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A decade of European field trials with genetically modified plants†

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This article analyzes the development of notifications of genetically modified plants field trials in the European Union from 1991 to 2001, based on the data collected at the European level in the Summary Notification Information Format database. During this time period, a total of 1687 field trial notifications were received. The number of field trial notifications dropped by 76% between 1998 and 2001, mainly due to the *de facto* moratorium in place since 1999. Input traits (77%) dominated the field trial notifications during the last decade, while output traits were relevant in only 18% of all notifications, with a decreasing relevance during the last six years. In particular, field trial notifications on molecular farming were almost absent in the EU. Large companies focused their field trials on crops with a high grown area in the European Union and resistance traits, while public institutions showed interest in a large diversity of plants and traits. Finally, some conclusions on future impacts of the results of the study are drawn in this article.

Keywords: genetically modified plants / European Union / field trial notifications / EU SNIF database

INTRODUCTION

In 2002, genetically modified (GM) plants were grown on an estimated area of 58.7 million hectares worldwide (James, 2002). The global adoption rate of GM crops — the main ones being maize, soybean, cotton, and oilseed rape — is among the highest for any new technology in agriculture (Nap et al., 2003). In Europe, the situation is static, with only minor areas of GM crops grown, 25 000 ha of *Bt* maize in Spain, and a *de facto* moratorium in place since October 1998 on any new authorization for marketing of GM plants. Currently, the European Commission has received 21 notifications (as of September 23rd 2003) under part C of Directive 2001/18/EC (amending Directive 90/220/EC). Seven of these are products that were pending under Directive 90/220/EC at the time of its repeal (European Commission, 2003a).

Prior to commercialization of GM plants, 8–12 years of research and development are needed. GM crops are first developed in the laboratory (for example, identifying the desired gene, isolating it, inserting or suppressing it and *in vitro* tests), then tested in experimental field trials. Field trials are a prerequisite step when applying for market approval. The aim of the field trials is to test, in small-scale experiments and in a natural environment, the stability of the inserted gene, the characteristics of the GM crop variety compared to other GM varieties or to conventional ones and, most importantly, to assess any potential risk to human health, animal health and the environment. The information obtained from field trials constitutes a core part of the information submitted to the regulator for safety assessment. Therefore, it often represents a long and expensive stage in the development process of a GM plant.

In the European Union, before undertaking a field trial with a GMO, a notification shall be submitted to the competent authority of the Member State within whose territory the release is to take place. According to Article 9 of Council Directive 90/220/EEC (amended by

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Directive 2001/18/EC), the competent authorities of the Member States of the European Union send to the European Commission (the Joint Research Center at Ispra) a summary of each notification received (SNIF: summary notification information format). The information is gathered in the SNIF database, which is updated weekly[1]. The EU SNIF database provides an overview of all notifications circulated so far among Member States since the implementation date of Directive 90/220/EEC (October 21st, 1991). Since the entry into force of Directive 18/2001/EC in October 2002, and in respect with Article 25 of Directive 18/2001/EC, the European Commission makes available to the public the information contained in the SNIF, the assessment reports of the competent authorities or the opinion of the scientific committees (European Commission, 2003a).

In a recent report of the European Commission (Lheureux et al., 2003), the different stages of development of GM plants (from research and development, experimental field trials up to the request for market authorization) have been analyzed and the results have been used to classify GM plants under three different time-periods of potential future commercialization in Europe. For the purpose of this study, the EU SNIF database (version February 2002) was analyzed in depth. In this article, we present the results of the analysis of the SNIF database for European GMO field trial notifications.

Methodology

The EU SNIF database for GMO field trial notifications was analyzed in detail, taking into account the information included as of February 2002. To harmonize the analysis, the traits were grouped into 11 categories. No suggested categorization of traits was pre-existing in the SNIF database, therefore it was necessary to go through all the summary notifications one by one, identify the trait(s) inserted, and group them into the 11 different categories that had been defined for the purpose of the study. The following categories were used throughout the study:

(i) input (agronomic) traits: herbicide tolerance, insect resistance, resistance to other pathogens (including fungi, bacteria, viruses, and other species), abiotic stress/yield, male sterility, and other input traits;

(ii) output (quality) traits: modified nutrients/ingredients, industrial use, health-related compounds (molecular farming), and other output traits;

(iii) markers and other traits.

