The Contraction of Product Quality Innovation in Agricultural Biotechnology

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One-sentence summary:

Plant scientists continue to discover genetic improvements in nutritional content and quality characteristics of economically important plants, but a contraction since the late 1990s in the development of products with such traits means we may be foregoing gains to human welfare and the environment.

Abstract:

Genetic engineering of product quality traits in plants, such as better nutritional properties, product compositions, food safety, flavor, appearance, and convenience, has progressed, with some leading innovations likely to be commercialized in the next few years. The most significant impacts are likely to be increased human and animal nutrition and processing efficiencies while at the same time conserving resources and mitigating environmental burdens in production. However, in spite of the continuing growth of scientific publication since the 1980s and several products pending commercial release, we find there has been a general contraction in product development activities since the late 1990s. A lower rate of commercial innovation implies that the full potential social value of this emergent technology is being foregone. The contraction likely results from a combination of technical challenges and economic factors—including market demand, the intellectual property landscape, and regulatory policies— all of which have been affected by reactions to the commercialization of first-generation genetically engineered crops containing pest control traits.

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The commercial applications of recombinant DNA technology in agriculture have, to date, predominantly been for insect and weed control in major field crops. These pest control biotechnologies improve production efficiency, reduce use of chemicals, and lower the price of agricultural commodities, thereby benefiting technology providers, farmers, consumers, and the environment (*1-3*), yet they are not perceived by many consumers to provide direct benefits. According to a major survey, only 20 percent of U.S. consumers perceive benefits from biotechnology in the form of reduced chemical and pesticide residues on food, while only 10 percent perceive benefits in the form of reduced food costs (*4*).

In contrast, there has been very little commercial application of biotechnology to improve product quality—providing characteristics directly valued by users downstream of the grower—despite its anticipation since the earliest days of plant genetic engineering (*5*). In fact, the first commercial genetically engineered crop, since discontinued, was a quality enhanced fresh market tomato (*6*). Yet, a range of innovations with consumer-oriented quality improvements are reported to be in some stage of research and development (R&D), including characteristics like healthier fatty acid compositions of vegetable oils, elimination of food allergens, and enhanced natural flavors. A number of processor-oriented and animal feed qualities are also in R&D. Processor traits include examples like high starch corn for increased extraction efficiency, low protein grains for better brewing, and reduced wood lignin for easier pulping. Animal feed traits include traits like balanced essential amino acids, bioavailability of minerals like phosphorus, reduced toxins and antinutrients, and improved digestibility. In all cases, consumers, processors, or livestock operations, all downstream of the grower, would be willing to pay more for the harvested product because of the newly imparted genetic characteristic. Thus, they are broadly defined as quality or “output” traits.

Many have suggested that when such innovations reach the market and provide qualitative benefits for consumers, public perceptions of genetically engineered crops will improve (*7,8*). In addition, product quality innovation could expand the range of potential markets for plant biotechnology. Most significantly, quality innovations could deliver efficiency gains in global agricultural and natural resource systems, with resulting economic welfare, public health, and environmental benefits not necessarily tangible or visible to consumers. The actual scope and status of quality innovations in the R&D pipeline has not been assessed. We have therefore undertaken a pair of surveys of product quality innovation in agricultural biotechnology and its potential impacts (*9*).

The first, “backward looking” survey drew upon published reports of transgenic plants with improved quality characteristics. It found 358 scientific papers and articles, 2403 registered field trials (in 19 countries), and 36 regulatory filings (in six countries). These public records were aggregated to reconstruct the histories of 558 innovations or “product candidates”, documenting the progress of each from primary research through various stages of the R&D pipeline (Summarized in Table 1, Survey 1). To integrate the information obtained from these multiple sources, we used a simple set of common denominators to define an individual product candidate: (a) the plant species genetically transformed, (b) the type of trait, and (c) the innovating organization. Examples include corn with high lysine at Monsanto or tomatoes with high lycopene at University of Nottingham (*10*).

The second was a “forward looking” survey of expectations by companies and industry analysts of future product commercialization events. It found 49 product quality innovations that are expected to be released by 2015 (Summarized in Table 1, Survey 2).

The results of these surveys illustrate the filtering or “pruning out” function of R&D, whereby candidates for further development are removed from R&D based on technical and economic performance criteria. Of the 558 unique innovations identified in the first survey, 355 entered initial field trials, 51 reached advanced field trials, and 14 were submitted for regulatory approval. From those, five products were commercialized, and just two are still on the market (*11*) (Table 1, Survey 1). Of the 49 product candidates identified in the second survey, the commercialization of 20 of them is expected before 2010; and of the other 29, between 2010 and 2015 (Table 1, Survey 2). Yet, only a handful of the 49 had reached the stage of regulatory filings during the timeframe of this study. Filtering in the later stages of R&D most certainly will mean that fewer than the 49 predicted will actually be commercialized.

