FRANCE

BROADENING PRECAUTIONARY EXPERTISE

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‘Safety Regulation of Transgenic Crops: Completing the Internal Market?’

A study of the implementation of EC Directive 90/220

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OVERVIEW

1996 marked the start of public controversy in France about the commercialisation of transgenic crops. Indeed, the EU-wide dispute about the commercialisation of transgenic crops such as insect-resistant maize and herbicide-resistant soyabean, following as it did closely on the heels of the BSE crisis earlier in the year, also marked the start of the French debate about GMO regulation. On 1st November 1996, Libération, one of the biggest French daily newspapers, headed its front page ‘Alerte au soja fou’ (Beware of the mad soyabean), in an article about the impending arrival of US imports of genetically-modified soyabean. By making a direct link between the crisis about mad cow disease and transgenic crops, this provocative title anticipated a widespread public controversy about the place of the precautionary principle in the public decision-making process.

As new actors have entered the debate and raised new issues with the experts, the uncertainties have tended to increase and the previous standards of precaution have been contested. The public controversy has focused on the inability of the regulatory advisers to take into account scientific studies from disciplines other than molecular biology (such as ecology), and also the model of agriculture that underlies plant biotechnology. In response, the French government has begun to open up the regulatory process in order to involve citizens, NGOs and scientists within the official structures of debate and expertise. The commercialisation of transgenic crops has created a debate which has prompted policy actors to adopt the precautionary principle under pressure from NGOs. The risks are being redefined as a wider range of scientific advice is taken into account.

However, contradictions within the existing European GMO regulatory system counteract such attempts to improve the precautionary content of public policy on transgenic crops. Indeed, in October 1998 the European Commission warned the French Government about its decision to impose a two year moratorium on two herbicide-tolerant oilseed rape market consents (because of uncertainties about the spread of the herbicide-tolerant trait in the environment) and for its failure to respect the 90-day period specified by Directive 90/220 for responding to market applications.

Public controversy

Environmental and health risks

Before 1996, the French debate about transgenic crops had been limited to a few actors such as officials, experts, companies and several scientists who had been involved for a long time in transgenic crop research (plant breeders, geneticists, agronomists). NGOs such as Greenpeace, France-Nature-Environment and consumer unions were not involved. Now, what was previously a technical and agricultural debate has turned into a public controversy.

As Limoges et al. (1995) have shown, public controversies are characterised by the involvement of a broad range of actors who do not belong exclusively to the scientific community. Public controversies do not focus only on the scientific dimensions of risks:

“They are first and foremost debates about social choices in which actors carry with them a multidimensional social experience of technology, trust, credibility and decision-making institutions.” (Limoges et al., 1995).
The debate in France has helped to clarify the implicit assumptions which underpin the scientific expertise and the risk assessment. For example, actors such as the Confédération Paysanne and Greenpeace have criticised the belief in agricultural productivism that they consider underlies the development of plant biotechnology. According to them, the so-called plant biotechnology revolution will make farmers more dependent on companies such as Monsanto, AgrEvo and Novartis. In the context of the BSE crisis, they see these criticisms as strengthening the case for organic farming as an alternative to biotechnology.

The most widely reported demonstrations against transgenic crops have been those carried out by Ecoropa and the Confédération Paysanne. Thus, after the French decision to approve the cultivation of the Ciba/Novartis Bt maize in November 1997 (see Table 1), several members of the Confédération Paysanne were convicted for destroying stocks of Bt maize seed in a Novartis warehouse in the following January. NGOs used the court proceedings as an opportunity to criticise the agricultural model underlying the development of transgenic crops by the companies. Several environmental NGOs organised demonstrations at the sites of trials of transgenic crops (for example, of glyphosate- and glufosinate-tolerant oilseed rape). Some trials were destroyed during 1997 and 1998. In order to avoid further unfavourable publicity, AgrEvo decided in March 1998 to destroy all its glufosinate-resistant oilseed rape in France after some NGOs had raised concerns about herbicide-tolerant transgenic crops. Moreover, French farmers seemed reluctant to grow transgenic crops given the public hostility. Novartis had hoped that 30 000 hectares of Bt maize would be planted in the first year of its commercialisation in France (1998), whereas only 2000 hectares were actually grown.

NGOs such as Greenpeace and the Confédération Paysanne (one of the biggest of the French farmers’ unions), and scientists in the association Ecoropa, criticised the risk assessment conducted by the Commission du Génie Biomoléculaire (CGB) for the market approval of the Ciba/Novartis insect-resistant maize. Indeed, they argued that since many uncertainties remained about the behaviour of transgenic crops in the environment, their commercialisation might cause damage. Several scientists therefore asked for a moratorium on large-scale releases, within the framework of market approval. When the French government authorised the cultivation of the Ciba/Novartis Bt maize in February 1998, Greenpeace, the Confédération Paysanne, Friends of the Earth and Ecoropa took action to revoke the decision by appealing to the Conseil d’Etat (a constitutional court). They argued that the CGB and the French government had not applied the precautionary principle since the risk assessment had not covered all the potential impacts on environment and public health (Le Monde, 27 and 28 September 1998). Their main concern was that the antibiotic-resistant marker gene had been ‘omitted’ from the risk assessment, according to Greenpeace and Ecoropa:

“This is in spite of the fact that the most recent scientific evidence (by Professor Courvalin, May 1998) shows that the return of antibiotic-resistant marker genes by horizontal transfer to soil bacteria and to the gut of mammals is possible, with all the negative consequences that this implies for public health and the environment”. (Etienne Vernet from Ecoropa, quoted in FoEE Mailout, 1998c).

In September 1998 in its first advice, the Conseil d’Etat acknowledged that the precautionary principle had not been applied by the French government. In December, the final step of the appeal procedure led the Conseil d’Etat to ask the European Court of Justice (ECJ) to advise on the sovereign right of the French State to revoke its approval decision.
<table>
<thead>
<tr>
<th>Year</th>
<th>Event Description</th>
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<tbody>
<tr>
<td>1994</td>
<td>Ciba-Geigy submits a market approval file for a Bt maize to the CGB.</td>
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<td>Apr. 1995</td>
<td>Without raising any objection, the French advisory committee forwards the file to the European Community.</td>
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<td>Spring 1996</td>
<td>The CAs of several other member states raise objections about the ampicillin-resistant marker gene.</td>
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<td>Dec. 1996</td>
<td>The Commission nevertheless approves the Bt maize.</td>
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<td>Feb. 1997</td>
<td>The French Prime Minister (at that time Alain Juppé) decides to ban cultivation of the Bt maize, while still allowing its import for consumption. The French government argues that some risks relating to cross pollination are still unknown. This decision leads the CGB’s chairman (Axel Kahn) to resign the following day, arguing that his credibility has been undermined given that maize cannot hybridise with other plants since it has no wild relatives in Europe.</td>
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<td>Summer 1997</td>
<td>The new Minister of the Environment (Dominique Voynet) seeks the advice of several scientists and environmental NGOs about the cultivation of the Bt maize.</td>
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<td>Sept. 1997</td>
<td>Dominique Voynet asks the Comité de la Prévention et de la Précaution (the CPP, which answers to the Ministry of Environment) for its advice about the risks associated with the cultivation of several transgenic crops (Bt maize and herbicide-tolerant oilseed rape and sugar beet) before approving their cultivation. The CPP’s advice is positive for Bt maize but not for oilseed rape and sugar beet.</td>
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<tr>
<td>Nov. 1997</td>
<td>The Government follows the CPP’s advice by approving the cultivation of the Ciba/Novartis Bt maize. It places a two-year moratorium on the cultivation of oilseed rape and sugar beet pending further research on the risks of cross pollination. It decides to require market stage monitoring of all transgenic crops, including the Bt maize. It announces that a citizen’s conference will be held in June 1998.</td>
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<td>Early 1998</td>
<td>NGOs appeal to the French Conseil d’Etat against the decision to allow Bt maize cultivation to go ahead, saying the original risk assessment was incomplete and, in particular, failed to consider the ampicillin resistance.</td>
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<tr>
<td>Sept. 1998</td>
<td>The Conseil d’Etat accepts the precautionary principle has not been applied.</td>
</tr>
<tr>
<td>Dec. 1998</td>
<td>The Conseil d’Etat asks the European Court of Justice to advise on the right of the French state to revoke an approval decision.</td>
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Previously, in June 1998, the French Institut de la Recherche Agronomique (INRA) had published a report about GMOs in agriculture and food emphasising that ‘extreme caution is necessary in the face of a major innovation which has, as yet, unknown effects’ (FoEE Mailout, 1998b). Moreover, in early 1998 INRA decided to give up its herbicide-tolerant oilseed rape breeding programme involving private seed companies. The risk of cross pollination demonstrated by scientists from INRA (Chêvre, 1997) was one of the main reasons for this decision. Given the public controversy, INRA wanted to reaffirm its scientific role rather than its commercial activities.

