Chapter 2
HTV Diffusion and Use

The previous chapter (see Sect. 1.4) described the principal HTVs currently available for use by farmers. Chapter 2 will characterise these varieties' global diffusion and the economic and regulatory contexts relating to their use.

This chapter consists of four sections. The first section presents statistics describing the scale and scope of HTV adoption, geographically and over time. These data are partial, however, and relate primarily to transgenic HTVs cultivated in North America.

The next section describes the range of arguments advanced to explain the adoption of HTVs by farmers. Expected advantages and disadvantages of HTV adoption are identified within the information offered by the firms developing and commercialising them, within the guidelines offered to farmers by agricultural advisory services, and within the data drawn *a posteriori* from field trials and surveys.

The massive adoption of transgenic HTVs in the United States having been the focus of the most complete analyses, a third section is dedicated to this topic. Taking this as a case study, we can identify the commercial strategies of companies involved in HTV development, the reasons given by farmers for their use of HT seed, and the consequences of this choice in terms of herbicide use. The limits of this example, however, must be borne in mind when seeking to transpose these results to the French context.

A fourth section will present the specific social and legal contexts of HTV adoption in Europe.

2.1 HTV Adoption Worldwide

At the global level, the most highly developed HTVs at the present time (in terms of the range of varieties available to farmers and total area under cultivation) are those tolerant to a non-selective herbicide, making possible in theory the elimination of all weeds in a single pass. As a result, transgenic varieties tolerant to glyphosate have

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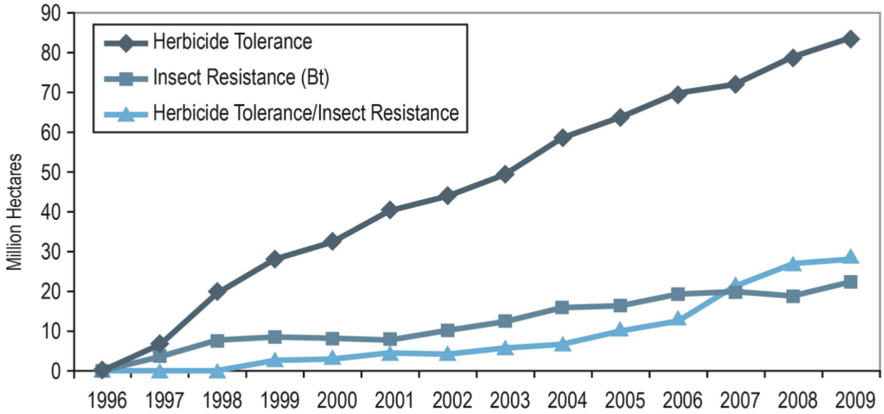

Fig. 2.1 Global area (Mha) planted to transgenic varieties by trait, 1996–2009 (Source: ISAAA, Global Status of Commercialised Biotech/GM Crops, 2009)

been the example considered by the majority of scientific papers on the subject, including studies of farmers' adoption of these varieties. Only one long-term statistical comparison of the adoption of varieties tolerant to a non-selective herbicide, adoption of varieties tolerant to a selective herbicide, and adoption of non-HT varieties was found in the literature.

2.1.1 Adoption of Transgenic Varieties Tolerant to a Non-selective Herbicide

The data supporting this section come from two reports reviewing, respectively, the state of adoption of transgenic varieties worldwide and the results of their use in the United States.

2.1.1.1 Global Data

The HT trait has been the most widespread trait present among transgenic varieties worldwide since their introduction in 1996 (Fig. 2.1): HTVs accounted for 83 % of the total global area planted to transgenic crops in 2010, or approximately 122 million hectares (Mha) (including varieties possessing one or several transgenic traits), located primarily in the United States, Argentina and Brazil.

The range of transgenic HT varieties available varies by crop. The principal species for which transgenic HTVs have been developed are soybean, maize, cotton and oilseed rape.

These varieties are tolerant to glyphosate (the Roundup Ready®, or RR® range), or more rarely glufosinate (the Liberty Link®, or LL® range, currently the only

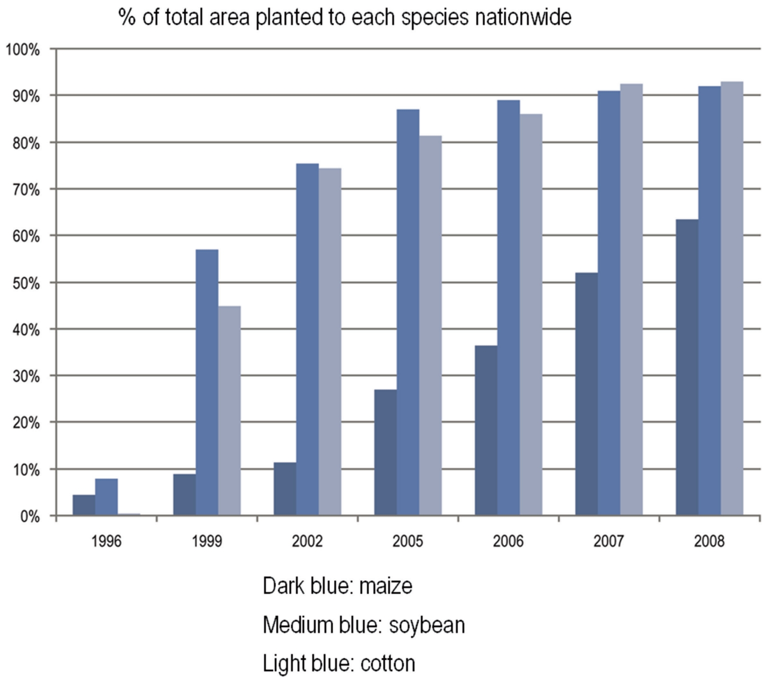

Fig. 2.2 Percentage of total crop area planted to transgenic HTVs in the United States for maize, soybean and cotton, 1996–2008

transgenic competitor to RR®). RR® soybean is emblematic of transgenic HTVs' commercial success over the past 15 or so years: in 2010, 81 % of global soybean area was planted to HT varieties. Among the three leading countries, RR® varieties represented 99 % of total soybean area in Argentina, 93 % in the United States and approximately 75 % in Brazil.

2.1.1.2 Specific World Regions

A recent review of 13 years of transgenic crop cultivation in the United States describes the change over time in the percentage of total crop area planted to HTVs for the three principal crop species (Fig. 2.2).

Herbicide-tolerant soybean, cotton and maize were introduced in the United States in 1996, representing in that year fewer than 3 Mha. Their cultivation spread extremely rapidly, attaining close to 53 Mha in 2008. While bromoxynil-tolerant cotton was cultivated from the mid-1990s until 2004 (when it was withdrawn from the market), the vast majority of the three HTVs represented in Fig. 2.2 are RR® varieties.

Sugar beet offers an example of particularly rapid HTV adoption. Roundup Ready® sugar beet has seen the most rapid adoption of all transgenic varieties in the United States, reaching 59 % of total sugar beet area in 2008 (its second year of cultivation) and 95 % in 2010. Introduced simultaneously in Canada, it showed a similar expansion in that country (over 59 % of total sugar beet area in 2008, 96 % in 2009).

Finally, a single study concerning the cultivation of varieties tolerant to a non-selective herbicide in Europe was found. Up until 2006, more than 100,000 ha of RR® soybean were cultivated in Romania. Upon its entry into the European Union in January 2007, however, Romania was forced to abandon cultivation of this non-approved crop in the EU.

2.1.2 Adoption of HTVs Developed Via *Mutation and Tolerant to a Selective Herbicide*

Varieties tolerant to a selective herbicide have seen relatively limited diffusion up to this point. The majority of these varieties are tolerant to ALS inhibitors: this includes all the varieties in the Clearfield® range, tolerant to imidazolinones (maize, wheat, rice, oilseed rape, sunflower), as well as STS® soybean, tolerant to sulfonylureas. The first ALS inhibitor-tolerant varieties appeared on the market in 1992.

Data describing their adoption and diffusion over time and space are extremely rare. One market study estimated their global surface area at approximately 2.4 Mha in 2007, equal to 2.5 % of the global cultivated area planted to all HTVs regardless of breeding technique.

In the United States, USDA statistics record wheat varieties planted for a number of states. These data show that in 2011, Clearfield® varieties accounted for 32 % of the area planted to soft winter wheat in Oregon, 23 % in Washington, and 5 % in South Dakota.

In Europe, available figures come for the most part from the Web sites of the companies developing the HTVs, and who present estimates of the total area planted or expected to be planted to a given crop. The only statistical data on current adoption rates are for sunflowers tolerant to ALS inhibitors, although details as to how these figures were obtained are not provided. Thus BASF provides on its Web site estimates of the total area planted to Clearfield® Sunflower since its introduction in various European countries (Fig. 2.3).