The advance of product candidates through the R&D pipeline has been uneven across trait categories. Traits governing the content and composition of macronutrients—proteins, oils, and carbohydrates—as well as genetic control of fruit ripening (Table 1, Survey 1) have reached the latter stages of R&D. For protein, oil, and ripening traits, expectations for product releases over the next ten years (in Survey 2) are consistent with the levels of R&D observed (in Survey 1). For carbohydrate traits expectations are lower and for plant digestibility traits expectations are higher than might be suggested by their observed levels of R&D activity. Very few products with enhanced micronutrients, functional components, or esthetic characteristics are expected (Survey 2).

There has been greater emphasis on R&D of characteristics important to producers at intermediate stages of the value chain than on characteristics for final consumers. In economic terms, innovation appears to have responded primarily to the pull of derived demand for processing and feed characteristics. Of the 558 innovations identified in the first survey, 53 percent provide characteristics primarily useful in food processing or animal feed, while 23 percent provide characteristics specific to consumers, and another 23 percent provide characteristics likely useful to both. Similarly, of the 49 product candidates identified in the second survey, approximately half provide distinct processing or feed benefits, a quarter provide distinct consumer benefits, and an additional quarter provide benefits to both.

In addition to meeting the demand of intermediate producers and final consumers, many of these quality improvements would create efficiency gains in agriculture and natural resources, thereby reducing environmental impacts associated with their production and use. In economic terms, there are both potential reductions in input requirements for a given level of output and potential reductions in negative externalities. The most significant example may be increased nutritional efficiencies of animal feeds, which could mitigate increases in land needed for feed cultivation as well as the volume of animal wastes generated as global meat production increases an expected 50 percent over the next two decades, driven largely by growing populations and incomes in developing countries (*12*). A second major example is increased pulping efficiency from low lignin wood fiber, which could significantly reduce chemical and energy requirements for producing pulp and paper (*13*). Crossover applications of low lignin technologies could also provide significant efficiency gains in biomass energy production (*14*). We find scores of such examples throughout the two surveys.

Product quality innovation is ongoing in many countries in both the public and private sectors of the economy (Figure 1). More than half of the innovations identified in the first survey (52 percent) arose in the U.S., while 28 percent were in Europe, 13 percent in other OECD countries, and seven percent in developing countries. The distribution between public and private sectors differs markedly across these four. Within the U.S. the private sector accounts for over half of all innovations in the pipeline; within Europe, just over a third; within other OECD countries, less than a quarter; and within developing countries, the private sector accounts for virtually none of the innovations in the pipeline. Notably, there appears to be a strong positive correlation between public and private sector innovation. With private sector innovation significantly greater where the base of public sector innovation is stronger, private sector innovation may be interpreted as complementary to public sector innovation: the private sector certainly does not appear to crowd out or replace the public sector.

Analysis of the dynamics of R&D activities, based on the first survey, shows an early phase of rapid growth or expansion followed by a latter phase of relative decline or contraction (Figure 2). From 1987 to 1997, the rate of entry of new innovations consistently exceeded the rate of exit, resulting in rapid net growth. This was followed by an abrupt leveling off in 1998, after which about 130 innovations were maintained in

R&D annually, with a turnover of about 50 per year. In 2000 the number of innovations in R&D began to decline. This coincides with the overall decline in number of field trials conducted in the U.S. and Europe for all types of transgenic plants (*15*).

Figure 3 illustrates the advance of innovations at each stage of the R&D pipeline, further illustrating two structural phenomena. First is the division of innovative labor between the public and private sectors (as seen in Figure 1). The public sector has tended to spread resources over multiple areas of investigation in the early discovery stages of R&D, producing an extensive range of publications and initial field trials. The private sector has focused greater resources onto a narrower set of commercially promising product candidates, evidenced in Figure 3 by its predominance in the advanced field trials and regulatory filings. The second phenomenon is that of filtering or "pruning out" (as seen in Table 1).

