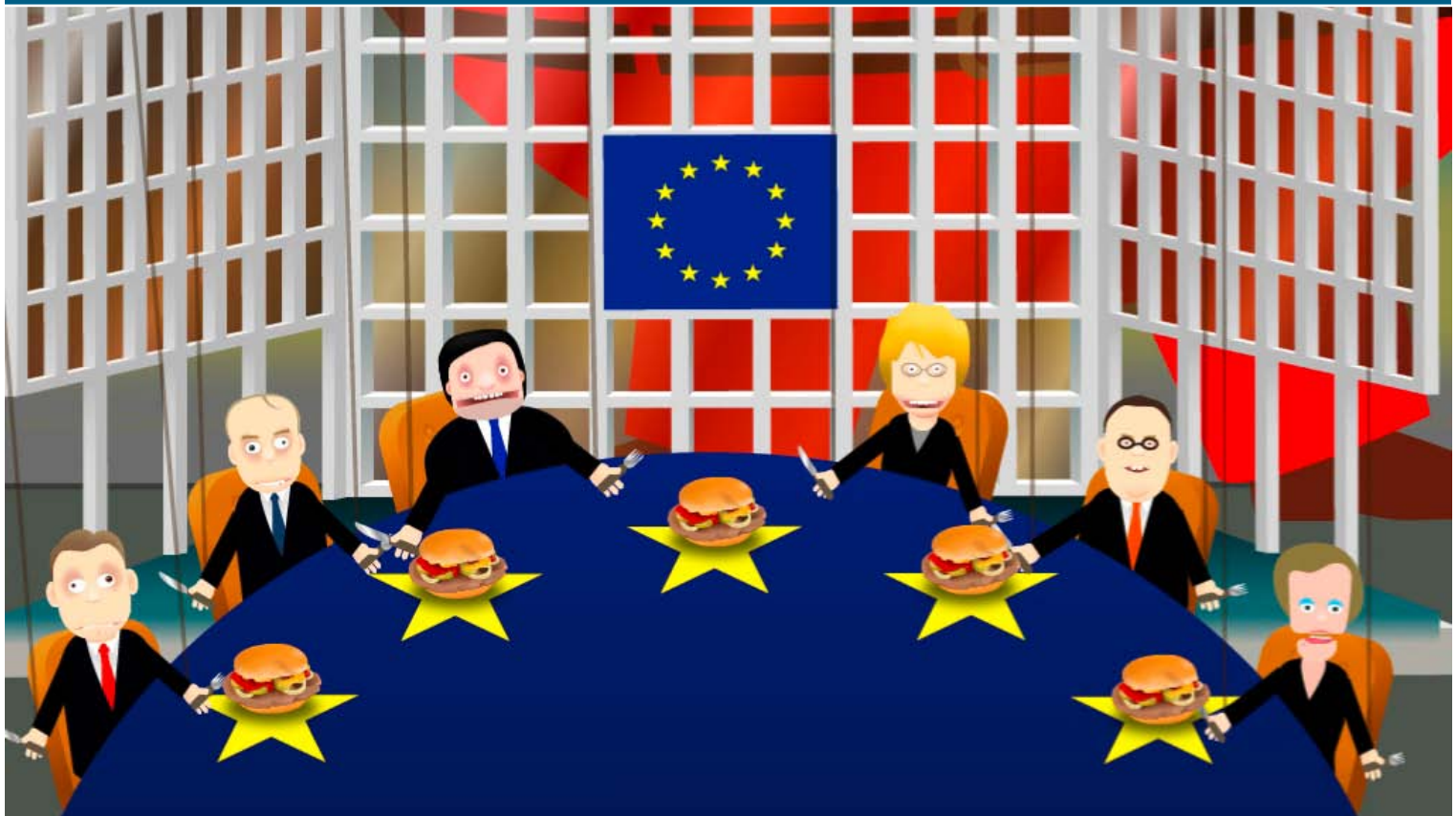




Conflicts on the menu

A DECADE OF INDUSTRY INFLUENCE AT THE
EUROPEAN FOOD SAFETY AUTHORITY (EFSA)

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Executive summary

In 2012 the **European Food Safety Authority (EFSA)** celebrates its 10th anniversary. EFSA has been strongly under attack, and increasingly so in the past few years. In this report **Corporate Europe Observatory** and **Earth Open Source** take stock of what there is to celebrate. But the reality is sobering.

Criticism of the way the way EFSA deals with the safety of products like pesticides, food additives, and genetically modified organisms (GMOs) is widespread and comes from many different sources: civil society groups, Members of the European Parliament, other public institutions, scientists, and, increasingly, the media.

Too often it's not independent science that underlies EFSA decisions about our food safety, but industry data. EFSA panels base their scientific opinions on risky products like pesticides and GMOs largely on industry-sponsored studies. EFSA has often been found to ignore independent research for unscientific reasons. The agency has issued controversial guidelines for the assessment of pesticides and GMOs that benefit industry, not the public interest. In some cases EFSA even copies wording from industry sources.

Nor are all of the EFSA experts who make these decisions independent. Many EFSA panel members have ties with biotech, food, or pesticide companies. EFSA's rules allow blatant conflicts of interest to persist. Food industry lobbies are even represented on the EFSA management board. Panel members and management have strong, systematic ties to the industry lobby group, the International Life Sciences Institute (ILSI), which is funded by major food, chemical, and biotech corporations. The 'revolving door' (where public officials move to industry jobs or vice versa) is also at work in EFSA.

EFSA revised its independence policy on scientific decision-making and conflicts of interest in 2011, but this resulted largely in a summary of the policies already in place. Despite some improvements, the new policy fails to address the fundamental problems of industry science and conflicts of interest.

EFSA and the European Commission claim that it is not realistic to exclude experts with industry links since EU and national policies promote public-private partnerships for the sake of innovation-driven competitiveness. But there may be other reasons for the high number of industry-linked experts, such as the fact that EFSA panel members do not get paid and work in their free time.

Important developments will take place in 2012 that will show whether EFSA and the EU institutions have any intention to bring about the radical changes needed. For instance, the membership of eight panels and the scientific committee will be renewed, EFSA is undergoing an official evaluation, and the European Commission will start this year with a revision of EFSA's founding regulation.

In anticipation of these developments, this report by **Corporate Europe Observatory** (CEO) and **Earth Open Source** (EOS) explains how EFSA works, what science is used, how conflicts of interest occur, and how industry influences the agency's work. With this report, Corporate Europe Observatory and Earth Open Source aim to contribute to the debate on what changes are needed in the interest of food safety, public health and the environment. We also aim to engage more people and organisations in the push for radical change at EFSA and to reverse its current pro-industry bias.

Introduction

Today's food products contain plenty of substances the eye does not see: food additives such as colourings and sweeteners, genetically modified organisms (GMOs), and pesticide residues. All have possible impacts on food safety, public health, and the environment. The responsibility for assessing these risks at the EU level lies with the European Food Safety Authority (EFSA). EFSA was set up to provide independent scientific advice to the EU institutions "on all matters with a direct or indirect impact on food safety".¹

EFSA's mission

"EFSA provides transparent and scientific advice to underpin the policies and decisions of risk managers in the European Commission, European Parliament and member states.

"It also provides effective and timely communication on all risks associated with the food and feed chain to a wide audience, including the public.

"The Authority is committed to the core values of scientific excellence, independence, openness, transparency and responsiveness." EFSA Management Plan 2010

Companies that want to market new food products or substances in the EU have to seek authorisation according to procedures laid down in EU laws. EFSA's risk assessment is key to getting your product onto the market. Huge economic interests hang on a green light from EFSA, with just a few big food companies dominating the European market. These companies have a particular interest in how the product is tested, who carries out the testing, and how the data are assessed.

EFSA was created by the EU as the voice of independent science, acting in the public interest. But EFSA has increasingly come under fire for being biased in favour of industry. As this report shows, this is partly due to the way EFSA was set up by the EU – and partly EFSA's own fault.

EFSA has been criticised by civil society organisations for years. But the criticism has recently intensified, including in mainstream media channels. Members of the European Parliament and independent scientists have voiced concerns.² Controversial cases include EFSA's interventions on the food and drink sweetener aspartame, the food packaging plastics chemical bisphenol A (BPA), and BASF's genetically modified Amflora potato.

Criticisms have focused on three main problem areas:

- ~ EFSA mostly uses 'industry science' to judge whether products are safe and resists taking on board independent scientific findings.
- ~ Some of EFSA's guidelines for risk assessments offer industry major loopholes.
- ~ Multiple conflicts of interest exist among EFSA management and scientific panel members.

EU law dictates that companies that want to market a product provide a dossier containing safety studies in support of their application. But these are the companies that stand most to profit from a verdict of 'safe to market' for the product. These studies are often unpublished and are sometimes hidden under commercial confidentiality rules, so they cannot always be examined or tested by independent scientists. Taking into consideration the findings of independent studies would bring some balance to the process, but EFSA often finds reasons to ignore or dismiss such evidence in its assessments.

EFSA also stands accused of setting guidelines for risk assessments that have originated or been promoted by industry with the aim of reducing the cost and rigour of testing and evaluation. EFSA's guidelines on GMOs and pesticides are examples.

Adding to EFSA's credibility problem is the fact that members of EFSA's panels on GMOs, food additives, and pesticides have been exposed as having conflicts of interest. Panel members are frequently involved with industry lobby group ILSI, the International Life Sciences Institute. EFSA's lax rules allow blatant conflicts of interest to persist. As a result, and at the request of the European Parliament, the EU financial watchdog, the European Court of Auditors is investigating whether the conflict of interest policies at EFSA and other EU agencies are sufficient.

All this is only the tip of the iceberg. It is now widely recognised that EFSA suffers from a lack of public trust and that radical changes are needed. There will be some opportunities this year. For instance, the membership of eight expert panels and the scientific committee will be renewed and the Commission will revise EFSA's founding regulation.

This report by Corporate Europe Observatory and Earth Open Source is intended to feed into these processes and to inform the public, civil society groups, independent scientists and policy-makers. The report explains how EFSA operates and summarises the main criticisms of the agency. It draws on publicly available documents and interviews with EFSA staff, MEPs, civil society groups, and scientists.³ It indicates where EFSA is responsible and where the EU institutions need to act. Finally, the report suggests changes that would help bring EFSA into line with the interests of public health and the environment.

1. How EFSA works

The European Food Safety Authority (EFSA) was set up in 2002 by the European Union as an independent source of scientific advice and communication on risks associated with the food chain.⁴ It is one of 24 specialised EU regulatory and policy agencies and is based in Parma, Italy. Other such agencies include the European Medicines Agency (EMA), the European Chemicals Agency (ECHA), and the European Environment Agency (EEA).

The original motivation for setting up EFSA was a series of food safety crises in the 1990s, notably the BSE ('mad cow disease') and dioxin scares.⁵ A second key motive behind EFSA's creation was to separate the responsibility for the scientific risk assessments

from 'risk management'. Before EFSA was created, risk assessments were done by expert committees that were part of the European Commission. At EU level, risk assessment is now EFSA's job, while the EU institutions are responsible for risk management.⁶

EFSA was supposed to provide independent scientific advice on food safety issues to the EU institutions without getting mixed up in politics.

With new environmental and health concerns emerging from food and animal feed products involving technologies like genetic engineering and nanotechnology, the establishment of EFSA came at a critical moment.

Risk assessment and risk management

Risk assessment is the process of identifying risks posed by potentially hazardous products and assessing the likelihood of unacceptable exposures. It is considered to be a purely scientific procedure. EFSA experts do not do any testing themselves. They mainly review studies done by the company that

requests authorisation for a product and opinions from government bodies.

Risk management is a political decision-making process to select steps to reduce risk to levels deemed acceptable.

EFSA's relationship with EU institutions

EFSA is known as an independent EU agency. But it was set up by the EU institutions – and they have an important role in deciding how EFSA works. The EU institutions established EFSA's founding regulation,⁷ which describes EFSA's mission and role, how it is organised, how responsibilities are divided, and how members of the expert panels are chosen. Importantly, too, the EU institutions decide who is on EFSA's management board.

But while the founding regulation lays down general principles, it mandates EFSA to design its own internal rules. So EFSA decides how the management board and the Advisory Forum and expert panels function. It also decides how its scientific opinions are shaped and how principles on transparency and confidentiality will work in practice.

Key to the theme of this report is that EFSA has shaped its own rules on how scientific decisions are

made in the panels and how conflicts of interest are dealt with.

The EU institutions, for their part, establish the rules governing the approval and use of the substances that fall within EFSA's remit. EFSA receives its mandates (tasks) and funding mostly from the EU institutions – predominantly the European Commission, but also the European Parliament and member states. The conditions and payment for each task are negotiated by the EU institution and EFSA. Here too the EU institution has influence over which questions are asked.

