THROWING CAUTION TO THE WIND

A review of the European Food Safety Authority and its work on genetically modified foods and crops.

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SUMMARY

The GMO Panel of the European Food Safety Authority (EFSA) has not made a good start. In just over a year it has published twelve scientific opinions, virtually all favourable to the biotechnology industry. These opinions have been used by the European Commission, which is under increasing pressure from the biotechnology industry and the United States, to force new GM products onto the market.

The Commission does not appear to be using the EFSA as a means to further scientific debate about GMOs and the concerns raised by scientists from around Europe. Instead, they are being used to create a false impression of scientific agreement when the real situation is one of intense and continuing debate and uncertainty. Concerns about the political use of their opinions have been expressed by members of the EFSA themselves.

Friends of the Earth Europe believes that members of influential scientific panels should have no involvements that could give rise to any suspicion of bias. However, there are concerns that the members of the EFSA GMO Panel do not meet this high standard. One member has direct financial links with the biotech industry and others have indirect links, such as close involvement with major conferences organized by the biotech industry. Two members have even appeared in promotional videos produced by the biotech industry. Eight members of the Panel, including the chair, are already involved in assessing GM applications at the national level, and so have a double involvement, meaning that they are often ineligible to make decisions in the panel.

Several members of the Panel, including the chair Professor Kuiper, have been involved with the EU-funded ENTRANSFOOD project. The aim of this project was to agree safety assessment, risk management and risk communication procedures that would "*facilitate market introduction of GMO's in Europe, and therefore bring the European industry in a competitive position*." Professor Kuiper, who co-ordinated the ENTRANSFOOD project, sat on a working group that also included staff from Monsanto, Bayer Cropscience and Syngenta.

The GMO Panel opinion on antibiotic resistance marker genes was remarkably similar to an earlier paper on the subject produced by the ENTRANSFOOD project, in places even down to the wording.

The EFSA scientific panels can also draw on outside expertise. Although there is a legal requirement to set out formal procedures for this selection, these have not been made publicly available. Disappointingly, one of the first experts used by the GMO Panel was a well known advocate of GM technology who has undertaken research for both Monsanto and Bayer CropScience.

In 2003, the GMO Panel set itself a 'self-tasking project' to examine the use of antibiotic resistance marker genes (ARMs) in GM crops. While Directive 2001/18 states that there should be identification and phase out of ARMs which "*may have adverse effects on human health and the environment*", the Panel decided to produce an opinion also "*taking into account the limited availability of alternatives".* The chair of the Panel even stated in an EFSA press release that the Panel's opinion confirmed that ARMs are required "*to ensure the efficient selection of transgenic events in plants*."[1]

Friends of the Earth Europe believes that a scientific committee whose purpose is to protect consumer safety should not be taking into account the technical constraints on industry if the current technology is found to be unsafe. Nor should it be concerned as to whether ARMs are an 'efficient' tool for the biotech industry - the assessment should focus solely upon whether ARMs could have adverse effects on the environment and human health.

In the case of the *ampR* gene which is contained in Syngenta's Bt176 maize, the GMO Panel classified this as being in a group of ARMs for which use "*should not be present in GM plants to be placed on the market*." However, the Panel failed to support Austria's ban on the GM crop stating that its conclusions should only apply to future GM crops.

During consideration of the application for approval of Monsanto's MON 863 maize, concerns were raised by many member states about a number of unusual results in a rat feeding study. The Director of the French National research body INRA said that he was struck by the number of anomalies, stating "*There are too many elements here where significant variations are observed. I never saw that in another file*." All the concerns were dismissed by the GMO Panel.

Following major disagreements between member states about MON 863, the Commission asked the EFSA to look at a new evaluation report submitted by the German national authorities. The report included a recommendation for a further test to specifically examine the possibility of unintended effects of the genetic modification on the maize. However, the GMO Panel dismissed this, repeating its assertion that no unintended effects had occurred. It is unclear upon what basis it made this judgement.

Similarly, in the case of Monsanto's GT73 oilseed rape, several member states raised concerns about the quality of studies done, and findings from a rat feeding studies that showed higher liver weights for rats fed GT73 oilseed rape. However, the GMO Panel provided a positive opinion. In contrast, the UK's statutory scientific committee on animal feed safety stated that "*it could reach a conclusion only on receipt of satisfactory data*".

The Commission's Communication on the use of the precautionary principle states that "*Decision-makers need to be aware of the degree of uncertainty attached to the results of the evaluation of the available scientific information*." However, the GMO Panel has not outlined the degree of uncertainty in its opinions.

Similarly, Article 14 of European food safety legislation (EC/178/2002) calls for the assessment of the long term effects of GMOs and effects of subsequent generations. However, to date the long term effects of eating or growing GM foods seem to be completely ignored.