The French Technical Centre for Oilseed Crops and Industrial Hemp (Cetiom[1]) claims that the area planted to Clearfield® sunflower (tolerant to imazamox; Pulsar 40, BASF), and Express Sun® sunflower (tolerant to tribenuron methyl; Express SX®, DuPont) reached more than a million hectares in Europe (Spain, Turkey, Greece and eastern European countries) in 2009 and close to two million hectares in 2010.

[1] http://www.tournesol-tolerant.cetiom.fr/gamme_varietale.htm

Sunflower-growing countries	Year introduced
Turkey	2003
Serbia, Spain	2004
Hungary, Slovakia, Romania,Bulgaria	2005
Ukraine, Moldova	2006
Croatia, Italy	2007
Russia	2008
South Africa	2009
Kazakhstan,**France**	2010
Czech Republic	2011

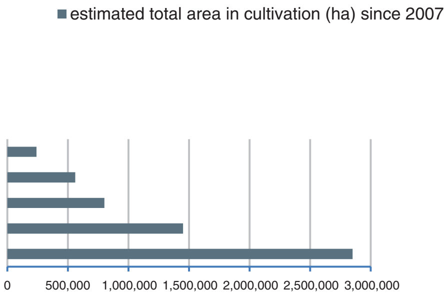

Fig. 2.3 Year of introduction into various countries and total area planted to Clearfield® Sunflower since 2007 (Source: http://www.agro.basf.fr/agroportal/fr/fr/cultures/les_oleagineux/le_tournesol/les_herbi/dossier_clearfield.html)

In France, BASF and DuPont estimate that Clearfield® and Express Sun® varieties accounted for 20,000 and 15,000 ha, respectively, in 2010, and 50,000 and 30,000 ha in 2011, or approximately 11 % of the total area planted to sunflower in France for that year.

2.1.3 HT Spring Oilseed Rape in Canada

In Canada, the range of available spring oilseed rape varieties (canola) is varied. Since 1995, three types of HT canola have been commercialised: glyphosate-tolerant (RR®), glufosinate-tolerant (LL®), and ALS inhibitor-tolerant (Clearfield®). Figure 2.4 presents data on the area planted to canola in Canada between 1995 and 2009, distinguishing between these different varietal types. How these data were gathered was not specified.

In Canada, transgenic HT canola accounts for the majority of canola hectares and has seen particularly strong adoption. Since 2003, both the total area planted to canola and the percentage of that area planted to transgenic HTVs have increased significantly. Figure 2.3 shows the dramatic reduction in crop area planted to conventional canola (notably between 1995 and 2000) upon the introduction of HT canola varieties, with conventional canola accounting for just 1 % of total canola hectares in 2009. Transgenic and non-transgenic HTVs were introduced in the same year and showed similar rates of uptake between 1996 and 1997. Adoption rates diverged from 1998 onwards, however: transgenic HTVs showing rapid adoption, while HTVs developed *via* traditional selection or *via* mutagenesis seem now to be in decline, after peaking in 2002. While the data seem to indicate a trend among varietal offerings toward varieties tolerant to a non-selective herbicide, no explanation of this trend was found in the literature.

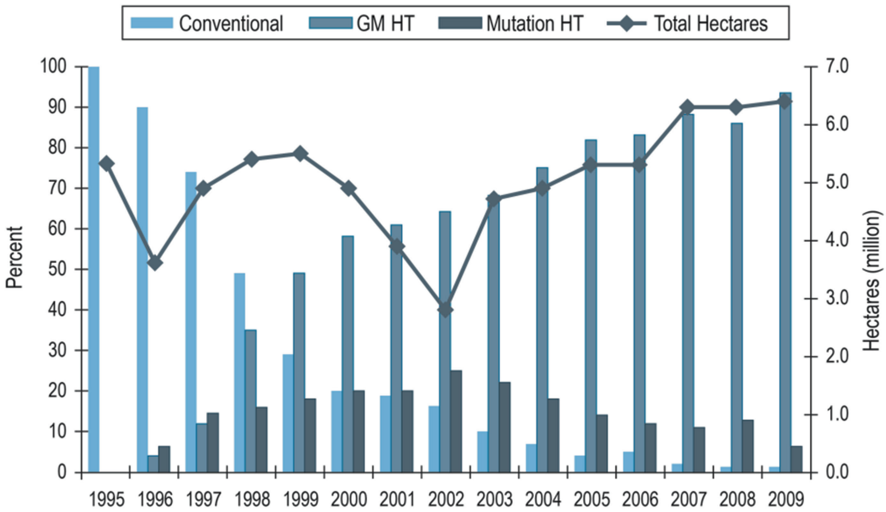

Fig. 2.4 Percentage of conventional, transgenic (RR® and LL®) and mutagenic (Clearfield®[2]) canola grown in Canada from 1996 to 2009 (and total canola area in millions of hectares) (Source: ISAAA, Global Status of Commercialised Biotech/GM Crops report, 2009)

2.2 Possible Drivers of HTV Adoption

This section describes the various advantages expected from HTVs – whether as claimed by the companies developing them, as shown experimentally, or as asserted by technical institutes or other parties. The current state of the literature does not always make it possible to specify whether a given claim has in fact been verified by actual use; and it is still more difficult to know how each of these arguments, whether backed by hard data or not, weighs in an HTV adoption decision. They are thus listed in this section without judgment as to their potential significance within a farmer's choice of HT seed, the literature reviewed not permitting such an evaluation.

2.2.1 A solution for Difficult Weed-Control Situations

Difficult weed-control situations can arise when weeds cannot be eliminated by any herbicide useable on the crop, as for example when weeds are closely related to the crop, botanically.

[2] Cultivation of Triton® oilseed rape, introduced in Canada in 1984, was discontinued in the mid 1990s.

2.2.1.1 Weeds Difficult to Eliminate with Traditional Selective Herbicides

Non-selective herbicides such as glyphosate and glufosinate make it possible *a priori* to enlarge the range of weed-control efficacy to all weeds, including those poorly controlled or not at all controlled by the selective herbicides approved for the crop. In theory, non-selective herbicides can thus prevent the development of weed species insensitive to traditional selective herbicides.

Tolerance to selective herbicides (such as ALS inhibitors) likewise enables the enlargement of the range of species controlled, complementing the action of herbicides traditionally used on the crop. This is an argument used by seed developers; some studies seeking to characterise the range of action of these HTV-associated herbicides confirm their efficacy on difficult-to-control weeds. Thus tolerance of this sort should permit the elimination of, for example:

- geraniums (*Geranium sp.*) and bur chervil (*Anthriscus caucalis*) in oilseed rape;
- jimsonweed (*Datura stramonium*), bur marigold (*Bidens tripartita*) and hedge bindweed (*Calystegia sepium*) in sunflowers tolerant to ALS inhibitors;
- green foxtail (*Setaria viridis*) and black bindweed (*Polygonum convolvulus*) in wheat resistant to imidazolinones;
- difficult-to-control warm-season grasses such as barnyardgrass (*Echinochloa crus-galli*), green foxtail and bristle grass (*Setaria spp.*) and crabgrass (*Digitaria spp.*); and perennial grasses such as couchgrass (*Elytrigia repens*) in maize tolerant to cycloxydime.

In addition to weeds causing problems in a specific crop, seed developers promote the idea that HTVs contribute to the fight against **invasive species** such as ragweed (*Ambrosia artemisifolia*), an allergenic species currently spreading across France (in cultivated areas, along roadsides, waste spaces, etc.) and already locally very abundant in the Rhône-Alpes region, particularly in sunflower fields where the use of varieties tolerant to ALS inhibitors would provide a means of controlling ragweed in cultivated fields.

Finally, field trials have shown that HTVs endowed with a target-site resistance (ALS, ACCase, EPSPS) can be used to fight against **parasitic species**, such as *Striga* in maize and broomrape (*Orobanche* sp.) in sunflower, since the herbicide does not affect the host plant but is transmitted intact, via the sap, to the parasite.

2.2.1.2 Weeds Closely Related to the Crop

Weeds belonging to the same botanical family as the crop usually respond to herbicides in the same manner as that crop, and thus are impossible to selectively destroy in conventional cultivation systems.

The emblematic example of the choice of an HTV to resolve this problem is that of oilseed rape resistant to triazines: this variety was adopted in Australia to fight against wild radish (*Raphanus raphanistrum*),a weed closely related to oilseed rape, despite the HT variety's being known to yield 15–20 % less than non-HT varieties.