The European Parliament has some power over EFSA, though it is limited. The Parliament's most concrete leverage over EFSA lies in its power to approve the way EFSA spends the money it gets from the EU ('the discharge'). Corinne Lepage MEP invoked this power in July 2011 when she proposed to

block 5% of EFSA's 2012 budget because of "recurring conflicts of interest".⁸ While there was no majority in favour of this proposal, in December 2011 the

discussion flared up again, with several Members of the European Parliament demanding that EFSA take action against conflicts of interest.⁹

What guarantees EFSA's independence?

Different types of interests – scientific, political, or economic – can lead to bias. However, in this report we focus solely on the most obvious conflict of interest: economic interests. When we talk of "independent" science or scientists, we mean independent of industry.

EFSA's founding regulation lays the basis for how EFSA is supposed to achieve scientific excellence, independence and transparency. Regarding independence, it says that everyone involved in EFSA "shall declare at each meeting any interests which might be considered prejudicial to their independence in relation to the items on the agenda".¹⁰ These 'declarations of interest' form the heart of EFSA's approach to dealing with conflicts of interest.

Over the years, EFSA has translated the founding regulation's principles into more detailed policies, including its 2007 Policy on Declarations of Interest.¹¹ In addition, EFSA has established a set of implementing rules on issues such as how experts are selected, how panels operate, and the responsibilities of staff members.¹²

But faced with a deluge of criticism on its use of science and conflicts of interest in its ranks, in early 2011 EFSA launched a review of its independence policy, including a public consultation. Executive director Catherine Geslain-Lanéelle acknowledged,

"EFSA's independence is occasionally challenged," and "public perception of our independence can be strengthened".¹³

In December 2011 EFSA published its new independence policy.¹⁴ However, it is little more than a summary of previous policies. It contains some useful changes, but the bottom-line problems remain (see section 4, "EFSA rules allow serious conflicts of interest"). No strong rules against conflicts of interest have been introduced, so there is a serious risk that these will continue. Also, the new policy does not remind the expert panels of their obligation under certain EU laws to take independent science properly into account in assessments, rather than rely overwhelmingly on industry studies.

In March 2012 eight panels and the scientific committee will be renewed. This will be an important moment to see whether EFSA has changed its attitude to conflicts of interest – in spite of its lack of robust rules. The Commission has also requested an evaluation of EFSA. Following that, EFSA's founding regulation will be revised, creating an opportunity to correct flaws such as the composition of the management board. There will also be a chance to force EFSA to implement strict rules on conflicts of interest and to take a more robust stance on using independent science.¹⁵

How EFSA is organised

EFSA is governed by a management board that oversees its work and appoints the executive director – currently Catherine Geslain-Lanéelle, a former high-ranking official in the French ministry of agriculture – who is responsible for day-to-day operations.

The core of EFSA's work is done by its expert panels and units. The agency also allocates work to external experts registered on its special database. EFSA's work is supported by around 450 permanent staff members.¹⁶ It has an advisory forum that connects it with the national food safety agencies and advises on scientific matters and emerging risk issues.

EFSA management board

EFSA's management board has considerable influence, as it sets EFSA's budget, approves its annual work programme, and appoints the experts on its scientific panels.

As laid out in the founding regulation, its members are appointed by the EU member states (the Council) in consultation with the European Parliament. Members are chosen from a shortlist of candidates drawn up by the European Commission, following a public call for expression of interest. A representative from the European Commission sits on the management board.¹⁷ Management board members are

appointed for four years, a term that can be renewed once.

While the founding regulation says that four of the 14 board members “shall have a background in organisations representing consumers and other interests in the food chain”,¹⁸ it also states that they are appointed in a personal capacity and are supposed to act “independently in the public interest”.¹⁹ Nevertheless, Corporate Europe Observatory found that at least five board members have industry affiliations.²⁰ One is chair Diana Bánáti, who was on the board of directors of the industry body, the International Life Sciences Institute (ILSI) (see section 2). She stepped down from her ILSI role after a controversy broke out about her conflicts of interest (see section 4, “Conflicts of interest exposed”).

Expert panels and scientific committee

The core work in EFSA (risk assessments, scientific opinions, and guidance documents) is done by the experts who sit on 10 scientific panels, such as the GMO panel, the pesticides (PPR) panel, and the food additives (ANS) panel.

Each panel has around 20 members. These panels are renewed every three years, when, on average, one-third of the members are replaced. EFSA has imposed a limit of three terms in a row for any one expert to remain on the same panel.²¹ The experts are not paid – they are volunteers who only get their costs reimbursed.

Panel members are selected following a call for expressions of interest. A team of EFSA staff evaluates eligible candidates. EFSA’s executive director finally presents a shortlist of candidates to the management board, which takes the final decision.

EFSA’s selection criteria do not include independence from industry.²² The candidates have to declare any interests when they apply, but EFSA’s policies have not made clear what level of industry interest is tolerable (see section 4, “Conflicts of interest exposed”).

EFSA’s scientific committee consists of the chairs of all panels, plus six experts who do not belong to any panel. It has an important role, writing ‘opinions’ on cross-cutting scientific matters, such as methods of risk assessment, and advising EFSA’s executive director. So conflicts of interest for members of this committee are especially serious.

In some cases, an EFSA panel or its scientific committee can establish a working group on a particular issue, consisting of some of its members and some external experts.



2. The EFSA-ILSI connection

Many people have heard of Monsanto, BASF, Bayer, and Syngenta. But few know about ILSI, the International Life Sciences Institute. For many EFSA staff and experts, however, ILSI is a familiar ally.

ILSI is a Washington DC-based industry lobby group, with offices throughout the world, including in Brussels. It is primarily funded by its member corporations from the food, chemical, and biotech industry, such as Ajinomoto (the world's leading producer of aspartame), BASF, Coca-Cola, Danone, Kraft, McDonald's, Monsanto, Nestlé, Syngenta, and Unilever.

ILSI says its mission is to “build science into regulations” by bringing scientists from academia, government and industry together in what it calls “neutral fora”, typically workshops and conferences.²³ It strongly denies that it is a lobby group.^{24 25}

Many members of EFSA's scientific panels and its scientific committee actively collaborate with ILSI, joining ILSI task forces and working groups, authoring influential ILSI reports on risk assessment, or chairing sessions at ILSI conferences. In this way, food and chemical corporations can influence EFSA panels, in addition to their own lobbying of the EU institutions.

ILSI not an industry lobby group?

An Earth Open Source report concluded that ILSI's “neutral fora” in fact promote industry-friendly ways of evaluating the safety of a product to government experts. The report found that ILSI's proposals on risk assessment follow a trend of making safety testing procedures less rigorous and cheaper for industry – at the expense of public health and the environment.²⁶

ILSI is accused by its various critics of:

- ~ Influencing EFSA's recommendations for the risk assessment of pesticides, including watering down the data requirements (tests industry has to do in support of its applications for approval).²⁷
- ~ Weakening EFSA's guidelines for the risk assessment of GM crops.²⁸
- ~ Weakening the risk assessment of potentially hazardous chemical compounds such as bisphenol A.²⁹

Slide from presentation by Nico van Belzen (ILSI Europe) at ESFA independence workshop, Brussels, October 2011



ILSI's denial that it is a lobby group³⁰ is contradicted by its own claims of having influenced EFSA's guidelines on GMOs. The German organisation Testbiotech reported that Monsanto employee and chair of an ILSI task force Kevin Glenn boasted at a workshop in 2006 that ILSI's input had a huge impact on EFSA's guidelines. ILSI repeated this claim in one of its reports.³¹

EFSA has granted ILSI credibility as a 'scientific' organisation by organising joint events, paying experts to attend ILSI events, and by being officially represented on ILSI working groups.

In 2005, for example, EFSA and the World Health Organisation (WHO) organised a conference "with the support of the International Life Sciences Institute" on the risk assessment of substances that both damage DNA and cause cancer.³²

EFSA food packaging panel expert Mona-Lise Binderup's declaration of interest stated that she was "paid by EFSA" to participate in an ILSI event "as a representative of EFSA's working group on nanotechnology".³³

In another example, Pesticide Action Network found that two EFSA staff members acted on behalf of EFSA on an ILSI task force on the toxicological threshold of concern (TTC), a concept that enables industry to avoid expensive toxicological testing of chemicals.³⁴

But in 2010 EFSA's management board acknowledged that involvement with ILSI could lead to conflicts of interest. Commenting on Diana Bánáti stepping down from her role at ILSI, the board said that she had "resigned from positions which may create a potential conflict of interests with EFSA activities." (See section 4, Industry on EFSA management) EFSA added that the chair of the management board should not have a role in an organisation "representing interests of the food chain, other than public interests."³⁵

ILSI restricted from WHO activities because of funding sources

US groups have been aware of the nature of ILSI's activities for several years. In 2005 the Natural Resources Defense Council, Physicians for Social Responsibility, the Breast Cancer Fund, International Federation of Journalists, Environmental Working Group, United Steelworkers of America, and other groups wrote a letter to the WHO, objecting to ILSI's role in setting standards.

The letter said that ILSI "has a demonstrated history of putting the interests of its exclusively corporate membership ahead of science and health concerns... ILSI's special status with the WHO provides a back door to influence WHO activities."³⁷

In 2006 the WHO decided that ILSI could no longer take part in WHO activities setting safety standards for food and water, because of its funding sources.^{38 39}

However, EFSA apparently finds it acceptable for other management board members to hold leading positions in ILSI. When Milan Kováč declared his new interest as a member of ILSI's board of directors in March 2011,³⁶ no queries were mentioned in the minutes about the conflict of interest this would represent. Following media scrutiny, he left this position in July 2011.

It is unacceptable for an agency that is supposed to represent independent science and to operate in the public interest to tolerate infiltration by this industry-funded group.

3. The science behind our food safety

What science underpins the way products like pesticides, GMOs and food additives are approved for the EU market? In part, EU regulations and directives decide what science is used. But EFSA has considerable influence on the approvals process. It

writes 'guidance' documents on how the laws should be interpreted, which tests industry has to carry out on its products, and how the products should be assessed for risk.

How the authorisation process works

When a company applies for a particular product or substance to be approved, it has to present EFSA and the EU institutions with a dossier of studies it has carried out or commissioned on the substance for risk assessment.

At the request of the Commission, the relevant EFSA scientific panel examines the industry dossier and publishes a scientific opinion on the substance.

Based on EFSA's opinion and other considerations, such as the perceived need for the substance, representatives of the EU member states meet in specialised committees and vote on the product application. If the member states are unable to reach agreement, as has been the case with GMOs, the Commission can take the decision.

Approval periods vary, depending on the product. For pesticides, it's 15 years,⁴⁰ for GMOs, ten.^{41 42} At the end of this period, the company can apply to renew the approval. EFSA reviews the substance and writes a new opinion. If the data requirements for the substance have changed, the company can be asked to provide new data.

If new information comes to light after a product's approval that throws doubt on its safety, the Commission can ask EFSA to review it. The Commission and individual member states have the power to order an immediate withdrawal of the product from the market.

Why the authorisation process does not protect the public

The authorisation system for risky products or substances often works in industry's interest, not the public interest, for a number of reasons (see below). Some are within EFSA's control, others not.

EFSA bases its evaluations primarily on studies carried out by industry

EFSA generally bases its risk assessments on the dossier of studies carried out by the very same companies that stand to earn enormous profits from the product's approval.

The problem with this system is that it is biased in favour of industry. Many scientific reviews comparing industry-sponsored or -affiliated studies with independent studies show that industry studies are much more likely to conclude that the product is safe.

The best known example is tobacco industry studies, which successfully delayed regulation for decades by manufacturing doubt about the effects

of smoking.^{43 44} But the same situation affects many products in everyday use, including the plastic food packaging ingredient bisphenol A (BPA),^{45 46} other chemicals,⁴⁷ mobile phones,⁴⁸ pharmaceuticals,⁴⁹ medical products,⁵⁰ and genetically modified foods.⁵¹

EFSA can decide to initiate its own scientific work (self-tasking) if it believes a particular issue requires further research. But this does not extend to carrying out or commissioning its own safety testing on a substance or product. According to Dirk Detken, head of legal affairs at EFSA, the agency does not have the resources to do so, adding, "That would also be against the principle whereby it is the [industry] applicant who has to prove the safety of the product/substance in question, and not EFSA."⁵²

However, the examples of aspartame and bisphenol A (see Case studies I and II in this report) show that the current system to ensure a product's safety is not robust. This is made worse by the fact that EFSA appears unwilling to take on board independent

scientific findings that reveal problems (see section below).