1. INTRODUCTION

Under increasing pressure from the biotechnology industry and the United States, the European Commission – the European Union's executive arm - has started to license new genetically modified (GM or GMO) foods and crops in Europe. While member states remain split over the long-term safety and desirability of GM, the final decisions for any approval falls legally to the Commission. After a 6-year lull in approvals the Commission has recently given the green light to two GM imports and is set to push through a whole range of other foods, crops and animal feeds. The justification for overriding the deadlock between EU member states comes from the assessments of the GMOs by the European Food Standards Authority (EFSA). If the EFSA say it is safe to eat then the Commission uses this to push new products onto the market. So who is the EFSA, what do they say about the safety of GM foods and whose views do they favour? This briefing looks at the role of the EFSA in the decisions made over GM foods and crops in Europe.

2. WHAT IS THE EFSA?

The EFSA was set up in 2002 following the coming into force of EU Regulation 178/2002, which laid down the general principles and requirements of EU food law and established the EFSA. The mission of the EFSA is to provide scientific advice and scientific and technical support to the European Commission and member states in the field of food and feed safety. Within the EFSA are eight scientific Panels, one of which is the GMO Panel, upon which this report will focus.

2.1 The EFSA GMO scientific Panel

Between May 2003 and November 2004, the GMO Panel issued twelve scientific opinions on GM related issues. One opinion came from a "self tasking" assessment of the use of antibiotic resistant marker (ARM) genes, one was a guidance note, three have been about the positions various countries have taken and the other seven are opinions on individual applications from the biotechnology industry (see Appendix A).

Apart from asking for more studies on one application, all opinions on the GM applications and member state positions have been positive to the biotechnology industry. The Panel stated that all of the GM maize and GM oilseed rape lines they had considered are as safe as their non-GM counterpart, although there were concerns from member states in every case. The GMO Panel also ruled that neither the Austrian or Greek governments had provided "*new scientific evidence*" in support of decisions to restrict the growing GM crops in their countries. Whilst it can be accepted that the GMO Panel is still relatively new this seems to be the start of a worrying trend.

3. HOW THE EFSA IS USED BY THE COMMISSION

The EFSA plays a key role in the decisions made about GMO products. Each member state is required by law to have a committee that can look at the health and environmental safety of GM crops. If the scientists from these different country committees have differing opinions with regard to any application, or the long-term safety of a GM product, then the European Commission asks the EFSA for their opinion. However, rather than using this as a vehicle to further scientific debate about the issues and concerns raised by scientists

from around Europe, the Commission only appears to be using the EFSA opinions to push new GM products onto the market.

For example, in July 2004 the Commission gave the green light to a GM maize made by Monsanto, called NK603. Margot Wallström, Commissioner for the Environment, said:

> "*The NK603 maize has been subject to a rigorous pre-market risk assessment. It has been scientifically assessed by the European Food Safety Authority as being as safe as any conventional maize. Its safety is, therefore, not in question, and neither is the question of user or consumer choice*."[2]

What she failed to say was that there had been different opinions from member states about the safety of NK603, but the Commission decided to rely solely upon the EFSA point of view to license this product. The Commission appears to be using the EFSA to create an impression of scientific agreement about the safety of GM crops, when the real situation is one of intense and continuing debate and uncertainty.

In order to either reject or authorise a GM food or feed, the member states of the EU need to reach a 'qualified' majority, either for or against. A qualified majority is how many decisions are made in Europe. Each country has a weighted vote – depending on the size of their population – and the total vote for any proposal must reach a certain level for a decision to be made. Currently this decision-making threshold is 232 votes out of a total of 321.

So far, member states have been totally divided on the GM applications considered, and so it has not been possible for them to reach a qualified majority either for or against an application. When this is the case the decision automatically goes to the Commission to make. With the support of a positive EFSA opinion the Commission can simply give the product the go ahead regardless of the safety arguments from the member states. For example, in the case of Bt 11 maize, for which the Commission recently gave the go-ahead, only six member states actually voted in favour of approving it.

The EFSA has a legal obligation to try and resolve differences of scientific opinion with member states, and in the case of GMOs, this is a clear area where that role should be coming into effect. Instead, the Commission is using the GMO Panel opinions to justify its GM approvals. With over twenty applications in the pipeline for new GM foods and feeds, it can be seen that the EFSA opinions have gained a key level of political importance in the approvals process.

Interestingly, this view seems to be shared by the scientific Panels themselves. Researchers commissioned by EFSA into how stakeholders view the authority, interviewed the scientific Panels and reported that "*GMO was mentioned as one very complex issue and there was some concern that the isolation of the safety assessment from other debates (socio-economical, biodiversity...) was somewhat artificial and that the EFSA 'safe' stamp could potentially be abused for political purposes to legalize GMO*." [3]

4. THE EFSA GMO PANEL SCIENTISTS

Members of the EFSA GMO Panel have to declare any direct or indirect financial interests they have. While most of the Panellists have not declared financial links with the biotechnology industry one scientist, Mike Gasson, has declared direct links[4]. He is a consultant to Danisco Venture - a venture capital company that invests in biotechnology companies. It is also part of Danisco, which together with Monsanto wants to market GM fodder beet in the EU. He also has shares in Novacta – a pharmaceutical and biotechnology company. Friends of the Earth Europe questions whether scientists who are also employed by biotech companies should be participating in the decisions being made about GM foods.