A list of traits (without categorization) is now available at the JRC website[2]. Following the same process, notifiers were classified into five groups: large companies (more than 500 employees), small and medium-sized enterprises (SMEs, less than 500 employees), universities, public research institutes, and other actors (such as cooperatives). The statistical analysis of the EU SNIF database was performed using the program for statistical analysis (SPSS) (version 8).

Several assumptions were necessary in order to perform a meaningful analysis of the database: when a notification document includes several locations over a period of several years, it is assumed that the field trial is carried out each year and therefore the number of field trial notifications for the whole time-period is higher than the current number of notifications (total of 1687 notifications to February 2002). In case a notification included several plants and/or traits, crops and traits were counted separately: therefore, the total number of traits and crops exceeds the number of notifications. Finally, we have assumed that all field trials notified were effectively carried out for the time-period for which the notification document is valid.

RESULTS

General trends

The total number of GM plant field trial notifications in the EU was 1687 (up to February 2002). Analysis of the annual number of field trial notifications of GM plants in the EU from 1991 to 2001 reveals a drastic drop of 76% between 1998 and 2001 (Fig. 1). In 2001, the Joint Research Center received only 61 notifications[3] for field trials with GM plants. This slowdown is generally regarded as an effect of the 1999 decision of the EU Council of Environment Ministers to block any new

[1] Available at http://biotech.jrc.it. GMO releases notified under Directive 2001/18/EC can be consulted on the new website http://gmoinfo.jrc.it

[2] http://gmoinfo.jrc.it/

3 This study refers exclusively to GM plants and does not include field trials with other organisms. This explains the difference in the number of field trial notifications estimated at 88 for the year 2001 in a communication of Commissioner Busquin (European Commission 2002b) (http://food.jrc.it/gmo/index.htm).

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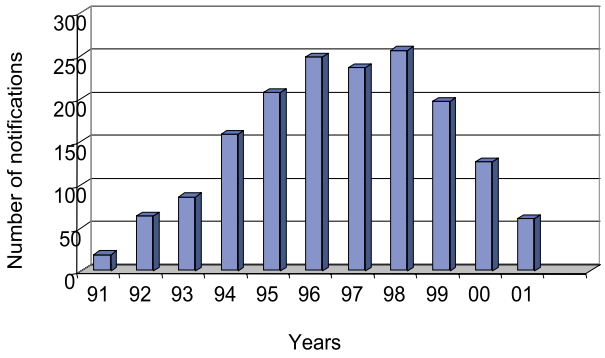

Figure 1. Annual number of field trial notifications for GM plants in the EU between 1991 and 2001.

commercial release of GMOs[4], as well as the widespread tendency of the European public to reject GMOs (Lheureux et al., 2003). The recent results of the *Eurobarometer* 'Europeans and biotechnology in 2002' confirms the widespread lack of consumer acceptance in plant biotechnology, contrasting with a strong support for medical uses (Gaskell et al., 2003).

In contrast to the decline in field trial notifications in Europe, the number of authorizations for GMO field trials in the USA is on the rise (APHIS, 2002). In the USA, over 8400 field trials have been registered since 1987 (APHIS, 2002). A direct comparison between the numbers of notifications in the EU and the USA is not feasible, due to differences in how the data is collected. The US system requires a notification for every year, while EU notifications can cover trials lasting more than one year. Nevertheless, when taking into account the average field trial duration in the EU of 2.6 years (Lheureux et al., 2003), it is still clear that the negative trend found in annual notifications in the EU since 1999 does not exist to the same extent in the USA.

In many non-OECD countries in Asia, Africa and South America, the number of field trials is also increasing (Nap et al., 2003) with China having the largest plant biotechnology research capacities outside the USA (Huang et al., 2002).