In practice, it falls on the public to prove that a substance is unsafe, often years after the product was first released onto the market and after millions of people have been exposed to it. Clearly, this system is unsafe and unjust. It is also impractical, since by the time one unsafe chemical is withdrawn, numerous others have come onto the market – meaning that the public and regulators are forever running to catch up.

A common sense solution to the bias arising from reliance on industry studies would be for the EU to commission independent laboratories to carry out testing. The companies seeking approval would pay for testing through a publicly administered fund. A barrier would be created between industry and the testing laboratories, which would be under a clear mandate to deliver scientifically rigorous results. For objectivity, the laboratories could be blinded to the identity of the manufacturer and even to the exact identity of the substance.

This alone would require major changes in the EU laws governing the authorisation of risky products. But other far-reaching changes are needed too.

EFSA ignores or dismisses independent studies

The system of having industry test its own products prior to marketing is laid down in EU law and EFSA has no power to change it. But EFSA does have the freedom to obtain a more balanced view by taking independent scientific studies into account, where such studies exist. Indeed, the new pesticide regulation⁵³ and the REACH regulation on chemicals⁵⁴ require EFSA to take into account independent

studies from the open scientific literature in its risk assessments.

Generally, independent studies on a product or substance only appear after it has been released onto the market, as only then can independent scientists get hold of it for testing. So in most cases, EFSA will only be able to consider independent studies when a product's approval comes up for renewal.

Yet EFSA has repeatedly ignored or dismissed hundreds of independent studies showing harm from products it evaluates, choosing instead to rely on industry studies that claim these products are safe. Controversial cases have included bisphenol A and aspartame.

Dirk Detken, head of legal affairs at EFSA, has defended the agency's record, saying, "In case EFSA is aware of independent studies questioning the safety of the substance, product or claim, the Authority certainly takes those into account and weighs them against the information submitted in the dossier by the [industry] applicant."⁵⁵

But Hans Muilerman of Pesticide Action Network said that all too often, EFSA seems *not* to be aware of independent studies: "EFSA experts don't appear to read or keep up with the independent scientific literature on the substances they evaluate. They only consider independent studies if progressive member states like Denmark or Sweden submit them.

"Even when EFSA is made aware of the studies, it generally rejects them and does not use them to form their opinions. The Commission is not very active in pushing EFSA on this point. More pressure from Members of the European Parliament and the media is needed."



Our Daily Poison

In her documentary, *Our Daily Poison* (Notre Poison Quotidien, produced by ARTE TV), Marie-Monique Robin shows with shocking clarity that the way chemicals (around 100,000 commercialised since 1945) are tested for safety is fundamentally flawed. These chemicals have been added by agro-industry to food products, based on studies mostly not available to regulators. Taking pesticides, aspartame and bisphenol A as examples, Robin links everyday exposure to these substances to the continuous rise of diseases like cancer,

Parkinson and diabetes in Europe. Some of the cornerstones of today's food safety system, the 'acceptable daily intake' (ADI) and the 'maximum residue level' (MRL) are shown to be scientifically highly questionable. However, they are defended by EFSA staff and experts.

Robin interviewed scientists and regulators from EFSA, the FDA, and the WHO for this revealing documentary, which can be ordered from ARTE TV or watched online.

Public health at risk: Glyphosate scandal

A recent case in which EFSA has potentially placed public health at risk by ignoring independent studies is an opinion it issued on glyphosate, the main ingredient in the widely used herbicide Roundup.

Since glyphosate herbicides were first commercialised, hundreds of independent studies showing harmful effects have been published.⁵⁶ Recently, EFSA had the opportunity to take these studies into account when Monsanto and the German government asked for an increase in the allowed residue level for glyphosate in lentils.

In an opinion issued in January 2012, EFSA acted as if over a decade of research on glyphosate and Roundup had simply never happened. It failed to cite a single independent peer-reviewed study. Instead, EFSA cited 'grey literature' – unpublished documents of unknown reliability – from bodies including the European Commission, the OECD, and the Food and Agriculture Organisation (FAO), which in turn summarised grey literature from industry.⁵⁷

Needless to say, EFSA's opinion gave the green light to increase the existing limit a massive 100 to 150-fold, from 0.1 mg/kg to 10 or 15 mg/kg. The hike in the allowed residue level was needed to accommodate glyphosate residues far above the existing limit in imported lentils.

EFSA's move followed an earlier decision by EU regulatory authorities to raise the limit on glyphosate residues allowed in soy 200-fold, from 0.1 mg/kg to 20

mg/kg.⁵⁸ This decision was made in 1997, the year after GM glyphosate-tolerant soy was authorised for use in food and animal feed in Europe.

In the case of glyphosate residues, EFSA's practice of ignoring independent studies is dangerous. Based on industry studies, EFSA assumes that the acceptable daily intake (ADI) for glyphosate is 0.3 mg per kg of body weight per day (mg/kg bw/d). EFSA then works out from current residue testing that the highest daily intake of glyphosate through the diet will be no more than 46.7% of this ADI – 0.14 mg/kg bw/d. Because this level is under half of its assumed ADI, EFSA considers it safe.

But a report by international scientists published by Earth Open Source⁵⁹ showed that taking independent studies into consideration gives an ADI at least 12 times lower than the figure EFSA uses – 0.025 mg/kg bw/d.⁶⁰ This ADI is calculated from the results of two studies that used an animal and an exposure method approved by EFSA in its guidance on the use of independent studies in pesticide assessments.⁶¹

EFSA ignores the known toxicity of glyphosate established by independent studies such as these in setting its new allowed residue limit. But taking these into account, the 0.14 mg/kg of glyphosate residue that EFSA allows in our daily diet is a massive 560% of the ADI based on independent studies – some six times the safe daily dose.

EFSA relies on industry science to set safe levels

Tony Tweedale, a Brussels-based toxics consultant who works for civil society organisations, said EFSA's lack of awareness of independent science directly threatens public health. Tweedale explained that at the heart of every risk assessment is the determination of the acceptable daily intake (ADI) level. That's the level of a substance that regulators consider safe for a human to be exposed to over a long period.

EFSA, like other regulatory bodies, uses the highest dose at which no toxic effect is found to set the ADI. But the problem, Tweedale explained, is that EFSA uses industry studies rather than independent studies to set the ADI. And independent studies on any given substance consistently find toxic effects at doses at which industry claims no effect.

Tweedale said: "EFSA bases its safe dose on what industry studies say is the 'no effect' dose, not on what independent studies say it is. If the industry studies

are wrong, as independent studies often suggest, then EFSA's safe doses may not be safe after all."

EFSA rejects independent studies for unscientific reasons

The most common reason EFSA gives for rejecting independent studies is that they are not carried out according to the norms for industry tests for regulatory purposes – Good Laboratory Practice (GLP) rules and standardised test designs set out by the Organisation for Economic Cooperation and Development (OECD).^{62 63 64 65} But these rules – and EFSA's attachment to them – are increasingly coming under fire from independent scientists and public interest groups.

Good Laboratory Practice: Certified reliable science?

EFSA and other regulatory bodies often treat conformity with Good Laboratory Practice (GLP)

rules as a key indicator that a study is 'reliable'. On this basis, EFSA dismisses large numbers of independent studies, which are not carried out according to GLP rules.

But GLP is *not* a hallmark of reliable science. Nor was it ever meant to be. GLP is a set of laboratory management rules for how experiments are to be carried out, recorded, and archived. GLP was first implemented by regulators in the 1970s to combat widespread industry fraud in testing for regulatory purposes.⁶⁶

GLP is a valuable tool in ensuring that industry adheres to basic standards of traceability, so that if fraud is later suspected, there is a paper trail that enables investigators to see who was responsible. Consequently industry must never be allowed to sidestep GLP standards.

But GLP specifies nothing about what matters most in cutting-edge science: the quality of the research design, the sensitivity of the test methods, or whether the methods employed are current or out-of-date.⁶⁷

But GLP is now being mis-used by industry and industry-friendly regulators as a shield to defend industry's products against inconvenient findings in independent studies.

Professor Gilles-Eric S  ralini from the independent CRIIGEN research institute in France said that when independent scientists publish studies showing harm from products, EFSA's response is often: "Well, we don't believe you because you have not followed GLP guidelines. Of course only the industry follows [those guidelines], because it is very expensive" – due to the high labour costs of the monitoring and recording required.

S  ralini added that in the case of bisphenol A, "EFSA disregarded 250 papers on [the chemical] because they were not done according to GLP guidelines."⁶⁸

In 2009 a group of 36 publicly-funded scientists published a peer-reviewed paper criticising the regulatory fixation on GLP on both sides of the Atlantic. The researchers pointed out that the real and long-established measure of scientific reliability is not GLP compliance but "independent replication, and use of the most appropriate and sensitive state-of-the-art assays, neither of which is an expectation of industry-funded GLP research."

The researchers concluded, "Public health decisions should be based on studies using appropriate protocols and the most sensitive assays. They should not be based on criteria that include or exclude data depending on whether or not the studies use GLP. Simply meeting GLP requirements is insufficient to guarantee scientific reliability and validity."⁶⁹

Are only OECD test designs 'relevant'?

EFSA and other regulatory bodies also dismiss independent studies on the grounds that they do not conform to standardised OECD test designs and are therefore not 'relevant' to human risk assessment. As only industry studies conform to OECD designs, independent studies are, by this logic, excluded from consideration.

But standardised OECD test designs used for risk assessment are criticised by independent scientists for being outdated and insensitive.^{70 71 72 73 74 75}

Common criticisms are that OECD tests:

- ~ Are not designed to test effects of long-term exposure to a chemical at the low doses that humans commonly experience. Such effects are common with endocrine disrupting chemicals (chemicals that disturb the hormonal system and can affect development and the organs and functions of the body)
- ~ Assume that toxic effects always increase with the dose in a uniform way and ignore evidence that does not conform to this model
- ~ Ignore the effects of mixtures of toxic substances (the 'cocktail effect'), in which the whole is often much more powerful than the 'sum of the parts'
- ~ Ignore vulnerable life stages, such as development in the uterus and during infancy, despite evidence that exposure during these periods results in significant increases in cancer⁷⁶ and other diseases. Yet human beings are exposed to toxins during vulnerable periods.
- ~ Kill the animals around two-thirds of the way through their lives, before long-term effects can show up. For example, rats are killed at two years old – the equivalent of only 60–65 years in human terms. The majority of most types of cancers appear after this age and so are not seen in OECD tests.⁷⁷

In sum, the key chronic toxicity tests that agencies such as EFSA rely on *simply do not test reality*.

Brian Wynne, professor of science studies at Lancaster University, said: "The OECD standards are pragmatic compromises. Nobody says this is the best possible science. Everybody says this is the

best compromise between best science and best economics.”

Because testing is expensive, Wynne said, a compromise is made in OECD test designs on the exposure period. Better results would be obtained if more tests were done, and the effects of exposure were observed for longer periods.

Wynne added, “Some studies have tried extending the test periods, and have found significant indications of harm which were not observed for the shorter, OECD-advised test periods.”⁷⁸ This reflects the Ramazzini Institute findings on aspartame in studies using the lifetime protocol (see Case study II).

EFSA has no power to change the OECD test designs, though the EU member states and the Commission do.⁷⁹ OECD member countries must accept industry studies performed according to OECD guidelines, under the MAD (Mutual Acceptance of Data) agreement. But the EU Commission has the power to authorise any additional testing system it thinks fit, as is made clear in the EU’s REACH regulation for chemicals.^{80 81} We suggest that this should include peer-reviewed research by independent scientists, screened for industry conflicts of interest.

Meanwhile, EFSA’s clear responsibility is to stop using non-compliance with OECD guidelines as a reason to reject independent studies of superior design.

Industry studies are seldom peer reviewed

In the independent scientific community, scientific rigour has little to do with GLP or OECD rules and everything to do with peer-reviewed publication. The peer-reviewed publication system, while not perfect,

has important quality control measures that are missing from industry science.

In the peer review process, qualified scientists are invited by a scientific journal editor to examine a study being considered for publication. The scientists give feedback to the journal editor, such as their analysis of the quality of the study, suggestions for revisions, and recommendations for or against publication. Based on this feedback and the editor’s judgement, the study will be rejected, published, or published with the authors’ revisions.

Once a study is published, other scientists can examine and discuss it. They can also repeat (replicate) the experiment to see if their findings are the same. This repeat-testing is considered a cornerstone of scientific reliability.

In contrast, most industry studies used in the regulatory process fall into the category of ‘grey literature’, documents that have not been peer-reviewed or published and are of unknown reliability.

