

# Approving the GM potato: conflicts of interest, flawed science and fierce lobbying

How EFSA and BASF paved the way for controversial GM crops in the EU

Corporate Europe Observatory – November 2011

#### **Summary**

In June 2009, experts from the European Food Safety Authority (EFSA)'s panel on genetically modified organisms (GMO panel) approved the use of an antibiotic marker gene for GMOs.

This controversial decision was key for the European Commission in giving the green light in March 2010 to grow BASF's genetically modified Amflora potato in the EU.

Amflora is now being cultivated in open fields in Germany, Sweden and the Czech Republic, and two other GM plants (both cottons developed by Monsanto) containing the same antibiotic marker gene are in the pipeline waiting approval for cultivation.

The Amflora potato contains the *nptll* gene, an antibiotic resistance marker gene for neomycin and kanamycin. There are concerns that this antibiotic resistance could be transferred from the potato cells to bacteria dangerous to humans. Such a migration would reduce the effectiveness of these antibiotics in humans.

The approval of Amflora was the result of a fierce lobbying battle by BASF – which included an avalanche of letters sent to the Commission, threats to relocate outside the EU, and even legal action against the Commission.

This report by Corporate Europe Observatory (CEO) presents findings that make the EFSA June 2009 opinion even more controversial. Firstly, more than half of the GMO panel experts who signed the approval had conflicts of interest, as defined by the Organisation for Economic Co-operation and Development (OECD).

These conflicts ranged from receiving research funding from the biotech industry, being a member or collaborator in a pro-biotech industry association, to writing or reviewing industry-sponsored publications. Some conflicts revealed a conflict of scientific interests, with some panel members involved in working on the creation of transgenic plants – including potatoes – with antibiotic-resistant marker genes – including *nptll*.

Secondly, although none of EFSA's GMO panel members were medical experts in the use of antibiotics in human medicine, they decided that neomycin and kanamycin were antibiotics with "no or only minor therapeutic relevance". The World Health Organisation (WHO) classified these antibiotics as "critically important" in 2005.

This research shows that the Dutch scientist Harry Kuiper, chair of the GMO panel who had close links to the biotech industry, played a key role in the framing of this disputed key

scientific advice. The opinion in fact reconfirmed an April 2004 GMO panel opinion, which itself was almost entirely a copy-paste of a "review paper" sponsored by a controversial EU-funded research project called ENTRANSFOOD, in which the biotech industry played a major role. For some reason this review paper was not credited by the GMO panel in 2004.

CEO found that (a) the authors of that review paper did not appear to have the necessary medical expertise to credibly classify some antibiotics as having "no or only minor therapeutic relevance", (b) several authors appear to have been positively biased towards the biotech industry, and (c) all the authors were selected by Harry Kuiper, who was at that time coordinator of ENTRANSFOOD.

What is more, the original GMO panel decision appears to have been an attempt to protect GMO crops from an incoming EU directive, which sought to phase out the use of antibiotic resistance marker genes which may have adverse effects on human health and the environment.

In the light of these new findings, CEO is calling for an immediate independent reassessment of the scientific green light given to BASF's Amflora potato and of the health and environmental risks of antibiotic resistance marker genes present in GM plants. The ongoing approval procedures for cultivation in the EU of the other GM plants containing the controversial *nptll* marker gene should be put on hold.

EFSA should remove members of the GMO panel that have industry ties, and should reestablish a panel made up entirely from independent scientists.

On 2 March 2010 John Dalli, in one of his first acts as Health Commissioner, gave the green light to BASF's controversial genetically modified Amflora potato for commercial growing in Europe. It was the first time in 12 years that a new genetically modified organism (GMO) was granted authorisation for cultivation in the EU.

This decision appears to have been the result of an aggressive lobbying battle by chemical giant BASF, combined with disputed scientific advice from a European Food Safety Authority (EFSA) expert panel riddled with conflicts of interest and positively biased towards the biotech industry.

BASF's lobbying strategy involved putting constant pressure on the Commission, with at least nine letters sent to the then Environment Commissioner Stavros Dimas and EU Commission President Jose Manuel Barroso, an open letter to Commissioner Dimas published in major EU newspapers, threats to relocate BASF's research activities outside the EU, and legal action against the Commission for its failure to act (see Box 1).

### Box 1 | BASF's fierce lobbying battle to impose its GM potato

BASF's first application for approval for Amflora in the EU dates back to 1996, but the company had to wait until 2006 (after the 1998-2004 EU moratorium on genetically modified products had expired) to receive a green light from EFSA<sup>1</sup>. The EU food safety agency concluded that Amflora was as safe as conventional potatoes for humans, animals and the environment.

The then Commissioner for Environment Stavros Dimas recommended approval for cultivation. According to the procedure defined by EU legislation, he forwarded his proposal for authorisation to the so-called Regulatory Committee, a body made up of representatives from all EU Member States.

The votes in the Regulatory Committee (December 2006) and then in the Council of Agricultural Ministers (July 2007) were both inconclusive. Wary of public opinion, no-one wanted to bear the political responsibility for giving the green light to the first GMO since 1998. According to EU procedure, Dimas should have adopted the proposal for cultivation at this point. But he didn't.

A second round of voting again produced no qualified majority in the Standing Committee (October 2007) or in the Council of Agricultural Ministers (February 2008). The Amflora decision was passed to the EU Commission, which did not move.

BASF stepped up the pressure. It sent an open letter to the Commissioner, expressing its "dissatisfaction" with Dimas' handling of the approval process, published in major EU newspapers. It read: "Amflora is safe, environmentally friendly, and brings advantages to farmers and industry in Europe!"<sup>2</sup>.

Less than three weeks later, in a last-ditch strategy to delay its decision, the Commission requested EFSA to prepare a new "consolidated" scientific opinion on the use of antibiotic resistance marker genes in GM crops.

BASF immediately filed an access-to-documents request to obtain all EU Commission documents related to the authorisation procedure. These documents did not reveal any new scientific evidence regarding the safety of Amflora.

BASF then filed an action with the European Court of First Instance against the Commission

for "failure to act". The complaint also sought to quash the Commission's request to EFSA to look at the use of marker genes for resistance to antibiotics. BASF deemed this request was not scientifically-based, but done to delay authorisation.

Behind the scenes, BASF also threatened the Commission and the German government, saying it would move its research activities outside the EU if the potato was not authorised before the end of February 2010<sup>3</sup>.

An access-to-documents request filed by Corporate Europe Observatory to the Commission revealed that BASF sent at least nine letters to Commissioner Dimas and President Barroso pushing for Amflora, between January 2007 and September 2009 (see Appendix 1).

Hans Kast, the chief executive officer of BASF and Stefan Marcinowski, the chairman of the board met with Commissioner Dimas behind closed doors on 15 April 2008 to discuss the Amflora case.