Other scientists have declared that they have indirect links with the biotech industry. For example, Pere Puigdomenech works at an institute which also does research for biotechnology companies. He is also Co-chair of the 7th International Congress on Plant Molecular Biology – an event sponsored by companies such as Monsanto, Bayer and DuPont.

Worryingly, either some Panellists are not completing their declarations fully or the EFSA website is not fully updated. For example Hans-Jorg Buhk was also on the steering committee of the Agriculture Biotechnology International Conference that took place in Germany recently. This high-profile pro-GM conference "Europe's most important date for AgBiotech in 2004" was sponsored by companies including Bayer, KWS, DuPont and BASF[5]. There is no mention of this role in Buhk's declaration of interest. Friends of the Earth Europe believes that members of such an influential scientific panel should have no involvements that could give no rise to any suspicion of bias.

Furthermore, the two German scientists, Hans-Jorg Buhk and Detlef Bartsch, are well-known for their pro-GM views and have even appeared in promotional videos produced by the biotechnology industry[6] (a suspicion of bias is therefore likely to arise). Friends of the Earth Europe questions whether people who have publicly promoted GM crops in this way should be playing a key role in the approval of GM foods.

Friends of the Earth Europe also has two other areas of concern about the membership of the GMO Panel.

4.1 Independence

Eight members of the GMO Panel – nearly one third and including the Chair - also sit in regulatory agencies at the national level. This means that they are involved in making initial assessments of GM crop applications for their governments. In other words, these members have already worked on the applications and reached a conclusion as to their safety.

The GMO Panel decided for itself that, "*there was no conflict of interest and that the involvement in the national safety assessment process did not compromise the assessment*" of GM dossiers. It remains to be seen whether it should be up to the Panel to make this judgement itself. However, its solution to the problem is that those members involved in national level evaluations "*can contribute to the scientific discussions but will not take part in the final adoption of the opinion*."[7]

This has led to the bizarre arrangement whereby the Panel, who are supposed to be arbitrating the scientific discussion about the safety of GM crops, is partly made up of people who may have already made their judgement about the GMO in question. The result is that, at any one time, up to one third of the Panel members have had to declare themselves ineligible to make decisions on the GM applications in front of them. The following table, drawn from the official minutes of the EFSA meetings, highlights the number of scientists with this double-involvement.

GMO	**Scientists declaring their involvement involved in the national assessment**
Monsanto NK603 maize	Hans Christer Andersson, Detlef Bartsch, Hans-Joerg Buhk, Andrew Chesson, Sirpa Kärenlampi, Gijs Kleter, Harry Kuiper and Joachim Schiemann
Monsanto GT73 oilseed rape	Detlef Bartsch, Hans-Joerg Buhk, Marc De Loose, Harry Kuiper, Joachim Schiemann and Jeremy Sweet
Monsanto MON863 and MON863X810	Hans Christer Andersson, Detlef Bartsch, Hans-Joerg Buhk, Sirpa Kärenlampi, Harry Kuiper, Joachim Schiemann and Jeremy Sweet.
Syngenta Bt11 maize	Hans Christer Andersson, Detlef Bartsch, Hans-Joerg Buhk, Marc De Loose, Colin Hill, Sirpa Kärenlampi, Harry Kuiper and Joachim Schiemann.
1507 maize	Hans Christer Andersson, Detlef Bartsch, Hans-Joerg Buhk, Michael Gasson, Colin Hill, Sirpa Kärenlampi, Harry Kuiper and Joachim Schiemann.

This raises a serious question about the role of the GMO Panel. Can it really provide impartial oversight when so many members are involved elsewhere in the evaluations process? The EFSA, in a letter to Friends of the Earth Europe, has stated that *"an intellectual interest*' is by no means the same as a '*conflict of interest*'" and dismisses any concerns about the lack of independence.[8] However, if this is purely an intellectual matter as EFSA suggests, why do members of the Panel feel obliged to abstain from decision-making. This issue clearly needs resolving.

4.2 ENTRANSFOOD

Prior to the GMO Panel being formed, the EU Commission sponsored a program on GM safety assessment, referred to as ENTRANSFOOD. The stated purpose of the project was to agree safety assessment, risk management and risk communication procedures that would "*facilitate market introduction of GMO's in Europe, and therefore bring the European industry in a competitive position*."[9]. The membership of the group was drawn largely from industry and government bodies – only one NGO was involved, and then only in a sub-group looking at social concerns.

The whole project was chaired by Harry Kuiper, who is now chair of the GMO Panel, and he sat on the working group on safety assessment procedures. This working group also included staff from Monsanto, Bayer CropScience and Syngenta. Four other members of the Panel also sat on working groups of this project. Friends of the Earth Europe is concerned that so many members of the GMO Panel should have been involved in a

project which not only had the stated aim of helping to facilitate the market introduction of GM crops, but which also involved close working with the biotechnology industry.