Food labelling

Labelling is probably one of the most tricky aspects of transgenic crops for public policy because of its link with public acceptability. Uncertainties about the scientific standards for establishing equivalence, regulatory gaps at the EU level concerning labelling, questions about the reliability of detection methods, and difficulties with implementing the segregation of transgenic crops add to consumer mistrust of policy makers and industry.

The debate about labelling is still confused as most retailers and food processors want to avoid GM products. Anticipating consumer doubts about GM food products, major retailers such as Carrefour and Leclerc favour clear labelling and have refused to use GM ingredients in their own-brand foods. The French government has promised transparency and information without taking any clear decision.

In April 1998, the National Consumption Institute published a study showing 20% of the food products they tested contained genetically modified maize without being labelled. NGOs protest that consumers are being used as ‘guinea-pigs’ since, despite the labelling regulations, they do not have the information to allow them to choose to avoid GM foods. As emphasised in September 1997 by the Comité de la Prévention et de la Précaution (the CPP, one of the Ministry of Environment’s scientific committees) such a situation will not improve public acceptability even if the problem is not a safety issue but rather a matter of consumer information and choice.

Towards more stringent precaution?

In the light of increased criticism from NGOs about the commercialisation of transgenic crops, the French government decided in February 1997 to approve the import of the Ciba/Novartis Bt maize for consumption but to ban its cultivation (having previously recommended its approval to the EU without such a condition). Since that decision, the links between scientific expertise and GMO decision-making have changed. Previously, authority for the French decision procession lay with the Ministry of Agriculture. The ‘mad cow’ crisis and the public controversy about Bt maize provided an opportunity for the Ministry of the Environment to argue that other actors should be involved in the regulatory process.

The government of Lionel Jospin, elected in spring 1997, has promoted a changed policy framework for the regulation of transgenic crop. Shifts in the link between expertise and policy became apparent with the French government’s decision in November 1997 to approve the cultivation of the Ciba/Novartis Bt maize. The main events relating to the B maize controversy are summarised in Table 1.
The next section examines how the November 1997 decision challenges the risk assessment framework established by the CGB and addresses some of the precautionary concerns raised during the controversy. The new government policy also addresses some of the concerns raised by the CGB, for example, by imposing a moratorium on the cultivation of herbicide-tolerant oilseed rape and sugar beet.

Commercialisation and the precautionary principle

When the French government approved the cultivation of the Bt maize in November 1997, it decided to require market stage monitoring (for three years) in order to detect any adverse effects (corn borer resistance to Bt, effects on non-target insects and soil bacteria, and ampicillin-resistance in the gut flora of cattle fed transgenic corn). A Comité de Biovigilance was temporarily constituted, under the authority of the Ministries of Agriculture and the Environment, to monitor the Ciba/Novartis Bt maize (Arrêté du 5 février, 1998). This committee includes scientists with expertise in ecology and population dynamics, and representatives of seed companies and environmental NGOs (Greenpeace and the Confédération Paysanne). The diverse membership has led to an additional adverse effect being included within the existing monitoring framework established by the National List Registration decree. Cross pollination between transgenic and non-transgenic maize will be assessed in case the proximity of transgenic maize affects a farmer’s choice to grow non-transgenic maize. Since a new variety can only be cultivated after it has been legally approved by the Ministry of Agriculture, once it has been accepted by the National List Registration’s notification committee, variety registration becomes a means for implementing a more precautionary approach than under Directive 90/220’s risk assessment procedure. Precaution is being achieved within the last stage of commercialisation. Market stage monitoring implies that commercial crops are being used as a further experimental step, as suggested by Levidow et al. (1997).

In the case of the cultivation of herbicide-tolerant oilseed rape and sugar beet, the government decided to impose a two-year moratorium, since cross pollination had been demonstrated by INRA. In effect, the moratorium only translated into official policy a measure that the CGB had been unofficially operating before.

The CGB considered that the question of gene flow was an agronomic issue, and as such lay beyond the direct effects it considered to be within the remit of Directive 90/220. However, the CGB did consider the economic risks linked to the cultivation of broad spectrum herbicide-resistant transgenic crops in order to alert government authorities and other professionals to potential problems. In granting market approval to herbicide-tolerant oilseed rape, the advisory committee decided to set up temporary market stage monitoring. Funding population dynamic studies allowed the CGB to think about the collection and quantification of data in order to define the parameters which market stage monitoring should include. Since ecological models ‘are too far from what really happens in the field’, according to one expert when interviewed, the CGB supported an experiment conducted by several technical institutes (in collaboration with chemical firms such as Rhône-Poulenc, Monsanto, AgrEvo and Novartis) which simulates the rotation of crops. By planting several plots of transgenic crops resistant to bromoxynil, glyphosate and glufosinate-ammonium together in the same field, this study investigates the probability of multiple herbicide tolerance developing and the consequences for agricultural practice. Although the CGB is not the official sponsor, this study serves to inform decision making about market approval. Indeed, the CGB has proposed that variety registration of any herbicide-tolerant oilseed
rape should be delayed until the results of the study are known. Meanwhile, the CGB asked the variety registration committee (CTPS) to take precautionary measures to prevent any cross pollination in national list trials. In response, the CTPS argued that in order to give advice on herbicide-tolerant crops such as oilseed rape tolerant to glyphosate, glufosinate or bromoxynil, the three crops should be tested together because variety assessment has to focus on the new character inserted. The CGB disagreed, arguing that to avoid the risk of multiple-herbicide tolerance, each variety trial must be conducted separately under the conditions of Directive 90/220 Part B. It seems that this argument was used as a pretext to delay commercialisation. The moratorium imposed by the French government in November 1997 resolved the conflict.

Citizens’ conference

The president of the Parliamentary Office of Scientific and Technical Choices Assessment (Office Parlementaire d’Evaluation des Choix Scientifiques et Techniques), Jean-Yves Le Déaut, was given the task of preparing a report about the use of GMOs in agriculture and food. As part of his mandate, he organised a citizens’ conference in June 1998. Fifteen citizens were selected by an institute which carried out an opinion poll. After two weekends of training sessions on the scientific, regulatory and economic aspects of GMOs, the citizens put questions to several experts. The main conclusions of the citizens were:

- Antibiotic resistant marker genes must be avoided since they serve no function in transgenic crops and may represent a risk for clinical treatment of several diseases.
- The CGB must be divided into two committees: a scientific committee and a general committee. The general committee should advise on the social and economic impacts of biotechnology products.
- All advice must be publicly available, and the information made public should include the instances of disagreements among experts.
- Studies on the ecological impacts of transgenic crops must be carried out before they are approved for commercialisation.

One of the main conclusions from the citizens’ conference was that scientific experts do not have all the means to assess risk comprehensively. The creation of a general committee, to address the social and economic issues, would help ensure that the final advice would not be based solely on the normative judgements which underlie experts’ assumptions. In addition, having two committees would help improve the transparency of the scientific committee’s procedure.

