involve a request for a new test from the regulator and the firm's response to this request. This might occur several times during the market approval procedure and the firm's behavior can influence the duration of the examination which could depend on how quickly the firm provides the new test. Secondly, market approval of plant protection products may act as a barrier to entry which might affect the industry structure. For instance, stricter regulation may be associated with the formation of fewer small businesses. It can lead to predatory behavior

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[1] Reviewers are allowed 20 months out of a total review time of 32 months for the entire process. This could mean that the reviewers must be taking a very small share if they are reviewing only once.

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from incumbents which can discourage entry strategically (see Heyes (2009) for a survey). Thirdly, a lengthy review of a new plant protection product may delay profits and diffusion of the product which may be costly for firms and farmers.

Research on pesticides in the economics literature mainly studies issues related the use of these types of products and their impact on farmers' productivity. The present study focuses on the regulation of these innovative products by investigating review times employing duration models. A key feature of our empirical analysis is that it is based on both standard survival and competing risks models. To the best of our knowledge, this is the first study of the duration of the review of plant protection products. Moreover, our data cover 393 active substances reviewed between 1993 and 2013 by the EFSA. We find that the risks related to pesticide use, namely, carcinogenicity, toxicity and eco-toxicity, the pesticide use, biological activities such as herbicides, insecticides, and fungicides, the role of regulatory factors, seniority of active substances and the geographical zone of the rapporteur country and the characteristics of the agri-chemical firms, in our case their geographical origin, all have significant effects on the length of time that a phytosanitary active substance is under consideration. Log-logistic and log-normal survival models are the preferred parametric specifications, and our results suggest that the hazard function is nonmonotonic over time. The rest of the paper is organized as follows: in Section 2, we present a review of the related literature. Section 3 provides some background information on the European market approval procedure for active substances. Section 4, presents models on standard survival analysis and competing risks. Section 5 describes data and Section 6 presents the main results. Section 7 concludes the paper.

2. Related literature

Most economics studies on pesticides focused on issues associated with their use. In particular, most studies examine the main determinants of farmers' pesticides use and its impact on agricultural productivity (Carpentier et al., 2005; Sexton et al., 2007; Carpentier, 2010). Only a few papers conduct analyses of the regulation of pesticides. Ollinger and Fernandez-Cornejo (1998) provide an empirical examination of the impact of pesticides regulation on the number of new pesticide registrations and pesticide toxicity. They show that increasing regulatory costs, decreases the number of pesticides brought to the market. Hence, regulation encourages agri-chemical firms to develop less toxic pesticides, although this reduces overall innovations in pesticides. In this paper, the regulatory costs are measured by research expenditure on human health and environmental testing. Cropper et al. (1992) investigate empirically the determinants of the U.S. EPA decision making in the case of pesticide regulation. They estimate a model that explains the probability that a pesticide is disallowed for use on a particular crop, as a function of the risks and benefits associated with its use and as a function of some political variables. They find that the EPA adjusts the stringency of its regulation, in particular the allowed level of pollution, in response to the costs and benefits to consumers, farmers and firms. Several papers study the impact on trade of the regulations on pesticide Maximum Residue Levels (MRLs). These MRLs are the upper legal levels of concentration for pesticide residues in or on food or feed based on good agricultural practices and to ensure the lowest possible consumer exposure. MRL on food imports are specified by each country and are imposed as standards at the border (Wilson and Otsuki, 2004). Drogué and DeMaria (2012), Yue et al. (2010), Jongwanich (2009), Disdier et al. (2008), Otsuki et al. (2001a) and Otsuki et al. (2001b) show that stringent and more heterogeneous sanitary and phytosanitary (SPS) standards can impact negatively on trade. However, Drogué and DeMaria (2012) find that this negative effect on trade between developing and developed countries disappears if they have similar MRLs. Our paper offers new insights on these issues of pesticide regulation by studying the market approval delays related to new phytosanitary active substances.

A number of studies have investigated the duration of the examination process related to drugs regulations and patenting. These empirical analyses in these fields identify three categories of determinants which can affect the review process and which are related to the characteristics of both firms and products as well as some regulatory aspects. The setup in our paper has some similarities to the with literature on the drugs approval process. Previous research shows that the review times for approval of new drugs are influenced by drug-specific characteristics such as the importance of the drug. Dranove and Meltzer (1994) examined drug approval by the U.S. FDA. and show that more important drugs[2] are both developed and approved more quickly compared to less important drugs. A drug's importance is measured in this case by its commercial and therapeutic significance. Other studies analyze the rate at which drugs are reviewed by the Food and Drug Administration (FDA) according to the characteristics of firms submitting a product. For instance, Olson (1997) finds that both more R&D intensive and less diversified firms receive faster reviews for their new-drug applications than either less R&D intensive or more diversified firms. The intuition here is that these characteristics are perceived by the regulators as signaling either the quality of the drug or the reputation of the firm. This information reduces regulators uncertainty about the approval of a dangerous or ineffective drug and leads to a faster review.

In the case of the patent examination process, Regibeau and Rockett (2010) conduct a theoretical(using a simple approval model) and empirical investigation of the link between the length of the patent review process and the importance of the inventions. They find that, controlling for the position in the innovation cycle, more important innovations are approved more quickly than less important innovations. Harhoff and Wagner (2009) obtain a similar result. In a recent paper, Xie and Giles (2011) analyze the length of time it takes for a patent application to be approved by the United States Patent and Trademark Office (USPTO), conditional on an eventual patent. They show that the number of claims, the number of citations, the technological category of the patent and the type of patent applicant have significant effects on the duration of patent approval.

The results of these papers are interesting but most take account only of approved products while review of an innovative product can end in approval, rejection or withdrawal of the product. An exception here is the paper by Harhoff and Wagner (2009) who use competing risks models.

3. Background information on the market for plant protection products and their approval process in Europe

The pesticides market is characterized by three main segments: herbicides, insecticides and fungicides. Herbicides are used to kill weeds that compete with crops; fungicides are chemical compounds or biological organisms used to kill or inhibit fungi which could cause severe damage to crops; insecticides are pesticides used at eliminating insects which cause damage by feeding on the crop. In the pesticide market, we can distinguish also by two types of agri-chemical firms. On the one hand, there are firms such as Dow, Dupont, Bayer, BASF and Syngenta which make large R&D investments in order to create new molecules. On the other hand, there are producers of generic products which exploit molecules no longer protected by patent (Lemarié, 2003).

[2] Importance here is measured by citations in medical textbooks, medical journals, subsequent patent applications, the extent of worldwide introduction, and U.S. sales.