The Commission finally yielded to BASF pressure and gave the go ahead for Amflora just before BASF's 'deadline'. The decision was made public on 2 March 2010.

The Commission finally bowed down to BASF's lobby efforts, but only after having attempted to seek some protection by opening up the 'EFSA umbrella'. In May 2008, EU Commission President Barroso clearly stated that the Commission would adopt the pending decision to approve Amflora for cultivation "if and when" EFSA confirms its safety<sup>4</sup>. This confirmation was published in June 2009<sup>5</sup>.

What was it about? The so-called "consolidated scientific opinion" the Commission asked EFSA to issue concerned the use of antibiotic resistance marker genes in genetically modified plants – including Amflora. The main focus of controversy around the BASF potato was the inclusion of an antibiotic resistance marker gene called 'nptll' (see Box 2). This extra gene is designed to make the potato resistant to the effects of two antibiotics, neomycin and kanamycin.

There is a risk that this extra gene could be transferred to bacteria dangerous to humans. That is why the use of such antibiotic resistance genes in GM plants has been banned by the EU, but Amflora and some other 'old' GMOs were authorised before the ban came into force. Such a migration from Amflora to a dangerous bacterium – called 'horizontal gene transfer' – would reduce the effectiveness of neomycin and kanamycin in humans. But EFSA didn't take such a possibility seriously.

Its controversial position was called a "consolidated" opinion because a previous opinion on the same issue had already been published by EFSA's scientific panel on genetically modified organisms (GMO panel) in April 2004<sup>6</sup>, and updated by the same panel in April 2007<sup>7</sup>.

# Box 2 | What extra genes are in Amflora and why?

The Amflora potato contains a 'pack' of two extra genes: the so-called "granular binding starch synthase gene" (gbss) coupled with an antibiotic resistance gene called "neomycin phosphotransferase II" (nptII)<sup>8</sup>.

The only purpose of the *nptll* gene is to act as a 'selection marker' for selecting the potatoes which have taken up the genetic modification that the BASF scientists wanted to transfer.

After that initial phase, it does not have any other function<sup>9</sup>. But it is nevertheless reproduced in each single plant that is grown.

Monsanto owns the dominant patents covering all antibiotic resistance genes<sup>10</sup>. The *nptll* gene was "the first marker used in plant genetic transformation and is still the most commonly used marker in the selection of transformed plants", according to EFSA's scientific panel on genetically modified organisms (GMO panel) in 2004<sup>11</sup>. It is still widely used in GMOs cultivated around the world.

All natural potatoes already have a *gbss* gene which encodes an enzyme directing amylase starch production. The extra *gbss* gene in Amflora suppresses the expression of the natural *gbss* gene via a mechanism called 'co-suppression'. The natural gene is 'switched off' by the extra gbss gene, and the production of amylase is interrupted.

So instead of producing a mixture of amylase and amylopectin starch, Amflora produces only amylopectin starch – a substance which is valued for technical applications in the food, paper, and chemical industries. BASF claims that Amflora will mean that industry will no longer need to separate the two starch components, making the process cheaper.

#### Two other *nptll*-containing GM plants waiting approval for cultivation

Amflora is now being cultivated in Germany, Sweden and the Czech Republic<sup>12</sup>, and two other GM plants containing the same antibiotic marker gene are in the pipeline waiting approval for cultivation. These are insect-resistant cotton MON531<sup>13</sup> and Roundup-tolerant cotton MON1445<sup>14</sup>. They both have been developed by biotech giant Monsanto.

 Size, source [name of donor organism(s)] and intended function of each constituent fragment of the region intended for insertion

Summary of the genetic elements intended for insertion in IPC 531

Sequence	Size (Kb)	Source	Function
78 3'	0.44	Soybean	Ends transcription and directs polyadenylation
cry1Ac	3.54	Bacillus thuringiensis subsp. kurstaki	ORF encoding resistance to Lepidoptera
P-e35S	0.62	Cauliflower Mosaic Virus (CaMV)	Promoter
aad	0.79	Transposon Tn7	ORF allowing bacterial selection
NOS 3'	0.24	Agrobacterium tumefaciens	Ends transcription and directs polyadenylation
nptH	0.97	Transposon Tn5	ORF allowing plant cell selection
P-35S	0.32	Cauliflower Mosaic Virus (CaMV)	Promoter
Ori-V	0.39	Plasmid RK2	Origin of replication

The *nptll* gene has been inserted in Monsanto's insectresistant cotton MON531 waiting for approval for cultivation in the EU.  Size, source [name of donor organism(s)] and intended function of each constituent fragment of the region intended for insertion

Summary of the genetic elements intended for insertion in RR 1445

Sequence	Size (Kb)	Function	
E9 3'	0.63	Poly A termination signal for cp4 epsps gene	
cp4 epsps	1.36	Gene encoding CP4 EPSPS	
CTP2	0.23	Transit peptide to direct CP4 EPSPS to chloroplasts	
CMoVb	0.57	Promoter for cp4 epsps and gox genes	
aad (3'')	0.79	Confers bacterial resistance to spectinomycin/streptomycin	
NOS 3'	0.26	Poly A termination for nptII and gox genes	
nptII	0.79	Plant selectable marker	
P-35S	0.32	Promoter for nptII	
ori-V	0.39	Origin of replication	
ori-322	0.43	Origin of replication	
gox	1.3	Gene encoding GOX	
ctp1	0.16	Transitpeptide to direct GOX to chloroplasts	

The *nptll* gene has been inserted in Monsanto's Roundup Ready cotton MON1445 waiting for approval for cultivation in the EU.

#### More than half of GMO panel members in 2009 had conflicts of interest

Several problems compromising the independence of the original GMO panel in 2004 were raised in a report by Friends of the Earth Europe. According to the environmental NGO, panel members were biased or too close to industry, and their declarations of interest were not consistent or accurate <sup>15</sup>.

To gauge the independence of the GMO panel experts who signed the June 2009 "consolidated" opinion towards the biotech industry as a whole, CEO analysed the details of the declarations of interest they made to EFSA at that time and also investigated their ties with the biotech industry (see Table 1; full details in Appendix 2).

According to the Organisation for Economic Co-operation and Development (OECD), a conflict of interest occurs "when an individual or a corporation (either private or governmental) is in a position to exploit his or their own professional or official capacity in some way for personal or corporate benefit. <sup>16</sup>" Put this way, the simple fact of being in such a position, even if no unethical or improper act results, represents a conflict of interest.

According to EFSA's guidance document on declarations of interest, panel experts must annually declare both their current interests and all their relevant interests in the five years preceding the filling in of their declaration of interest<sup>17</sup>.

Twelve out of 21 members of the GMO panel – more than half – had a conflict of interest as defined by the OECD. This means they had some form of involvement with the biotech industry and were in a position to exploit their official capacity in some way for corporate or personal benefit in the five-year window taken into account by EFSA.