Risk assessment expertise

Scientific composition of the CGB According to the CGB’s former chairman, the environmental risks of a GMO can be assessed from a knowledge of the precise nature of the genetic modification:

“It is possible to conduct an accurate assessment of the potential risks linked to the release of a GMO in the environment if the genetic modification is as limited as possible, if it is precisely known and previous research has allowed the elimination of all risks which are detectable. (Kahn, 1996)
Now, it is recognised that the advisory committee over-emphasised molecular constructs in its risk assessments. Environmental expertise was not sufficiently represented in the advisory committee. The organisation and composition of the CGB is to be changed.

Formerly, risk assessment appears to have been based mainly on the intrinsic characteristics of the genetic modification. Indeed, simplicity of genetic construction has been considered an indispensable pre-condition for assessing the safety of transgenic crops. Furthermore, according to the CGB’s former chairman, genetic engineering can lead to improved safety as the biological mechanisms are better known and consequently can be better controlled than in the case of conventional breeding. One of the criticisms of NGOs is that most of the transgenic crops granted market approval under Part C of Directive 90/220 were considered safe by the CGB on the basis of their molecular aspects only.

Several scientists have expressed objections to the limited range of potential risks which were assessed by the advisory committee. Public controversies tend to broaden the boundaries of uncertainties because critics (including scientists) introduce new ideas to a subject previously monopolised by a few scientific models and experts. Most of the scientist critics emphasise the lack of knowledge about the dissemination of the herbicide-tolerant gene in oilseed rape (Darmency, 1997) or about the impact of transgenic crops on bees (Pham-Delègue, 1997).

The CPP stressed in its advice on transgenic crops in September 1997 that horizontal gene transfer from plant to bacteria should be studied (even if the frequency of such events is low), as the number of traits being introduced into crops is increasing. They emphasised the necessity of developing ecological models to study the impact of gene spread in the environment.

Economic and agronomic aspects. On the economic and agronomic issues relating to the cultivation and consumption of transgenic crops, Marie-Angèle Hermitte argued that the CGB went beyond its remit, for example, in tackling technical impacts such as the potential loss of efficacy of broad spectrum herbicides (Le Déaut, 1998). Indeed, concerning the Ciba/Novartis Bt maize and the PGS oilseed rape, the CGB considered that they belonged to the class of transgenes that would produce a selective advantage exclusively in a specific agricultural context (Kahn, 1996). The probability of loss of efficacy of herbicides such as glufosinate-ammonium was considered in the risk assessment of the PGS oilseed:

“The Commission of Biomolecular Engineering also estimated that in the current state of knowledge, potential risks related to a release of the plants and herbicide-resistant genes were more economic and industrial than ecological, concerning cultivation methods and the future of the considered herbicides². (CGB, 1995).

It was recognised that the CGB was not the best place to debate the economic and agronomic impacts of transgenic crops since its remit is mainly scientific. Even though some NGO members were present in the CGB, their representation of consumers’ and farmers’ interests was not integrated into the CGB’s advice since it focused on the safety aspects only. This is why the citizens’ conference and Jean-Yves Le Déaut proposed a committee where NGOs, lawyers, farmer trade unions, and economists could settle such aspects. Some scientists and even some NGOs do not believe that a scientific advisory committee open to non-scientists would work because non-scientists do not share the same knowledge base and do not ask the same questions (interviews with experts 20/11/1997, and with the consumers association 14/5/1997). Moreover, they wonder what contribution
they could make when most of the requests are related to field trials. They feel they could contribute more usefully to decisions about market approvals since these cover more general issues.

After the citizens made their recommendations, the French government decided that a scientific committee such as the CGB does not have the legitimacy to address normative judgements. The French Minister of Agriculture, Louis Le Pensec, noted that Directive 90/220 does not take into account agricultural impacts such as the loss of broad spectrum herbicides (Le Pensec, 1998). France is trying to address this matter at the EU level through the revision of Directive 90/220.

**Food.** Until now, France has not had a committee with expertise relevant to the Novel Food Regulation. In cases where scientific data and references already exist, the CGB deals with the toxicological, allergy and foodstuff aspects under Directive 90/220. In cases where the situation is new, the CGB asks the advice of the Conseil Supérieur de l’Hygiène Publique (CSHP, answering to the Secretary of State for Health). The Prime Minister, Lionel Jospin, has announced that in future GM food safety assessment will be the responsibility of the new Food Security Agency, created by law in July 1998 and modelled on the US Federal Drugs Agency.

**Conclusion**

Since 1997, the French government has tried to implement the precautionary principle by adopting a broader definition of ‘adverse effects’. At least implicitly, the French authorities have accepted the expert advice of those who emphasize environmental uncertainties, including the advice of INRA, the official public agricultural research institute. This challenge to the technocratic model of expertise, where public decision making is exclusively based on scientific knowledge, has led to a revision of the remit of scientific expertise. France is moving towards a wider form of GMO assessment, involving consideration of social and economic concerns. While these trends may help address problems of consumer acceptance, it is difficult to see how they will accommodate harmonization of safety standards within the European market.
1 REGULATORY BOUNDARIES

1.1 National debate and policy

Since the importation of soybean and Bt. maize in autumn 1996 and the “first” market approval of Ciba’s maize in February 1997, a public controversy has been taking place in France (see chronology below). Due to the mad cow crisis, several environmental and consumer NGOs have expressed their concerns toward the commercialization of transgenic crops concerning environmental and food safety. The regulatory process and the expertise were widely criticized by these actors. Therefore the Bt. Maize crisis and the public controversy have given the Ministry of Environment the opportunity to claim a stronger precautionary content of transgenic crops safety regulation. From a technical and an agricultural debate limited to few officials inside a linear policy process, the situation has turned into a broadened involvement of actors. At the same time, the risk is being redefined as other scientific advice is being taken into account.

In September 1997 the French minister of environment asked the Ministry’s own advisory committee — the Comité de la Prévention et de la Précaution (CPP) — for advice about the deliberate release of such transgenic crops as Bt. maize, herbicide resistant sugar beet and oilseed rape. This request was motivated by the pending decision of market-approved crops such as Novartis maize and glyphosate, glufosinate-ammonium resistant oilseed rape. The CPP gave positive advice for maize cultivation claiming that it couldn’t cross with other related species in Europe. Concerning the controversial ampicilline gene, the committee reiterated the statement that it was not functional in the plant but suggested refusing any antibiotic resistant genes in the future since it is technically possible to avoid it. Conversely, the CPP thought that the approval of herbicide resistant sugar beet and oilseed rape for cultivation was premature given the uncertainties about cross pollination. More generally, the committee emphasized the necessity to implementing more studies about transgenic crops before and during (see post-market monitoring) their cultivation and their introduction into the food chain. Moreover, the need to think about how to diversify the production of scientific knowledge on risk was also underlined.

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<th>Date</th>
<th>Events and decision</th>
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<tr>
<td>February 12 1997</td>
<td>Juppé approves of Bt. maize importation only for food consumption</td>
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<tr>
<td>February 13 1997</td>
<td>Axel kahn resigns from the presidency of the CGB</td>
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<tr>
<td>May 1997</td>
<td>general election ; socialist government</td>
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<tr>
<td>Summer 1997</td>
<td>Dominique Voynet, minister of environment consults with numerous scientists and NGOs about transgenic crops.</td>
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<tr>
<td>September 1997</td>
<td>The Comité de la Prévention et de la Précaution gives advice to Dominique Voynet about transgenic crops and especially Bt. maize after giving scientists an audition</td>
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<tr>
<td>November 27</td>
<td>Minister of Agriculture Louis Le Pensec signs Part C authorization for</td>
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1997  EU-wide approval of Novartis’ Bt. maize cultivation in France while oilseed rape and sugarbeet are delayed and announces the organization of a public consensus conference on transgenic crops for 1998. A post-market monitoring is decided for each transgenic crop which will obtain a market approval as will be done for Bt. maize.

February 3 1998  3 members of La Confédération Paysanne (France’s second biggest farmer’s union) are convicted in Agen for having destroyed Bt. maize seeds in a Novartis’ warehouse in January.