[4] In June 1999, a *de facto* moratorium was initiated by the EU Council of Environment Ministers: several ministers (from Denmark, Italy, Luxembourg, France, Greece, joined by Germany and Belgium in October 2001) agreed to suspend all approval applications for GMOs until the implementation of the revised Directive 90/220/EEC, to provide a stricter legal framework covering not only safety, but also labelling and traceability of GMOs.

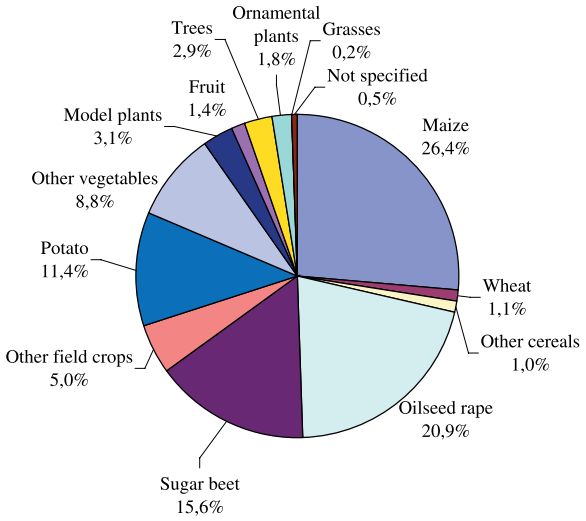

Figure 2. Distribution of crops in field trial notifications with GM plants between 1991 and 2001. Total number[5] of crops: 1748.

With more than 500 notifications, France accounted for almost one third of the total number of EU notifications, followed by Italy (272), the UK (209) and Spain (180). The average duration of a notification is 2.6 years, with 80% of the notifications having a duration of less than four years (except Austria, Germany, Ireland and the Netherlands with an average duration of more than four years). Almost 60% of the notifications referred to one single location, while references to more than five locations on average were found in notifications originating from France, Ireland and the Netherlands.

Types of crops

It emerges from the analysis that field trial notifications with GM plants in the EU cover a large diversity of crops and traits. However, four crops (maize, oilseed rape, sugar beet and potato) dominate and account for 75% of all field trial notifications (Fig. 2).

[5] Some notifications include more than one crop so the total number of crops is higher than the total number of notifications of 1687. Other cereals include barley, buckwheat, rice and rye. Other field crops include cotton, coffee, cowpea, flax, fodder beet, mustard, peanut, soybean and sunflower. Other vegetables include asparagus, aubergine, bean, broccoli, cabbage, carrots, cauliflower, celery, chicory, cucumber, fennel, horseradish, lettuce, mint, olive, pea, pepper, radish, squash, tomatoes, yam and winged bean. Model plants include tobacco and *Arabidopsis thaliana.*

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Table 1. Type of traits of main crops in the EU field trial notifications (1991–2001).

Trait category	Traits	Maize	Wheat	Oilseed rape	Sugar beet	Potato	Tobacco	All crops
Herbicide tolerance	Herbicide tolerance	378	13	311	261	5	13	1124
Insect resistance	Insect resistance	211		4		26		289
Resistance to other pathogens	Fungi resistance	5	2	34	6	45	5	145
	Bacteria resistance			1	1	10		14
	Virus resistance	4			68	33	4	175
	Resistance to other species			1		6	2	10
Abiotic stress / yield	Resistance to abiotic stress	6		10	5	5	5	39
	Yield influencing factors	6		3	6	15	9	64
Male sterility	Male sterility	31	1	119	5	2	1	212
Modified nutrient / ingredients	Antinutritive ingredients	1		4			8	17
	Enhancement of nutritional value	7		4	1	2	2	25
	Fatty acid metabolism			32				35
	Protein metabolism	2		6	3	3		22
	Oligosaccharides metabolism	2		2	14	22		45
	Starch metabolism	7	5	2	8	146		169
Industrial use	Food processing		3			17		41
	Non-food applications	2		28			2	43
	Enzyme production	4		2		2	10	19
Health	Health-related compounds (molecular farming)	6					9	16
Other output traits	Modification of colour/form	3				3	3	21
	Modification of ripening		1	2		7		49
Marker / other traits	Marker	1	2	4	5	11	2	77
	Other traits	1	1	4	2	2	2	27
Total number of notifications		677	28	573	385	362	77	2678*

* Several notifications have more than one trait. Therefore, the total number of traits in this analysis is higher than the number of notifications.