Experiments show that similar problems have been resolved with Clearfield® varieties (tolerant to imidazolinones) of rice in order to eliminate red rice (*Oryza sativa*), and of wheat to eliminate jointed goatgrass (*Aegilops cylindrica*).

In sugar beet cultivation, controlling populations of weedy forms of beet belonging to the same species (*Beta vulgaris* ssp. *vulgaris*) requires recourse to mechanical weed control (two passes with a mechanical cultivator) and even manual pulling. Field experiments have shown that glyphosate or other non-selective herbicides to which transgenic sugar beets have been rendered tolerant are effective for the control of weedy beet.

Agrochemical companies and studies examining herbicide molecules' spectrum of activity likewise emphasize the efficacy of ALS inhibitors against weeds of the same family as the crop in fields of oilseed rape or sunflower. Technical guidelines distributed to farmers and underlining the need to eliminate "wild" sunflowers (see Sect. 3.1.3) advocate HT sunflowers as a tool in the fight against these weeds.

2.2.2 Reduction in Quantities of Herbicides Used

The herbicides currently chosen for association with HTVs are products used post-emergence – that is to say, on crops and weeds that are already well established. This possibility of post-emergence treatment, which did not exist for certain crops prior to the introduction of HTVs, makes it possible in theory to adapt weed-control practices to the actual level of infestation, to the distribution of weed populations (homogeneous vs. patchy), to the types of weeds present and to the level of threat they pose to the crop. HTVs should thus contribute to the elimination of "insurance" applications of pre-plant herbicides, reducing the costs of weed control. Moreover, certain of these targeted herbicides, such as glyphosate, are currently inexpensive and can be substituted for selective herbicides that are often more expensive.

This possibility of only applying herbicides as needed is likewise one of the environmental benefits anticipated from the use of HTVs. A second argument is the possibility of replacing an older selective molecule with a newer one with a better toxicological or eco-toxicological profile and a lower application rate in terms of grams of active ingredient per hectare. These two arguments are not specific to HTVs, however, but belong more generally to a set of arguments made by companies promoting the development of new herbicides or new formulations.

2.2.3 Ease of Use

The use of a single (broad-spectrum) product simplifies farmers' work, making it possible to eliminate pre-plant weed control, to no longer have to think about associating different active ingredients with complementary ranges of activity, or again to eliminate supplementary mechanical weed control. A commercial offering including multiple HTVs (for example with canola in Canada; see Sect. 2.1.3) allows farmers to choose the mode of herbicide action or application method most appropriate for their local conditions.

The fact that the crop variety tolerates the herbicide application regardless of the crop's stage of development creates flexibility in terms of application dates, makes it possible to apply herbicides under the most favourable conditions and above all increases flexibility within the farm's seasonal work schedule. In the case of sunflower, agricultural advisory services underline the fact that HTVs make it possible to treat post-emergence (previously impossible), reducing the farmer's dependence on soil moisture conditions with regard to pre-emergence treatments.

The flexibility provided by HTVs also makes it possible to avoid the problem of residual phytotoxicity from herbicides applied on a previous crop (an example in Canada is that of HT flax planted after a cereal crop, due to the persistence in the soil of sulfonylureas).

Compatibility with No-Till

The effectiveness of chemical weed control achieved in the HT system can make it possible to forego mouldboard ploughing (an operation requiring a powerful tractor operating at low speed), or even all pre-plant soil preparation, and to eliminate mechanical and/or manual weed control. The elimination of these tasks – and especially the transition to no-till – can save time, fuel and machinery costs, as well as reducing erosion in some contexts. In Argentina and the United States, the rapid parallel development of no-till systems and RR® soybean constitutes a clear illustration of the idea that a major interest of HTVs is their compatibility with the abandonment of ploughing without the risk of not being able to control weeds.

2.2.4 Yield and Harvest Quality

The realisation of higher yields can be one consequence of improved weed control resulting from the effectiveness of the active ingredient, better timing of herbicide application, the absence of a phytotoxic effect on the crop, or again from an enlarged spectrum of herbicidal activity. By permitting more effective weed control, HTVs contribute to the improvement of yields in cases where conventional methods are insufficient to ensure the control of weeds. The use of Triton® oilseed rape tolerant to atrazine is a case in point (see Chap. 1).

While the principal negative impact of weeds is their competitive effect on the crop, their elimination can also serve to protect crop quality, which can be compromised by the presence of weed seeds (as in the case of wild mustard [*Sinapis arvensis*] seeds harvested with oilseed rape, which can raise erucic acid levels above acceptable levels). This motivation is however a tangential concern evoked by certain groups only (cooperatives, producers' unions).

2.3 The North American Example: The Expansion of Transgenic HTVs and Its Consequences

The international scientific literature features a large number of peer-reviewed studies on the deployment of transgenic HTVs in the United States, the grounds for this widespread adoption and its consequences on herbicide use. The references available on non-transgenic HTVs are less numerous, primarily because the use of non-transgenic HTVs has been followed mainly by technical institutes and extension service centres, which are less likely to publish their results in scientific journals. Furthermore, the selective herbicides associated with these HTVs are not specific to such usage, making it difficult to track the evolution of their use in HT systems.

This section will thus focus on the market introduction and adoption of transgenic HTVs in the United States. The adoption of these HTVs in the North American context has been the object of farmer surveys and other research seeking to identify the motives behind farmers' HTV adoption decisions and the effects of those decisions on herbicide use, making possible an assessment of this technology over a 15-year period. The economic forces at work in the constitution of varietal offerings are less well understood, however, since the companies concerned do not make their commercial data available.

2.3.1 Marketing Strategies for HTVs

The marketing conditions for HTVs influence the nature of their adoption and spread, and thus their attractiveness for the agricultural biotechnology firms and other agro-economic actors involved. In economic terms, the particularity common to all HTVs resides in the fact that they create a link on the market between demand for the variety and demand for the herbicide to which that variety is tolerant.

2.3.1.1 Marketing Strategies for HT Seeds and Their Associated Herbicides

This question has been addressed in depth by just a few articles in the literature. A theoretical economic study examining the relationship between companies' strategic positioning with respect to the variety-development and pesticide markets on the one hand, and the development of new transgenic traits on the other, showed that the incentives to develop HTVs are stronger if a company also holds the rights to the associated herbicide. In this situation, the company can control the price of the two products and thus obtain a larger profit. And indeed, with 15 years' hindsight, we can see that HTVs (including non-transgenic HTVs) have been mostly developed by firms who are also key players on the herbicide market (e.g. Monsanto, Bayer, BASF, DuPont).

Given that HT seeds are specifically designed to be used with the herbicide to which they are tolerant, several articles analyze the marketing strategies that have been developed to link sales of the HT seed to sales of its complementary herbicide. Two forms of such linkage strategies exist: tying and bundling.

Tying requires purchasers of HT seeds (the tying product) to also purchase the associated herbicide (the tied product), making it impossible to purchase the HT seeds alone. This practice can be attractive for a company that markets an HT seed and its associated herbicide while no longer holding exclusive rights to the latter – as for example in the case of Monsanto, which currently sells RR® seeds and glyphosate, although its patent on the latter expired in 2000. Tying thus makes it possible to limit competition from potential new entrants on the glyphosate market. While examples of tying were observed in the United States with respect to glyphosate-tolerant varieties, these practices violated market competition laws and thus have been discontinued by judicial order.

Bundling consists of marketing of an "HT seed and associated herbicide" package. Purchase of the package is optional, farmers retaining the right to purchase the HT seed alone. Competition laws do not prohibit such a practice, but this strategy seems not to have been generally adopted. One reason may be the difficulty of defining a package made up of a quantity of HT seed and a corresponding quantity of herbicide that is nevertheless suitable to a wide range of different field conditions.

In practice, these two marketing strategies thus seem to be relatively rare, although no research data are available to accurately assess their extent. Other strategies, however, have been put in place by companies seeking to preserve their market share while staying within the bounds of competition law. For example, in order to preserve the market share of Roundup® within the overall glyphosate market despite competition from less expensive generic products, Monsanto has retained its monopoly on the most effective product formulations through the use of specific adjuvants. The company also offers a more attractive guarantee[3] with regard to the efficacy of the crop's herbicide tolerance if the farmer uses Roundup®. This latter practice is legal since it does not specifically prevent the use of competing herbicides.

The academic literature does not make it possible to evaluate the role within companies' commercial strategies of the brand names often used for the HT technology (RR®, LL®, Clearfield®, etc.).