June 31 1998  Prime Minister announcement concerning genetically modified plants. The moratorium imposed to oilseed rape and sugar beet, the post-market monitoring (Biovigilance) are officially confirmed and the CGB is divided in to committee.

September-December 1998  NGOs took action to revoke the government’s decision to approve the Ciba’s maize market stage (i.e. national list registration of 3 varieties; see Arrêté du 5 février 1998) by appealing to the French State Council in early 1998. They argue that the CGB and the government did not take a precautionary decision given data were missing in the dossier about an antibiotic resistant marker gene. In September the State Council gave a favourable opinion to NGOs. Commercialisation of Bt maize is suspended. In December, the final step of the procedure lead the Sate Council to ask the European Community Law Court to come to an advice about the sovereignty of the French State in the case of the market approval revocation. Furthermore, NGOs repeated the same action concerning two others transgenic maize which have been approved in August: AgrEvo TR 25 for glufosinate-ammonium resistance and Monsanto MON 810 for insect resistance (Arrêté du 3 août 1998 which approved 12 lines of transgenic maize). However, concerning these two others transgenic maize, the argument of antibiotic-resistant gene seems to be irrelevant as they do not carry such genes (SCP 1998a and 1998b). Thus we can wonder about the conclusion of the French State Council about this legal action.

October 7 1998  The European Commission warned French authorities concerning some irregularities: the moratorium imposed on oilseed rape and sugar beet and the refusal to deliver final market consent for two PGS’s oilseed rape varieties and non-respect of the 90 days period foreseen under Directive 90/220 concerning several transgenic crops market applications which have been submitted by companies.

### 1.2 Crop/food boundary

When in 1995 several market approvals of herbicide resistant oilseed rape were submitted to the CGB, food safety demonstration (oil, seeds and meal) was requested under 90/220 following the principle of substantial equivalence. The CSHP (Conseil Supérieur de
l’Hygiène Publique place under the authority of the State Secretary of Health) was solicited on this question. It appears that the food part has postponed for two years the approval of most requests at the French level. Concerning the toxicological, allergy and foodstuff aspects, the CGB deals with the cases for which scientific references about safety are existing. If the situation is new, the CGB asks the CSHP for a study. Until now, France has not had any committee which could claim a specific expertise under the Novel Food Regulation. This impasse should be resolved as the Prime Minister, Lionel Jospin, announced GMOs food security assessment will be achieved by the new Food Security Agency created by the law of the 1st July 1998.

1.3 Crop/pesticide boundaries

Pesticides’ market approval, whom usage is regulate for specific purposes, is granted by two committees (Commission des Toxiques et Comité d’Homologation) which are placed under the authority of the Ministry of Agriculture. For herbicide resistant crops such as oilseed rape, the CGB has considered the use of herbicide on this plant as a relevant issue for the Gmo’ safety assessment process. Metabolites and residues data were especially important in this respect. Despite the fact that most chemical firms mention that data on pesticide usage are not relevant to 90/220 (but to 91/414), information on the use and approval of herbicides were given as a background information regarding health issue. Regarding toxicity, the CGB has always considered that the increase in one herbicide application could have adverse effects on the crop’s metabolism (e.g. new toxic metabolites). This request has been progressively accepted by notifiers as an important point for market approval.

1.4 French-European dynamics

France has been the country where most field releases of transgenic crops have been conducted. Thus the CGB has always interpreted its role in promoting France as a leading country in agricultural biotechnology. The CGB requested specific information (e.g. residue and metabolites for herbicide resistant crops, or data related to the transgenic fragment inserted in a commercial plant - “limited to what is indispensable to the desired effect” — and its molecular description) as relevant for assessing the safety of transgenic crops. Some of these arguments became standards among the European CAs and at the Commission.

Also, there were a lot of pressure imposed by French officials to influence policy process at EU-level such as the Novel Food Regulation. Thus, as soon as the CGB found out about the content of the draft NFR in 1994-1995, the secretary of the French advisory committee tried to convince European regulators that the food safety assessment had to focus on the genetic modification, on the new molecular and biochemical mechanisms involved in the additional gene.

Furthermore, many synergies seem to exist between France, Germany and the United Kingdom in order to influence Europe’s GMO regulation.
2 NORMATIVE JUDGEMENTS

Since the first field releases of transgenic crops, the CGB has emphasised the “precision” of molecular constructs inserted in plants. Thus, the safety and social acceptability of transgenic crops are linked to the intrinsic characteristics of genetic transformation. According to the CGB, “the goal of genetic engineering in agriculture is not only to produce more, but also to produce with increased safety standards” (Kahn, 1996). Consequently, Axel Kahn (CGB’s chairman) has always considered that any risks would be unacceptable concerning plant biotechnology, given that public opinion has never sought any transgenic crops. But as soon as several crops such as herbicide-tolerant oilseed rape, sugar beet and maize or insect-resistant maize were ready to request market approval, the French advisory committee has been confronted by the dilemma of whether or not agricultural practices are relevant to environmental risks under Directive 90/220.

2.1 Predictive/normative links

The PGS oilseed rape proposed by UK in 1994 was probably the main case through which the CGB has dealt with the definition of what is an environmental effects within agricultural practices (Levidow, 1996; Kahn 1997). Concerning its herbicide-resistant marker gene, the PGS oilseed rape was considered to belong to the class of transgenes which can produce selective advantage exclusively in a given agricultural context (Axel Kahn, 1996). By developing this argument, the CGB raised an implicit definition of risk: as environmental safety is acquired, the issue move into agronomic perspective within which alternatives solutions exist if any problems occur. As environmental risks are being covered, the potential risk becomes more acceptable as it is limited to the agricultural context of transgenic crops use.

However, concerning the use of broad spectrum herbicide such as glyphosate or glufosinate-ammonium on several transgenic crops such as oilseed rape, sugarbeet and maize it seems that the judgement of the CGB has changed. Indeed, given the range of problems linked to multi-herbicide-resistant crops within cultural rotations, herbicide-resistant weed and herbicide-resistant volunteers, the CGB considered as a concern the risk of loosing “benign herbicides” (from an environmental point of view) which could lead to use again “classical” herbicides. The CGB tried to alert agricultural professionals in order to make them aware about the negative aspects of this situation. Given this argument, the CGB proposed to grant market approval for five year in order to detect any adverse effects within post-market monitoring. As notice by Levidow (1997), such a legal restriction raises doubts as the CGB excludes any environmental risk. Thus, the matter concerns the characterisation of the scope of the risk: "The term environment should be understood in a broad sense: herbicide-resistant weeds can be an environmental problem for the relevant agrosystem." (Axel Kahn cited by Levidow, 1997).

By contrast, we can noticed that the CGB didn’t defined as such the risk of Bt insect-resistant for the Novartis’ Bt maize.

2.2 Risk assessment

What Axel Kahn (1996) calls the “philosophy” of the CGB could be summarised as follows:
- “The goal of genetic engineering in agriculture is not only to produce more, but also to produce with increased safety standards.

- It is possible to conduct an accurate assessment of the potentials risks linked to the release of a GMO in the environment if the genetic modification is as limited as possible, if it is well known and previous research has allowed to eliminate all risks which are detectable.

- Risk acceptability is relative and depends on the importance for the population of the firms’ goals. Thus, risks are accepted in medicine in order to treat an incurable disease. On the opposite end, in agriculture, any identifiable risk would probably be unacceptable to people because in our industrial countries they don’t have any special needs in this field.

- Risk assessment is a process which is based upon the definition of risk: the product between a level of danger and its probability. Thus, the CGB studies potential hazard, based on all the knowledge about the transgene, its interactions with the recipient plant and the previous releases. In the case of a potential risk, the committee tries to tackle the probability of its occurrence “.