Both the division of innovative labor and the filtering of candidates shifted around 1998 in the transition between the phases of expansion and contraction (Figure 3). During the expansion phase, the public sector contributed about two thirds of initial research publications, only about one quarter of initial field trials, and very little beyond that. At the same time, private sector activity grew steadily in each of the observed stages—with filtration and lag between stages—all the way through to regulatory filings. During the contraction phase, after 1998, public sector activity continued to grow consistently, achieving considerably higher rates of publication and initial field trials, while also expanding forward into mid-stage field trials. Activity by the private sector, however, did not continue to grow overall and declined in advanced field trials and regulatory filings. The core firms in the industry concentrated efforts on a set of most promising product candidates, while most others—including food companies and smaller biotech firms—reduced or abandoned their efforts. While the public sector appears to have filled some of the vacuum left by reduced private sector activity in early and mid-stage field trials, it has not once carried a transgenic product quality innovation through the regulatory approval process to release it commercially. Overall, the rate of filtration clearly increased after 1998, with significantly fewer candidates advancing to the final stages of R&D, despite an ever-larger pool of early stage candidates from which to draw.

There are likely two general causes for the observed decline in product quality innovation after 1998. The first is technical, with initial exuberance likely having been sobered by difficulties encountered in the complexity of engineering nutritional and quality characteristics. The second is economic, with projected costs having grown and projected demand having declined. Possible reasons for higher projected costs include the growing complexity of managing regulatory compliance and intellectual property. Possible reasons for declines in projected demand include availability of reasonably close non-transgenic product substitutes, consumer uncertainties over food uses of biotechnology, activism against genetically modified crops, and in some countries an actual or effective ban on the technology.

Overall, very few of the innovations projected for commercialization within the 10-year timeframe appear to offer dramatic breakthroughs in health, convenience, or esthetics. Even among those that deliver consumer benefits, many could pass unnoticed by consumers, as they constitute close substitutes for available products. We conclude that the most significant effect of transgenic product quality innovations would be cumulative reductions in the resource requirements and environmental impacts of the agricultural and natural resource industries, while at the same time making more nutritious or safer products more affordable and thus more broadly available to resource-constrained consumers. The overall downturn in the trajectory of new product development in the last decade suggests that foregone gains in social welfare from a decreased rate of innovation in second-generation product quality biotechnologies may be a significant side effect of regulatory, intellectual property, and market barriers that have mounted since the launch of first-generation pest control biotechnologies.

Trait category	Survey 1: Highest stage attained by 2004							Survey 2: Expected commercialization		
	Publication only	Field trials: Initial (1-3)	Field trials: Mid-stage (4-9)	Field trials: Late-stage (≥10)	Regulatory	Commercialized	**Total for Survey 1**	by 2010	2010-2015	**Total for Survey 2**
Proteins and amino acids	33	47	12	7	1	0	**100**	8	6	**14**
Oils and fatty acids	15	22	8	5	2	1	**53**	4	4	**8**
Carbohydrates and sugars	32	65	16	10	0	0	**123**	2	1	**3**
Micronutrients and functional metabolites	47	15	3	1	0	0	**84**	0	2	**2**
Reduced non-nutrients, allergens, or toxins	18	6	0	2	0	1	**9**	3	0	**3**
Ripening, freshness, or shelf life	19	41	10	6	5	2	**83**	4	3	**7**
Esthetics and convenience	15	21	5	2	1	1	**43**	0	3	**3**
Fiber quality for digestibility and pulping	22	16	5	1	0	0	**44**	5	1	**6**
Plant bioremediation	2	8	0	0	0	0	**12**	0	0	**0**
Multiple or unspecified quality traits: ‘seed composition’ and ‘feed quality’	0	2	2	3	0	0	**7**	2	1	**3**
Total	**203**	**243**	**61**	**37**	**9**	**5**	**558**	**28**	**21**	**49**

Table 1. Surveys of actual and expected progress in ten categories of transgenic product quality innovation. The first survey combined records from scientific publications, field trial records, and regulatory filings to identify 558 transgenic plants with quality improvements and determine how far they had progressed through stages of R&D by 2004, including: *(a)* those that had only published in the scientific literature; *(b)* those that had reached initial field trials (defined as having completed 1 to 3 field trials), mid stage field trials (4-9 field trials), or advanced field trials (more than 10); *(c)* those that had entered regulatory filings; and *(d)* those that were commercialized. The second survey canvassed expectations of firms and analysts about the likelihood and timeframe for future commercialization of transgenic product quality innovations. Complete one-to-one correspondence between individual observations of the two surveys was not possible. (See Supporting Online Materials for survey details).