The importance of the ENTRANSFOOD project can be seen from its influence:

For example, the biotechnology industry has received criticism from scientists worldwide for using antibiotic resistance marker genes (ARMs) in their GM crops, as they could be picked up and used by bacteria. In April 2004, the EFSA GMO Panel published a scientific opinion on the use of ARMs. But the ENTRANSFOOD project had also looked at this issue, and a paper was submitted to a scientific journal in November 2003[10]. Astonishingly, the assessments of antibiotic resistance markers by the two groups were virtually identical, in places even down to the wording. For example, this is what the ENTRANSFOOD and GMO Panel papers say about deciding how to classify the risk posed by ARMs:

ENTRANSFOOD (Nov. 2003): "*If the transfer of an antibiotic resistance gene from the genome of a transgenic plant to that of a bacterium should occur at all, this event should be seen against the background of the given distribution of the respective antibiotic resistance gene in soil and enteric bacteria and related to its importance for the therapeutic use of the relevant antibiotics*."

GMO PANEL (April 2004): *"If the transfer of an antibiotic resistance gene from the genome of a transgenic plant to that of a bacterium should occur at all, the risk associated with this very rare event should be viewed against the presence of antibiotic resistance genes in soil, plant, water and enteric bacteria. Furthermore, consideration must be given to the importance of specific antibiotics in therapeutic use."*

In another example, here is what the ENTRANSFOOD paper and the GMO Panel say about 'class I' ARMs

ENTRANSFOOD: *"Group I contains antibiotic resistance genes (Table 1) which (a) are already widely distributed among soil and enteric bacteria; and (b) confer resistance to antibiotics that have no or only limited therapeutic relevance in human and veterinary medicine, so it can be assumed that, if at all, the presence of these antibiotic resistance genes in the genome of transgenic plants does not have an effect on the spread of these antibiotic resistance genes in the environment."*

GMO PANEL: *"Group I contains antibiotic resistance genes which (a) are already widely distributed among soil and enteric bacteria and (b) confer resistance to antibiotics which have no or only minor therapeutic relevance in human medicine and only restricted use in defined areas of veterinary medicine. It is therefore extremely unlikely (if at all) that the presence of these antibiotic resistance genes in the genome of transgenic plants will change the already existing bulk spread of these antibiotic resistance genes in the environment*"

It can be seen that the comments are virtually identical.

The ENTRANSFOOD project also set out a proposal for the general procedures for conducting safety assessments. In the conclusion, of which Prof Kuiper was one of the authors, it is stated that its proposals "*could serve as a reference standard for data*

generation and risk assessment in the framework of the new EU regulation on GM Food and feed (1829/2003)"[11]. Friends of the Earth Europe considers that the ENTRANSFOOD project, which so closely involved biotech companies, can hardly provide a credible reference for the regulatory assessment of GM foods. It is disturbing that the current chair of the GMO Panel should have agreed to this suggestion.

5. AD HOC EXPERTS

The EFSA scientific Panels can also draw on outside help if certain expertise is inadequately represented in their own membership. The EFSA states that "*The outside experts are without exception selected on the basis of their internationally recognized scientific excellence and/or expertise and are subject to consensus approval of the respective Panel*."[12] EU law demands that formal procedures are set down for selecting additional experts[13], but Friends of the Earth Europe has been unable to find any published procedures for the EFSA. From the little public information available they come mainly from other EFSA scientific Panels. The GMO Panel has already used a small number of experts from outside its membership. In one case, during their deliberations to establish guidance notes for applications the GMO Panel used the services of Dr Richard Phipps from the University of Reading, UK. Dr Phipps is known to favour the introduction of GM crops and is a signatory to a declaration in support of agricultural biotechnology[14]. He has carried out research for the biotechnology companies Monsanto and Bayer. He has even been quoted in a Monsanto press release from 1999 stating that US dairy farmers were "fortunate" to be able to use the GM growth hormone rBST – a product that has been banned in Europe on scientific and animal welfare grounds.[15]

It is unclear why the EFSA GMO Panel decided to choose Dr Phipps, but it is worrying that the Panel was either unaware or unconcerned about his work for the GM industry. It is extremely disappointing that virtually the first outside '*ad hoc'* expert chosen by the GMO panel was someone who has publicly expressed enthusiasm for GM crops.

6. BEYOND THEIR REMIT? THE EFSA AND ANTIBIOTIC MARKER GENES

The use of antibiotic marker genes (ARMs) in GM foods and crops has been highly controversial. Biotechnology companies use ARMs to identify whether the insertion of novel genes was successful or not. Beyond the laboratory stage they provide no use but remain in the food or plant. Their use has been widely criticised by scientific institutions, including the British Medical Association and the Pasteur Institute, and member states. The concern is that antibiotic resistance, which is already a global problem in medicine, may pass from the GM food to bacteria in the animal or human consuming it, thus passing on the resistance.