As baseline, the CGB has always considered that genetic engineering increases safety as the genetic information is precisely known and the genetic transformation process is more controlled than classical plant breeding. In this respect, adverse effects are more predictable as the knowledge of genetic modifications have reached an unprecedented level (Axel Kahn “Pourquoi tant de haine contre ce pauvre maïs ?” in *Le Monde*, 09/12/97). This assertion illustrates the main idea which underlines genetic engineering: “one gene, one function”. Consequently, as the genetic structure of the insert is perfectly determined and the properties of the protein whose synthesis it regulates, genetic interactions and metabolism between the new gene and the host plant should be analysed.

In 1996, the CGB published a book which draws up a balance sheet of 10 years of activity. In the presentation of the risk assessment framework which has been applied, Axel Kahn underlines:

- “The French Biomolecular Engineering Commission does not consider that genetic engineering used to improve plant varieties is by itself dangerous. Consequently, the potential risk of the cultivation of such transgenic plants can only be appreciated on a case-by-case basis. The risk assessment procedure takes into account:

  - the nature of the transgene,
  - the genetic construct,
  - the plant species and variety,
  - the culture condition and the ecosystem,
  - the food or the industrial use.

According to these various elements, the Commission successively assesses:

- toxic risks,
- food and feed risks for animals and humans,
– allergic risks,
– ecological risks
– economic risks “.

The first three categories of risk encompass the technical knowledge mastered rather well within the scientific community. On the other hand, ecological risks and economic risks seem to be of another nature insofar as they are located at the limit of experimental capacities and the mandate of the CGB.

For ecological risks, the CGB underlined four types of risk:
– the proliferation in the ecosystem of a transgenic plant or an interfertile species into which genes were inserted, which could confer them a selective advantage
– the effect on the insect population equilibrium
– plant selection of pathogenic properties
– the horizontal transfer of DNA, in particular onto the soil bacteria

These elements induced the CGB to classify transgenic crops into 3 categories:

**Class 1** corresponds to transgenes which do not confer host plants a selective advantage: male sterility trait, amino acid content;

**Class 2** corresponds to transgenes which can produce a moderate selective advantage in a given agricultural context. Thus **under-class 2a** relates to characters which do not have a selective advantage apart from an agricultural selection pressure like the use of a herbicide. **Under-class 2b** gathers plants whose selective advantage can be observed on any occasion like bacteria resistance genes to viruses or fungous;

**Class 3** gathers characters which can produce a strong selective advantage with plants like the increase in the performances of the biological cycle. This category is modulated according to the capacities of the plant to be disseminated by crossing or dormancy.

Concerning ecological risks, the transfer of herbicide-resistant genes from oilseed rape to wild species — or the possibility of having volunteers which have acquired several herbicide resistances within cultural rotations — has always represented a major problem for the CGB within the framework of transgenic crops’ market approval.

For ecological risk linked to agricultural practices, the CGB has always considered that field trials does not allow to answer these interrogations. It is then necessary to implement tests appropriate for agricultural practices as much as possible.

Moreover, even if economic risks seems to be secondary under Directive 90/220 (such as those which encompass the cultivation of broad spectrum herbicide-resistant transgenic crops) they were tackled by the CGB in order to alert government authorities, agricultural technical institutes and plant biotechnology firms rather than conducting an assessment within the Directive 90/220 market approval notification.

**2.3 Familiarity**
Although “familiarity” is a key concept concerning risk assessment related to transgenic crops, it has never been explicitly used as a tool of analysis within the framework of the CGB’s expertise.

However, familiarity is implicitly implemented through the restriction of molecular constructs inserted in the transgenic crop. Biohazard is expected to be reduced if genetic modifications are limited as much as possible to what is strictly necessary to the desired effect. Familiarity is then implicitly linked to the simplicity of the novel DNA fragment as theoretically the plant’s behaviour is only affected by a single gene. Thus, unpredictable effects are proportional to the complexity of the genetic construction. For example, recombination between plant DNA and soil micro-organisms may be avoided by removing procaryotic replication origins (ORI) (Kahn in OECD, 1993).

Familiarity is also implicitly used as a reference in several stages as in the case of toxicological assessment. Indeed, the toxicity of the new protein or enzyme is assessed by comparing it with the main existing molecules or enzymes known for their toxicity which are referred to in the database. It was the case in the assessment of the enzymes’ metabolism which degrades the herbicide (as for instance Glyphosate, Glufosinate-ammonium and Bromoxynil).

Generally, the assessment of herbicide influence on the plant metabolism has allowed the CGB to see if the higher use of pesticide on a given plant (on which it was never used) causes some unintended effects which could be harmful. Consequently, the goal of the question was to compare a new weed-control system with the previous one.

2.4 Specific cases

**PGS oilseed rape**

In its 1994 annual report, the CGB has presented its analysis of PGS market approval. The assessment has mainly carried on the glufosinate-ammonium resistance trait expressed by the gene Bar. The assessment focused on the consequences which result from the transfer of this gene towards wild relatives’ species. Furthermore, the risk of seeing oilseed rapes becoming volunteers in other cultures was assessed. The CGB estimated it did not have enough data concerning the spreading of the Basta resistance traits. On this basis the Commission concluded that:

“However, according to the Commission of Biomolecular Engineering, these hybrid seeds do not constitute a risk for man and the environment justifying a refusal to approve the market request because the selection pressure which may occur in this particular case is low. Indeed, the use of the herbicide is limited since the glufosinate will be employed only during the production of seeds and not within agricultural practices.

The Commission of Biomolecular Engineering also estimated that in the current state of knowledge, potential risks related to a dissemination of the plants and herbicide-resistant genes were more economic and industrial than ecological, concerning the cultivation methods and the future of the considered herbicides”.

This judgement has been challenged in November 1997 when the government decided to impose a two years moratorium for the commercialisation of herbicide-oilseed rape in order to wait for more scientific data about the agronomic impact of herbicide-resistant
gene release. Thus, agronomic issues are being included in the range of adverse effects which have to be assessed within the framework of market approval’s safety norms.

Moreover, two others herbicide-resistant oilseed rape applications were submitted by PGS to the French advisory committee in 1995 for unrestricted cultivation (Ministère de l’Agriculture/Ministère de l’Environnement, Commission du génie biomoléculaire: activité en 1995). The CGB gave a favourable advice to these applications. But we do not have any information about the analysis which was developed by the CGB about these files. Thus, did the CGB proposed the same analysis for the PGS application proposed by UK in 1994? We doubt about this given herbicide selection pressure is greater for cultivation than for hybrid seeds production. However, the French government also applied a moratorium for these two others applications.

**Bt. maize**

Concerning the market approval request of Novartis Bt. maize, the CGB went through one of the most difficult stages since its creation. Indeed, its assessment has mainly concerned the gene cryIA(b) expressing the Bt. toxin rather than the ampicilline resistance gene. Thus, in the 1994 annual report (Ministère de l’Agriculture, de la Pêche et de l’Alimentation/Ministère de l’Environnement, Commission du Génie Biomoléculaire: activité en 1994.) there appears a short description of the request for Ciba market application to which the CGB delivered a favourable opinion, the Commission estimated that the gene Bar expressing resistance to the glufosinate did not raise any problem insofar as corn could not cross with other wild species in Europe.

Concerning the Bt. gene, the report indicates:

“ To assess the expression by the transgenic plants of Bacillus thuringiensis (Bt.) toxin, the Commission of Biomolecular Engineering considered that Bt. toxins are very specific and that they are known for their harmlessness concerning the nontarget insects and other animal species. The plants expressing the Bt. toxin replace often difficult and expensive processing and constitute a security against the predators whose attack is only partially foreseeable.

Consequently, the Commission of Biomolecular Engineering delivered a favourable opinion considering that in the event of the appearance of toxin target-resistant insects, there are alternative means to fight against these predators ".


In an article published in *Le Monde* (December 9th 1997), Axel Kahn wrote that European Corn borer resistance to Bt. has still never been detected in the world. Speaking about the Bt maize he wrote:

“ If such a resistance would occurred, the only hazard would be to be brought back to the current situation, e.g. this variety would lose its interest “.