When considering the evolution in field trial notifications during the last 10 years, maize, oilseed rape, potato and sugar beet were the dominant crops during the decade, while tomato, tobacco, fodder beet and cotton were present, but less represented between 1991 and 1998, and even almost completely disappeared between 1998 and 2001. On the other hand, wheat and chicory have had a limited but constant presence during the last five years.

The review of the EU SNIF database shows few projects on GM cotton (1.7% of all notifications, mainly in Spain). This is mainly due to climatic conditions that limit the growing of cotton to certain regions in Europe (primarily Greece and the south of Spain). Nevertheless, an important development of GM cotton might be expected in Europe, since three notifications for the placing on the market (part C) of GM cotton are listed in the new EU-JRC SNIF database (C/ES/99/01, C/ES/96/02 and C/ES/97/01). Outside Europe, an increasing number of GM cotton varieties are approved for commercial use in the USA, China, India, South Africa, Argentina and other countries (Whitfield, 2003). China has the highest year-on-year percentage growth with a 40% increase in its *Bt* cotton area between 2001 and 2002, corresponding to 51% of the national cotton area (James, 2002).

Types of traits

The type of traits of the main crops used in the EU field trial notifications with GM plants for the period 1991–2001 is presented in detail in Table 1. We can observe

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that, over the period 1991–2001, input traits (2072 notifications) were more prevalent in field trial notifications compared to output traits (502 notifications) (77 *versus* 18% respectively). Of the 77% of field trial notifications which refer to input traits, 66% of all traits tested concerned 'resistance' traits, including herbicide resistance (42%), insect resistance (11%) and other pathogen resistance (13%). This relates in particular to GM plants with a high potential cultivation area, and thus a large volume of seed markets in the EU like maize, wheat, oilseed rape or sugar beet (Tab. 1). Some field trials with resistance traits were conducted for potential environmental implications. Crops with a high risk of gene flow, such as maize, oilseed rape and sugar beet (Bock et al., 2002; Eastham and Sweet, 2002; Tolstrup et al., 2003) are targets of intensive safety research for evaluating environmental and agronomic risks (Conner et al., 2003; Kessler and Economidis, 2001).

Output traits like modification of nutrients/ingredients, change in color/form and ripening, changing characteristics for industrial uses and GM plants for the production of health-related compounds (molecular farming) accounted for 18% of all notifications. This rather small percentage of notifications shows that the development of output traits is still in the early phase of research and development. Other reasons to explain the low number of field trial notifications with an output trait might be technical and economic difficulties (due to the high cost of production and identity preservation) (Arundel, 2002). Crops with specific output traits (that is, quality traits) have already been obtained through traditional breeding methods, but are not widespread so far due to their high cost of production. GM technology provides a new tool for achieving the same goal more quickly, but might generate additional costs (Arundel, 2002).

Evolution in time

For the period 1995–2001, we have observed a decline in the number of field trial notifications with output traits, especially for modified nutrients/ingredients (such as starch and fatty acid metabolism) and modifications for non-food industrial uses (Fig. 3).

This phenomenon is observed in the USA as well, indicating the specific difficulties associated with the development and marketing of GM plants with output traits (Arundel, 2002). For their future perspective, this implies that the presence of GM plants with output traits at a commercial level in Europe should be considered with reserve, as very few potential products are in the pipeline for the coming years. As evidence, among the

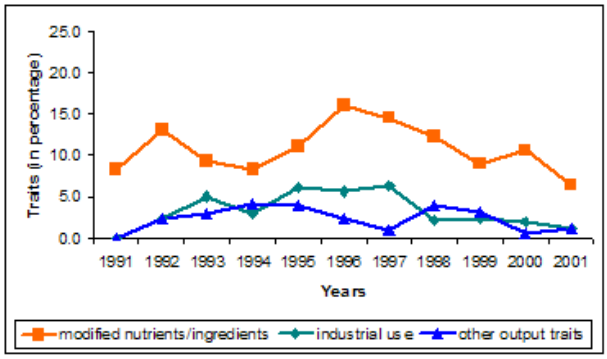

Figure 3. Share of GM Plant field trial notifications for certain output traits between 1991 and 2001.