The EU regulatory process causes concern in the scientific community because while it ignores or dismisses important scientific findings in the public domain, the studies it relies on from industry are often not available because of their unpublished status and/or commercial confidentiality rules and so cannot be replicated.

Commenting on this situation, Brian Wynne, professor of science studies at Lancaster University, said: “There are restrictions both in terms of independent reading of the company’s studies and peer reviewing them, as you would review a scientific paper, and also in terms of experimentally repeating and replicating or testing those results which are reported in such studies.”⁸⁵

Is EFSA too busy to look at independent studies?

One possible reason why EFSA often does not consider independent studies is a lack of capacity. The MEP Kartika Liotard, who is responsible for liaison between the European Parliament and EFSA, has pointed out that EFSA experts are under pressure from an enormous workload that they are ill equipped to deal with.

She told Corporate Europe Observatory: “They get more and more work in a lot of files. Do they have enough skilled people to handle the questions in time?”⁸²

This may explain why EFSA appears keen to limit the amount of data that it is required to assess.

Herman Koëter, a former scientific director of EFSA,⁸³ was reported as saying when he left the agency in 2008: “We were equipped to do several hundreds of claims per year. However in the first year we received 40,000 claims. [Executive director] Geslain-Lanéelle limits what and how we have to research. That is practical, but not according to my standards.”

No one is suggesting that industry submit its studies performed for regulatory purposes to a scientific journal for peer-reviewed publication. Scientific journals are interested in cutting-edge research, not routine industry tests carried out according to outdated methods. But it is a simple matter for regulators to make industry studies available for scrutiny by publishing them on a website, a practice now followed by the Australian and New Zealand GMO regulator, FSANZ. At the very least, such studies must be made available to the public on request.

Example of grey literature: Glyphosate assessment

An example of industry 'grey literature' used in risk assessment is the EU's 2002 approval of glyphosate, the main ingredient of Roundup herbicide. This approval is still in force today. The assessment of the industry dossier on glyphosate pre-dated EFSA and was carried out by the German government consumer protection office BVL and a Commission expert panel.

BVL's list of industry studies taken into consideration in the assessment⁸⁶ makes clear that all the studies were funded by industry. Next to each study, BVL noted the company or companies that funded it (the "owner" of the study). For example, the abbreviation "MOD" refers to the chemical companies Monsanto and Cheminova.

BVL has marked most of the studies as unpublished – and many as not even having been done according to Good Laboratory Practice (GLP).

In 2010 Pesticide Action Network asked the European Commission for access to several of industry's toxicological studies on glyphosate. The Commission replied that it did not have them and passed the request to BVL, which refused to release the studies on the grounds of commercial confidentiality. Pesticide Action Network is continuing to press for disclosure through the courts.⁸⁷

Risky products: What we're not allowed to know

If independent scientists want to check industry test data and replicate the tests themselves, they need access to the test designs, the industry test findings, and the materials tested. Access varies depending on the type of product and the regulatory agencies involved.

Industry test designs are standardised by the OECD and can be freely accessed on the internet.

But industry test findings are often not available because they are unpublished. So even if scientists replicated an industry test design, they would not be able to compare their findings with those of industry.

In addition, EU laws allow companies to ask for certain information submitted in the authorisation dossier to be kept commercially confidential. Companies argue that disclosure of the information would enable competitors to use it for their own profit. In such cases the data must still be released to EFSA's experts and other regulators but is not shared with independent scientists or with the public.

Industry toxicological studies on pesticides are often hidden under commercial confidentiality rules. As the studies are often not held by EFSA but by the 'rapporteur' member state responsible for the pesticide, this is outside EFSA's control.

But EFSA does have a policy of transparency for industry toxicological studies on GMOs. In 2011 EFSA and the Commission said that only a small amount of the industry data on GMOs is kept confidential, such as details of the genetic sequence of the GMO. Most other data, including toxicological studies, can be accessed on request.^{88 89} This may be due to an important test case on public access to industry data on GMOs, described below.

Monsanto's GM maize study: Test case on hidden industry data

In 2002 Monsanto applied for market authorisation for its genetically modified MON863 maize in Germany. Its dossier included a rat feeding study. EFSA examined Monsanto's study and in April 2004 published a favourable opinion, which concluded that the results "do not indicate adverse effects" and that "there are no concerns" over the safety of the maize.⁹⁰

In May 2004 Greenpeace asked the authorities in Germany, where Monsanto had applied to commercialise the GMO, to release the rat feeding study. EFSA, which was only founded in 2002, did not hold the documents. So Greenpeace applied for disclosure to the German authorities. Monsanto tried to prevent disclosure by going to court. But in June

2005, an Appeal Court in Germany declared that the study must be released.⁹¹

In 2005 the EU authorities approved Monsanto's MON863 GM maize for import as food and animal feed. The following year Monsanto published its own interpretation of its rat feeding study, concluding that MON863 was safe to eat.⁹²

Professor Gilles-Eric Séralini of CRIIGEN analysed the disclosed Monsanto data and reached a radically different conclusion. He found that the data showed clear toxic effects, notably liver and kidney toxicity, in rats fed the GM maize for only 90 days. His verdict: "It cannot be concluded that GM corn MON863 is a safe product."⁹³ Séralini added that in the public interest, such health data "should not be secret or confidential".⁹⁴

Since the GM maize affair, the EU authorities have overhauled their transparency performance on industry toxicological studies on GMOs.

Were the EU authorities forced to change their stance by the GM maize affair? Christoph Then, who worked for Greenpeace at the time it applied for disclosure, said: "After the MON863 case, the Commission came up with statements that made clear that these documents have to be made public. So it was a stepwise process that influenced accessibility of these data in the EU. I think the MON863 case was important in that process."

As well as deceiving the public over health risks, keeping industry studies secret can conceal failings on the part of the regulators. The GM maize affair brought into question EFSA's objectivity in reviewing and interpreting industry studies, since the company's own study had shown toxic effects that EFSA had dismissed as irrelevant.⁹⁵ Unless such studies are made public, there is no way for the public or independent scientists to know whether EFSA – or any other public body – is accurately reporting industry findings.

No access to GMO research materials

While European citizens can access industry data on GMOs from EFSA, the materials needed for independent testing are not available, as these are in the control of the biotech industry – which seemingly does not want them to be investigated by independent scientists.

To carry out an investigation, scientists need access to the whole GM plant that is to be commercialised and the original non-GM plant from which the GMO was produced. In order to find out whether the GM process has caused any changes in the makeup or toxicity of the plant, scientists need to compare the GM plant with the non-GM original.

But biotech companies prevent such research by restricting access to the materials. Former biotech advisor to the US Environmental Protection Agency Dr Doug Gurian-Sherman explained that biotech corporations such as Monsanto and Syngenta "have often refused to provide independent scientists with seeds, or they've set restrictive conditions that severely limit research options."⁹⁶

This applies not only to the GM seeds but to the non-GM original plants. Increasingly, biotech companies will not even release these to regulators. This situation has led EFSA to allow for situations where the non-GM original is simply "not available" for comparative research.⁹⁷

The restrictions placed by the biotech industry on independent researchers have been condemned by the editors of Scientific American, who wrote, "Unfortunately, it is impossible to verify that genetically modified crops perform as advertised. That is because agritech companies have given themselves veto power over the work of independent researchers."⁹⁸

In contrast, commercialised pesticides are available to independent researchers, as is evident from the large number of independent studies in the literature.

EFSA guidance: Favouring industry?

EFSA is often asked to develop guidelines ('guidance' documents) that provide detail as to how a certain EU law should be interpreted. It can, for instance, outline which tests industry has to carry out on a certain type of product (the data requirements), and how the risk assessment should be carried out. These guidance documents are written by an expert panel or working group. In the case of horizontal topics affecting different areas, guidance documents are written by EFSA's scientific committee.

Some of EFSA's guidance documents have been criticised for being biased in favour of industry interests, at the expense of public health. These guidance documents are often used in the approval of risky products without having been officially agreed by the EU institutions – raising the question of whether the intended separation between 'risk assessment' (EFSA) and 'risk management' (EU) is being blurred.

Examples include EFSA's guidance documents on the new pesticide regulation and on GMO risk assessment.

Pesticide guidance teaches industry to ignore independent science

In the new pesticide regulation of 2009, the European Parliament and Council made clear that pesticides must no longer be assessed only on the basis of industry science. The regulation demands explicitly that independent research is taken into account.⁹⁹

But Pesticide Action Network and Earth Open Source have accused EFSA's 2011 guidance on this issue of undermining the intent of the regulation by giving industry permission to exclude independent science from its dossiers.^{100 101 102}

EFSA lists some reliability criteria which industry can use to select independent studies to include in dossiers. The first example on the list is the so-called Klimisch study, published in 1997 in an industry-owned journal and authored by three employees of the chemical company BASF. Klimisch gives a list of categories of reliability. His 'most reliable' category consists of studies conducted according to GLP rules. But normally, only industry studies follow GLP rules. So according to this logic, industry studies are most reliable. Klimisch classifies independent studies, which do not follow GLP/OECD rules, as less reliable or even as unreliable.¹⁰³

It is true that Klimisch is only one of several papers that EFSA puts forward to guide industry on judging the reliability of studies, but the other papers reinforce Klimisch's definition of reliability. However for the independent scientific community, replicability of results, not conformity with GLP or OECD rules, is the key indicator of scientific reliability.¹⁰⁴

While EFSA does say that lack of GLP compliance "does not imply that the study is irrelevant", it goes on to nail the coffin lid firmly down on independent studies: "Reliability appraisal for non-GLP studies may be more difficult [than for GLP studies]." Translation: industry remains free to ignore independent studies.

Hans Muilerman of Pesticide Action Network criticised EFSA's approach, saying: "It is unacceptable that EFSA keeps favouring industry tests and undermining a democratically established law. The Parliament and Council must reject the guidance and take on board truly independent scientific advice."¹⁰⁵

In April 2011 Pesticide Action Network and environmental lawyers ClientEarth launched a legal action against EFSA, citing the agency's lack of transparency over how the guidance was decided.¹⁰⁶ The groups are demanding that EFSA release documents revealing how, and at whose suggestion, the industry-friendly Klimisch recommendation got into the text.

Hans Muilerman of Pesticide Action Network reports that EFSA twice refused to disclose the documents. He added, "Only after we persisted with our case did they release the documents, though they blacked out the names of those who asked for Klimisch to be included."¹⁰⁷

In a statement claiming it was "committed to openness and transparency", EFSA said the names were blacked out because of EU rules on the protection of personal data.¹⁰⁸

The groups continue to press EFSA to reveal the identity of the Klimisch promoters.

EFSA adopts industry approach to assessing GMO safety

EFSA's guidance on the environmental risk assessment of GM crops¹⁰⁹ was strongly criticised by the German civil society group Testbiotech in

2010. Testbiotech warned that EFSA’s guidance was “inadequate” in providing consumer and environmental protection.¹¹⁰

Testbiotech argued that the problem originates in EFSA’s assumption that GM plants are equivalent to non-GM plants. The process of genetic engineering changes plants in unpredictable ways that can lead to health and environmental risks. But the guidance only requires comparison of the levels of a few basic nutrients, such as protein and fat, in the GM plant with the levels in a non-GM plant. As a result, unexpected changes will be missed.

This approach, known as “comparative assessment”, was, in fact, developed by industry and ILSI between 2001 and 2003. During this period, Harry Kuiper and Gijs Kleter (both members of the EFSA GMO panel since 2003) were active within the ILSI Task Force that developed this concept (see section 2, “ILSI not an industry lobby group?”).¹¹¹ In 2004, EFSA adopted the concept in its GM food and feed guidance.¹¹² So the same people who developed this concept for industry lobby group ILSI sit on the same EFSA GMO panel that makes the rules on GMO risk assessment.

This story was repeated in 2008, when EFSA published a review arguing that animal feeding studies on GMOs should not be mandatory but should only be conducted if the comparative assessment showed that they were needed¹¹³ – an unlikely scenario, given the weakness of the comparative assessment process, as explained above.

Testbiotech compared the EFSA review with a key ILSI text and found substantial parts of the text in both documents to be almost identical (see extracts below). Testbiotech’s report concluded, “The document published by EFSA to explain why feeding trials are not necessary, was at least partially plagiarized from an ILSI paper.”¹¹⁴

ILSI	EFSA
In addition, livestock feeding studies with target species are sometimes conducted to establish the effect of the new feed resource on animal performance with endpoint measurements such as feed intake, level of animal performance, feed conversion efficiency, animal health and welfare, efficacy, and acceptability of the new feed ingredient.	Livestock feeding studies with target species are sometimes conducted to establish the effect of a new feed material on animal performance with endpoint measurements such as feed intake, animal performance, feed conversion efficiency, animal health and welfare, efficacy, and acceptability of the new feed material.