2.3.1.2 Licensing Agreements Between Seed Companies and the Rights Holders of Biotech Traits

In North America, as in Europe, plant varieties are in most cases covered by property protections conferring on their holders the exclusive right to develop and market the variety. With some rare exceptions, any seed company wanting to produce

[3] With this type of guarantee, the supplier offers to reimburse the farmer if the product doesn't perform as advertised.

and distribute the variety or plants derived from it must obtain permission to do so by means of a license, paying royalties to the rights holder. The rights granted to third parties with respect to an HTV or an HT trait thus depend on the payment of fees established by these license agreements.

Very little information is available with regard to the content of these license agreements between companies, or more generally with regard to the partitioning of the market within the agricultural seed sector. Economic studies are thus mainly based on theoretical models that are difficult to calibrate with actual data. A few studies, however, make possible the comparison of theoretical results and real situations.

In situations in which seed companies are of roughly the same size, a first theoretical result suggests that when the patent-holder of an HT trait is vertically integrated into seed production and sales (which is generally the case), that patent-holder will have an interest in granting non-exclusive licenses to other seed companies wishing to make use of the trait, so long as the license fees are at least partially proportional to the quantity of seeds sold (in other words, the patent-holder has an interest in favouring the trait's distribution). This prediction is confirmed by data on soybean in the United States that show that 75 % of transgenic HT seed sales were made by seed companies not belonging to the patent-holder.

The rapid, nationwide adoption of HT soybean varieties, moreover, raises the question of whether all non-HT varieties will eventually be replaced by their HT counterparts, resulting in a reduction in farmers' seed choice options. In the case of soybean in the United States, recent studies have shown that non-HT options still exist, but in reduced quantities and only in certain segments of the market. Theoretical analysis shows that offering both types of seed (HT and non-HT) can be advantageous for a seed company seeking to target the maximum number of farmers in situations in which weed-control problems at least moderately variable. Thus the disappearance of non-HT varieties should only occur in market segments primarily targeting farmers with difficult weed-control situations.

Two elements lead us nevertheless to qualify this last conclusion, which is drawn from a relatively simple analytical framework. On the one hand, the details of the license agreements established between HT trait patent-holders and seed companies are confidential, making it impossible to evaluate their potential additions effects on the division of the market between HT and non-HT seeds. On the other hand, the theoretical conclusion outlined above may be invalidated over time, depending on how selection programs evolve. Two organisational models can be supposed to exist. The first consists in making genetic improvements on non-HT material, then introducing the HT trait in the final stages of selection. In this configuration, it is unlikely that the reduction in the non-HT offering will imply the abandonment of selection work on non-HT seed. The reverse may be observed in the second model, however, in which the HT trait is introduced into most of the basic material used in ongoing plant breeding programs. The extent to which these two strategies have been adopted by the seed-development sector is difficult to assess, and depends both on the crop species in question and on the larger market orientations within the seed sector in different geographic regions.

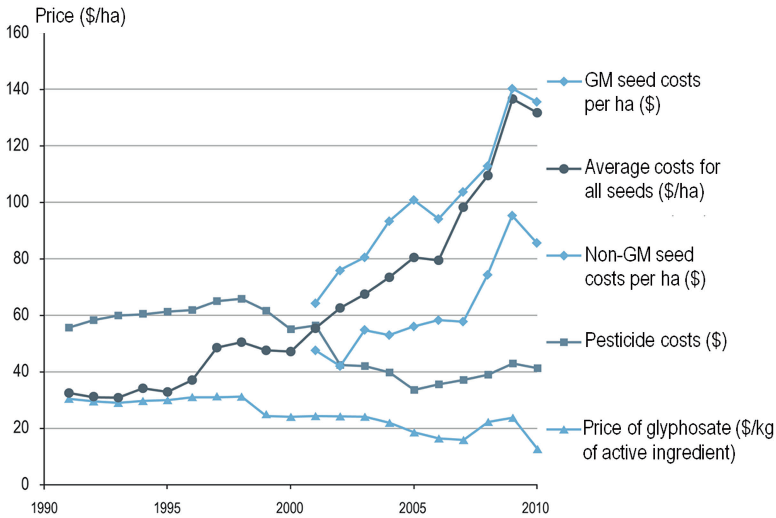

Fig. 2.5 Trends in seed and pesticide costs for soybean in the US, 1992–2010 (Source: Bonny 2011, using USDA statistics)

2.3.1.3 HTV Pricing

The pricing of HTVs and their associated herbicides has been seldom studied except for the extremely widespread RR® varieties. Models applied to data obtained from farmer surveys have made it possible to study the effects of the glyphosate-tolerant trait on seed prices overall.

In the **United States**, changes in the price of RR® **soybean** seed have been studied for the period 2000–2007 (Fig. 2.5). The difference between the price of HT and non-HT seed remained stable, with HT seed 50 % more expensive on average than non-HT seed.[4] Analysis of the price of the HT trait in RR® **maize** over the same period is more difficult because the combination of multiple transgenes is more developed in maize varieties. After breaking down the effects of each trait on the total seed price, studies show that the price premium attached to the HT trait is lower when combined with another trait.

In **Argentina**, where the HT trait is not protected by patent, seed companies can introduce it into their own **soybean** varieties without paying royalties to Monsanto. Study data nevertheless reveal a price premium of about 30 % for glyphosate-tolerant seed, attributable to the voluntary payment of fees to Monsanto by Argentine seed companies as a way of assuring their access to future genetic innovations.

Finally, the price of **canola** seed has been the focus of studies in **Canada**, where varieties tolerant to various herbicides are marketed to farmers. A recent study found that since 2000, when glyphosate entered the public domain, only glyphosate-

[4] In absolute terms, the price of soybean seed in 2007 averaged $55/ha for conventional seed and $85/ha for glyphosate-tolerant seed.

tolerant seeds have shown a price premium. The two other active ingredients (glufosinate and an ALS inhibitor) still being under patent, the companies holding these patents prefer to focus on market expansion by not adding a price premium to the seed, making their profit instead on sales of the complementary herbicide.

Monsanto's Roundup® was the only herbicide containing **glyphosate** up until the expiration of the patent in 2000, prompting its drop in price. The average price of other herbicides also fell between 1997 and 2005 (Fig. 2.5). The diffusion of RR® varieties from 1996 onwards led to the partial substitution of glyphosate for herbicides previously used on these crops. As a result, agrochemical firms producing these herbicides lowered their prices in an effort to minimize their loss of market share. Initially, all US soybean producers benefited from a decreasing cost of herbicides. From 2005 to 2007 on, however, the price of glyposate-based herbicides fluctuated significantly, as did the volumes produced.

It is difficult to draw conclusions with regard to the overall evolution of the "HT seed + herbicides" portion within farmers' total production costs, since the situation varies widely by crop species and by country, suggesting the need for a case-by-case analysis. Price fluctuations are observed not just for HTVs and their associated herbicides, moreover, but for non-HT seed and pesticides more generally. In the case of soybean in the United States, the average price for all seeds has risen since 1996, and especially since 2000, as a result of increased concentration in the seed sector. In general, from 1997 to 2010, "seed + herbicides" costs have risen compared to the period 1980–1997.

Finally, theoretical studies have sought to evaluate what HTV prices would be in countries in which they have not been adopted. The potential demand for HTVs has been estimated based on what farmers spend on weed control. In **France**, these studies estimate that the price premium for **RR® oilseed rape** would be €50/ha. At the **European level**, a premium of €50–€147/ha has been estimated for **RR® sugar beet**, depending on the country (€87/ha for France), or €95/ha in Europe overall if a uniform seed price were imposed.

2.3.2 Economic Analysis of Factors Involved in HTV Adoption by Farmers

A farmer can decide to use an HTV based on expected results (*a priori* analysis) and/or based on observed results after one or more years of HTV use (*a posteriori* analysis). Evaluating the economic attractiveness of an innovation is nevertheless complex due to the diversity of farm situations and due to spatio-temporal fluctuations in prices and costs, leading to significantly different results from year to year or according to the geographic context. In general, as with other agricultural techniques, HT crops are likely to be adopted if they offer a better return than non-HTV crops – that is, if the extra cost of transgenic seed is more than compensated for by other factors – and/or if they contribute to a reduction in production-related risks.

Studies conducted in the United States in the late 1990s, when transgenic HTVs of soybean and maize first became available, found that farmers adopting these varieties expected to realize improved yields and savings on input costs. More recent studies show that the reasons that led a majority of US farmers to adopt HTVs were the presence of specific weed-control problems and/or badly weed-infested areas, the new technology's flexibility of use, and its effectiveness in combination with no-till (often adopted previously), leading to significant time savings.

2.3.2.1 Adoption Factors Linked to Changes in Production Costs and Returns

The prospect of increased yields and reduced production costs were thus considered as explanatory factors for HTV adoption. However, studies using data from the late 1990s soon revealed that the yield gains predicted by experimental evaluation of HT soybean crops in the United States were not confirmed by observations of real conditions in the field. Thus agricultural economists began to seek other explanations for the rapid, widespread adoption of HTVs.