23 notifications (as of September 23rd 2003) for placing on the market according to part C of Directive 18/2001/EC, only one deals with output traits (C/SE/96/3501 potato with altered starch composition for cultivation and production of starch).

Molecular farming

Health-related compounds in GM plants (molecular farming) are almost absent from EU field trial notifications. No more than 16 field trials involving this trait category have been notified in the EU for the period 1991–2001. Traits included are the synthesis of albumin, antibodies, collagen, human alpha-1 antitrypsin, glucocerebrosidase protein, lactoferrin, putrescine methyl transferase, and rabies virus G glycoprotein cDNA synthesis. Industrial enzymes are not included. This is a significant difference compared to the development of GMOs in the laboratory (R & D phase) where 11% of projects involve traits with health-related compounds (Lheureux et al., 2003). Thus, R & D activities in this field in the EU are limited to the early phase of development of GMOs, and often check the feasibility of the approach in model 'factory' plants (such as tobacco). Nevertheless, the European Agency for the Evaluation of Medicinal Products (EMEA) is considering the new development of molecular farming, and has issued a concept paper offering guidance on 'quality-related points that should be considered by applicants proposing to market medicinal products with pharmacologically or immunologically active substances produced in transgenic plants' (EMEA, 2001).

This situation is to be compared with the USA where 198 permits/acknowledgements for GM plants with health-related compounds (corresponding to 315 outdoor field trials with an average size of two hectares) were

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Table 2. Combination of traits in field trial notifications for the main GM crops (1991–2001).

Crop	Combined traits	No of field trial notifications
Maize	Herbicide + insect resistance	132
	Herbicide tolerance + male sterility	29
Oilseed rape	Herbicide tolerance + male sterility	114
	Herbicide + fungi resistance	8
	Modification of fatty acid composition + industrial use	22
Sugar beet	Herbicide + virus resistance	24
Potatoes	No dominating combination of traits	

issued by the US Department of Agriculture (USDA) on a case-by-case basis between January 1991 and June 2002. The majority of the field trials were carried out between 1999 and 2002, indicating that interest has increased in the last three years (Freese, 2002). The Food and Drug Administration (FDA) and USDA (FDA, 2002; USDA, 2002, 2003) have already released draft documents that provide a set of points to consider to demonstrate the safety and effectiveness, but also the environmental issues and the confinement measures adopted for products produced by molecular farming. These guidance documents demonstrate the willingness of the US government to facilitate the development of this field into a commercial sector. The difference between Europe and the USA is significant. Europe might engage more in this field as this emerging technology seems likely to have significant impacts on basic research as well as on the pharmaceutical, agricultural and biotechnology industries (USDA, 2002). In March 2003, the USDA produced a document strengthening the permit conditions to field test plants genetically modified to produce pharmaceutical and industrial compounds (USDA, 2003).

Stacked traits

Several traits can be 'stacked' into a GM plant by genetic engineering approaches or by conventional crosses between GM varieties (in this context, a trait used as a marker gene is not regarded as a 'stacked' trait). It is very probable that the presence of stacked traits in European field trial notifications will increase in the future. Worldwide, two crops (cotton and maize) with stacked traits for herbicide tolerance and insect resistance represented 8% of the global production area with GM plants in 2001. This percentage has been increasing regularly in the last few years, being 6% in 1999 and 7% in 2000. This increasing trend is expected to continue in the coming years (James, 2001).

In the EU, even if the parental GMO lines have been considered and approved for commercialization, a GMO in which two traits are combined by traditional breeding is considered a new GMO and thus needs a new authorization process. The EU Scientific Committee on Plants released in 2000 a positive opinion on the cultivation in Europe of the first GM maize variety with stacked traits in the EU (T25 and MON810) (C/NL/98/08 from Pioneer (now Dupont), insect and herbicide tolerant). The application has been withdrawn, but since the entry into force of Directive 18/2001/EC, applications for several GM maize lines with stacked insect and herbicide tolerance traits have been presented (European Commission, 2003a).