Most of these conflicts were due to current or recent ties (less than five years) with the biotech industry, such as receiving research funding from the industry, being a member or collaborating with a pro-biotech industry association (International Life Sciences Institute, British Crop Protection Association, Dutch Biotechnology Industry Association, Public Research and Regulation Initiative, French Institute for Nutrition...), writing or reviewing industry-sponsored publications, or having a financial interest in the field of biotechnology. Some conflicts were also scientific in nature, with at least three panel members involved in work on creating transgenic plants – including potatoes – with antibiotic-resistant marker genes – including *nptll*.

# Table 1 | EFSA's GMO panel members who signed the June 2009 opinion on which the EU Commission based its green light to Amflora

KRYSPIN-SØRENSEN Ilona (Denmark)<sup>Ω</sup> ANDERSSON Hans Christer (Sweden)\*

KUIPER Harry A. (Netherlands)\* ARPAIA Salvatore (Italy)

NES Ingolf (Norway)<sup>Ω</sup> BARTSCH Detlef (Germany)\*

BOHSE HENDRIKSEN Niels (Denmark)<sup>Ω</sup> PANOPOULOS Nickolas (Greece)<sup>Ω</sup>

PERRY Joe (UK)\* CASACUBERTA Josep (Spain)

DAVIES Howard (UK)\* PÖTING Annette (Germany)

SCHIEMANN Joachim (Germany)\*<sup>™</sup> DU JARDIN Patrick (Belgium)\*

SEINEN Willem (Netherlands)\* **HERMAN Lieve (Belgium)** 

SWEET Jeremy (UK)\* KÄRENLAMPI Sirpa (Finland)

KISS Jozsef (Hungary)\* WAL Jean-Michel (France)\*

KLETER Gijs (Netherlands)\*

Dutch scientist Harry Kuiper, the chair of the GMO panel, has a long-standing relationship with the biotech industry, either directly or through the International Life Sciences Institute (ILSI), a controversial food and biotech industry-funded scientific think tank and lobby group. Kuiper wrote several key reports for ILSI and recently reviewed and commented on an article sponsored by biotech companies including Syngenta, Monsanto and Bayer.

Joe Perry, who was vice-chair of the GMO panel, was being paid by a company working for BASF, Bayer, Monsanto and Syngenta to carry out "development and pre-sales trials" on a wide range of crops. Up until 2006, Perry was a GMO researcher in a private institute sponsored by Syngenta, Bayer, DuPont and Dow AgroSciences.

Jeremy Sweet, also a former vice-chair of the GMO panel, received research funding from Monsanto, Bayer and BASF in 2006. He also gave seminars in Japan and Korea for the controversial pro-biotech think tank and lobby group ILSI. Since 1995, he has been a member of the biotech industry lobby group, the British Crop Protection Association, alongside GM seed manufacturers BASF, Bayer CropScience, Dow, DuPont, Monsanto, Nufarm and Syngenta. In 2008, he co-signed a scientific paper redesigning the risk assessment of GM insect-resistant crops, with employees from Monsanto, Dupont, Syngenta and BASF.

A long-time member of the GMO panel, Joachim Schiemann is also a member of the Public Research and Regulation Initiative (PRRI) which has been described as an "industry-funded pressure group that campaigns for weaker biosafety legislation" 18. Schiemann's mandate on the GMO panel was not renewed by EFSA because of a "potential" conflict of interest in June 2009, a few days after the publication of the consolidated opinion on antibiotic resistance marker genes.

Jean-Michel Wal's lab currently receives funding from pro-GM giant Nestlé. Wal has been involved in ILSI working groups and workshops since 2002. He has also co-authored scientific articles with food and biotech industry employees, including from Nestlé and Unilever. Wal is a member of the French Institute for Nutrition (IFN), sponsored by pro-GM companies including Kraft, Nestlé and Unilever.

<sup>\*</sup> Had a conflict of interest – having an involvement with the biotech industry of some form –, as defined by the OECD, during the five years before the opinion was signed.  $^{\Omega}$  Left the panel in June 2009.

Detlef Bartsch is a former consultant for Monsanto. In 2002, he appeared in a promotional video produced by the biotech industry. In 2008, he co-signed an article aiming at redesigning the risk assessment of GM insect-resistant crops, along with employees from Monsanto, Dupont, Syngenta, BASF and GMO panel colleagues, Schiemann and Sweet.

Jozsef Kiss's lab was formerly funded by GM seed producer Pioneer Hi-Bred to conduct field studies on the environmental impact of GM maize. Pioneer Hi-Bred also had several contracts with researchers from Kiss's institute from 2006 to 2009.

Gijs Kleter, a member of Kuiper's team, was a scientific contributor to ILSI from 1997 to 2007. He was also involved with the Dutch biotechnology industry lobby group (NIABA) as an 'observer' from 2000-2008.

Patrick du Jardin was a paid consultant for Monsanto in 2006. In November 2007, he appeared to act as a lobbyist on behalf of the biotech industry by handing over an open letter to the then Environment Commissioner Stavros Dimas. Over the last decade, du Jardin has developed research on GM plants using several antibiotic-resistant marker genes, similar to those used by BASF in the Amflora potato.

Howard Davies is a GM potato researcher. His institute has received funding from Monsanto to introduce GM potatoes in Kenya and it has external contracts with BASF and Bayer. Some of its sponsors are not disclosed "for commercial reasons". Davies has spoken at ILSI conferences and has been a scientific reviewer for ILSI and biotech industry publications.

Willem Seinen has had a strong financial interest in the field of biotechnology since December 2006 as the manager of three start-up biotech companies. He was previously a member of an expert panel set up by oil giant Shell, a company which has invested billions of dollars in "advanced biofuels" using biotechnology.

Hans Christer Andersson has been regularly involved in ILSI conferences and workshops over the last decade. He co-authored an article with employees from Nestlé, Danone and ILSI, coordinated by ILSI Europe which influenced a piece of EFSA guidance in 2008.

Although his former activities do not fall within the five-year window taken into account by EFSA to assess conflicts of interest, Salvatore Arpaia also appears to be a supporter of the biotech industry. He was a former GM plant designer who developed a transgenic pest-resistant aubergine with the help of Monsanto in the late 1990s, using the same marker gene (nptll) as BASF used for the Amflora potato.

See Appendix 2 for full details.

#### EFSA's GMO panel's first controversial opinion on antibiotic resistance

In its April 2004 opinion, EFSA's GMO classified the *nptll* gene as being in "group 1" of antibiotic resistance genes. This classification relates to 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" <sup>19</sup>.

The EFSA experts could have classified the *nptll* gene in group 2 (related to antibiotics "used in defined areas of human and veterinary medicine") or group 3 (related to antibiotics "highly relevant for human therapy") which would have meant that these marker genes should have been banned "irrespective of considerations about the realistic value of the threat").