Supplementary investigations suggest first of all that this paradox seems to be specific to the case of soybean in the United States. On the one hand, yield gains in HT systems vary according to the crop species/geographic region interaction and the degree of weed-control improvement made possible by HTV adoption. On the other hand, many studies emphasize the weed-control cost savings enabled by HTV adoption as a result of increased work flexibility: fewer herbicide applications and the ability to make those applications post-emergence. Cost reductions are also attributed to the decrease in price of HTV-associated herbicides. More recent studies, however, suggest that these savings in production costs may be undermined by the appearance of herbicide-resistant weeds.

The price premium for HT seeds also has a dampening effect. This has been shown to constitute a barrier to adoption for two-thirds of non-adopters of HT soybean in the state of Delaware.

Finally, several studies have found a correlation between HTV adoption and adoption of reduced tillage methods. Some researchers even speak of a "co-evolution" of these two technologies. This correlation is found for several crops and cropping systems. The direction of causality between adoption of the two technologies hasn't been firmly established, however. To our knowledge, only one study concluded that adoption of reduced tillage was an explanatory factor in HTV adoption (in the case of HT cotton in the United States).

The potential benefits of HTV cropping systems beyond the year of the HT crop itself have also been explored. One recent study on HT oilseed rape (Clearfield®, RR® and LL®) in Canada focused on the effects of an HT oilseed rape crop planted in year *t* on the subsequent crop in the rotation. The study found that 44 % of farmer respondents thought that the HT crop improved weed management conditions and reduced weed-control costs in year *t+1*. Although the estimated cost savings varied according to the herbicide used (Roundup® was considered to be the best performer in this regard), failure to include this "externality" over time leads to an underestimation of the advantages delivered by HT oilseed rape. For the authors of the study, the benefit of this first-year rotation effect represented between 19 and 28 % of the total net benefit of the new technology.

The effects of HTV adoption have also been studied at the farm level. One study of HT soybean in the United States found that the improved flexibility in weed management obtained by the use of the HTV freed up time for the farmer, which he or she could then invest in off-farm activities, contributing to an increase in non-farm revenue for the household.

2.3.2.2 Non-pecuniary Adoption Factors

Farm size, farmers' educational level and the use of new information technologies (NIT) have been considered *a priori* as non-pecuniary factors in HTV adoption. Large farms managed by well-educated farmers with access to new information technologies for farm management are thought to be more likely to adopt HT seeds. The economic literature shows however that farm size and farmers' educational levels impact the adoption decision differently for different crops. For HT soybean, farm size and NIT use constitute factors positively impacting the likelihood of HTV adoption.

The search for improved risk management has also been shown by some studies to be a factor in HTV adoption among US farmers: a desire for protection against yield losses, for improved economic security in the management of weeds and for a reduction of risks linked to climatic variations appear to be important explanatory factors in HTV adoption.

Finally, the existence of regulatory incentives for the use of reduced tillage methods in geographic regions where erosion is a problem can be regarded as a factor impacting HT seed adoption. A causal link has been shown in this regard, but is the focus of debate.

2.3.3 Impact of HTV Adoption on Herbicide Use

The first estimates of the reduction in quantities of herbicides applied on transgenic HTVs were highly favourable. They were based on small-scale field trials, comparing treatment methods with an herbicide tolerated by the HTV to weed control regimes typically applied in the region. Trials in France on sugar beet, for example, showed that varieties tolerant to a non-selective herbicide made it possible to eliminate pre-emergence treatments and to replace the use of post-emergence mixtures with a single product: instead of a total of four passes, only two passes were made with glyphosate on the standing crop. Since a portion of the previously utilised herbicides were old formulas requiring higher doses to be effective, the mass of herbicide spread per pass (in grams of active ingredient) was reduced.

An *a posteriori* evaluation of herbicide consumption was made possible by the quinquennial surveys conducted by the USDA National Agricultural Statistics Service in 2002 and 2007 and by the surveys of a private research firm (DMRKynetec). These results were then used to extrapolate benefits over an entire region based on ten regional reference points, where the most common conventional weed control methods in 1990 were compared to the use of transgenic HT crops. On this basis, it was estimated that a savings of 27,600 metric tons of herbicide was achieved in the United States in 2005, equivalent to roughly 10 % of total agricultural herbicide use.

Efforts to quantify reductions – or the lack thereof – in herbicide use achieved with HTVs have given rise to considerable debate: discussions centre on methods of data gathering, the quality of different sources of information, variations among geographic regions, the extrapolation of results to larger regional levels, methods of statistical interpretation, and in particular on the types of herbicides and methods of weed control used as a basis of comparison with conventional systems. Moreover, even in cases where raw data are available, such comparisons are already biased by the fact that HTVs have been adopted in areas where weed control challenges were or are the most problematic, whereas herbicide consumption by non-adopters of HTVs is representative of areas with less difficult weed control situations. Adjusted methods have been developed in order to compare situations in which the intensity of weed control challenges is similar.

An analysis of the few reports on the subject thus reveals a variety of different estimates, often difficult to reconcile. For example, one researcher found that the total quantity of herbicides used on maize in the United States was reduced by a fifth in 2007 compared to 1996, while another researcher found an increase of 10 % over the same period. These discrepancies arise from the use of different data sources, different data treatment methodologies, and different means of establishing the baseline comparison figure for herbicide consumption on non-HT varieties.

Overall, two phenomena are at work in changes in relative herbicide consumption. In the first place, weed control problems appearing after several years' use of the HT system demand an increase in the quantities of herbicides used on these crops. The different reports thus show an increase in herbicide consumption over a period of 13 years (Fig. 2.6), even if estimates of their precise level are dissimilar. Moreover, herbicide consumption on non-HT varieties has diminished as a result of market competition, which has led to the development of more effective formulas or the introduction of new herbicides. These two trends have resulted in a change in the difference between herbicide consumption in HT and non-HT systems – initially in favour of HTVs, but now unfavourable, particularly for cotton and soybean.

Data from 2011 confirm these trends, with similar results appearing for soybean, particularly in Brazil and Argentina. Herbicide use on varieties of HT maize is thought to remain lower than that on conventional varieties, despite a significant reduction in the gap between the two. Herbicide use on HT oilseed rape remains lower than on non-HT oilseed rape in the United States and Canada.

These increases in herbicide consumption have been interpreted in terms of changes in weed control methods necessitated by changes in weed flora in the new cultivation system (see Chap. 3), including the selection for weeds resistant to the

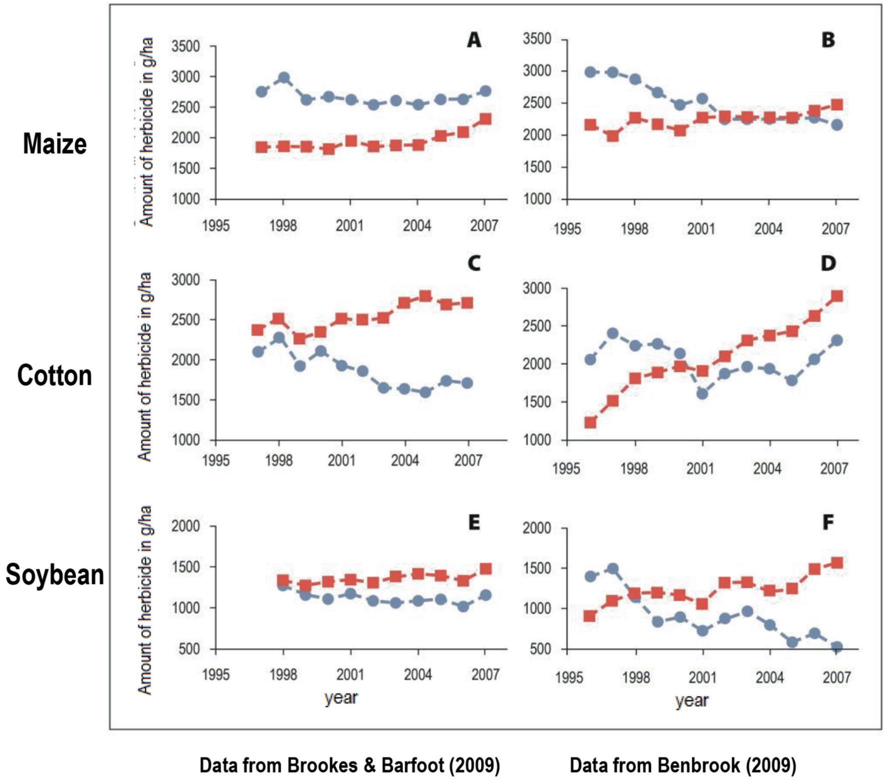

Fig. 2.6 Average US herbicide use for transgenic HT (red squares) and non-HT (blue circles) crops of maize, cotton, and soybean, according to two separate reports

herbicide used with the HTV. This latter phenomenon has attracted close attention among US farmers: a 2009 study found that 59 % of cotton growers, 54 % of soybean growers, and 48 % of maize growers surveyed said they were concerned with this problem, even if not all of them considered it serious enough to cause them to discontinue their use of HTVs. For example, only a quarter of oilseed rape growers surveyed reported increased difficulty in managing herbicide-resistant weeds.