When several traits are mentioned in one notification document, the SNIF database does not inform whether these are stacked genes or whether they refer to several independent GMOs. Therefore, we have analyzed all notifications that refer to more than one trait. The analysis shows that 33.6% of the notifications refer to two traits and 8.4% refer to three traits. From these numbers, some experts estimate that the share of field trials with stacked traits notified in the EU SNIF database does not exceed 15% (Arundel, 2002). The most common combinations of traits are input traits, such as herbicide tolerance/insect resistance in maize, and herbicide tolerance/male sterility in oilseed rape (Tab. 2). Sugar beet is mainly modified to include herbicide tolerance/virus resistance.

In the USA, if each trait inserted in a specific plant has been found safe by the regulatory bodies, then the GM plant with the stacked genes does not need a new risk assessment. It can be submitted for commercialization based on the information provided for each individual trait. The Animal and Plant Health Inspection Service (APHIS) database of GMO field trials gives limited information on stacked genes. Field trials with two stacked genes are the most common (for example, on maize herbicide/insect resistance), and only very few field trials

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Table 3. Distribution of GM crops per actor groups between 1991 and 2001 (in percentage).

Plants	SME*	Large company	Public research institute	University	Total
Maize	17.9	30.0	5.8	5.7	26.5
Wheat	0.0	0.5	3.3	0.0	1.1
Other cereals	3.6	0.2	5.4	2.3	1.1
Oilseed rape	13.4	22.6	14.2	24.1	20.8
Sugar beet	7.1	20.8	3.8	9.2	15.3
Other field crops	4.5	10.7	1.7	0.0	7.5
Potato	25.0	6.7	21.3	16.1	10.1
Tomato	8.9	3.1	11.3	1.1	4.4
Other vegetables	8.9	1.7	10.8	5.7	4.7
Model plants	2.7	2.5	1.3	11.5	3.2
Fruit	0.0	0.5	5.0	19.5	2.0
Trees	0.9	0.5	7.1	3.4	1.4
Flowers	7.1	0.2	9.2	1.1	1.7
Grasses	0.0	0.2	0.0	0.0	0.1
Total number of notifications	**112**	**1276**	**240**	**87**	**1972****

* SME: Small and Medium Enterprises.
** Several notifications have more than one notifier. Therefore, the number of plants in this analysis is higher than the number of notifications.

were found with three or more traits. The most common combinations of traits are herbicide tolerance/insect resistance in maize, herbicide tolerance/modification of nutrients/ingredients (starch for maize, protein for oilseed rape), and herbicide tolerance/male sterility in maize and oilseed rape. Recent data on the adoption of GM crops in the US (ERS, 2003) indicates that stacked cotton (herbicide tolerant and *Bt* traits) accounts for 27% of the cotton planted in 2003 and stacked maize (herbicide tolerant and *Bt* traits) represents 4% of maize planted in 2003. GM Plants with two *Bt* genes are also being used (cry1AC and cry2Ab from Monsanto (Monsanto, 2002a)). Another case is GM cotton in Australia (Monsanto, 2002b). A further classic example is potato for virus resistance/insect resistance.

Activities of different actor groups

In the EU, the main actors in field trial notifications with GM plants are large companies, accounting for 65% of all notifications. Small and medium enterprises (SMEs), public research institutes and universities are less well represented with 6%, 12% and 4% of all notifications, respectively (other actors, 13%). The distribution of crops and traits per actor group is presented respectively in Table 3 and Figure 4.

Large companies focus their field trials on crops with a high grown area in the EU with 73% of field trial notifications carried out in three crops (maize 30%, oilseed rape 22.6% and sugar beet 20%) while universities and research institutes show interest in a large diversity of plants (*e.g.*, tomato, model plants, fruits, flowers and trees).

The private sector includes large companies and SMEs. Of all the field trial notifications in this group, 68% involve resistance traits (herbicide, insect, other pathogens) and 23% output traits. SMEs present a broader spectrum of applications and give relatively more importance to output traits (16.2% involving modified nutrients/ingredients compared to 8.9% for large companies). This can be explained by the business strategy adopted by SMEs in plant biotechnology, in which they are looking for products with a potential niche-market, acting also as the gatekeeper between universities and large firms.