Instead, the GMO panel considered it "extremely unlikely" that the presence of the nptll gene in the genome of transgenic plants "will change the already existing bulk spread of [this antibiotic resistance gene] in the environment or will impact significantly on human and animal health".

However, one can wonder how qualified this panel was to make this judgement. The GMO panel members have not been selected for their medical expertise in the use and relevance of antibiotics, or of antibiotic resistance of micro-organisms.

Retrospectively, the timing and the controversiality of this classification by EFSA feeds the suggestion that this was in fact a last-ditch political move to protect GMOs created with the widely used nptll marker gene. An EU directive passed in March 2001 (2001/18/EC), intended to mitigate the risk of transfer of antibiotic resistance marker genes to bacteria dangerous to humans, states that any antibiotic resistance marker gene "which may have adverse effects on human health and the environment" should be phased out by December 2004<sup>20</sup>

### GMO panel takes text from "EU's GM food promotion agency"

In fact, as Friends of the Earth reported at the time, the GMO panel's classification of marker genes into three groups in April 2004 – including the classification of the nptll gene in "group 1" – clearly drew heavily on a "review paper" authored by a working group from the EU-funded ENTRANSFOOD research project.

The review paper was published online on 12 April 2004<sup>22</sup> and EFSA's opinion was published just four days later<sup>23</sup>. It is common in scientific publications to refer to articles which are "in press", i.e. not yet published but that have been accepted for publication. But, strangely, the GMO panel did not even bother to mention it.



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The relevance of gene transfer to the safety of food and feed derived from genetically modified (GM) plants

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Review paper by Working Group 3 of the EU-funded ENTRANSFOOD research project, published on 12 April 2004. Its substance features integrally in the EFSA GMO panel scientific opinion on horizontal gene transfer published on 16 April 2004, but the source is not mentioned.

ENTRANSFOOD was an ambitious European Commission-sponsored research consortium which ran from 2000 to 2003 and which cost the EU tax payer €8.4 million<sup>24</sup>. It was to provide solutions for the unwillingness of the European public to accept GM food, in other words to find out how to introduce GM crops in Europe "in a way that is largely acceptable to European society"<sup>25</sup>.

ENTRANSFOOD's aim was to work towards agreement on issues of safety, risks and communication. Such agreement would "facilitate market introduction of GMOs in Europe, and therefore bring the European industry in a competitive position" The project was described by the UK magazine Private Eye as "the EU's GM food promotion agency". In 2003 ENTRANSFOOD's concluding conference made several pro-GM recommendations and was approvingly reported by Monsanto<sup>28</sup>.

The project coordinator was the Dutch scientist Harry Kuiper – who became the head of EFSA's GMO panel in 2003<sup>29</sup>. Before and during his mandate as a so-called independent expert for EFSA, Kuiper has maintained his ties with industry (see above and Appendix 2 for details on Kuiper's ties to the food and biotech industries). Four other GMO panel members were active on ENTRANSFOOD working groups, according to Friends of the Earth.

The membership of the group was drawn largely from industry and government bodies. ENTRANSFOOD's partners involved pro-GM food giants Unilever and Nestlé; biotech corporations Monsanto, Aventis and Syngenta; and the controversial food and biotech industry-funded think tank and lobby group, the International Life Sciences Institute (ILSI Europe)<sup>30</sup>.

In ENTRANSFOOD's final 'overarching report', Kuiper wrote: "In particular, the hard work and driving force of Ariane König in putting the Overarching Report together is acknowledged"<sup>31</sup>. At that time, Ariane König was an EU lobbyist for Monsanto. She was in charge of regulatory affairs in the agricultural sector for Monsanto Service International Brussels, in Belgium<sup>32</sup>.

Astonishingly, the EFSA GMO panel assessment of antibiotic resistance markers was "virtually identical, even down to the wording" to ENTRANSFOOD's working group 3 review paper, Friends of the Earth Europe found (see Box 3)<sup>33</sup>.

# Box 3 | EFSA copy-pastes from ENTRANSFOOD

The excerpt below shows that the classification of antibiotic resistant genes used by EFSA is almost a word-for-word copy of the ENTRANSFOOD paper. It was not the only one found in the EFSA opinion to be identical to wording from the ENTRANSFOOD paper

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."

The ENTRANSFOOD review paper's aim was "to provide a comprehensive overview to assist risk assessors as well as regulators" in understanding the safety issues related to horizontal gene transfer. But, again, none of the 12 authors appear to have been medical experts in the use of antibiotics, as would seem necessary for them to credibly classify antibiotics as having "no or only minor therapeutic relevance" to human healthcare.

Harry Kuiper, in his role of project coordinator of ENTRANSFOOD, was responsible for "identifying and approaching suitable partners" for the project.<sup>34</sup>

# **ENTRANSFOOD:** qualified to judge importance antibiotics?

Looking at the scientific publications of these 12 scientists<sup>35</sup> shows that they mainly have technical expertise in biotechnology and microbiology: they are experts in bacteria interactions in the digestive system of mammals, in genetic detection methods of microorganisms (bacteria, viruses), in DNA transfer from GM food to gut bacteria, or in DNA transfer from plants to soil bacteria.

What is more is that several of them also appear to have links with the biotech industry or have done work related to GMOs with antibiotic resistance marker genes. The chair of the Working Group 3, Guy van den Eede, is a former team member of the GMO pioneer Marc Van Montagu's lab at the University of Gent, Belgium.

Jos Van der Vossen has an interest in antibiotic resistance marker genes and has even inserted some kanamycin resistant marker genes – the same type as in Amflora – in plasmid vectors (biologic tools used to transfer extra genes into the genome of a plant, to create a GM plant).

In 1998 Wilfried Wackernagel developed a system for the sensitive detection of *nptll* genes and between 1998 and 2003 his research was cosponsored by the German Chemical Industry Fund (Fonds der Chemischen Industrie) in which BASF has invested money and a BASF employee currently chairs the Board of Trustees. One of Wackernagel's industry-sponsored articles focused on transgenic potato plants with the *nptll* gene as a selection marker.

Gilles-Eric Seralini, professor of molecular biology at the University of Caen in France, and president of the scientific council for independent research on genetic engineering (CRIIGEN), told CEO: "These 12 people seem to be experts in microbiology of gene transfer, but not physicians with expertise in infectious diseases who regularly see patients needing amputation or dying of multi-resistance to antibiotics" <sup>36</sup>.

Some 25,000 deaths annually in Europe are associated with multidrug-resistant bacteria<sup>37</sup>.

#### EFSA's classification ridiculed by WHO and EMA

This classification of neomycin and kanamycin as antibiotics with "no or only minor therapeutic relevance" by ENTRANSFOOD's Working Group 3 and EFSA's GMO panel was ridiculed in 2005 by the World Health Organisation (WHO) which classified both antibiotics as "critically important"<sup>38</sup>. Kanamycin also features in the WHO Essential Medicines Library as a drug against multi-drug resistant tuberculosis – a disease increasing worldwide<sup>39</sup>.