The GMO Panel itself notes that "the presence of [antibiotic resistance marker genes] in the notified GMO products is often a reason" for member state objections to the marketing of GM crops. In 2003, it decided to look at the issue as 'self-tasking' project - ie something they decided to do themselves[16].

Under article 4(2) of Directive 2001/18, member states have an obligation to ensure that, when carrying out their assessments of GM marketing applications, they take into particular consideration the risks associated with GMOs which contain genes expressing resistance to antibiotics.

However, the Directive does not require the EFSA to look at this issue, and there is no public record of any member states or the Commission asking the GMO Panel to do so. In fact a working group of the competent authorities of the member states was already looking at the issue of ARMs in GM crops when the GMO Panel proposed to undertake its assessment of ARMs.

As the GMO Panel had not been asked any questions by the Commission or member states on this matter, they were able to set their own terms. Directive 2001/18 states that there should be identification and phase out of ARMs which "*may have adverse effects on human health and the environment*", but the Panel gave themselves a remit to produce an opinion on ARMs also "*taking into account the limited availability of alternatives".* Friends of the Earth Europe believes that a scientific committee whose remit is to protect consumer safety, should not be taking into account the technical constraints on industry if the current technology is found to be unsafe. Yet this appears to have been a significant consideration in the process – the chair of the Panel, Harry Kuiper, even went so far as to state in an EFSA press release that:

"*The Panel has confirmed that ARMs are in the majority of cases still required in order to ensure the efficient selection of transgenic events in plants*."[17]

Yet the Directive does not ask for confirmation of whether ARMs are an efficient tool for the biotech industry; the assessment required is whether they could have adverse effects on the environment and human health.

The Panel's opinion classified ARMs into three risk groups and recommended that the high risk group of ARMs should not be used at all; that the middle group to be used only for test sites; and gave a green light for the low risk group. However, this last group still contains ARMS that are used in medicine and veterinary care. For example:

- Kanamycin and neomycin are components in some formulations used for localised treatments of infections in skin, eyes and ears. (As acknowledged by the GMO Panel);
- Neomycin is used to treat calves, pigs and poultry for intestinal infections (enteritis);
- Kanamycin is still used as a reserve agent for treating tuberculosis.

Despite these uses, the GMO Panel proposes that the ARMs providing resistance to these antibiotics should still be allowed in GM products. Incidentally, this group of ARMS is also the most widely used in GM plants by the biotechnology industry.

As mentioned previously, some of the wording of the GMO Panel opinion was nearly identical to that of the ENTRANSFOOD project. Perhaps therefore, it should not be surprising that the GMO Panel took an approach that so clearly included economic implications for the biotech industry (ie the costs of finding alternatives to ARMs).

6.1 EFSA and Bt176

Syngenta's Bt 176 GM maize contains a gene for ampicillin resistance (*ampR*) that has raised serious concerns from the competent authorities of member states. When the UK authorities looked at the data on Bt 176, they realised that the gene is structured in such a

way that it could be used immediately by any bacteria that picks it up and it is different to naturally occurring *ampR* genes because it would allow bacteria to be able to break down ampicillin antibiotics much more rapidly than they could otherwise[18]. During the original approvals process, 12 out of 15 member states were against granting European marketing approval for Bt 176, but they were over ruled by the Commission. The GMO Panel appears to have ignored the unique properties of the *ampR* gene in Bt176, but even so they classified this gene as being in a group for which use "*should be restricted to field trial purposes and should not be present in GM plants to be placed on the market*."[19]

However, when the GMO Panel was later asked by the Commission to consider the ban on Bt 176 put in place by the Austrian government, it stated that it was "*of the opinion that the use of these genes should be avoided **in future** GM plants to be placed on the market*" (emphasis added) and therefore that the Austrian Government did not have a good case for a ban. This is an odd interpretation of their own opinion on ARMs - it is unclear why the Panel considers that one GM crop, which Syngenta is already selling to farmers, should be safe if it believes that in the future similar crops shouldn't be allowed on safety grounds.

In the end, it has taken the Spanish food safety authority to act. In a press release on 23 April 2004 they stated that Bt176 would not be permitted to be grown from January 2005. This shows, once again, that the competent authorities are consistently taking a more precautionary approach than the EFSA.

7. GM AND EFSA – THROWING CAUTION TO THE WIND?

One of the key roles of the EFSA is to provide scientific opinions on new GMO applications. As mentioned earlier, the European Commission has started to use EFSA opinions to push through new GM products when member states disagree over their safety. All of the EFSA's opinions on new applications have so far been positive (although for one they have asked for one more trial). So even though member states have raised scientific concerns about the long-term safety of some products the EFSA has concluded otherwise. These substantial differences have not escaped the attention of the Management Board of EFSA. At the meeting of the Board on 27 April 2004 concerns were raised about the different outcomes on risk assessment carried out by the EFSA and by the national authorities.