2.3.4 Specific Context and Limits of the North American Example

The scientific literature on HTVs consisting almost entirely of studies conducted in North America, conclusions must be extrapolated with caution. The unique characteristics of North American cropping systems and the HTVs adopted there should thus be noted.

2.3.4.1 Specificities of US Agriculture

Farmers in the United States operate within a simplified production logic – based for economic or climatic reasons primarily on spring-planted crops – which increases the challenges of weed control and admits only chemical responses to new weed-control problems. The adoption of HTVs in North America does not appear to have modified prevailing cropping systems, which were already highly simplified (for example, a corn-soybean rotation using no-till planting).

The place granted to soybean is another important characteristic of American cropping systems. Soybean is a species inherently weakly competitive against weeds, and thus one that demands highly effective weed control, which conventional herbicide strategies don't always provide. The appearance on the market of varieties tolerant to a non-selective herbicide thus had an immediate appeal for farmers. This situation explains both the rapid replacement of non-HT crops by HT crops in the United States and the expansion of HT soybean in Argentina, including on land newly brought into cultivation and thus posing difficult weed control challenges.

Compared to these North and South American situations, regional cropping systems in Europe remain more highly diversified, with a more important and even expanding place granted to winter crops. Such systems are not subject to the same weed control difficulties as simplified systems, and they have a larger range of available tools with which to respond. Tolerance to a non-selective herbicide can nevertheless be attractive, as shown by the cultivation of RR® soybean in Romania before its entry into the EU.

These American examples also foreground the link between HTV use and reduced tillage practices, HTV adoption either making possible or facilitating the abandonment of mouldboard ploughing, depending on the situation. Among the elements that favour this shift to reduced tillage practices, some are specific to the American context. The promotion of no-till "conservation agriculture" (or conservation tillage) *via* financial incentives in areas sensitive to erosion is one example. On the other hand, farmers' desire to reduce work time and the costs related to ploughing constitute more widespread economic motives.

The determinants of the transition to no-till are thus somewhat different in Europe, where erosion risks are less significant. In France, in particular, the shift to no-till is developing in the absence of HTVs, but it is rarely definitive and entire: farmers have recourse to periodic ploughing as a means of controlling certain weeds and for other reasons (see Chap. 4).

In North America, the massive adoption of HTVs primarily involves varieties tolerant to glyphosate, and three crops: soybean, cotton and maize. Use of non-transgenic varieties tolerant to a selective herbicide is on the other hand almost unknown. In the one well-documented case, varieties tolerant to a non-selective herbicide appeared on the market at the same time as varieties tolerant to a selective herbicide (oilseed rape in Canada). In this case, farmers adopting HTVs seemed overwhelmingly to prefer the non-selective herbicide option, as the relative number of hectares planted to varieties tolerant to a selective herbicide declined within a few years.

In France, HTVs for which requests for registration in the French Catalogue of varieties of agricultural species have been submitted consist entirely of varieties tolerant to a selective herbicide, whether of maize, oilseed rape, or sunflower (no sunflower variety tolerant to a non-selective herbicide has been commercialised anywhere in the world).

Finally, it should be emphasized that, particularly in the United States and in Argentina, transgenic varieties have benefited from a social context favourable to their development, although it is impossible to measure the weight of this factor in HTV adoption. In these countries, many organisations have lent their support to agricultural biotechnologies, and the perception of GMOs by society at large may be characterised as relatively good.

2.3.4.2 Measuring Herbicide Use

In the North American research literature reviewed for this ESCo, herbicide use is estimated in terms of weight of active ingredient. Tonnage, however, is a poor indicator for comparing practices, since the standard dose – the amount of product needed to assure agronomic efficacy of the treatment – varies greatly from one herbicidal substance to another (from several kilograms to a few grams per hectare).

Another way of estimating herbicide consumption is the Treatment Frequency Index (TFI), which measures the number of standard doses used per hectare (for example, an application at half the standard dose or applied to only half the field will only count for 0.5 points in the TFI). The TFI thus eliminates the weight bias, focusing instead on pesticide biological activity. The adoption of this indicator in France facilitates comparisons among different weed control systems (see Chap. 4).

As for the impact on the environment, this will depend on the eco-toxicological characteristics of the herbicide and its manner of use. A number of other indicators have been proposed, notably the Environmental Impact Quotient (EIQ) (cf. Chap. 5).

2.4 Specificities of the Social and Regulatory Context of HTV Adoption in Europe

The European context of HTV adoption currently differs from the North American context in two respects: the extent of popular opposition to GMOs, and the nature of the legal framework regarding intellectual property and the introduction of new plant varieties.

Within this general European context, HTVs obtained *via* mutagenesis are currently the focus of an incipient opposition, as illustrated by the positioning of agricultural unions on the subject, by the organised demonstrations of "volunteer reapers" and by the activities of biotechnology watchdog groups.[5] After considering how this opposition may be interpreted, this section will describe the legal framework governing HTVs in Europe, both in terms of intellectual property protections and in terms of the evaluation process they must undergo before being placed on the market.

In legal terms, HTVs as such are not subject to special procedures within the general rules regarding the protection and marketing of plant varieties. Only HTVs obtained by transgenesis are subject to special rules in Europe.

2.4.1 The Social Context of the Emerging Debate Over HTVs

Publicity issued in the wake of crop destruction campaigns (in 2009, 2010, and 2011) targeting HT sunflowers obtained by mutagenesis echoed recommendations issued by the Confédération Paysanne (the Peasants' Confederation, a union of small farmers) to avoid using HTVs obtained by mutagenesis (initial press release in the spring of 2010, reiterated in autumn 2011 with additional mention of HT oilseed rapes in pending inclusion in the official Catalogue). Nevertheless, the available literature in the social sciences does not report any public or professional controversies surrounding the use of mutagenesis in the creation of plant varieties.

Activists in these crop destruction campaigns have made use of the same arguments as those mobilised in protests against GMO field trials. These events and the motives advanced to justify them within the fight against GMOs, however, have yet to be studied with regard to the anti-GMO conflict, although the broader debate over GMOs has been the focus of sociological investigation.

Work in the social sciences makes it possible to place the debate over GMOs in historical perspective. Initially taking form within the debate over recombinant DNA techniques underlying the biotechnology innovations of the 1970s, the public discussion surrounding GMOs intensified with the introduction of transgenic crops in the 1990s. One of the focal points of this debate centres on the evaluation of risk within the market authorisation process. The situation in Europe intensified with the moratorium in June 1999, followed by the ramping up of crop destruction campaigns. What needs to be understood, thus, is the reception of HTVs within the public sphere in light of this deepening of the GMO conflict, insofar as at the global level a large number of varieties carrying an HT trait have been obtained by transgenesis.

The question raised by crop destruction campaigns targeting HT sunflowers is that of the extension of the anti-GMO conflict to other biotechnological techniques

[5] Infogm.org

besides transgenesis. The debate comes down to whether or not these mutated HT plants should be categorised as genetically modified organisms. European Commission Directive 2001/18/EC, relying on the definition of GMOs as established in 1990, considers mutagenesis as a technique of genetic modification but places organisms obtained by mutagenesis outside its domain of application. Plants obtained by mutagenesis are thus exempt from the regulations applying to plants obtained by transgenesis with regard to prior evaluation, market authorisation, traceability and labelling (see Sect. 2.4.4).

A re-examination of the definition of GMOs has likewise been undertaken with respect to the organisms created by new biotechnologies. This re-examination is being led at the European level by the work of the Joint Research Centre on new technologies of varietal selection (see Chap. 1).

The debate over GMOs, including the opposition to GMO field trials (especially in France), has led to a hardening of positions around the definition and evaluation of collective risks. This polarisation of opinions is part of a larger movement scrutinizing different models of food consumption and characterized by the drawing of symbolic territories opposing “junkfood” and “healthy food”, the health risks of industrial food versus the innocence of “natural” food. These protests are maintained by a well-established ecological consumers’ movement with strongly defined cognitive categories, validated by certain objectives within the Grenelle on the Environment, and emerging from debates and protests against pesticides as well as against GMOs.