The public sector includes universities and public research institutes. Of all their field trial notifications, 44% involve resistance traits, 31% output traits and 13% markers/other traits. In contrast to private companies, public research institutes and universities show less interest in field trials with the classic input traits (herbicide tolerant and/or insect-resistant plants), and more interest in GM field trials related to resistance to

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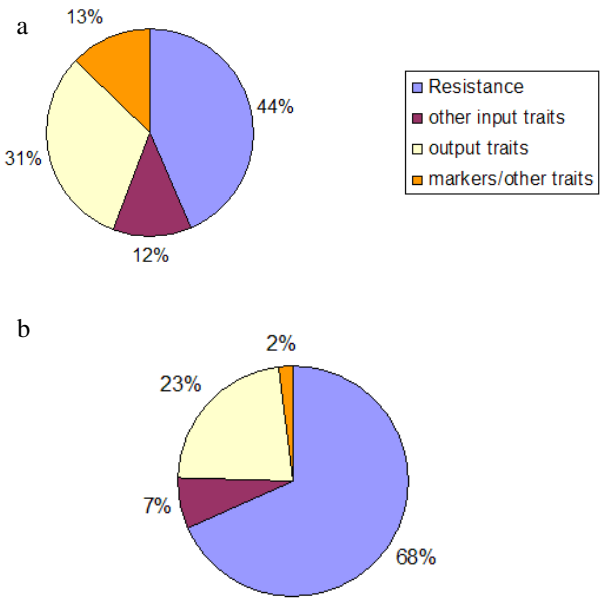

Figure 4. Distribution of traits[6] in field trial notifications by the public sector (a) and the private sector (b) between 1991 and 2001.

other pathogens, and GM field trials with output traits, abiotic stress/yield and genetic markers.

DISCUSSION AND CONCLUSIONS

This study has shown a drastic decrease in the number of field trial notifications for GM plants since 1996 (76% decrease). What could be the future impact on activities of a prolonged slowdown of the research and development field trial for agricultural GMOs in the EU? (i) New GM varieties and applications might not be expected in the short term; (ii) SMEs, which have already scaled down their GMO-related R & D programs, will restrain or stay in stand-by mode for this technology and most probably will not engage in new innovative plant biotechnology research. This limits the capacity of 'recovery' of research activities after a prolonged slowdown; (iii) in the current context of uncertainties, large biotech companies will continue relocating their research, conducting GMO field trials, and commercializing new GM plants outside of the EU. Without field trials being carried out in the EU, many request for authorization for GM plants in the EU would be for import and processing only; (iv) it can be expected that young researchers in plant biotechnology might move away from Europe to the USA to conduct their research, resulting in a possible 'brain drain' of Europe's most promising scientists (Mitchell, 2003). And finally (v) outside Europe, the interest for GM technology has not abated, and many applications of this new technology in agriculture can be found in research (The Pew Initiative, 2001), and being followed-up by field trials experiments. Without proper and complete research into GMOs, Europe risks becoming dependent on key technologies developed elsewhere (European Commission, 2003b; Hellemans, 2003).

A recent analysis of the performance of scientific publications in different subfields of biotechnology (Reiss and Dominguez Lacasa, 2003) combined with the findings of Lheureux et al. (2003), shows that the unclear legal situation with respect to the commercialization of GMOs which emerged in the second half of the 1990s led to the cutting-down of research activities in plant biotechnology, which can be measured as decreasing scientific output. In more general terms, the unclear legal situation related to GMOs on the commercial side seems to have a negative feedback on the science base. This could give cause for concern that, once the legal environment becomes more stable and/or more favorable for the marketing of GMOs, the EU knowledge base would be less prepared to provide the required know-how.

[6] Resistance traits: herbicide tolerance, insect resistance, other resistance (such as fungi, nematode). Other input traits: abiotic stress/yield characteristics, male sterility. Output traits: modified nutrients/ingredients, industrial use, health-related ingredients, other output traits.

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