The assessment of insect-resistance to Bt maize impact raised by the CGB was challenged by the French government in November 1997 as the cultivation approval has been linked to a 3 years post-market monitoring in order to detect such events. As in the case of herbicide-resistant oilseed rape, Bt insect-resistance is considered as relevant within the assessment of adverse effects.
**Antibiotic resistant marker gene**

In the same article, Axel Kahn, speaking of ampicilline gene, emphasises that even if it is not “attractive”, it does not raise any problem as it is not functional in the plant. The transfer of this gene onto the bacterial flora is “highly improbable”. Nevertheless, if the transfer occurred, it would be harmless, since 50% of pathogenic bacteria of men and cattle’s digestive flora still carry such resistance among many others. “In other words, there is really no possibility that Novartis maize would increase this dramatic problem of antibiotics resistance release”.

However, this controversial gene is still ambiguous regarding the French risk assessment. In November 1997, the French government approved of the cultivation of Novartis Bt. maize and emphasized that no antibiotics gene would be accepted for market approval in the future as technical methods exist to eliminate such fragments. Nevertheless, such an explanation remains ambiguous for public acceptability and trust in expertise and public policy.

The contradictions which have been raised by this decision, have generated many oppositions inside the political community. Thus the following press release from the Ministry of Environment (09/12/97) reflects the difficulties to make a balance between public acceptability and scientific judgements when economic and political interests underlie a public decision.

“Conscious of the importance of this subject, at the suggestion of Mrs Dominique VOYNET, the Government will not authorize a new marketing nor the cultivation of genetically modified plants containing antibiotic-resistant genes; this question will be subjected to public discussion animated by the Parliamentary Office of the Scientific and Technological Choices, and the Government will make its final decision on this question in the light of this debate.

In addition, the authorization of importation and consumption of the Novartis corn was given by the preceding government. It was not called into question by the current government, taking into account the opinion of the consulted scientific committees, which are French, European or American. The latter showed the improbable passage from ampicilline-resistant genes to the bacteria of the digestive tract and especially noted that this gene is already largely present in the ecosystem (50% of the pathogenic bacteria of the digestive tract of animals and men have this gene of resistance. For this reason, the secretary of State for Health gave a favourable opinion for the authorization to set this corn into culture”.

But, as the French government authorized the cultivation of Novartis’ Bt. maize on 4th February 1998, Greenpeace and Ecoropa took action to revoke the decision by appealing to the French State Council (Conseil d’Etat). According to Greenpeace and Ecoropa, the main concern of the complaint focused on the antibiotic-resistant marker gene which have been “omitted” by the advisory committee’s risk assessment. “This is in spite of the fact that the most recent scientific evidence (by Professor Courvalin, May 1998) shows that the return of antibiotic-resistant marker genes by horizontal transfer to soil bacteria and to the gut of mammals is possible, with all the negative consequences that this implies for public health and the environment.” (FoEE Mail Out, Vol. 4, Issue 6, 15th SEPTEMBER 1998). Finally, on 25th September 1998 in its first advice, the French State Council acknowledged that the precautionary principle has not been apply by the French government.
3  RISK-ASSESSMENT RESEARCH

3.1 General

By funding risk-assessment research, scientific expertise tends to influence the way in which the definition of risk occurs and how adverse effects and predictability are taken into account.

Thus, cross-pollinisation in the case of herbicide-resistant oilseed rape has been one of the main concern on which the CGB has focused its attention. Many studies have been funded in this respect (however, most of them have been conducted within European research programs as BRIDGE or BIOTECH) and have given results which were published in the best scientific revues (Chêvre et Renard). Thus, in October 1997 a research team of INRA (Institut National de la Recherche Agronomique) published in Nature an article in which they confirmed the intergeneric gene flow ability by transgene introgression within the genome of oilseed rape’ weeds as wild radish and the viability of progeny. This result seemed to have an influence on the French government’s decision to delay herbicide resistant oilseed rape market approval. As well, this result was relevant enough to convince some plant breeding scientists to choose to delay using genetic engineering tools in creating new varieties (Michel Renard et Anne-Marie Chêvre, CNRS, Avril 1997).

Nevertheless, in relation to the precautionary principle, expertise has to deal with the way of using results provided by risk-assessment research. Then, the problem is to define which data are relevant for approving of the cultivation of a transgenic crop. In considering that: agronomic consequences related to cultivation at the same time as several herbicide-resistant crops are not easy to assess within the framework of small-scale field trials ; and that gene flow studies do not provide relevant information allowing decision-making, the CGB has proposed to set up a post-market monitoring system (système de biovigilance) in order to detect all adverse effects related to the cultivation of herbicide and insect-resistant crops (such as oilseed rape, sugar beet and maize). Marketing became thus possible only upon this condition. Indeed, the CGB has always estimated that only agricultural practices could answer these questions, i.e. on significant surfaces and within the framework of cultural rotations implying different crops (corn, oilseed rape, beet, fallow) and different herbicide-resistant traits (Glyphosate, Glufosinate, Bromoxynil).

In 1993-1994, the CGB funded studies which use theoritical model of population genetics in order to collect numerous parameters concerning the biology of oilseed rape. This task was aiming at building a database in order to implement the post-market monitoring.

“The idea is to use this model to define important parameters, which can inform us on eventual biological desequilibrium at early stages among different parameters, for example, one can ask whether survival of seeds is very important or not. Or is the fact that the pollen can move over ten kilometres, or over only one meter, important or not ? We hope that after one year, some important parameters can be defined and being used to check, to surveille, the environment”. (Aigle in Institut of Hygiene and Epidemiology, 1994).

But the CGB came to idea that such a model was too theoretical and raised much more question than answers. Such difficulties were summarised during a workshop in 1994 on this subject as follow:
“I must admit I am at a loss to know how you monitor for things that you don’t know what they are. [...] But I confess, until I see the results of that model, I have doubts as to whether it’s a practicable proposition. I do know that if you have a model with about 42 parameters, then you can explain the meaning of life in the universe and everything. I mean that follow mathematically if you like. However, as soon as you simplify your models, you start ruling out some of these other unforeseen things. Thus, the latter just does happen to conform to your particular simplified model. This just happen to adequately describe the present situation. You can only ever predict the past. You can only guess at the future”. (Institut of Hygiene and Epidemiology, 1994, p. 55).

So the CGB progressively gave up its funding priorities on population genetics studies. The CGB came to the idea that parameters have to be collected from field trials which simulated agronomic practices. In 1995, such an idea was implemented through a 3 years trials conducted by technical institutes (see Section 3.2).

When in September 1997, the Ministry of Environment asked the CPP to give its advice about risks related to transgenic crops, the committee stressed that several kinds of scientific research haven’t been developed enough and should be carried out: e.g. allergenic risks and ecological studies.

Insects’ resistance studies have been also funded by the French authorities. Thus, a research team from INRA conducted a study on insect (bees)-resistant oilseed rape which produces protease inhibitors and found out that for instance such genetically modified crops do not affect the bees’ mortality (Picar-Nizou A. L. et al., Transgenic Research, 1995). However, the author emphasized that this kind of study must be continued in order to test further uncertainties.

3.2 Large-scale monitoring

As mentioned above, large-scale monitoring has always been considered as the only way of linking market approval to precaution. Indeed, in 1994/1995 several transgenic crops were ready to request market approval e.g. glyphosate, glufosinate, bromoxynil resistant oilseed rape, maize and sugar beet, Bt. resistant maize, etc. In this respect, the large-scale cultivation of these crops altogether raised questions about cultural rotations; Firms and scientists managed to convince the French advisory committee that gene flow was an agronomic problem as opposed to an environmental one. Post-market monitoring was seen to be the best solution to articulate market approval with a public decision made within the precautionary principle.