The GMO/non-GMO opposition has become an unavoidable reference point both in commercial terms and in the public sphere, shaping the views of socio-economic actors with regard to the evaluation process for new plant varieties, once falling under the jurisdiction of approval committees focused exclusively on these varieties’ agronomic value.

2.4.2 Intellectual Property Protections Applicable to HTVs in Europe

The development of an HTV, by whatever technique, leads to the creation of a new plant variety, which is to say a genotype that can be protected by varietal development rights. The genetic information responsible for the HT trait, moreover, can also be the subject of an independent protection by means of a patent, if it respects the conditions of patentability. The goal of intellectual property protection is to grant to its developer, for a limited term (20–30 years according to the regime), a monopoly on the use of the variety or the invention in return for sharing it with the industrial and scientific community. The conditions of this right of exclusivity are set by the French Intellectual Property Code and can establish mechanisms by which access to the innovation and its exploitation may be granted to third parties.

2.4.2.1 The Plant Breeder's Right: Protection for Plant Variety Development

The International Union for the Protection of New Varieties of Plants (UPOV), created in 1961 by the International Convention for the Protection of New Varieties of Plants, established a specific protection known as a PBR. To obtain a Plant Breeder's Right in Europe, a plant variety (whatever its mode of development or advertised traits) must satisfy three criteria, known as the "DUS" criteria:

– distinctness from all other protected plant varieties
– uniformity in its ensemble of characteristics across individuals
– stability of these characteristics across generations.

To these traditional criteria is added a criterion of novelty common to most intellectual property protection rights.

2.4.2.2 The Patent: Protection for Varietal Innovation

Applications for patent protection can be made at the national, European, or international levels, to be handled respectively by the National Institute for Industrial Property (INPI, or other competent national patent office), the European Patent Office (EPO), or the World Intellectual Property Organisation (WIPO).

In Europe, Directive 98/44/EC allows for the application to living organisms of the patent system instituted by the European Patent Convention (1973). In European patent law, only sub-varietal innovations (gene, cell) are patentable, provided that the general principles of patentability apply: novelty, inventiveness, and the potential for commercial application. Thus the genetic information responsible for the HT trait can be the focus of a patent if it constitutes a biotechnological invention – that is to say, a technical solution to a technical problem. Moreover, the technical feasibility of the invention must not be limited to a single variety. Above all, when a genetic sequence is patented, all biological material in which it is expressed is protected by this patent: the cell, but also the plant. Finally, the patentable processes that made development of the plants possible must not make use of exclusively natural phenomena (called "essentially biological" processes).

Table 2.1 shows the forms of intellectual property protection applicable to HTVs according to whether they have been developed by traditional selection, mutagenesis, or transgenesis.

Thus, an HT plant can in some cases be protected in Europe by both a PBR and a patent, provided that the genotype claimed by the developer fulfils the DUS criteria and the DNA sequence coding for the HT trait is expressed by the plant. In practice, while nearly all varieties in Europe are protected by PBRs, the HT trait is not always protected by a patent.

The extent of the rights conferred by each of these protection "tools" is different since they do not all provide for precisely the same monopoly privileges for the rights holder. There are three types of limitations:

Table 2.1 Means of protection possible for HTVs and for HT genetic information according to breeding technique

"Types" of HT plant		Focus of protection	
Falls under 2001/18/EC	Breeding technique	Protection of the HTV (Genotype)	Protection of the HT genetic information (Gene)
No	Introgression of a spontaneous mutation *via* crossing and selection (classic varietal selection) *e.g. DUO System® maize, Clearfield® sunflower*	European countries: PBR	European countries: Product patent possible[a]
	Existing mutagenic techniques *e.g. Express Sun® sunflower, Clearfield® oilseed rape*		European countries: Product patent possible[a] Process patent possible[b]
Yes	Existing transgenic techniques *e.g. RR®, LL®*		

[a]if the DNA sequence and its function are specifically isolated and identified for the first time (information that has never come into the public domain)
[b]if the process is new, applicable to other varieties and reproducible by skilled persons

- the research exemption, authorising use of the protected variety for experimental purposes;
- the farmer's privilege, authorising use of farm-saved seeds obtained from the protected variety with payment of fair compensation;
- the breeder's exemption, authorising use of a protected variety in order to develop a new variety, the commercialisation of which is free of protection obligations if it can be shown that the new variety is not a "variety essentially derived" (VED) from the initial variety (the two varieties must be substantially different).

Table 2.2 summarises these provisions as they apply to a PBR and a patent.
From these differences of regime the following practical points may be derived:

- A plant breeder always has the possibility of using a plant variety protected by a PBR in order to develop a new, freely marketable variety.
- A plant breeder always has the possibility of using a plant variety protected by a PBR and incorporating a patented HT gene for the purposes of variety selection. However, the breeder will not be able to commercialise the new variety without permission from the patent holder if the gene in question remains active.
- To alleviate these possible situations of blockage between plant breeder and gene patent-holder, Directive 98/44 instituted a system of obligatory cross-licensing determined by judicial decision.

Thus, for varieties protected both by a PBR and by a patent, the only exemptions provided for by European legislation are the research exemption and the farmer's privilege. In France, although tolerated in practice, the use of farm-saved seeds is explicitly forbidden by law for varieties protected by a PBR. Pending legislation

Table 2.2 Limitations on the monopoly granted by a patent or a PBR

	PBR (UPOV convention)	Patent (Directive 98/44/EC)
Research exemption	Provided for at the European Union and national levels	
Farmer's privilege	Provided for at the EU level (EC regulation established in 1994) **France**: tolerated in practice, but explicitly prohibited in the absence of branch agreements (which currently exist only for spring wheat)[a]	Provided for at the EU and national levels
Breeder's exemption	Provided for at the EU level for new varieties not judged VED **France**: the VED principle has not yet been adopted by French law[a]	Not provided for at the EU level **France**: alignment of the EC directive authorises unencumbered commercialisation of the new variety if the patented element is not expressed by the plant

[a]French legislation has evolved on this point since the delivery of this ESCo's findings and the publication of the present document. Law no. 2011-1843, 8 December 2011, relating to Plant Breeder's Right, authorises the use of farm-saved seed for 21 cultivated species, provided the farmer pays an indemnity to the holder of the relevant PBR. This law also incorporates the notion of the "essentially derived variety".

from 8 July 2011 (currently only approved by the Senate) would modify Intellectual Property Code rules in favour of the farmer's privilege. This privilege is also provided for in French patent law following adoption of Directive 98/44/EC.

The rules and principles of protection for varietal innovations vary by global region. In the United States, plant variety developers may protect their varietal innovations either by patent or by a protection similar to the UPOV (the ability to choose between these two alternatives depends on the plant species in question). Contrary to UPOV protection, US patent law does not include provisions for the breeder's exemption nor for the farmer's privilege; these differences in the extent of monopoly rights conferred has led variety developers overwhelmingly to choose protection by patent.

2.4.3 Conditions for Market Introduction

2.4.3.1 General Rules

In the European Union, in order to obtain a market authorisation, all plant varieties falling under the "regulated species" category (whatever their advertised traits and by whatever methods they were developed) must be submitted for registration on one of the 27 official national catalogues, and must satisfy two tests:

– the DUS test: criteria are identical to those required for a PBR and have been standardised across all European member states;

– for major field crops, the "VCU" test, which seeks to characterise the value for cultivation and use of the new variety (yield, days to maturity, nutritional value, etc.).

In France, variety registration is governed by Directive 2002/53/EC as well as by a series of directives specific to each seed type. Registration takes effect by decision of the Minister of Agriculture, based on the advice of the Permanent Technical Committee for Selection (CTPS), which considers the results of experiments conducted under the direction of the study group GEVES (Varieties and Seeds Study and Control Group).

Following a recent study relating to the expansion of the VCU test to include environmental criteria, a new standard, known as VATE, figures among changes proposed by the CTPS in a report titled, "Seeds and Sustainable Agriculture" (May 2011). In keeping with an overall goal of reducing inputs, the VATE seeks to give better consideration to pest and disease tolerance, varietal performance under different environmental conditions, and genotype/environment/cropping system interactions within registration decisions. In practice, environmental criteria such as tolerance of certain diseases (making possible reductions in fungicide use) are already taken into consideration in the evaluation of varieties.

Registration on one of the national catalogues leads to automatic registration on the EU catalogue after 1 year. The catalogue entry constitutes market authorisation for the registered variety, which is to say it authorises production, multiplication (for seed production purposes), commercialisation and distribution of the variety within all European countries.