According to EU Regulation 178/2002 (Article 30), when different scientific opinions emerge the EFSA and the member state(s) "*are obliged to co-operate with a view to either resolving the divergence or preparing a joint document clarifying the contentious scientific issues and identifying the relevant uncertainties in the data. This document should be made public*."

The use of this Regulation to deal with different opinions is also recognized by the Commission. In a recent meeting of the Standing Committee on the Food Chain, "*the Chairman clarified that if diverging scientific opinions between EFSA and the national food safety assessment bodies exist, Article 30 of Regulation (EC) N° 178/2002 should be applied*."[20]

Despite the substantive differences between some member states and the EFSA on virtually every opinion, there has been to date no evidence that there are attempts to

resolve these differences and certainly no such joint documents have been made public. Considering the legal obligation the EFSA has this is quite astonishing.

7.1 Monsanto's maize

On April 19 2004 the EFSA issued its opinion on MON 863 maize.[21] This maize has been modified to resist some insect pests by producing a toxin in the plant. A large number of concerns were raised by member states about this application, however the GMO Panel gave a positive opinion. Friends of the Earth believes that this opinion particularly highlights the problems with EFSA's approach.

According to the GMO Panel opinion, member state authorities "*questioned the adequacy of the compositional analyses undertaken*" (para 3.2.3), pointing out, for example, that there were consistent statistically significant differences between MON 863 and control varieties in the levels of the palmitic fatty acid, a saturated fat, and there were differences in copper levels. However, the GMO Panel dismissed both these differences as being "*within the historical background range*" .

Concerns from member states were also raised about the results from a feeding study on rats. The fact that white blood cell counts for rats fed MON 863 maize were significantly different from the non GM maize were "*not considered to be biologically meaningful*" by the GMO Panel because they "*fall within the standard deviation of the reference control population*". Differences in other blood cell parameters, kidney weights and kidney structure for rats fed MON 863 were similarly dismissed by the committee. In contrast, the French Commission for Genetic Engineering (CGB) concluded that it was not possible to show the absence of harm to animals on the basis of the data. In fact, the Director of the French National research body INRA (who examined the dossier as a member of the CGB) said that, "*I hear the argument of natural variability, but what struck me in this file is the number of anomalies. There are too many elements here where significant variations are observed. I never saw that in another file*."[22]

Dismissing all concerns

In fact, member states raised a large number of concerns about the quality of the assessment of MON 863. But the GMO Panel dismissed every one of the concerns and questions about MON 863 listed in its opinion as having been raised by scientific committees of the member states. This seems astonishing as it is hard to credit that so many scientists across Europe could be wrong in their concerns. It appears that the GMO Panel takes a far less precautionary approach to food safety than many of the member states own scientific bodies.

EFSA asked to think twice

Following major disagreements between member states at a regulatory committee meeting in September, at which Friends of the Earth Europe understands that only four out of 25 countries supported MON 863, the European Commission asked the EFSA to look at a new evaluation report submitted by the Germany national authorities. The German report specifically examined the feeding study using rats and suggested that an additional testing provision should have been used in the testing protocol. The additional test would include a feeding sample containing non GM maize 'spiked' with the novel GM proteins taken from

MON 863 maize, and it would provide additional information on whether any observed adverse effects resulted from unintended alterations in the GM maize, such as the creation of unexpected toxins.

The GMO Panel acknowledged in their response that such an approach "*is worthwhile in case there are indications of the occurrence of unintended effects with the GM food/feed derived product.*" But they then go on to state that *"This is however not the case with MON 863 maize.*" This is a puzzling conclusion, because in their original opinion the Panel stated that they were *"reassured by the availability of a 90-day sub chronic toxicity study using MON 863 maize fed to rats… which provides evidence that no harmful novel proteins have been created."* In other words, they used the study as a support for their conclusion that no unintended effects had occurred in the GM maize, while at the same time stating that it was unnecessary to include in that study measures to detect unintended effects.[23] In addition, the GMO Panel has not provided any clear guidance as to what they do consider to be "*indications of the occurrence of unintended effects*". In the case of Mon 863 maize, it would appear that even statistically significant differences in blood values of animals fed GM and non GM maize were not believed by the panel to indicate that no unintended effects had occurred! Friends of the Earth Europe believes that the GMO Panel should provide clear guidance as to what criteria it would choose to assess unintended effects, what it would consider to be sufficient evidence that unintended effects had occurred, as well as allowing wider scientific discussion on its guidance.

The EFSA statement reaffirmed its original conclusions that MON 863 is safe.

7.2 Monsanto's GM oilseed rape GT73

The EFSA GMO Panel assessment of GT73 also highlights the permissive position of the committee. Friends of the Earth does not consider that it is taking a precautionary approach.