Several agricultural technical institutes (CETIOM, AGPM, ITB & ITCF) in collaboration with chemical firms such as Rhône-poulenc, Monsanto, AgrEvo and Novartis have been conducting since 1995 large-scale field trials in order to study the impact of herbicide-resistant oilseed rape within agricultural practices. This trial aims at collecting data in order to get parameters for the post-market monitoring. By harvesting in the same field several plots of transgenic crops maize, oilseed rape, sugarbeet) which are resistant to bromoxynil, glyphosate and glufosinate-ammonium, this study aims at looking at the probability and the consequences of herbicide multi-resistances on agricultural practices, and also gene flow by looking to weedy relatives around the plots.
Even if the French advisory committee is not the official supervisor of this study, this plan of action appears as a decision-making auxiliary inside the public market approval decision-making process. Thus, the CGB proposed to delay any herbicide oilseed rape variety registration until the end of inter-instituts study (Autumn 1998) (see Section 3.3).

### 3.3 Plant variety registration

**Herbicide tolerant oilseed rape**

The way of linking plant variety registration field trials to risk assessment under 90/220 has been a recurrent issue between the CGB and the French List authorities (Comité Technique Permanent de la Sélection). Indeed, as there were concerns about gene flow, the CGB has always been reluctant to the idea of conducting plant variety registration trials without a full part C clearance. Thus, as CTPS argued that in order to produce advice on the herbicide-resistant oilseed rape ability tests should aim at comparing altogether the 3 crops as variety assessment has to focus on the new character inserted. CGB argued that such a test would present some multi-herbicides-resistant risks. Thus, the French advisory committee suggested spatially separating the two herbicide resistant oilseed rape varieties.

In the case of herbicide-resistant oilseed rape, It seems that the CGB wanted to block the list registration experimental protocol until the end of the trials conducted by several technical institutes in collaboration with chemical firms such as Rhône-Poulenc, Monsanto, AgrEvo and Novartis (see Section above). Thus, the French government resolved the conflict between the CGB and the CTPS by imposing a moratorium in November 1997. It seems that the CGB was not able to block herbicide-resistant oilseed rape market consent because no direct environmental adverse effects were found. Thus, given the CGB has interpreted Its remits within the scope of the Directive 90/220 by removing agricultural impacts from the range of environmental direct effects, the advisory committee did not raised any clear objections based on agronomic aspects. By imposing a delay to variety list registration process not motivated on clear argument, the CGB has implemented an informal moratorium. Such an impasse has been overcome by a strong decision from the government to impose an official moratorium which could not be contested by anyone.

In the case of the PGS’s plant variety registration, this issue has been resolved as the test aims at assessing the hybrid characteristics as opposed to glufosinate resistance.

**Bt maize**

When the French government approved the cultivation of the Bt. maize in November 1997, it decided to implement a post market-monitoring within the framework of the Comité de Biovigilance (place under the authority of the Ministry of Agriculture and the Ministry of Environment) in order to detect any adverse effects such as insect-resistance to Bt. (it would be so for each market approval). Moreover the approval (National List Registration) was granted for 3 years (Arreté du 5 fevrier 1998.). This unusual decision to approve cultivation only for 3 years in order to detect any adverse effects (i.e. Bt. corn borer resistance, effects on non-target insects effects on ground bacteria, effects on cattle’s bacteria digestive flora due to feed produced from transgenic corn in order to detect any ampicilline resistant events) was criticised by some scientists insofar as it was not enough time to observe any of them. The Comité de Biovigilance was temporarily created and constituted in order to follow Novartis’s Bt. maize. The committee is composed by several
scientists (ecologist, population dynamics), seed companies and environmental NGOs (*Greenpeace*, *Confédération paysanne*). Given the diversity of the committee an additional adverse effect has been included within the existing monitoring framework previously enacted in the list registration decree. Cross pollination between transgenic maize and non-transgenic maize has been assessed in order to study if the proximity of both may affect farmers choice to cultivate non-transgenic maize.

Thus, as cultivation is legally approved by the Ministry of Agriculture after the notification of the CTPS, (National List Registration’s notification committee), variety registration becomes a mean for implementing risk assessment within a precautionary approach (*see also, EU-Level Issues, Section 3.3.2*). Precaution is being achieved within the last stage of commercialisation. Indeed, post-market monitoring "implied that commercial use would be an experimental step" (Levidow, 1997).

### 3.4 Familiarity

The CGB used to consider that market approval should be granted only if the considered transgenic crop couldn’t have been obtain with traditional plant breeding methods. On this basis, the risk assessment is carried out upon the comparison of several adverse effects between the transgenic crop and its traditional counterpart. Thus, following the analytical framework used by the French advisory committee (see Section 2.2), the application file for market registration of genetically modified oilseed rape tolerant to herbicides demonstrates harmlessness by comparing each potential adverse effect between the transgenic crop and its classical counterpart. Thus, safety assessment is implicitly based upon the familiarity criterions notifiers define the burden of evidence by demonstrating that the genetic modification does not change any biological or chemical behaviour compared to the non-modified counterpart., other than the inserted gene.

But it appears that this way of using familiarity criterion is not relevant in every case of adverse effect such as gene flow. Indeed, even if gene flow does not occur more frequently with herbicide resistant oilseed rape than with classical winter oilseed rape, it does not mean that the risk is equivalent. Thus, the problem becomes different if we are to consider that herbicide-resistant gene could give a selective advantage when using a broad spectrum herbicide such as glyphosate or glufosinate-ammonium. Even if that kind of example seems to be trivial, it shows the limit to which the familiarity criterion could lead us in assessing the ecological impact of transgenic crops. This is the reason why most scientists, chemical firms and regulators came up with the idea of conducting large scale field trials within post-market monitoring releases for herbicide-resistant oilseed rape, maize and sugar beet and Bt. maize.

### 3.5 Ecology

Although ecological models (*génetique des populations*) have been funded by the Ministry of Agriculture in the early 90s for assessing gene flow, the French advisory committee didn’t pay many attentions to these results. Indeed, according to an expert interview, ecological models “are too far from what really happens in the field. We were expecting models which could be tested in agricultural conditions”. Therefore, gene flow studies conducted in “the field” where genetic mechanisms can be directly observed have an advantage over ecological theories. What this interviewed expert wanted to emphazise is
that expertise and decision makers need realistic and concrete data upon which an advice or a decision could be based.

Since 1996-1997, a public controversy has developed in France supported by environmental NGOs such as Ecoropa, la Confédération paysanne or Greenpeace which request a moratorium for GMOs releases. Moreover, one of the main critics addressed to the government was an insufficient consideration of ecological models within expertise. Thus, feeling an important public opposition to transgenic crops, the French government is now intending to pay more attention to ecological models. As the composition of the CGB will be revised in the next months, several officials suggest including more ecologists in the advisory committee following the idea that CGB have been too monolithic so far.

4 LABELLING PRACTICES

4.1 General

As many others European countries, France has ”suddenly discovered” in 1996 that the food produced from genetically modified maize and soya imported from the United-States were arriving into the consumers‘ kitchens. Thus, on February 2nd 1997 through some official advice to economic operators, France decided to guarantee the total information on such products without waiting for the Novel Food Regulation to come into being. Because of the context of distrust linked to several food safety crises such as BSE, the French government paid a lot of attention to the opportunity of labelling foodstuffs produced from GMOs. Facing the impossibility to detect most GMOs (Soy lecithin) incorporated in foods, many consumers and environmentalist NGOs demanded strong decisions on the part of the government. Labelling became a major issue linked to public acceptability of transgenic crops in France. In April 1998, the National Consumption Institute published a study which demonstrates that several food products contain genetically modified maize without being labelled. NGOs do not hesitate to protest that consumers are used as “guinea-pigs” since, they don’t have any choice in the matter although the Novel Food Regulation is existing.

Following a strong distrust feeling among consumers toward GMOs, major food retailers such as Carrefour and Leclerc have pronounced in favour of a clear labelling practice and refused to use GMOs in any foodstuff which belongs to their own trademark.

However, the GMOs’ labelling controversy does not really arise in term of safety. It rather appears as a public acceptability issue to all economic, political and social actors. Thus, with food labelling, the tranngenic crops debate has brought the controversy to a public level (Limoges and Cambrosio). This issue is mainly a question of giving consumers the right to choose what they want to eat.