At the Commission's request, the European Medicines Agency (EMA, formerly EMEA) confirmed the WHO's position in 2007, concluding that neomycin and kanamycin "cannot be classified as of no or only minor therapeutic relevance" <sup>40</sup>.

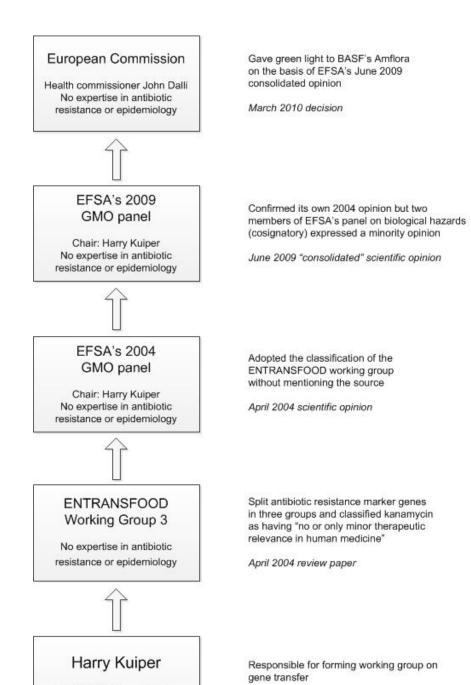
Institutionally humiliated, the GMO panel was forced to acknowledge its mistake in a statement: "The GMO panel agrees with the EMEA that the preservation of the therapeutic potential of [kanamycin and neomycin] is important" <sup>41</sup>. But it failed to draw the logical conclusion which would have been to re-classify both antibiotics in "group 3" related to antibiotics "highly relevant for human therapy".

But in blatant contradiction, the panel stuck to its earlier conclusions "that the use of the *nptll* gene as selectable marker in GM plants (and derived food or feed) does not pose a risk to human or animal health or to the environment." Even though the GMO panel itself wrote in the 2004 opinion, and reconfirmed in 2009, that marker genes conferring resistance to antibiotics that are "highly relevant for human therapy" should be avoided in GM plants "irrespective of considerations about the realistic value of the threat".

EFSA's panel on biological hazards (BIOHAZ) also signed this key opinion. However, two members took an unprecedented minority view. For the first time in EFSA's history, the agency issued a split opinion on GM crop safety<sup>42</sup>. The two scientists raised concerns about the risks associated with antibiotic resistance marker genes and objected to EFSA's conclusion that adverse effects of these genes on human health and the environment "are unlikely".

One of these experts, Ivar Vågsholm, stated:

"given the magnitude and multitude of exposures from the foreseen use of GM plants with antibiotic resistance marker genes [...] the cumulative probability of transfer could range from unlikely to high. [...] To be able to determine whether the risk is high, low or unlikely, one needs to be able to estimate probabilities of antibiotic gene transfer from GM plants to bacteria. These probabilities are below the detection limits for the studies reported. [...] At the global level adverse affects on public health and environment resulting from this possible transfer cannot be assessed." [emphasis added]



Harry Kuiper, chair of the GMO panel and close to the biotech industry, played a key role in the framing of the scientific green light to Amflora and other GMOs containing the controversial *nptll* gene.

Around 1998-1999

#### Conclusion

The origin of the GMO panel's 2009 classification of neomycin and kanamycin as antibiotics "of no or minor importance to human health" lies in a paper produced by the EU-funded project ENTRANSFOOD with considerable involvement of the biotech industry. This EFSA classification gave a green light to the cultivation of BASF's GM potato Amflora in March 2010 and will allow the cultivation of two other GM plants in the EU in the coming months.

ENTRANSFOOD coordinator

ILSI collaborator

The chair of the GMO panel, Harry Kuiper, has played a key role in the framing of this disputed key scientific advice which drew on an April 2004 GMO panel opinion, which itself was a discreet rewriting of an EU-funded "review paper" uncredited by the GMO panel in 2004.

It appears that (a) the authors of that review paper do not have medical expertise in the use of antibiotics that seems necessary to be able to classify antibiotics as having "no or only minor therapeutic relevance", (b) several authors appear to be positively biased towards the biotech industry, and (c) all the authors have been selected by Harry Kuiper, then coordinator of ENTRANSFOOD.

Finally, more than half of the GMO panel experts who confirmed the controversial classification in June 2009 had a conflict of interest, as defined by the Organisation for Economic Co-operation and Development (OECD), meaning involvement of some sort with the biotech industry.

In light of these findings, CEO believes that EFSA should remove members of the GMO panels that have industry ties, and should re-establish the panel using independent scientists. Furthermore, an independent reassessment of the scientific green light given to BASF's Amflora is urgently needed, as well as a new independent scientific opinion on the health and environmental risks of antibiotic resistance marker genes present in GM plants.

The ongoing approval procedures for cultivation in the EU of other GM plants containing the controversial *nptll* marker gene should be put on hold until that has happened.

# APPENDIX 1: Lobbying letters regarding Amflora sent by BASF to the European Commission

- 30/01/2007: letter from Hans Kast, CEO of BASF, to Commissioner Dimas, with copy to Barroso, Kyprianou, Verheugen, Potocnik, Fischer Boel, Mandelson, Catherine Day, Peter Carl, Robert Madelin.
- 08/05/2007, letter from Hans Kast, CEO of BASF, to Commissioner Dimas, with copy to Barroso, Kyprianou, Verheugen, Potocnik, Fischer Boel, Mandelson, Catherine Day, Peter Carl, Robert Madelin.
- 23/11/2007, letter from Hans Kast, CEO of BASF, to Commissioner Dimas, with copy to Barroso, Kyprianou, Verheugen, Potocnik, Fischer Boel, Mandelson, Catherine Day.
- 17/03/2008, letter from Stefan Marcinowski, chairman of the BASF board of executives directors, to Commissioner Dimas, with copy to Barroso, Kyprianou, Verheugen, Potocnik, Fischer Boel, Mandelson, Catherine Day.
- 16/04/2008, letter from Hans Kast, CEO of BASF, and Stephan Marcinowski, chairman of the BASF board of executives directors, to Commissioner Dimas, with copy to Barroso, Kyprianou, Verheugen, Potocnik, Fischer Boel, Mandelson, Catherine Day.
- 23/07/2008, letter from Marcinowski, chairman of the BASF board of executives directors, to Jose Manuel Barroso, president of the European Commission, with copy to Dimas, Kyprianou, Verheugen, Potocnik, Fischer Boel, Mandelson, Catherine Day.
- 01/12/2008, letter from Marcinowski, chairman of the BASF board of executives directors, to Jose Manuel Barroso, president of the European Commission, with copy to Dimas, Kyprianou, Verheugen, Potocnik, Fischer Boel, Mandelson, Catherine Day, Vassiliou, Ashton, Mandelson.
- 15/06/2009, letter from Hans Kast, CEO of BASF, and Stephan Marcinowski, chairman of the BASF board of executives directors, to Jose Manuel Barroso, president of the European Commission, with copy to Dimas, Kyprianou, Verheugen, Potocnik, Fischer Boel, Mandelson, Catherine Day, Vassiliou, Ashton, Mandelson.
- 25/09/2009, letter from Marcinowski, chairman of the BASF board of executives directors, and Peter Eckes, CEO of BASF, to Jose Manuel Barroso, president of the European Commission, with copy to Dimas, Kyprianou, Verheugen, Potocnik, Fischer Boel, Mandelson, Catherine Day, Vassiliou, Ashton, Mandelson.