Based on this evidence, it seems that EFSA’s approach meets the needs of industry by providing an easier and cheaper approval process at the expense of the protection of public health.

Case study I

Who's (not) afraid of bisphenol A?



Some of EFSA's most controversial safety assessments have been on a chemical called bisphenol A (BPA). BPA is used to make shatter-proof plastic and coatings. It is found on the inside of almost all food and beverage cans and in dental fillings.

BPA is an endocrine disrupting chemical – a hormone disruptor. Endocrine disruptors have been found to cause cancer, birth defects, developmental problems, heart disease, disorders of the thyroid gland and nervous system, and even obesity, often at very low doses.¹¹⁵

The evidence against BPA is overwhelming – yet EFSA has repeatedly dismissed it. In 2009 EFSA (along with its US counterpart, the FDA) was criticised by 36 publicly-funded scientists in a peer-reviewed paper for rejecting hundreds of independent studies showing harm from low doses of BPA in favour of only two industry-funded studies showing safety.¹¹⁶

The scientists blamed EFSA's decision on its fixation on Good Laboratory Practice or GLP. The two industry-funded studies adhered to GLP, while the independent studies, as is usual for non-industry studies, did not.

Scientific monitoring since 2009 by the French organisation Réseau Environnement Santé shows that of 193 published studies on BPA, 96% find worrying effects. In many of these studies (31 of 118), effects are found at doses below the acceptable daily intake (ADI) level defended by EFSA.¹¹⁷

Dr André Cicoella, a spokesman for Réseau Environnement Santé and toxicologist at INERIS (the French institute for industrial risk assessment), explained: "The current ADI supported by EFSA is 50 micrograms/kg/day. But a study in mice found precancerous changes in mammary glands at only 0.025 micrograms/kg/day.¹¹⁸ That's 2000 times lower than the current ADI."

No ‘no-effect’ dose was found in this study. So taking into account the usual safety margin, Cicolella said, “The ADI should be no more than 25 picograms/kg/day – 2 million-fold below the current ADI. Clearly this is grounds for a ban.”

While EFSA did recommend a ban on BPA in babies’ bottles, it refused to lower its ADI or to ban it altogether. Instead it issued a series of opinions and statements reaffirming BPA’s safety.^{119 120 121 122}

But many members of EFSA’s food additives (ANS) panel who wrote two such opinions on BPA^{123 124} have ties with industry (Sandro Grilli, Fernando Aguilar) and links to ILSI (John Christian Larsen, Iona Pratt, Susan Barlow, Riccardo Crebelli, Ivonne Rietjens, and Jean-Charles Leblanc).¹²⁵

In September 2011 EFSA’s stance was directly challenged when the French food safety authority ANSES published two revolutionary reports on BPA.^{126 127} These concluded that health effects from BPA had been proven in animals and suspected in humans, even at lower levels of exposure than the so-called safe dose allowed by EFSA. On the basis of these findings it recommended no exposure to BPA for infants, young children, and pregnant or breastfeeding women – identified by ANSES as the most susceptible populations.

ANSES’s verdict stood in stark contrast to EFSA’s, mainly because ANSES took into consideration all the available evidence on BPA, including independent studies.

EFSA responded to ANSES’s reports by continuing to deny that there were any grounds for concern.¹²⁸ In this case EFSA’s response came from the CEF panel, which covers food packaging. In a pattern that has become familiar, at least four CEF panel members have been involved in ILSI activities on food packaging. Roland Franz is a member of the scientific committee of ILSI’s International Symposium on Food Packaging and Laurence Castle co-authored an ILSI study on “Estimating consumer exposure to chemicals migrating from packaging materials”.¹²⁹

EFSA’s decision was condemned by Dr Cicolella from Réseau Environnement Santé: “ANSES chooses to endorse 21st century toxicology, when EFSA sticks to good old 1960s toxicology,” Cicolella said. “By denying the reality of scientific data and accepting only two industry-funded studies relying on an obsolete protocol, EFSA behaves like a commercial agent for the industry.”¹³⁰

Réseau Environnement Santé is urging the European Commission and Parliament to intervene to force EFSA to operate in a way that guarantees the protection of public health.¹³¹

Following ANSES’s reports, on 12 October 2011, the French National Assembly voted to ban BPA in all food contact materials from 2014. Containers aimed at children under three will have to be BPA-free by the beginning of 2013 and all products will have to be labelled to warn sensitive populations of the dangers of exposure to the substance.¹³² Belgium is following the same path.¹³³

The CEF panel did admit that there is a lack of data on low-dose exposure, and is awaiting publication of new low-dose studies being conducted in the United States in 2012. Meanwhile many Europeans, thanks to EFSA’s defence of BPA, will continue to be exposed to potentially dangerous levels of the chemical.

Case study II

The not-so-sweet truth about aspartame

Aspartame – also known in Europe as E951 – is one of the most widely used artificial sweeteners. It is found in over 6000 food products, including low calorie soft drinks, and around 500 medicines.

EFSA based its ADI (acceptable daily intake) for aspartame on four industry studies, carried out by the manufacturers in the 1970s. But more recently, a number of large-scale studies on rats and mice have indicated that it causes cancer. EFSA has dismissed these findings, maintaining its position that aspartame is safe.

Yet at a public hearing in the European Parliament in March 2011 EFSA was forced to admit that the EU's scientific committee on food, which did the original evaluation in 1984 before EFSA existed, did not actually have the four industry studies, let alone review them, when it gave approval.¹³⁴

Dr Morando Soffritti, director of the European Foundation of Oncology and Environmental Sciences at the Ramazzini Institute in Bologna, Italy, published the findings of his initial study on rats in 2005 and 2006.^{135 136}

Soffritti said: “The previous [industry] studies were performed in the seventies and we were suspicious about the correctness of how the experiments were conducted.”¹³⁷

To overcome the limitations of OECD industry test designs, Soffritti used a ‘human-equivalent’ model that mirrors how humans are exposed to carcinogens (cancer-causing substances). The animals were allowed to live out their natural lifespan, rather than being killed two-thirds of the way through their lives, as OECD protocols demand. As most cancers show up in old age, years after the exposure that triggered them, this ‘lifetime protocol’ enables all cancers triggered by the chemical to be seen.

Under these realistic conditions, Soffritti's team found that aspartame causes an increase in cancer in rats at dose levels far lower than the acceptable daily intake level (ADI) set by EFSA. The researchers concluded, “On the basis of these results, a

reevaluation of the present guidelines on the use and consumption of [aspartame] is urgent and cannot be delayed.”¹³⁸

EFSA rejected Soffritti's study mainly on the grounds that it did not conform to OECD and GLP norms¹³⁹ (which only industry studies conform to). But this was precisely the study's strength – it reflected real human exposures. In real life, humans, unlike the rats in OECD tests, are not killed two-thirds of the way through their lives.

EFSA also objected to the fact that many old rats had lung infections, which it saw as a confusing factor that helped invalidate the findings¹⁴⁰ – even though this reflects the reality of human old age, when lung infections are common.

Soffritti went on to conduct further experiments, first on rats¹⁴¹ and then on mice.¹⁴² He explained: “To test the potency of one carcinogenic agent it is necessary to test it in at least two species, rat and mice. Because if the result is that it is carcinogenic in two species of animals, there is more probability that it is also carcinogenic in humans.”¹⁴³

This time, Soffritti extended the ‘human-equivalent’ model to include exposure during foetal development. Again, this reflects the way humans are exposed to carcinogenic chemicals. Soffritti found that aspartame's cancer-causing effects increase even more when exposure begins in the womb.^{144 145}

The European Commission asked EFSA to comment on Soffritti's new mouse study. EFSA rejected it, chiefly – and predictably – because it did not conform to OECD norms. EFSA said in a statement that two of its panels concluded that “there was no indication of any genotoxic [damaging DNA] or carcinogenic potential of aspartame” and therefore no reason to revise the acceptable daily intake for aspartame.¹⁴⁶

EFSA said the tumours could have occurred spontaneously and that such tumours in mice are “irrelevant” to human risk assessment. EFSA cites an impressive-looking list of five scientific papers to back

up this claim, but closer examination reveals that these are :

- ~ A non-peer-reviewed piece of 'grey literature' summarising the outcomes of an ILSI workshop¹⁴⁷
- ~ A paper sponsored by the chemical company Rhône-Poulenc¹⁴⁸
- ~ A paper authored by Alan Boobis,¹⁴⁹ a long-term ILSI insider who has also served on EFSA expert panels for many years,¹⁵⁰ which cites ILSI as a main authority for its argument
- ~ An ILSI paper¹⁵¹
- ~ A paper sponsored by the chemical company Dow AgroSciences.¹⁵²

Far from representing an independent scientific consensus or even a reasoned debate, this list of papers is little more than an industry chorus. All follow the time-honoured industry-ILSI line of argument that mandatory cancer testing in mice in addition to rats should be abolished in regulation – without offering an effective alternative. Their reasoning? Tumours such as Soffritti found in aspartame-exposed mice are “irrelevant” to human risk assessment.¹⁵³ EFSA uncritically adopted the same line of argument promoted by industry and ILSI.

Soffritti has rejected EFSA's criticisms, but argues that the key issue is that a proper evaluation is carried out: “What I think should be pushed very strongly is an evaluation of the safety of aspartame and the carcinogenicity of aspartame. You cannot avoid a review of the documents, the raw data of the past experiments. If, on reviewing that data, you find that the adequacy of that experiment is very poor, you cannot say, ‘Well, that data is poor but we don't believe the result of the Ramazzini Institute,’ because in that case you have to repeat the study. The [EFSA] opinion is not enough”.¹⁵⁴

In Marie-Monique Robin's film 'Notre Poison Quotidien', Soffritti reveals that one day, a high ranking EFSA official had told him: “Doctor Soffritti, if we admit that the results of your study are valid, we would have to ban aspartame from tomorrow morning. You are well aware that that is not possible.”

In a March 2011 hearing in the European Parliament, Corinne Lepage MEP and Antonia Parvanova MEP criticised EFSA's refusal to re-evaluate its advice in the face of the new evidence. Lepage expressed shock at “the failure to examine the subject more thoroughly”.¹⁵⁵ Following this meeting, the new deputy general of DG SANCO Ladislav Miko wrote to EFSA asking for a new assessment by 2012.¹⁵⁶

Hugues Kenigswald, the head of EFSA's food additives (ANS) panel, indicated in a letter to Réseau Environnement Santé in May 2011 that this would be difficult because EFSA did not have the dossier of original experimental data, and as far as he was aware, nor did the European Commission.¹⁵⁷

This revelation raises an important question: On which information did EFSA base its original approval decision? On science, or on wishful thinking?

Kartika Liotard, the Member of the European Parliament responsible for liaison between EFSA and the Parliament, commented: “The Parliament – and I was one of the initiative takers – asked over and over again for new research. Not only to make an evaluation of research done by other research centres, but for EFSA to do its own new research if they say they can't use the data from the other scientists. We have been asking for this in the Parliament for the past six years.”¹⁵⁸



Photo: julesreyes

4. Conflicts of interest and revolving doors: How independent are EFSA experts?

EFSA's reliance on industry science operates against the public interest. But this bias is reinforced – perhaps even caused – by industry conflicts of interest among EFSA staff and experts. It has come to light that many panel members are too close to industry.

We have already looked at the systematic infiltration of EFSA panels by the industry lobby group ILSI. In this section we look more deeply into the problem of conflicts of interest on EFSA panels and the lack of rules in place at EFSA to prevent them. We also consider the problem of the 'revolving door', when people move jobs from a public body like EFSA to industry, or vice versa, resulting in a conflict of interest.



What is a conflict of interest?

A conflict of interest is a situation where an individual in a position of trust faces a conflict between their private interests and their official responsibilities.¹⁵⁹ Until December 2011, EFSA did not even have a clear definition of conflict of interest. Corporate Europe Observatory and Earth Open Source use the definition proposed for the public sector in 2007 by the Organisation for Economic Co-operation and Development (OECD), since it is broad enough to cover any problematic tie with industry:

“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.”¹⁶⁰

By this definition, the simple fact of being in such a position, even if no unethical or improper act results, represents a conflict of interest. The conflict can be mitigated through disclosure, but it can only be resolved by removing the individual from the position.¹⁶¹

In December 2011 EFSA's management board adopted the OECD definition as part of its new independence policy. However, it is not clear whether, or how, this will affect EFSA's practices.