For example, during their consideration of Monsanto's application, seven member states particularly queried the adequacy of measures to prevent seed spillage[24]. The UK authorities requested specific monitoring to assess the possibility of spillage and gene transfer. However, Monsanto disagreed largely on the grounds that, in its opinion, imported GM oilseed rape would only be processed at facilities within ports. The GMO Panel agreed with Monsanto and over-ruled the concerns of the member states.

Several member states raised concern that one of the rat feeding studies showed higher liver weights for rats fed GT73 oilseed rape. The GMO Panel concludes only that this is an "incidental finding". They also seemed unconcerned with the quality of evidence provided by the applicant, despite the fact that they themselves had to discard the results of three feeding studies submitted by Monsanto because the animals had been fed a mixture of GT73 and another GM oilseed rape. In contrast, the UK's statutory scientific committee on animal feed safety stated that "*it could reach a conclusion only on receipt of satisfactory data*". Once again, member states can be seen to be taking a more precautionary position than the EFSA.

Two member states raised concerns about the impact of glyphosate residues in the GM oilseed rape and the fact that no information on this issue had been provided by Monsanto. Pesticide residues in food have the potential to cause health implications for

consumers and so it is important to know what the likely level of these residues might be. However, the GMO Panel could not examine this issue because Monsanto simply refused to provide the data, stating that it had been provided under the 91/414 procedures for assessing pesticides. Friends of the Earth Europe considers that the GMO Panel should not allow applicants to avoid issues of concern by using this type of regulatory manoeuvring, as it increases the likelihood that important safety or environmental issues are overlooked.

8. DEALING WITH UNCERTAINTY

A basic requirement of risk assessments is to identify areas where scientific uncertainty remains. In July 2002, Commission decision 2002/623/EC set out guidance how to conduct the environmental risk assessment (ERA), which includes safety for human and animal health. It includes a specific requirement to identify the level of uncertainty relating to assessments of risk and decisions made[25]. The guidance states that

> " The overall uncertainty for each identified risk has to be described, possibly including documentation relating to:
> — assumptions and extrapolations made at various levels in the ERA,
> — different scientific assessments and viewpoints,
> — uncertainties,
> — the known limits of mitigation measures,
> — conclusions that can be derived from the data."

The requirement to consider uncertainty is also placed firmly upon the EFSA by the Commission Communication in 2000 on the use of the precautionary principle in policy and decision-making[26]. The Communication specifically states that:

"*Decision-makers need to be aware of the degree of uncertainty attached to the results of the evaluation of the available scientific information*."

However, the EFSA GMO Panel has not addressed uncertainty as outlined above in its opinions, even in the case of unexpected results.

For example, the EFSA noted that "2 or more" new and unintended messenger RNA species could be produced as a result of transcription starting within the inserted DNA sequence and continuing into the native maize genetic material[27]. Such a transcription event indicates that there could be an unintended effect on the genetic functioning of the GMO. However, the GMO Panel simply asserted that this is not a concern because the unpredicted transcription "***is not expected*** *to have a regulatory function*." (emphasis added). However, the situation is not this simple, because the GMO Panel failed to mention that there is still scientific uncertainty relating to the expression of such unknown RNA and the role of non-coding RNAs and RNA in genetic function[28] [29] [30]. The importance of such an omission is shown by the fact that the GMO Panel's conclusion about the unintended RNA supports its overall conclusion that no unintended effects have occurred as a result of the modification.

By failing to frame its opinion within the context of continuing scientific debate and uncertainty about fundamental issues relating to its conclusions, the Panel has failed to

provide decision makers with an adequate analysis of scientific uncertainty, as required by the Commission Communication on the precautionary principle.

8.1 Long term effects

European food safety legislation (EC/178/2002) calls for the assessment of the long term effects of GMOs and effects of subsequent generations. Article 14 of the regulation explicitly states that:

"In determining whether any food is injurious to health, regard shall be had to:
(a) not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations;
(b) to the probable cumulative toxic effects;
(c) to the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers."

To date the EFSA GMO Panel has not required any long term tests of any GM crop investigated. The long term effects of eating or growing GM foods seem to be completely ignored.

9. CONCLUSIONS

The GMO Panel of EFSA has not made a good start. In just over a year it has published twelve scientific opinions, virtually all favourable to the biotechnology industry. These opinions have been used by the European Commission to force new GM products onto the market.

Some of the scientists on the GMO Panel are known to have pro-GM views. One scientist has direct financial links with the industry itself. Nearly a third of the Panellists are involved in the approval of GMOs at a national level and so have to remove themselves from decision making.

Some of the Panellists have been involved in an EU funded project (ENTRANSFOOD) with the biotechnology industry to agree safety assessment, risk management and risk communication procedures that would “facilitate market introduction of GMO’s in Europe”. The Panel has also used a scientist with biotech industry links as an extra *ad hoc* expert. Some of the Panel’s conflicting interests have not been publicly declared.

The Panel went beyond its remit when considering its scientific opinion on the use of antibiotic resistant genes. Their final opinion was, in places, virtually identical to a prior ENTRANSFOOD report on the issue .