#### Copies of the letters are available at:

http://www.corporateeurope.org/sites/default/files/publications/BASF Amflora letters.pdf

# APPENDIX 2: The 13 GMO panel experts' dangerous liaisons with the biotech industry

# 1. Harry Kuiper (chair), biotech enthusiast and ILSI's Trojan horse at EFSA

Harry Kuiper, the chair of the GMO panel, is a long time biotech enthusiast. While speaking at a conference in Rome in 2003, Kuiper "stressed that GM products are the most studied and understood of any food products that have been introduced to consumers", according to a US cable released by WikiLeaks<sup>43</sup>. Kuiper is also a long time collaborator of the controversial food and biotech industry-funded scientific think tank and lobby group, the International Life Sciences Institute (ILSI). In 1997, ILSI set up a European working group to deal with 'novel food'. The RIKILT team (Institute of Food Safety) at the University of Wageningen, in the Netherlands, including Harry Kuiper and Gijs Kleter (see below), cooperated with ILSI<sup>44</sup>.

In June 1998 Kuiper was the overall rapporteur for a three-day ILSI workshop on the detection methods for novel foods derived from GMOs<sup>45</sup>. He drafted a 28-page report summarising the workshop.

From 2000 to 2007<sup>46</sup>, Kuiper was a key member of ILSI's International Food Biotechnology Committee (IFBiC) 'task force' on Nutritional and safety assessments of foods and feeds nutritionally improved through biotechnology.

According to ILSI, this task force successfully influenced EFSA's guidelines for the risk assessment of new GM plants<sup>47</sup>. In 2006, the chair of the ILSI task force, Monsanto's Kevin Glenn, boasted at a workshop in Greece that a key 2004 ILSI report co-drafted by Kuiper and Kleter<sup>48</sup> had had a huge impact on EFSA's guidelines<sup>49</sup>. The so-called 'comparative assessment', based on the assumption that the GM crop plant and its conventional crop counterpart can be seen as equivalent, was implemented as a starting point for risk assessment by EFSA (as a result, the risks of GM plants are less rigorously investigated than they would be if EFSA assumed that genetic engineering and conventional breeding are fundamentally different in substance).

In fact, while acting as an expert for EFSA Kuiper has always kept close ties with the biotech industry. Besides his involvement with ILSI, he reviewed and commented on an article sponsored and written by biotech companies including Bayer, Syngenta, Monsanto, Pioneer, and Dow in 2009<sup>50</sup>. In March 2011, Kuiper was invited to speak at a workshop organised and chaired by a Monsanto employee in Washington<sup>51</sup>.

# 2. Joe Perry, works for a company contracted to BASF, Bayer, Monsanto and Syngenta

Joe Perry is a private consultant in biometry and ecology "with a minor component of GMO-related work in 2006 and 2007, exclusively for Rothamsted Research", according to his declaration of interests<sup>52</sup>. From 1976-2006, Perry was a researcher into GMOs at Rothamsted Research<sup>53</sup>, a private institute which is sponsored by Syngenta<sup>54</sup>, Bayer<sup>55</sup>, DuPont<sup>56</sup> and Dow AgroSciences<sup>57</sup>, and which works with BASF Plant Science<sup>58</sup>. Perry now works for Dewar Crop Protection Ltd. (DCP), a company doing "development and pre-sales trials on a wide range of crops for chemical companies"<sup>59</sup>. BASF, Bayer, Monsanto and Syngenta represented the majority of DCP's clients in 2007 (the most recent list of clients published online)<sup>60</sup>. Other clients included one of the world's leading agricultural chemical companies NuFarm, which manufactures the pesticide Credit® Xtreme used with Roundup Ready corn, soybeans, cotton and sugarbeet<sup>61</sup>. DCP's boss Alan Dewar, who like Perry, also had a career at Rothamsted Research, has also faced criticism for his conflicts of interest in the UK<sup>62</sup>. Is Joe Perry really "independent" when vice-chairing the GMO Panel at EFSA? Taking a scientific decision at EFSA that would adversely affect a client of his employer DCP could in turn affect his consultancy work for DCP.

### 3. Jeremy Sweet, formerly on the payroll of Monsanto, Bayer and BASF

In 2006 environmental consultant Jeremy Sweet received research funding from Monsanto, Bayer and BASF<sup>63</sup>, and gave seminars for the controversial pro-GM think tank International Life Sciences Institute (ILSI) in Japan and Korea<sup>64</sup>. Sweet is the chairman of the Symposium Committee of the International Society for Biosafety Research (ISBR) which, in November 2010, organised a symposium on the biosafety of GMOs<sup>65</sup> – an event sponsored by ILSI and Croplife International, a lobby group for the manufacturers of genetically engineered seeds. pesticides and other agricultural chemicals<sup>66</sup>. Since 1995, Sweet has been a Council member of the British Crop Protection Association, whose members include GM seed manufacturers BASF, Bayer CropScience, Dow, DuPont, Monsanto, Nufarm and Syngenta<sup>67</sup>. Sweet has argued that the risks of GMOs are exaggerated. In 2003 he wrote in a book review: "We already widely use GM technology in medicine, we now expect to buy a greater diversity of introduced food crops and products from around the world, with associated depletion of non-renewable resources, and introduced alien whole genomes abound in our cities, towns and countryside. How long will it take to put the introduction of a few novel genes in our food crops into the correct perspective?" 68. In 2008, with two fellow EFSA GMO panel members he co-signed a scientific paper redesigning the risk assessment of GM insect-resistant crops with employees from Monsanto, Dupont, Syngenta and BASF<sup>69</sup>.

#### 4. Joachim Schiemann, removed by EFSA for 'potential' conflict of interests

German scientist Joachim Schiemann was removed from the GMO panel by EFSA's administration in June 2009, just five days after the long-awaited publication of EFSA's consolidated opinion on the use of antibiotic resistance marker genes in GM plants<sup>70</sup>. Schiemann, who had been a member of the GMO panel since its creation in 2003<sup>71</sup>, cosigned this key opinion. The reason for his dismissal was his appointment as head of the Institute for Biosafety of Genetically Modified Plants at the Julius Kühn Institute (JKI) in Quedlinburg, which raised concerns about a possible conflict of interest<sup>72</sup>. "It is a matter of interpretation whether my appointment as head of the Institute for Biosafety of Genetically Modified Plants increased my involvement in risk management issues and – as a consequence – might have generated a conflict of interest", Schiemann told Corporate Europe Observatory<sup>73</sup>.