Conflicts of interest exposed

An avalanche of reports on conflicts of interest and ‘revolving doors’ cases involving EFSA’s management board and panels appeared in 2010–11 (see table below). But these were not the first. In 2004 Friends of

the Earth Europe reported on the GMO panel¹⁶² and in 2008 the Swedish newspaper Svenska Dagbladet investigated the ANS (food additives) panel.¹⁶³

Reported conflicts of interest at EFSA 2010–2011

When?	Who?	What?
24 March 2010	Suzy Renckens (GMO panel)	Head of the secretariat to the EFSA GMO panel takes lobbyist job at Syngenta (revolving door case). Testbiotech/ Corporate Europe Observatory joint complaint. ¹⁶⁴
29 September 2010	Diana Banati (management board)	EFSA management board chair Diana Banati’s conflict of interests case with ILSI Europe. José Bové’s press conference, Brussels. ¹⁶⁵ Banati resigned from the board of ILSI Europe and was re-elected chair of EFSA’s management board on 21 October. ¹⁶⁶
29 November 2010	Laura Smillie (risk communication unit)	EUFIC revolving door case. Corporate Europe Observatory report, Corporate Europe Observatory /Testbiotech/Food & Water Europe joint complaint. ¹⁶⁷
1 December 2010	Harry Kuiper (GMO panel)	ILSI conflict of interests case. Testbiotech report. ¹⁶⁸
23 February 2011	Milan Kovac Matthias Horst Jiri Ruprich Piet Vanthemsche (management board)	Conflicts of interest of four management board members with Danone, ILSI, EUFIC and COPA. Corporate Europe Observatory report. ¹⁶⁹
7 April 2011	Angelo Moretto Alan Boobis Theodorus Brock (PPR panel)	Conflicts of interest rife with Europe’s pesticide and food safety regulators. Report by Earth Open Source. ¹⁷⁰
15 June 2011	ANS panel	Eleven out of 20 experts on panel on food additives have a conflict of interest, as defined by the OECD. Four members of the panel fail to declare active collaborations with ILSI Europe. ¹⁷¹
13 September 2011	Ursula Gundert-Remy Riccardo Crebelli (ANS panel)	Two of five newly-appointed experts in July were found to be in violation of internal EFSA rules because they had failed to disclose consulting activities for ILSI. ¹⁷²
27 October 2011	Albert Flynn (chair of NDA panel)	NDA panel chair Albert Flynn has conflict of interest related to Kraft Foods; investigation by Süddeutsche Zeitung. ¹⁷³
7 November 2011	GMO panel	Twelve out of 21 experts on GMO panel have conflicts of interest, as defined by the OECD. Corporate Europe Observatory report. ¹⁷⁴
19 December 2011	EFSA working group on TTC	Ten out of 13 members of EFSA TTC working group have a conflict of interest. Pesticide Action Network report. ¹⁷⁵

Industry on EFSA's management board

In October 2010 the French Member of the European Parliament and farmer activist José Bové discovered that the Chair of the Board – Diana Bánáti – was also on the board of directors of the industry body, the International Life Sciences Institute (ILSI).

As a result, Bánáti resigned from ILSI – but kept her position at EFSA. Civil society groups criticised this outcome, saying that her ties with industry had been demonstrated so strongly that she should have resigned from EFSA. Bánáti was appointed to the ILSI board of directors in April 2010 but did not declare it until 28 September, after Bové held a press conference to expose her conflict of interest.

According to EFSA's founding regulation, four management board members are supposed to be drawn from organisations representing consumers and “other interests in the food chain”. EFSA says that out of these four board members, two are from industry:¹⁷⁶ Matthias Horst, the German food industry's chief lobbyist; and Piet Vanthemsche, who leads the Flemish union of industrial farmers and holds an executive position in Agri Investment Fund, which has shares in 19 agribusiness-related companies.

But Corporate Europe Observatory found that another two board members also had industry ties: Milan Kováč (director of ILSI Europe until July 2011); and Jiří Ruprich (Danone Institute). In allowing so many industry-linked people on the management board, the EU institutions are violating their own rules.

As Corporate Europe Observatory pointed out in a letter to EU Commissioner John Dalli, it is not

credible to claim that people with industry interests will act purely in the public interest on the EFSA management board.¹⁷⁷ Dalli's office admitted that these were “legitimate concerns” and that “the Commission has a governance responsibility” with regard to agencies like EFSA.¹⁷⁸

The European Court of Auditors too said in late 2011 that the scrutiny of conflicts of interest for members of EFSA's management board was “insufficiently rigorous”. The Court of Auditors is expected to publish an audit of conflicts of interests at EFSA in early 2012.¹⁷⁹

Conflicts of interest in EFSA's management can only be banned by a drastic change in the founding regulation to require only people without industry ties to sit on the management board. It is up to the European Commission to take this initiative.

Exposed: Conflicts of interest on EFSA panels

In June 2011 Corporate Europe Observatory published a report showing that 11 out of 20 members of the ANS (food additives) panel had a conflict of interest.¹⁸⁰ Six of them have active collaborations with ILSI, including the vice-chair (now the chair), Ivonne Rietjens. Four of them failed to declare these ILSI interests – John Christian Larsen (chair), Gerrit Speijers (rapporteur), Iona Pratt, and Jürgen König.¹⁸¹ Under EFSA rules, failure to disclose “advice or services in a particular field falling within EFSA's remit”, even if unpaid, can lead to the expert's dismissal – but in these cases did not.¹⁸²

The story was repeated in July 2011 when some members of the ANS panel were replaced after their mandates expired. Corporate Europe Observatory found that two of the five newly appointed experts, Riccardo Crebelli and Ursula Gundert-Remy, failed to disclose consulting activities for ILSI.¹⁸³

Harry Kuiper's vanishing ILSI connection

Harry Kuiper has been active with ILSI for at least a decade. From around 2001 he was an important member of the biotech taskforce set up by the ILSI International Food Biotechnology Committee and was still involved with ILSI as recently as 2010. The ILSI taskforce was headed by a Monsanto employee and included employees of Cargill, Bayer and Syngenta. Kuiper has been chair of EFSA's GMO panel since 2003.¹⁸⁹

But Kuiper has changed his EFSA declaration of interest (DoI) to exclude his most recent ILSI connections. In his 2010 declaration (before criticism of EFSA-ILSI connections went mainstream), he lists an ILSI interest from 2000 to “now” as an “independent expert” on GM foods. But in his 2011 declaration of interest, Kuiper states his most recent ILSI involvement as 2005.¹⁹⁰

A report by Earth Open Source exposed how two recent members and one current member of the pesticide (PPR) panel – Angelo Moretto, Alan Boobis and Theodorus Brock – had close ties to ILSI.¹⁸⁴

Another report by Corporate Europe Observatory showed that 12 out of 21 members of the GMO panel had a conflict of interest, mostly with the biotech industry.¹⁸⁵ This panel is responsible for several controversial guidance documents and opinions (see Case study III). Five members have past or current ties to ILSI: Harry Kuiper (chair), Gijs Kleter, Hans Christer Andersson, Jeremy Sweet, and Jean-Michel Wal. Collaborations ranged from authoring key reports to being a scientific contributor or a member of an ILSI working group.^{186 187 188}

A report by Pesticide Action Network revealed that 10 out of 13 members of the EFSA working group on TTC (threshold of toxicological concern) have a conflict of interest.¹⁹¹ TTC is an industry-driven approach to allow chemicals market access without toxicological testing. These members have developed or promoted TTC in the past jointly with industry.

Internal emails requested by Pesticide Action Network from EFSA and reported by Le Monde showed that Susan Barlow, chair of this working group, had a large say in the selection of the TTC working group members.¹⁹² Barlow is a private consultant whose clients include ILSI, Pfizer and Pepsico, and is at the same time a member of EFSA's scientific committee.

An investigation by the German newspaper Süddeutsche Zeitung highlighted the case of the nutrition (NDA) panel, chaired by Albert Flynn, who is also a member of an advisory board at Kraft Foods.¹⁹³ The NDA Panel decided in favour of a health claim made by Kraft on one of its products, and EFSA did not seem to see a problem with Flynn's conflicting role at the company.

EFSA's credibility undermined

Following questions in the European Parliament by MEPs including Corinne Lepage, Kartika Liotard, José Bové, Kriton Arsenis and Marc Tarabella, the European Parliament requested an investigation by the European Court of Auditors, which is expected to be published in February 2012.

In several discussions in the European Parliament's environment committee on EFSA's budget in late 2011 and early 2012, MEPs demanded a clear timetable

Wrapped by industry? EFSA panel on food packaging

Three of the current 18 members of the EFSA Panel on food packaging materials mention connections to ILSI in their declarations of interest.¹⁹⁴ Chair Iona Pratt (moved in September 2011 from the ANS panel on food additives, see section above) has now declared her collaborations with ILSI – chairing at an ILSI workshop and reviewing case studies. Laurence Castle declares that he was part of two ILSI expert groups and co-authored one ILSI publication. Svensson Kettil authored a 2002 publication by an ILSI task force on packaging materials, which had employees of BP, Coca-Cola, Nestlé and Dow among its members.¹⁹⁵

Some members have not declared their links to ILSI, indicating that the links could be much more frequent than EFSA documents reveal. This also shows that EFSA does not check the declarations of interest of the panel members. Roland Franz's declaration of interest on EFSA's website is outdated (November 2010) and fails to show his membership of the scientific committee of ILSI's 5th Symposium on Food Packaging, scheduled for November 2012 in Berlin.¹⁹⁶ Similarly, Jean Claude Lhuguenot did not mention that he chaired a session at ILSI's 4th Symposium on Food Packaging.¹⁹⁷

Scientific committee

At least six of the 16 members of EFSA's scientific committee have current or past ILSI links, including Susan Barlow, Harry Kuiper, Tony Hardy, Ivonne Rietjens, Joseph Schlatter and Iona Pratt.¹⁹⁸ This is particularly serious since the scientific committee's work deals with risk assessment approaches in general and is of a strategic nature, potentially having an impact on the approval of all products that pass through EFSA.

for concrete measures to restore EFSA's credibility. Corinne Lepage, vice-president of the committee, said: "Many of us have been calling for an investigation into the efficiency of EFSA and looking at its experts' links with ILSI." Particular concerns were raised about GMO panel chair Harry Kuiper. But a call for restrictions on EFSA experts' involvement with ILSI was not supported by a majority.¹⁹⁹

In its defence, EFSA has said, “High quality of scientific expertise is by nature based on prior experience” and “Having an interest does not necessarily mean having a conflict of interest.”²⁰⁰ Health and consumer affairs Commissioner John Dalli echoed this line in a letter to Pesticides Action Network, where he said it was important to “differentiate between interests and conflicts of interest”.²⁰¹

But these statements clearly conflict with the OECD 2007 definition that EFSA has now adopted, which makes clear that the simple fact of being in a position to exploit one’s official capacity at EFSA for personal or corporate benefit represents a conflict of interest. And as we will see in the next sections, a company’s interests are broader than any one product being discussed in a panel at a given moment.

EFSA rules allow serious conflicts of interest

EFSA’s own rules enable conflicts of interest to persist. EFSA does not have a clear definition of conflict of interest. Nor does EFSA have clear criteria defining what level of industry involvement is acceptable. As a result, experts with strong industry ties can serve on EFSA panels without a problem, although they can be excluded from particular discussions.

In the face of continued criticism, however, EFSA had to be seen as taking some action and started revising its independence policy in early 2011. The initiative included a public consultation and stakeholder workshop.²⁰² While some improvements were made, such as the new definition of a conflict of interest, the revised policy fails to deliver the fundamental changes needed to address the problems raised in this report.

Declarations of interest: Transparent but ineffective?

At the core of EFSA’s Independence Policy on conflicts of interests is the system of Declarations of Interest (DoI).²⁰³ Each panel member (as well as members of the management board, advisory forum, scientific committee and the executive director) is required to make an annual declaration of interests (ADoI) and a specific declaration of interests (SDoI) for each panel or discussion they are involved in. The annual declarations are in particular considered when panel members are being selected for the panels.

An EFSA guidance document describes which activities must be declared: past (in the last five years) and current employment, research funding, membership of a managing body or a scientific advisory body, consultancy or advice (paid or unpaid and “falling within EFSA’s remit”), and ownership of shares and intellectual property rights.²⁰⁴

EFSA uses three categories of “potential conflict of interest” – A, B, or C – to define the importance of relevant activities. “A” means that there is no conflict of interest. Level “B” means important, such as past employment, and level “C” means critical, such as current employment. EFSA’s executive director Catherine Geslain-Lanéelle has said that as a result of this policy, in 2010 EFSA staff “screened 5000 annual or specific DoIs, checked these against 35,000 agenda items, and had 24 experts excluded

from EFSA activities, 280 from drafting and 53 from specific agenda items”.²⁰⁵

This system has up to now been used both for screening the interests of experts who are already on a panel and those who are candidates for selection.