4.2 Leblling under Directive 90/220

1997 was not a good year for the CGB as a consequence of Axel Kahn’s resignation in February. The committee did not work until May and was dissolved the next November. Given the public controversy which took place in France, and due to a stronger involvement by the new government in the GMOs, the CGB has been less able to play a key role concerning NFR. GMOs policy guidelines are being elaborated at a higher level than they
were before. Thus, concerning decision 97/35/EC and also NFR, the CGB adopted a case-by-case attitude (linked to the pending market application) rather than a global one.

When decision 97/35/Ec was carried out, the CGB asked the pending market approval notifications to provide information related to the detection of the new DNA in products derived from the transgenic crop. Thus, each notifier was asked to provide oil DNA analysis even if such elements are not supposed to exist in oil and thus as a label would not be required in this case.

It seems that the CGB wanted to anticipate a wide labelling requirement policy at EU-Level. Moreover, as the social context was hostile to GMOs, the CGB wanted to make sure that each applicant got the technical means to implement GMOs detection in every case and at any stage. Firms interpreted this increase of requirements as a consequence of previous events related to Axel Kahn’s resignation. Also, the attitude of the new government toward GMOs seems to emphasize a wider precautionary approach than before. It may have increased the level of requirements regarding to detection, traceability and labelling.

### 4.3 Labelling under the Novel Food Regulation

The demonstration of equivalence delayed many market application files at the French level. Indeed, two herbicide-tolerant oilseed rape files were submitted for market consent in 1995 but were asking until 1997 additional data related to food safety. It seems that Substantial equivalence demonstration has been a difficult problem solving for CGB as an official acknowledge as follow: “I appreciate that the more organs we measure the higher the risk we have of finding a negative result”. According to this expert, It is difficult to set “objective” criteria in order to reach a “relevant” substantial equivalence analysis. Thus, each step of the assessment may revealed some irregularities which could not be due to the genetic transformation but rather to the diversity of compounds which are tested. It was recognized that substantial equivalence is not a safety assessment in itself but more an analytical exercise in comparative assessment against an existing food. Consequently, food safety is best suited assessing substances with a relatively simple composition which contains no toxins or anti-nutrients e.g. refined rape oil. In case of oilseed rape, anti-nutrients such as glucosinolates were one of the main problem within the substantial equivalence assessment.

Thus despite the French advisory committee required some additional data within the framework of substantial equivalence analysis, it was asking to notifier to remove some of these results from the market application files by considering it as French question. Thus, the CGB didn’t want to set a precedent by including data whose relevance was not scientifically based enough for being taken into account at the EU-level.

### 4.4 Animal feed

No data
5 A EUROPEAN MARKET?

Since 1996, a broad debate has been taking place in Europe concerning the commercialization of several transgenic crops such as the Monsanto soyabean and the Novartis Bt. maize. France has been widely affected by the EU situation as a public controversy has developed. The case of the ampicilline gene of the Novartis Bt. maize raises issues about how national expertise anticipates safety standards at the EU-level. Moreover, herbicide-tolerant oilseed rape shows how the precautionary principle becomes a policy and social concern at the market stage.

5.1 European versus national authority?

Until now, France has been the place were the higher level of transgenic crops trials and market approval were granted in Europe. Given this prevailing position, France tend to have a major role in the elaboration of safety standards at the Eu-level. Since the events related to RoundUpReady-resistant soybean importation and Novartis Bt. maize (Axel Kahn’s resignation) in February 1997, a large debate has took place in France toward genetically modified organisms. The cultivation of crops such as Bt. maize or herbicide-resistant oilseed rape has become a major question with regard to policy decision-making process. Thus, French’s GMOs public policy seems to move toward a stronger precautionary approach by involving social actors such as consumers and ecologists. Consequently, the centralism of the CGB seems also to decrease as others advisory committees (e.g. Comité de la Prévention et de la Précaution placed under the Ministry of the Environment) are involved in expertise.

Moreover, the French Ministry of Agriculture Louis Le Pensec (17th September 1998) even noticed that the directive 90/220 do not take into account (according to its interpretation) agricultural impacts such as the loss of broad spectrum herbicide in case of herbicide-resistant gene flow. France is trying to settle these concerns at the Eu level within the revision of the Directive 90/220.

5.2 Ciba/Novartis Bt maize

Ciba’s (now Novartis) Bt maize market approval could be describe as a textbook case regards to conflicts which arise from the different framework of risk assessment within European directive 90/220.

Cultivation of Bt maize have been blocked until February 1998 despite France was the rapporteur. Moreover, the French State Council (Conseil d’Etat) challenged in September 1998 the government decision of approving the cultivation of Novartis maize, given the action which have been taken by Greenpeace and Ecoropa (Section 2.4). If such a situation would occur, we can wonder if the EU-notification would be challenged too. In December, the final step of the procedure lead the Sate Council to ask the European Community Law Court to come to an advice about the sovereignty of the French State in the case of the market approval revocation (Le Monde, 13-14 December 1998). Thus, the market approval remain suspended. Furthermore, NGOs repeated the same action concerning two others transgenic maize which have been approved in August (AgrEvo TR 25 and Monsanto MON 810 in Arrêté du 3 août 1998). However, the prospect of this latest legal action could failed as these two transgenic maize do not contain the whole DNA sequences of the
antibiotic-resistant marker genes in both cases (neither they are linked with a bacterial promoter which may allow the replication of the gene into bacteria as it is the case concerning the Novartis Bt maize) as it was stressed by the opinions of the Scientific Committee on Plants/DG24 (SCP 1998a and 1998b).

From France, Ciba’s Bt maize raise many questions about the numerous contradictions which have been seen since the beginning of the EU-controversy in 1996. Indeed, what about the ampicilline gene? The CGB has always claimed not to approve any crops which contains an antibiotic-resistant genes if technical means are available to avoid it (see Section 2). Until the EU-dispute about the ampicilline-resistant gene, this gene has never been mentioned in any reports where the Ciba’s maize was presented. Even, in the 1994 annual report, the CGB did not mention it. Thus, explanations from officials, industrials or experts about this unexpected gene do not solve this contradiction.

Another contradiction, was the prime minister (Alain Juppé) decision in February 1997 to ban cultivation after the genetically modified maize was approved at the EU-Level. The prime minister argument was that several environmental uncertainties were existed as gene flow. As Axel Kahn estimated that a such argument was not scientifically based and that the credibility of the CGB was thus undermined by the French government.

When in November 1997, the French minister of agriculture Louis Le Pensec approved the cultivation of Novartis’ maize (for 3 years as the official decision mention it) others contradictions have been revealed. First, the government asserted to refuse any antibiotic-resistant genes in future although the Novatis’ Bt maize contained such a gene. Secondly, many officials and NGOs protested that the consent was premature as the government decided to organise a public debate on transgenic crops in June 1998. Several opponents to Bt. maize as Etienne Vernet of Ecoropa underlines: “Obviously, the French government surrendered to interests of multinational agrochemical companies and its decision is entirely commercially motivated” (FoEE Biotech Mailout, 15th December 1997, Vol. 3, Issues 8).

5.3 Monsanto soybean

Several supermarket (Carrefour, Casino) refused to include genetically modified soybean in their own-brand products. Thus, some of them asked to food wholesalers to certify that product which are composed with soybean were not coming from genetically modified crops.

5.4 Herbicide-tolerant oilseed rape

In the case of herbicide-tolerant oilseed rape, the French government decision to delay any market approval (e.g. cultivation) officialized the anxiety shared among scientists since articles published in Nature have demonstrated the high probability of cross-pollination between oilseed rape and its wild relatives and the consequence of getting herbicide-resistant fertile hybrids.

Moreover, as in the case of the cultivation of the Bt maize, France was the rapporteur of two hybrid oilseed rapes (with also an herbicide-resistant marker gene) which were approved at the EU level. Given the moratorium imposed on herbicide-oilseed rape, the French government refuse to sign the part C.
REFERENCES