Schiemann is also a member of the controversial Public Research and Regulation Initiative (PRRI)<sup>74</sup> described as an "industry-funded pressure group that campaigns for weaker biosafety legislation and against public access to information" – a description that PRRI has denied<sup>75</sup>. According to its website, PRRI receives funding from Monsanto and CropLife International<sup>76</sup> (the main lobby group for pesticide and GM seed producers<sup>77</sup>). Schiemann is also a trustee<sup>78</sup> of the Fraunhofer Institute for molecular biology and applied ecology (IME) in Aachen, which focuses on the development of GM plants such as a virus-resistant grapevine<sup>79</sup>. He is the treasurer of the International Society for Biosafety Research (ISBR) which organised a symposium on GMOs sponsored by ILSI and Croplife International in November 2010<sup>80</sup>.

Back in 1996, Schiemann filed a patent as inventor and owner of GM plants with fluorescent proteins to better identify them in the wild<sup>81</sup>.

#### 5. Jean-Michel Wal, a friend of ILSI whose lab is funded by pro-GM giant Nestlé

Jean-Michel Wal's laboratory on food immuno-allergy at the French Institute for Agricultural Research (INRA) has been funded by the Nestec Research Centre, a discreet subsidiary of agro-business giant Nestlé, since January 2006<sup>82</sup> to do research on allergenicity of milk proteins. According to Wal, this research has "no relationship with GMOs"<sup>83</sup>. But Nestlé's interests are not limited to the allergenicity of milk proteins and the company has always been overtly pro GM foods<sup>84</sup>. Genetically engineered ingredients have been found in Nestlé baby food sold in Russia<sup>85</sup>, Kazakhstan<sup>86</sup> and China<sup>87</sup>, and the Swiss giant is the owner of a patent on a GM coffee plant<sup>88</sup>. Nestlé has a duty to its shareholders to promote an industry-friendly climate within regulatory bodies and financing Wal's lab could be said to fulfil this goal.

Wal has been a regular speaker in working groups, workshops and scientific meetings organised by the controversial food industry-sponsored think tank ILSI Europe since 2002<sup>89</sup>. In November 2009 in Paris, Wal attended another ILSI HESI workshop on "Evaluating biological variation in non-transgenic crops" with GMO panel colleagues Howard Davies and Christer Andersson<sup>90</sup>. In May 2011, again in Paris, he participated in an ILSI biotechnology workshop with GMO panel colleagues Gijs Kleter and Christer Andersson<sup>91</sup>. Most of the speakers were biotech industry representatives from Monsanto (3), Pioneer, Bayer, DuPont and ILSI<sup>92</sup>.

Wal also regularly co-authors scientific articles with food and biotech industry employees. In 2007, he co-signed an article on the role of post-market monitoring (PMM) in the safety assessment of novel foods with employees from Unilever, Nestlé, Danone, Bayer and ILSI<sup>93</sup>. Jean-Michel Wal is a member of the French Institute for Nutrition (IFN), a food industry-sponsored organisation which corporate members include Coca-Cola, Kraft, Nestlé, Mars and Unilever<sup>94</sup>.

#### 6. Detlef Bartsch, former consultant to Monsanto

Detlef Bartsch has been scientific director at the Federal Office of Consumer Protection and Food Safety (BVL) in Germany since 2002. Well-known for his pro-GMO views<sup>95</sup> he even appeared in a promotional video produced by the biotech industry in 2002<sup>96</sup>. In 2008, Bartsch co-signed an article in the journal Nature Biotechnology with employees from Monsanto, DuPont, Syngenta and BASF, and with EFSA GMO panel colleagues Joachim Schiemann and Jeremy Sweet on redesigning the risk assessment of GM insect-resistant crops that produce their own pesticide and indiscriminately kill non-target arthropods – which may reduce biodiversity in fields 97. The article intends to "provide guidance to regulatory agencies" and to "help harmonize regulatory requirements between different countries and different regions of the world" – an old dream of the biotech industry. In 2004 Bartsch reviewed a Monsanto-funded report on the impact of agricultural biotechnology on biodiversity<sup>98</sup>. Since 2002 he is a member of the German Society for Plant Breeding (GPZ e.V.), which is funded among others by BASF, Monsanto, Syngenta, Pioneer<sup>99</sup>. In 2000, when he was a researcher at the Technical University of Aachen (RWTH), Bartsch launched an appeal to environmental groups called "Don't neglect the ecological advantages of plant biotechnology" 100. Bartsch has been a member of the International Society for Biosafety Research (ISBR) since 2002, sponsored by biotech companies through ILSI and Croplife International.

# 7. Jozsef Kiss's lab received funding from GM seed giant Pioneer Hi-Bred

From 2006 to 2009, GM seeds giant Pioneer Hi-Bred had several contracts with researchers from Jozsef Kiss's institute at Szent Istvan University, Hungary. According to Kiss's EFSA declaration of interests, the French subsidiary Pioneer Génétique signed a research and development agreement with his employer "to conduct field studies for instance on the impact of GM maize on non target arthropods" Kiss wrote he was "requested to technically lead the field study in 2006 but gave it up in middle of 2006" and some of his staff members took over the lead. He also added that he had "no direct or indirect financial interest in that study" and will not be involved in any publication related to this research.

#### 8. Gijs Kleter, ally of the biotech industry lobby ILSI

Gijs Kleter has been an active scientific contributor to the food industry-funded think tank and lobby group ILSI for six years. Kleter was a member of the so-called ILSI International Food Biotechnology Committee (IFBiC) task force 4 on the nutritional and safety assessment of nutritionally improved crops derived through biotechnology with his colleague Harry Kuiper from the university of Wageningen (see above), from 2002 to 2007. As part of this group, chaired by Kevin Glenn, a Monsanto employee 102, Kleter co-authored two scientific reports with biotech industry employees, including from Monsanto and Bayer 103. Although disbanded, the task force "continues to have impact" today, according to ILSI 104. Through partnerships, the task force's findings and recommendations, published in 2004 and 2007, have been conveyed "to hundreds of thought leaders around the world".

In May 2011 Kleter participated in an ILSI biotechnology workshop in Paris with GMO panel colleagues Jean-Michel Wal and Christer Andersson 105. Kleter has also been involved with the Dutch Biotechnology Industry Association (NIABA) as an 'observer' from 2000 to 2008 106. Funded by more than 70 corporate members, NIABA's mission is "to support the growth and development of biotechnology in The Netherlands by advocating favourable legislative and policy actions as well as providing valuable business networking opportunities" 107.