When someone is already on a panel, the specific declarations are checked against the products being discussed at each meeting. But a very narrow interpretation of ‘interest’ is used: only when an expert has a direct link (such as employment or ownership of shares) to the actual producer of the product, is a conflict of interest thought to be serious enough for the expert to be excluded.

But conflicts of interest can occur in many other ways. For instance, a company may have a strong interest in a certain product not as a *producer*, but as a buyer and user. Or it may have an interest in the same type of product or technology. Furthermore, many links (and therefore joint interests) exist between companies operating in the same sector. Someone being linked to an industry association such as ILSI presents another major loophole, since ILSI has many member companies with a wide range of interests.

Let’s take the example of Ivonne Rietjens, chair of the ANS panel on food additives, who is professor of toxicology at the University of Wageningen,

Netherlands. According to her declaration of interest, Rietjens is receiving continuous research funding from Swiss food giant Nestlé (since 2005), from BASF (since 2012) and from the International Organization of Flavour Industries (IOFI, since 2010). Many food additives assessed by the ANS panel will be of interest to Nestlé as a *user* of the final product. Yet with EFSA's approach, Rietjens can attend almost all discussions on all products, as they are not *produced* by Nestlé.

Indeed, Nestlé's interests and those of other companies are not limited to a single substance. Nestlé has a strong interest and duty to its shareholders to promote an industry-friendly climate within regulatory and advisory bodies. Financing Rietjens's lab might be considered a way to fulfill this role.

In addition, EFSA's approach relies on considerable subjective judgment from the staff member making the decision, usually the head of unit. The policy even enables someone with a clear conflict of interest to participate in a panel's work on a particular issue "in exceptional cases in which the concerned person's involvement in a particular activity is considered to be essential".

Other major flaws of this policy include:

- ~ Industry association involvement (notably ILSI but also EU and national food industry lobby groups) will be largely unaffected. These associations usually represent and are funded by a large number of corporations with a wide range of interests. Whether any one of these companies produces a specific product that an EFSA panel member may have to discuss or assess is beside the point.
- ~ When EFSA working groups or the scientific committee write opinions on methodologies, such as the toxicological threshold of concern, these clearly affect entire industry sectors and not just one company. These working groups and the scientific committee are equally affected by conflicts of interest.
- ~ EFSA does not always check the declarations for undeclared interests. It has been demonstrated that not all panel members declare all their interests – notably links with ILSI.^{206 207}

When EFSA selects new candidates for expert panels, the same A-B-C levels of interest are used. But it is not clear what level of interest is considered acceptable for an EFSA expert. Full-time employment by a relevant company seems not to be allowed. But as we have seen, EFSA experts can receive industry research funding, do consultancy work for companies, or be an active ILSI collaborator, without any problem.

EFSA's response: "Allegations contain factual mistakes and mislead the public"

EFSA has vehemently denied the allegations in the reports mentioned. For instance, responding to Corporate Europe Observatory's reports on the ANS panel, EFSA executive director Geslain-Lanéelle said they contained "factual mistakes" and "misled ... the public about EFSA."²⁰⁸

But the allegations of "factual mistakes" can easily be rebutted.²⁰⁹ Indeed, a few days after publication of the first report, the declarations of interest of panel experts John Christian Larsen, Gerrit Speijers, Jürgen König, and Iona Pratt were updated to include their collaborations with ILSI.

In response to Corporate Europe Observatory's complaint that two new ANS panel experts again

failed to declare links to ILSI, EFSA said: "According to EFSA's policy on declarations of interest, the experts ... were not required to declare those activities, as they are not related to their scientific panel's field of activities."

But EFSA's guidance document on declarations of interest clearly states that roles that must be declared are "advice or services in a particular field *falling within EFSA's remit*"²¹⁰ (our emphasis) – not just within the remit of the ANS panel. Clearly these people's work for ILSI does fall within EFSA's remit. So even by EFSA's standards, it should be declared, and by any objective standard, it should be disallowed.

Reform at European Medicines Agency not replicated by new EFSA rules?

Following similar criticism, the European Medicines Agency – the EU agency responsible for the scientific evaluation of the safety of medicines developed by pharmaceutical companies – introduced new rules on conflicts of interest for scientific experts. While not perfect, this new policy sets clear limits on the interests an expert can have.

Under EMA's new rules, scientific committee chairs and vice-chairs are not allowed to have held any "employment, consultancy or strategic advisory role within previous 5 years and at any time point during the term of the mandate" with a pharmaceutical company. Chairs and vice-chairs are also not allowed to have acted as an "investigator within previous 5 years and at any time point during the term of the mandate" for any industry-funded study – an activity considered an "indirect interest" in industry.²¹¹

Rapporteurs and panel members cannot have any current employment, consultancy, or strategic

advisory role with industry at any point during the term of their mandate. These activities are considered to be "direct interests" in industry.

If these rules were applied to EFSA, many panel members discussed in this report would not qualify as an EFSA expert. Yet as we have seen, EFSA's new independence policy²¹² fails to ban experts with industry links from scientific panels. One possible improvement is that the implementing rules, that are yet to be published, "will foresee stricter measures for chairs, vice-chairs of groups and rapporteurs of scientific documents".²¹³ Finally, two separate tables are being produced that will show what levels of interest are allowed when experts are selected, and when an expert is already on a panel.²¹⁴

Whether there is any real improvement should become clear soon. When eight scientific panels are renewed in March 2012, EFSA's choices will be scrutinised by many outside the agency.

Independent experts: As rare as the unicorn?

EFSA has repeatedly defended its scientific panel members from accusations of conflicts of interest by implying that high calibre experts who are also independent are not to be found. Executive director Geslain-Lanéelle said, "If we were to exclude all experts who had received money from industry at one time or another, we would not have many experts left."²¹⁵

Health and consumer affairs Commissioner John Dalli echoed this sentiment when he said, "Preventing scientists from having any ties whatsoever with industry, or parties with particular interests, is not only unrealistic, but could very well have a negative impact on the level of expert advice we receive."²¹⁶

The main reason given for the claimed shortage of independent experts is research policy in Europe. There is a growing tendency to support public-private partnerships in research and to privatise education. Geslain-Lanéelle said: "National and European research policies encourage, and in some cases, oblige researchers in the public sector to work with the private sector.

"This cooperation is neither recent nor confined to Europe. Nor are the increasing constraints on public finances and the importance of supporting innovation and competitiveness of the food industry likely to alter this trend. Many scientific experts working in the public sector are therefore involved to varying degrees in projects funded by, or involving, industry."²¹⁷

When EFSA reiterated this point in its public consultation on independence,²¹⁸ ILSI responded with a ringing endorsement of public-private partnerships, saying that they "greatly stimulate innovation ... and thereby human progress. Also, public-private partnerships are a key element in the 'fifth freedom' (free circulation of researchers, knowledge and technology)." EFSA revised its policy accordingly since this was "in line with the overall Union policy on research".²¹⁹

Corporate Europe Observatory and Earth Open Source disagree with ILSI's intervention. EFSA's primary role, as the supposed voice of independent science in the EU, is to protect public health and the environment. The increased influence of industry on the academic world is often problematic and certainly not a mark of "human progress".

That aside, the assumption that it is impossible to find 20 independent experts for each EFSA panel in the 27 member states combined for something as crucial as food and environmental safety is either nonsense or a clear call to immediate action. If it is

indeed the case that few independent scientists apply for a post on an EFSA panel, this might be for very different reasons.

What sort of expertise is needed in risk assessment agencies?

The question of what sort of expertise is needed in risk assessment agencies is being debated on both sides of the Atlantic. In 2011 representatives of eight US-based scientific societies focusing on human diseases published a letter in *Science* magazine pointing out the limitations of existing risk assessment methods that have resulted in people routinely being exposed to levels of chemicals known to cause ill effects in animal experiments.

The scientists said that assessing risks posed by the chemicals to which people are commonly exposed “requires the expertise of a broad range of scientific

and clinical disciplines”. They offered their combined expertise in reproductive biology, endocrinology, reproductive medicine, genetics, and developmental biology to the two main risk assessment bodies in the US, the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA), to help develop new testing methods and protocols that more accurately assess risk.²²⁰

It seems likely that similar eminent scientific societies based in the EU would be equally prepared to offer their expertise to EFSA.

Holiday in Parma, anyone? No pay for EFSA experts

Contrary to what one might expect, EFSA has not been granted the means to pay its scientific experts. As executive director Geslain-Lanéelle says, the experts “are not paid for their work (they only receive reimbursement for expenses) and share their expertise in addition to their everyday jobs, often devoting weekends and holidays to assist EFSA and other agencies.”²²¹

This means the scientists’ income must come from another job, which can include work for the private sector. Is it too far-fetched to assume industry would encourage people it works with to apply for an EFSA post, perhaps by allowing them to do EFSA work in paid time? For those whose employers or workload do not allow them to spend time on EFSA work, the situation is very different. Going through vast amounts of industry data at the weekends and making the long journey to EFSA’s headquarters in Parma on a regular basis seems a lot to ask from a volunteer.

Facing budget cuts, EFSA has argued that industry should pay fees for product assessment. Indeed, while in many countries people are charged for getting a passport or a permit of some kind, industry gets the risk assessment for their products for free. EFSA estimates that a GMO assessment, for example, costs the agency over €300,000.²²² It seems reasonable

that society should not have to bear this burden and that industry should be charged.

However, industry paying money directly to EFSA could have adverse effects. So industry money should be collected at arm’s length by a publicly-controlled institution which would commission EFSA to carry out the assessment. EFSA would be placed under a clear mandate to deliver scientifically rigorous opinions.

The European Commission’s revision of EFSA’s founding regulation in 2012 may offer an opportunity to levy fees on industry. But the Commission itself has killed any hopes that fees from industry would add to EFSA’s budget. Speaking at the December 2011 management board meeting, Ladislav Miko (DG SANCO) said that this was “not realistic”. Instead, these revenues would replace part of the public budget. But an EFSA management board member, Marianne Elvander, argued that the Commission effectively controls EFSA’s workload and, given its ever-increasing quantity, cannot expect EFSA to do more work for less money.²²³

Do independent experts want to work for EFSA?

EFSA's controversial reputation and the way the panels draw heavily on unpublished industry-funded studies may tend to exclude scientists who do not agree with that approach. Some experts in the field who work for civil society groups indicated that given the current perception of EFSA as being in the pockets of industry, they would not apply because it could damage their reputation.

Professor Brian Wynne said: "Until it's recognised that actually the whole institutional furniture needs rearranging, and redefining, then it would be pointless for any individual to accept a post [on a panel] and expect to be able to ensure an open-minded and independent risk assessment and review process."²²⁴

It is not just outsiders who level such criticism at EFSA. In 2008 *Herman Koëter* left EFSA after five years in top posts, including acting chief executive and scientific director. On leaving, he said:

"An internal survey shows that staff are very dissatisfied.... Fewer and fewer scientists are willing to work for EFSA.... Internally, [staff] scientists are afraid to have a diverging opinion, fearing for their contract."²²⁵

Professor Séralini of CRIIGEN confirms Koëter's statement, saying, "There is no contradictory debate because they are choosing in majority people who have the same cultural background and who favour industry."²²⁶

Séralini has chosen to proactively engage with the problem by applying for an EFSA panel position starting in 2012. He is also calling for a separate agency, including representatives of civil society, which would evaluate data that contradicts the industry data on which EFSA relies.

Revolving door: EFSA as springboard to lobbying career?

The 'revolving door' is a popular way for industry to influence the political agenda and decision-making in Brussels. EFSA has become embroiled in revolving doors scandals. In 2008 Suzy Renckens left EFSA as the scientific coordinator of the GMO panel and moved straight into a job as Syngenta's chief lobbyist for the EU.²²⁷ In this position she can use her network and knowledge of how EFSA works to lobby the EU institutions for her new industry bosses. And her new job deals with exactly the same issue as her old one – the regulation of GMOs.

EU staff members are supposed to ask for approval from their institutions before they accept any new post within two years of leaving office. Renckens "verbally informed" EFSA about her new job,²²⁸ but the agency did not raise any objections or inform her of any obligations regarding her move.

Four civil society groups called on EFSA to take action and enforce a cooling-off period for EU staff and decision-makers. Only after the groups exposed the case did EFSA send a few emails to Renckens to remind her of her obligations. Testbiotech filed a complaint with the European Ombudsman and won the case.