The Panel failed to support Austria’s ban on Syngenta’s Bt176 maize, which contains a gene conferring resistance to ampicillin antibiotics. Yet in its own opinion on antibiotic resistant genes, it recommended that crops containing such genes should not be approved for commercial growing.

When considering applications for new GM foods or feeds, the GMO Panel has consistently dismissed the concerns of other scientists working for national Governments. It appears to be less precautionary than member states when it comes to GMOs. Legislation about dealing with divergent scientific views appears to be ignored.

The GMO Panel disregards statistically significant differences between GM and their non-GM counterparts, instead agreeing with the industry that the results of such tests are not biologically relevant or treatment related. In addition the Panel ignores EU requirements to identify the level of uncertainty in its assumptions, and fails to take in legal requirements that regard is given to the long term effects of eating or growing GM foods.

10. RECOMMENDATIONS

Friends of the Earth regrets that such a critical report needs to be written so early into the life of the EFSA. However considering the political importance, not to mention the risks to human and environmental safety, of the EFSA opinions we are of the view that these issues need to be urgently addressed. Friends of the Earth therefore makes the following recommendations to the Management Board of EFSA:

1. The scientists who are involved in the national assessments of GM foods, have direct financial interests with the industry, or have helped with promotional activities for the biotech industry should be immediately replaced. This includes the Chair.
2. Panel members should not work with industry on projects such as the ENTRANSFOOD project: in order for the Panel to instil public trust, members need to be seen to be completely independent.
3. Ad-hoc experts should declare their interests as required under Regulation 178/2002. Scientific Panels should also make public the reasons why particular experts are chosen.
4. All opinions produced so far by the GMO Panel should be scientifically reviewed by an independent Panel and the results conveyed to the member states and the public.
5. The EFSA should apply Article 30 of Regulation 178/2002 and work with member states to resolve the divergence of scientific views. If this cannot be done then they need to prepare a joint document clarifying the contentious scientific issues and identifying the relevant uncertainties in the data. This is a legal obligation.
6. The GMO Panel must follow EU legislation and identify scientific uncertainty, take into account differing scientific opinion and give regard to the long term effects of eating or growing GM foods.
7. The EFSA should introduce the precautionary principle as one of its key policies and ensure that opinions relating to public and environmental safety do so without qualification by the economic concerns of the industry.

APPENDIX A

	Date	Opinion	EFSA Conclusion
1	4 July 2003	Question from the Commission related to the Austrian law prohibiting GMOs in Upper Austria	"no new scientific evidence, in terms of risk to human health and the environment, to justify the prohibition"
2	25 November 2003	Safety of foods and food ingredients derived from Monsanto's herbicide-tolerant GM maize NK603 under Directive 2001/18	"NK603 maize is as safe as conventional maize"
3	25 November 2003	Safety of foods and food ingredients derived from Monsanto's herbicide-tolerant GM maize NK603 under Novel Foods Regulations	"NK603 maize is as safe as conventional maize"
4	11 December 2003	Guidance note on GM micro-organisms	
5	11 February 2004	Safety of foods and food ingredients derived from Monsanto's herbicide-tolerant GM oilseed rape GT73	"as safe as conventional oilseed rape"
6	2 April 2004	Self tasking opinion on the use of antibiotic resistance marker genes	See section 7 of this report
7	2 April 2004	Safety of foods and food ingredients derived from insect-protected Monsanto's GM maize MON 863 and MON 863 x MON 810 under Novel Foods Regulations	"MON 863 will not have an adverse effect on human and animal health or the environment in the context of its proposed use." MON 863 x MON 810 – requested an additional 90-day rat study
8	2 April 2004	Safety of foods and food ingredients derived from insect-protected Monsanto's GM maize MON 863 and MON 863 x MON 810 under Directive 2001/18	"MON 863 will not have an adverse effect on human and animal health or the environment in the context of its proposed use." MON 863 x MON 810 – requested an additional 90-day rat study
9	8 July 2004	Austrian's use of Article 23 of Directive 2001/18 to provisionally prohibit the use and sale of 3 GM maize crops	"no new scientific evidence, in terms of risk to human health and the environment…that would justify a prohibition of these genetically modified crops"
10	8 July 2004	Greek's use of Article 23 of Directive 2001/18 to provisionally prohibit the use and sale of one GM oilseed rape line.	"no new scientific evidence, in terms of risk to human health and the environment…that would justify a prohibition of this genetically modified crop"
11	24 September 2004	Safety of foods and food ingredients derived from Pioneer Hi-Bred International/Mycogen Seeds insect-tolerant genetically modified maize 1507	"1507 maize will not have an adverse effect on human and animal health or the environment in the context of its proposed use."
12	20 October 2004	Statement on an evaluation of the 13-week rat feeding study on MON 863 maize, submitted by the German authorities to the European Commission	"the results of the rodent toxicity study with MON 863 maize did not indicate concerns about its safety for human and animal consumption."

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