#### 9. Patrick du Jardin, GM potato designer and ex-consultant for Monsanto

Belgian professor Patrick du Jardin is a well-known biotech enthusiast. In 1999 when asked by a journalist what risks GMOs present to human health, he replied: "None in terms of food security" 108. In 2003 du Jardin signed a petition against the destruction in France of GM field trials that petitioners deemed "essential to research in plant biology and plant breeding" 109. In 2006 du Jardin had a four-month contract as a consultant for Monsanto. His job was to "consolidate a report" on agrobiotech research in Sub-Saharan Africa, according to his declaration of interests to EFSA 110. In 2006-2007 he gave lectures at the university of Liège, Belgium, with a former Monsanto employee 1111.

While a member of EFSA's GMO panel, Patrick du Jardin appeared to act as a lobbyist for the biotech industry. On 28 November 2007 he handed over an open letter to the then European Commissioner for the Environment Stavros Dimas with two other pro-GM scientists from the European Federation of Biotechnology (EFB) – "a front for companies like Monsanto", according to Greenpeace 112. The letter was an answer to two draft decisions that Dimas had made public a week earlier and that could block marketing approval for new GMOs from Syngenta and Pioneer. The three scientists gave a press conference in front of the Berlaymont building 113. They were backed by Europabio, the biotech industry lobby group in the EU 114.

Du Jardin also has a scientific conflict of interests in the Amflora dossier as a result of his own research on GM potatoes with an antibiotic-resistant transfer gene similar to the one used by BASF in Amflora<sup>115</sup>.

# 10. Howard Davies, GM potato researcher and ILSI collaborator

Howard Davies has researched GM potatoes at the Scottish Crop Research Institute (SCRI), recently renamed the James Hutton Institute, for a number of years <sup>116</sup>. According to SCRI's 2009 annual report, Davies' employer was leading work to support virus-resistant GM potato introduction in Kenya as part of a project backed by The Monsanto Fund <sup>117</sup>. Monsanto supported the SCRI with a grant of £186,000 (€212,000). The SCRI also has external research contracts with biotech giants BASF and Bayer <sup>118</sup>. Another of the SCRI's external contracts has been on "potato breeding" but the name of the funder is undisclosed for commercial reasons <sup>119</sup>. In 2008, the SCRI also worked with Syngenta to develop a mathematical model <sup>120</sup>.

Davies is also directly linked to the biotech industry. He has collaborated with ILSI and several biotech companies, and spoken at an ILSI workshop. In 2004 and 2006, at ILSI's request, he acted as a reviewer of ILSI-led scientific articles before they were submitted for publication <sup>121</sup>. In 2007 he did the same for an article authored by employees from DuPont, Monsanto, Bayer, Cargill, Syngenta, BASF, Dow, and ILSI <sup>122</sup>. It is not clear whether he was paid for these jobs. In November 2009 Davies gave a presentation in Paris at an ILSI Health and Environmental Sciences Institute (HESI) workshop on "Evaluating biological variation in non-transgenic crops" <sup>123</sup>. Other speakers included employees from DuPont, Bayer and Monsanto <sup>124</sup>.

#### 11. Willem Seinen, manager of three biotech companies

Since December 2006, Seinen has been a member of the management team of three start-up biotech companies: Alloksys Life Sciences BV, Amrif Life Sciences BV, and SERM Therapeutics BV<sup>125</sup>. According to Seinen, these start-up companies have no involvement in or links with companies developing GMOs. Until 2007, Seinen was a member of an expert panel set up by Shell<sup>126</sup>, the oil and chemical giant which has invested billions of dollars in "advanced biofuels" made through biotechnology<sup>127</sup>. Back in 1996, he co-signed a study cosponsored by the Chemical Manufacturer's Association, an industry lobby group<sup>128</sup>.

#### 12. Hans Christer Andersson shaped EFSA opinion through ILSI with Nestlé, Danone

Over the last decade Andersson has been regularly involved in ILSI activities, participating in several ILSI workshops, including in Marseille in 2002<sup>129</sup>, in Brussels in 2005<sup>130</sup>, in Paris in 2009<sup>131</sup> and 2011<sup>132</sup>. In 2003, he co-authored an article coordinated by ILSI Europe's Natural toxin task force entitled "Guidance for the safety assessment of botanicals and botanical preparations for use in food and food supplements" with employees from Nestlé, Danone and ILSI <sup>133</sup> on "assessing the safety of [botanicals bred with the assistance of genetic engineering technology] with physiological (or functional) health benefits". In 2008, EFSA issued a scientific opinion with almost the same title: "Guidance on Safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements"<sup>134</sup>. The ILSI article was one of the key references for the EFSA's opinion.

# 13. Salvatore Arpaia, ex-GMO designer using same marker gene as BASF

Salvatore Arpaia's has worked for the Italian Agency for New Technology, Energy and the Environment (ENEA) since 2002. But from 1989 till 2002 he was an employee of Italian biotech company Metapontum Agrobios 135, which managed "several important biotechnological projects aimed to obtain insects and virus resistant plants and improve quality of industrial and agronomic species" 136. In 2006 and 2007 Arpaia received funding from his former employer Metapontum Agrobios to continue studies "on the evaluation of the environmental impact of Bt-expressing eggplant and potato" 137. During his career at Metapontum Agrobios, and in collaboration with the Italian Instituto Sperimentale per l'Orticoltura and Monsanto 138, Arpaia developed a transgenic aubergine resistant to the Colorado potato beetle, a common pest. To create this GM insect-resistant plant he and his team used the same antibiotic resistance gene npt/l that BASF used to create its Amflora potato<sup>139</sup>. In 2000, Metapontum Agrobios signed a petition to express his "support for the use of recombinant DNA as a potent tool for the achievement of a productive and sustainable agricultural system" 140. The petition was the centre piece of the AgBioWorld initiative led by the ultra-right Competitive Enterprise Institute (CEI) in Washington for its campaign against "death by regulation" 141. CEI is funded by corporate sponsors including Monsanto 142 and Dow 143.

Declarations of interests related to these cases are available at: <a href="http://www.corporateeurope.org/sites/default/files/GMO">http://www.corporateeurope.org/sites/default/files/GMO</a> panel Dols 2009.pdf

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- <sup>9</sup> Selection markers are used because transgenesis the process of introducing an exogenous gene or transgene into a living organism – is a random process: only one in several billion cells will take up the transgene. So rather than checking every single cell, scientists use a 'selective agent' (an antibiotic like neomycin or kanamycin) to kill all those that do not contain the transgene coupled with the antibiotic resistance marker gene. Only those with the transgene pass
- <sup>10</sup> Dominant patents on antibiotic resistance genes, PatentLens, <u>http://www.patentlens.net/daisy/Antibiotic/1153.html</u>
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