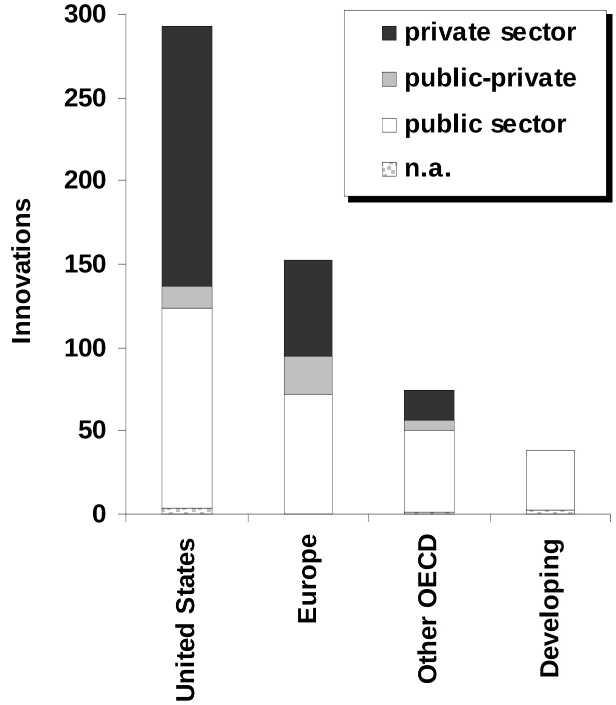

Figure 1. Location and economic sector of the organizations responsible for the 558 transgenic product quality innovations identified in Survey 1. The private sector consists of corporate and privately held firms. The public sector consists of government research agencies, universities, and non-profit research institutes. Innovations considered “public-private” involve collaboration between both types.

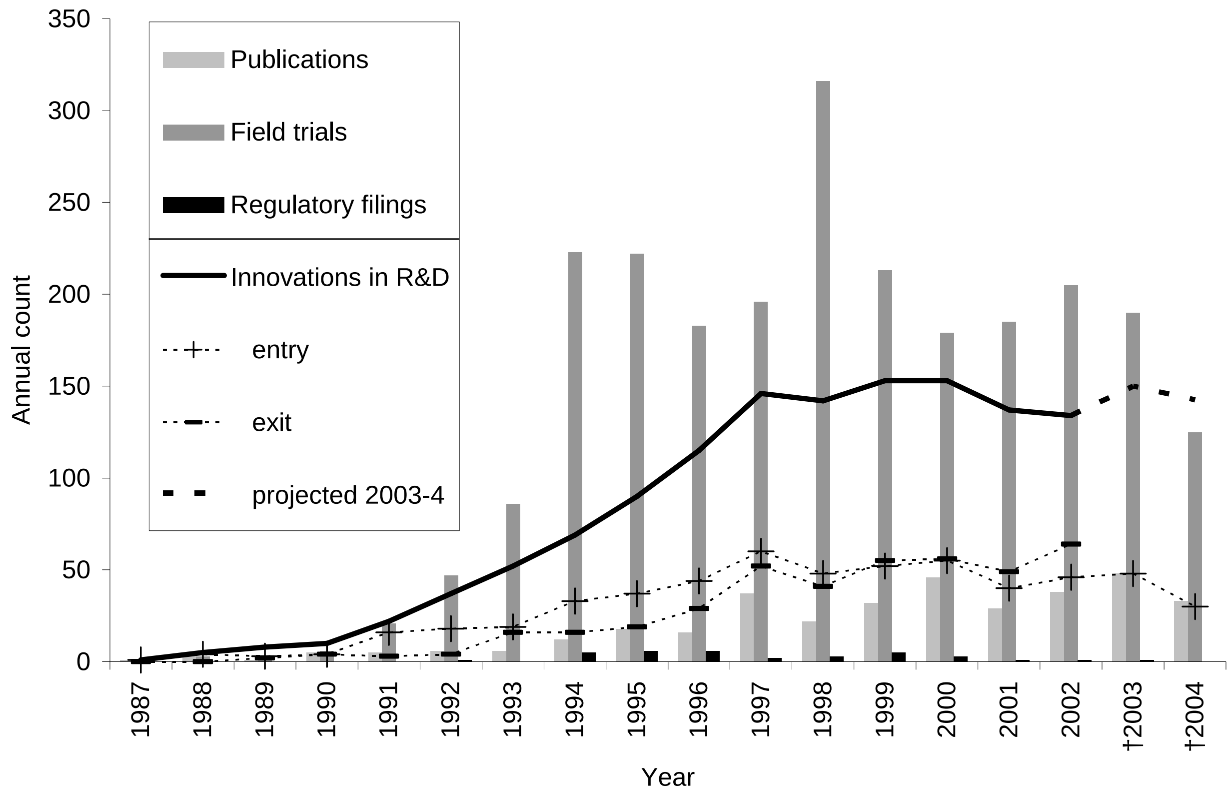

Figure 2. Annual count of product quality innovations in R&D identified in Survey 1. Annual counts of total publications, field trials, and regulatory filings, internationally, reviewed in Survey 1 are represented by the bars. For each of the 558 innovations identified based on these records, entry into the R&D pipeline is defined by the first year of documentation found for that innovation; exit is defined, conversely, by the last year of documentation found. An innovation is considered to be in R&D from its year of entry through its year of exit.