2.4.3.2 Current Discussions Linked to the Development of New Techniques

Faced with the emergence of new biotechnologies susceptible for use in plant variety development, a working group was formed by the European Commission in 2007 with the goal of establishing, for eight of these new biotechnologies, whether or not they constitute techniques of genetic modification, and thus if the organisms obtained by their use fall within the purview of European legislation (Directive 2001/18/EC). This discussion is ongoing.

Given the difficulty of determining how to classify these new techniques, some observers have begun to question the legal validity of the GMO/non-GMO distinction, and by extension the application of the precautionary principle – implying a specific evaluation of ecological and health risks – to plant varieties other than those obtained by transgenesis.

2.4.4 Specificities of Transgenic HTVs Within the European Context

For the users of HTVs – including farmers and other economic actors farther down the line – the conditions of HTV adoption depend on the regulatory requirements attached to the growing and/or marketing of these varieties. Thus in Europe, if transgenic HTVs were approved for on-farm use, or if non-transgenic HTVs were subject to the same requirements as transgenic HTVs, these regulatory constraints and their economic consequences would weigh in the decision of whether or not to make use of these varieties. Factors involved include: the conditions of market introduction, farmers' liability with respect to neighbouring farms, and the obligation to maintain separate product streams along the food chain, which is to say the management of coexistence.

2.4.4.1 Authorisation of the Transgenic Event: Prior Evaluation and the Possibility of a Moratorium

In addition to a Catalogue entry, placing a new transgenic variety on the market requires obtaining a market authorisation (MA) specific to the "transformation event": the plant variety developer must submit an application package including the results of health and environmental impact assessments for the cultivation of plants possessing this transformation event. This principle of prior authorisation is imposed by Directive 2001/18/EC, relating to the deliberate release into the environment or placing on the market of GMOs.

Implementation of these EU rules within France is regulated by the Environmental Code, which provides for the prior authorisation procedures relating to the deliberate release and placing on the market of GMOs, as well as the sanctions to be applied in cases of non-respect of the regulations (use without authorisation, breach of administrative procedures, non-respect of the authorisation specifications or obstructing the work of accredited inspection personnel). These sanctions were reinforced with the law of 25 June 2008 relating to GMOs.

Complementing these market authorisation procedures for transgenic varieties, Directive 2001/18/EC also permits member states to enact backup provisions in order to derogate an EU market authorisation. Directive 2001/18/EC states that only new or complementary information relative to health or environmental risks – coming to light post-authorisation – can justify recourse to such a backup mechanism. It was on this basis that France announced the suspension of maize MON 810 (resistant to codling moth, a pest).[6]

This distribution of authority between the European Union and its member states is being reviewed. One proposal to modify Directive 2001/18/EC currently under discussion seeks to grant more leeway to member states with regard to their stated motives for restricting cultivation of transgenic varieties within their borders. The invocation of these motives would however result in the assumption of responsibility by the member state before the relevant international authority (the World Trade Organisation). Critical analysis of this proposal has led jurists both in France and elsewhere to consider that the liberty of member states would not in fact be augmented by its implementation.

2.4.4.2 Users' Obligations

The Farmer's Responsibility

If a farmer's responsibility is engaged in legal terms, the consequences are ultimately economic, whether this means the purchasing of insurance or the compensating of another producer.

A new legal regime known as strict liability (or no-fault liability) makes a farmer growing an authorised transgenic variety responsible if an unintended transfer of the transgene into another farmer's crop causes economic damage to the latter. The French Rural Code establishes highly restrictive conditions for the determination of this responsibility, however, including limitations to fields and hives situated nearby, to crops grown in the same year of production and to economic damage resulting from the obligation to label the resulting crop or product as GMO. The Code proposes a system of obligatory insurance to cover this risk, but insurance of this type doesn't currently exist and no sanctions are specified in case of non-respect of this insurance obligation. A decree from the Council of State specifying the details of this new strict liability regime is awaiting publication.

Outside of this proposed, extremely restrictive regime, other liability regimes could potentially apply in cases of contamination (whether by transgenic or non-transgenic varieties): environmental liability, liability for defective products, neighbourhood disturbances, liability for outcomes and objects under an individual's supervision, liability for hidden defects or, finally, liability for fault. The application of these regimes appears problematic, however, since the damages they cover and the categories to which they refer (hazardous substances, for example) are not rel-

[6] The use of Directive 2001/18/EC to justify a moratorium on the cultivation of HT maize variety MON 810 was struck down by the European Court of Justice on 8 September 2011. The ruling specified that when a market introduction has been authorised under EC Regulation 1829/2003, the member state must found its emergency measures on Article 54 of the said regulation and not on Directive 2001/18/EC. This ruling has wide-reaching implications, notably that the state must be able to demonstrate "in addition to urgency, the existence of a situation likely to present a significant and manifest risk to human, animal or environmental health".

evant to such crop contamination situations. As a result, they have very rarely been made use of.

Obligation for Product Labelling

In order to respond to consumers' desire for information as to the nature of marketed products, the European Union has retained the principle of mandatory labelling for agricultural products containing GMOs (or their derivatives), whether for human or animal consumption. The obligation to maintain traceability, all but universal within the food and agriculture sector, is specifically taken up with respect to GMOs by Directive 2001/18/EC, which requires that their presence or absence be traced at all stages of the production and distribution chain. These obligations are also found within French law, notably within the Consumer Code.

The principle of GMO labelling, established by Regulation 1830/2003, applies to both human food and animal feed products. The regulation states that all GMO products must be labelled except those containing traces of GMOs below a threshold of 0.9 % when this presence is "accidental or technically unavoidable". In the majority of European member states it is the producer's responsibility to demonstrate the accidental or technically unavoidable nature of the contamination – ordinarily by showing that all possible measures were taken to avoid it.

Current discussions with regard to labelling are focused mainly on the conditions for labelling a product as "non-GMO". In a recommendation delivered on 26 October 2009, the Economics, Ethics and Social Council of the High Council of Biotechnology (HCB) proposed maintaining a threshold of 0.1 % transgenic DNA for products labelled as "GMO-free"; a report by the HCB on the implementation of this policy of coexistence is expected this autumn.[7] It should be noted that in Germany, Austria and Italy regulations have been adopted to govern use of the "GMO-free" label.

Costs of Identity Preservation

In the case of the creation of separate product streams, such as those necessitated by transgenic crops in Europe, coexistence must be managed from the field onwards (cf. Chap. 3), along the entire downstream chain, with a spatial and/or temporal separation of lots at the time of harvest, transport, storage, the various stages of transformation, etc. The absence of mixing and contamination must be verified by a control system including product purity tests applied at key or critical points along

[7] Following the advice of the HCB, France has chosen to formalize a "GMO-free" label with the establishment of a system for identifying food products derived from certified "GMO-free" production streams. This ruling will take effect 1 July 2012. The system is multi-tiered, recognising several levels of labelling according to the products' ingredients. For plant-based ingredients, products may be labelled as "GMO-free" if they are made from ingredients containing no more than 0.1 % GMO material.

the supply chain. Management of such a system can be optimised, but it will nevertheless incur costs, whereas there is no market at the current time to create added-value products derived from HTVs (contrary to the case of separate product streams for products possessing a technical, and hence an economic, value superior to that of standard production).

2.5 Conclusions

The study of the diffusion of HTVs worldwide reveals disparities in HTV adoption according to whether they have been developed via transgenic, mutagenic or traditional selection techniques.

Transgenic HTVs, for the most part glyphosate-tolerant varieties of soybean, maize, cotton and oilseed rape, have seen a massive and in some cases extremely rapid diffusion in North and South America; it is thus not surprising that the economic literature focuses on this case. This widespread adoption, despite higher seed prices, attests to farmers' interest in the technology. The link between no-till farming and HTVs appears to be a determining factor in the commercial success of these HTVs.

The diffusion of non-transgenic varieties tolerant to a selective herbicide, much less studied, appears to be more restricted worldwide. Their adoption appears to be limited, in countries where various types of HTV are available, by the existence of varieties tolerant to a non-selective herbicide.

In Europe, where the social and regulatory context is not favourable to the diffusion of GMOs, the only HTVs in cultivation are those developed from spontaneous or induced mutations. Their limited diffusion should perhaps be considered in light of their relatively recent introduction.

Recent studies conducted in the United States show that the difference in herbicide consumption between RR® and non-HT crops, initially in favour of HTVs, diminishes in several years, becoming unfavourable for soybean and for cotton. This increase overtime in the quantities of herbicides used on HTVs is explained by the recourse to remedial, supplementary herbicide treatments, notably to fight against weed species that have become resistant to glyphosate.

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