In December 2011 the Ombudsman ruled: "EFSA should acknowledge that it failed to observe

the relevant procedural rules and to carry out a sufficiently thorough assessment of the potential conflict of interests arising from the move of a former member of its staff to a biotechnology company."²²⁹ EFSA said in its defence that its procedures had been "significantly strengthened since that time" and committed itself to "providing records of any thorough assessment should a similar case arise in the future".²³⁰

In an environment committee debate at the European Parliament, however, the German Socialist MEP Jutta Haug, leading the debate as rapporteur, said EFSA had taken "far, far too long" to amend its rules on revolving doors and cooling-off periods.²³¹ The committee demanded twice-yearly reports from EFSA on how it was improving the implementation of its rules to stop future revolving doors cases.²³²

In a new and similar case, EFSA claimed it had taken such "appropriate action". David Carlander was an EFSA staff member, working on guidelines for the use of nanotechnology in food. In October 2011 he started his new job as chief lobbyist for the Nanotechnology Industries Association in Brussels.

This time, EFSA imposed some restrictions. For one year, Carlander is not supposed to be the "reference contact point" for EFSA staff on nanotech

issues or ask them for non-public documents.²³³ EFSA's executive director told Corporate Europe Observatory they could not impose more restrictions because EFSA staff "are on temporary contracts ... and they need to feed their families".²³⁴ However, Renckens and Carlander were hired for lobbying jobs in the same industries they were previously regulating, so it is clear that their new employers will benefit from their insider knowledge and contacts in EFSA.

The staff regulations for EU officials do grant the EFSA management board the power to forbid such activity:

"If [an occupational] activity is related to the work carried out by the official during the last three years of service and could lead to a conflict with the legitimate interests of the institution, the Appointing Authority may, having regard to the interests of the service ... forbid him from undertaking it."²³⁵

Another example of revolving doors reported by Corporate Europe Observatory is the case of Laura Smillie, who was hired in May 2010 by EFSA to develop new "risk communication guidelines".²³⁶ Less than three weeks before, she was still an employee of the European Food Information Council (EUFIC), where she worked for five years as communications manager. EUFIC is a food industry-sponsored think tank whose members and funders include companies such as Coca-Cola, Danone, Kraft Foods, Mars, McDonald's, Nestlé, and Unilever – all big players in the European food lobby.²³⁷

While at EUFIC she helped to develop an approach to risk communication that focused on limiting the media impact of a food crisis and the subsequent losses for the food industry. This constitutes a clear conflict of interest.

In revolving doors cases, EFSA, like other EU institutions, acts weakly or not at all. More on these and other cases can be found at Corporate Europe Observatory's RevolvingDoorWatch website.²³⁸



Case study III

Gambling with antibiotic effectiveness: GM potato

In March 2010, the European Commission approved BASF's genetically modified Amflora potato for cultivation in the EU. As the first new GMO approval for cultivation in the EU for 12 years, it caused uproar. At the heart of the debate was a highly questionable opinion from EFSA's GMO panel.²³⁹ Indeed, while BASF was lobbying hard to get the Commission to approve its GM potato, a Corporate Europe Observatory report showed that the GMO panel showed itself a loyal ally for the company.²⁴⁰

The Amflora potato contains nptII, an antibiotic resistance marker gene that makes the plants resistant to two antibiotics, neomycin and kanamycin.²⁴¹ Most 'first-generation' GM crops contained such antibiotic resistance genes.

The risk with these GM plants is that if this antibiotic resistance were transferred from the potato cells to bacteria dangerous to humans and animals, this would harm the effectiveness of the antibiotics for medical and veterinary uses. Antibiotic-resistant bacteria are now a global health concern, for instance in the fight against tuberculosis.²⁴²

The EU decided to ban the use of such marker genes, which it said "may have adverse effects on human health and the environment", by the end of 2004.²⁴³

Key to the Amflora approval, then, was EFSA's controversial opinion that there was no problem with the nptII gene in the GM potato. EFSA introduced

a classification of antibiotics into three groups, classifying neomycin and kanamycin as antibiotics in group 1: of "no or only minor therapeutic relevance".²⁴⁴

This position was strongly contradicted in 2005 by the World Health Organisation (WHO), which classified these antibiotics as "critically important".²⁴⁵ At the Commission's request, the European Medicines Agency (EMA) assessed the issue and in 2007 confirmed the WHO position, concluding that neomycin and kanamycin "cannot be classified as of no or only minor therapeutic relevance".²⁴⁶

Institutionally humiliated, the GMO panel was forced to acknowledge its mistake in a statement:

"The GMO panel agrees with the EMA that the preservation of the therapeutic potential of [kanamycin and neomycin] is important."²⁴⁷

But it failed to draw the logical conclusion – to reclassify both antibiotics in group 3, "highly relevant for human therapy". Instead, the panel reiterated its previous favourable opinion on the Amflora potato, based on the "low probability of gene transfer from plants to bacteria" and on the fact that this antibiotic resistance gene in bacteria is "already widespread in the environment".^{248 249} In doing so, EFSA contradicted its own opinion from 2004, which said that genes conferring resistance to antibiotics that are "highly relevant for human therapy" should be



Photo: Greenpeace / Christian Astlund

avoided in GM plants, “irrespective of considerations about the realistic value of the threat”.²⁵⁰

It is difficult to see how EFSA’s GMO panel could write such an opinion in the first place, since none of its members were experts on the importance of different antibiotics in human medicine. But as we have seen in the previous section, more than half of the GMO panel – one of the two panels responsible in this case – had industry interests. And once again, panel chair Harry Kuiper played a leading role.

In fact, the contested EFSA opinion of 2009 confirmed the one it made in 2004, which itself drew heavily on a paper sponsored by a pro-biotech research project called ENTRANSFOOD. In particular, the GMO panel’s classification of antibiotic resistance marker genes into three groups – including the classification of the nptII gene in group 1 – was a direct copy-paste from the ENTRANSFOOD paper.²⁵¹ Curiously, however, the ENTRANSFOOD publication was not named as a source in the GMO panel opinion of 2004.

ENTRANSFOOD was a research consortium led by Kuiper that ran from 2000 to 2003. It was backed by €8.4 million in EU funding.²⁵² It aimed to provide solutions to the problem of European public resistance to 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”.²⁵³ This would “facilitate market introduction of GMOs in Europe”, according to the Commission.²⁵⁴

The membership of the ENTRANSFOOD group was drawn largely from industry and government bodies. As coordinator, Kuiper was responsible for finding project partners. These included food and

biotech corporations Unilever, Nestlé, Monsanto, Aventis, and – of course – ILSI.²⁵⁵

Four other GMO panel members were active on ENTRANSFOOD working groups, according to Friends of the Earth.²⁵⁶

Meanwhile, behind the scenes, BASF staged an aggressive lobbying campaign and 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 2010.²⁵⁷

Commissioner John Dalli approved the potato for cultivation in March 2010. Freshly in office, he said his decision was based on “a series of favourable safety assessments carried out over the years by the EFSA”.²⁵⁸

BASF won, and in 2010 Amflora was being cultivated in open fields in Germany, Sweden and the Czech Republic.²⁵⁹ Even so, BASF carried out its threat to leave Europe. In January 2012 the company announced that it was moving its GMO division to the US due to the “lack of acceptance for this technology in many parts of Europe – from the majority of consumers, farmers and politicians”. The decision included halting the development and commercialisation of Amflora and other GMOs aimed at the European market, although “approval processes which have already started will be continued”.²⁶⁰

While Amflora is no more, the antibiotic resistance threat remains. Two Monsanto GM cotton varieties containing the same antibiotic resistance marker gene as Amflora are in the EU pipeline awaiting approval for food, animal feed, and cultivation.²⁶¹

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.

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.”

Conclusions and recommendations

Radical change is needed at EFSA to ensure food safety and to protect public health and the environment. EFSA's scientific decision-making favours industry, not the public, and many members of its management board and expert panels have conflicts of interest caused by their links to industry.

In addition, EFSA bases its safety assessments of new risky substances largely on industry dossiers. In its re-assessments of substances already on the market, it often ignores or dismisses independent studies showing harm. This has deeply undermined EFSA as a credible voice working in the public interest.

EFSA's problems are deeply embedded in EU laws and in the way the agency was set up. EU laws dictate that industry 'science' forms the basis of safety assessments of new risky products like pesticides and GMOs. But even when the laws insist that independent science is taken into account, EFSA has actively provided loopholes for industry.

EFSA has responded to allegations of conflicts of interest and revolving doors largely with denial, saying, "Having an interest does not mean having a conflict of interest". But where industry interests are concerned, this statement is not credible. More importantly, EFSA has failed to act on cases reported by the media, civil society organisations or Members of the European Parliament.

EFSA has never had proper rules in place to ban conflicts of interest. Its definition of a conflict of interest has been so weak that someone whose university lab was funded by Nestlé for years could chair the panel on food additives without a problem. It remains to be seen if EFSA's adoption of the OECD definition of a conflict of interest will mean a change in its practices. Much will depend on the wording of the implementing rules.

It will be especially interesting to see if EFSA correctly interprets the OECD definition to exclude people with ILSI affiliations. ILSI has proved to be a Trojan horse in influencing EFSA panels to favour industry's 'scientific' concepts, creating a more business-friendly regulatory environment.

If we are to believe EFSA and EU Commissioner John Dalli, it is "not realistic" to demand that the scientists that oversee our food safety are both highly qualified and independent. While the accuracy of these statements is unproven, there is clearly an urgent need to redirect research funding to public institutions and on public interest topics like food safety.

One fundamental problem is the current EU research policy, which promotes 'public-private partnerships' that primarily serve industry, not society at large. This forces researchers to accept industry funding for their academic projects, leading to a pro-industry bias among many academics.

Another problem is EFSA's lack of capacity. It is not realistic to expect this relatively small agency with unpaid experts to deal with an ever-increasing stream of products for assessment – a service delivered for free to those who will make money from it.

Urgent changes must be implemented at EFSA and at an EU level to ensure that EFSA fulfils its intended role of providing unbiased and up-to-date scientific advice to protect public health.

EFSA should:

- ✎ Base risk assessments on all available evidence, including all competent independent peer-reviewed studies
- ✎ Review its independence policy to exclude people with conflicts of interest from its management board, scientific panels, and scientific committee, and effectively close the revolving doors
- ✎ Proactively seek out independent experts and push the EU institutions to grant the agency the means to pay them for their work
- ✎ End collaboration with industry and industry-affiliated bodies such as the International Life Sciences Institute (ILSI)
- ✎ Ensure full transparency of its risk assessments and appointments of staff and experts.

The European Commission, member states, and the European Parliament should:

- ✎ Revise EU laws to mandate that risk assessments be based on studies done by independent laboratories paid for through a publicly managed fund. Industry should bear the costs
- ✎ Invite independent scientists to peer review EFSA's guidance documents and opinions.
- ✎ Implement a system of charging industry a fee for EFSA assessments – while ensuring that a strict barrier is maintained between industry and EFSA. This will ensure that EFSA has the capacity to protect food and environmental safety
- ✎ Grant EFSA the budget to pay its experts for their assessment work
- ✎ Change EFSA's founding regulation to exclude people with conflicts of interest from panels and management.

Until such changes are implemented, EFSA and the EU institutions cannot claim to provide a sufficient level of food and environmental safety.

List of abbreviations used in the text

ADI	Acceptable daily intake
ADoI	Annual declaration of interest
ANS panel	The panel on food additives and nutrient sources added to food
ARMG	Antibiotic resistance marker gene
BPA	Bisphenol A
CEF panel	The panel on food contact materials, enzymes, flavourings and processing aids
DG SANCO	Directorate General Health and Consumers
DNA	Deoxyribonucleic acid
DoI	Declaration of interest
ECHA	European Chemicals Agency
EEA	European Environment Agency
EFSA	European Food Safety Authority
EMA	European Medicines Agency
ENTRANSFOOD	European network safety assessment of genetically modified foods
EPA	Environmental Protection Agency (US)
EUFIC	European Food Information Council
FAO	Food and Agriculture Organisation (UN)
FDA	Food and Drug Administration (US)
GLP	Good Laboratory Practice
GMO	Genetically modified organism
GM	Genetically modified
ILSI	International Life Sciences Institute
NDA panel	The panel on dietetic products, nutrition and allergies
nptII	Neomycin phosphotransferase II
MAD	Mutual Acceptance of Data
MEP	Member of the European Parliament
OECD	Organisation for Economic Cooperation and Development
PPR panel	The panel on plant protection products and their residues
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SDoI	Specific declaration of interest
TTC	Threshold of toxicological concern
WHO	World Health Organisation

Endnotes

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Conflicts on the menu

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