†Publications data are subject to natural truncation, most significantly in years 2003 and 2004, and field trial data are truncated from at least August 2004. The trend for innovations in R&D projected through 2004 is a mean of trends based on assumptions of 0 and 100 percent realization, respectively, of observed levels of annual exit (not shown).

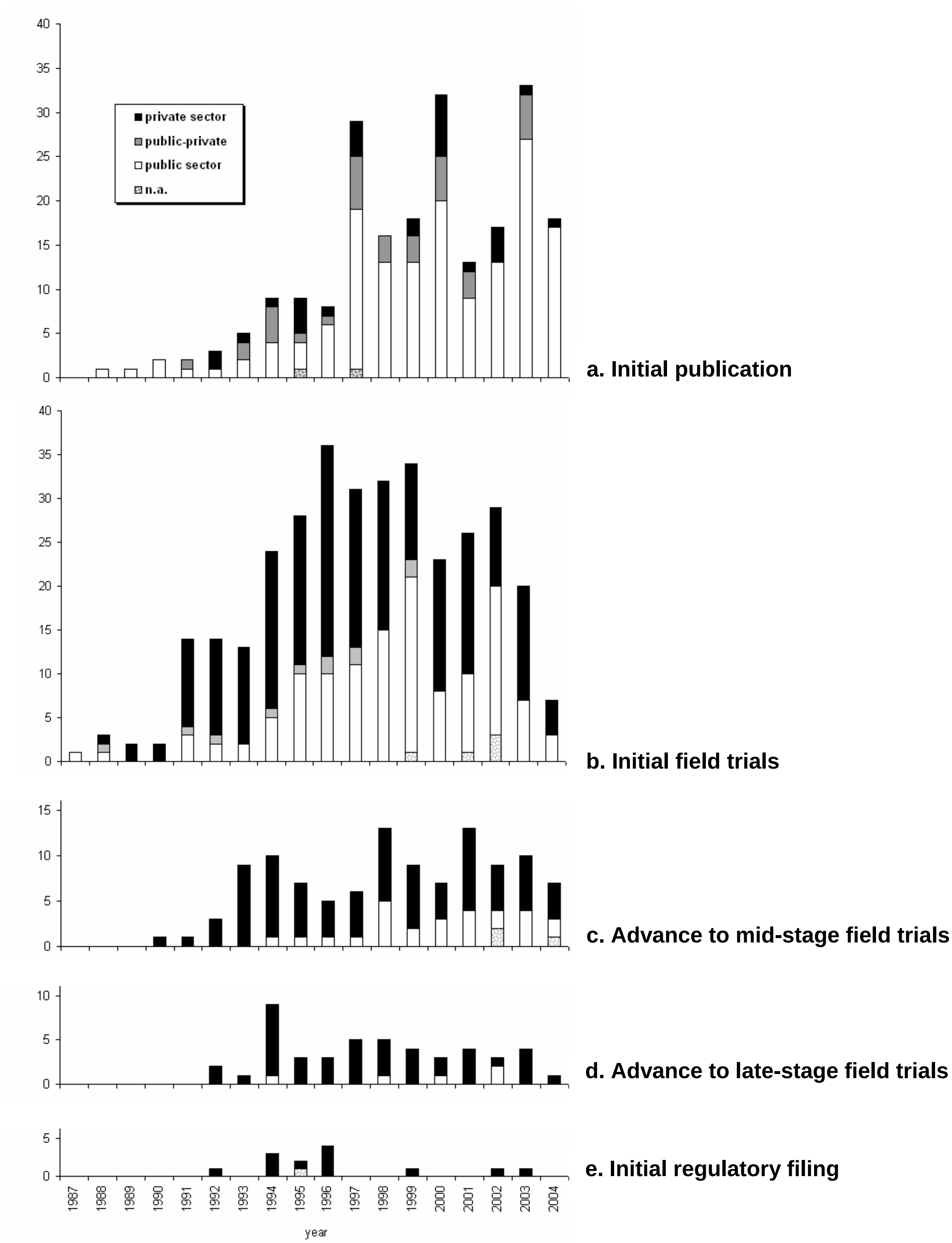

Figure 3. Annual count of product quality innovations entering each stage of R&D, as identified in Survey 1, by economic sector of the innovating organization(s). Private and public sectors defined as in Figure 1. Field trial stages defined as in Table 1.

References and Notes

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