Conflicts of interest at the European Food Safety Authority erode public confidence

Claire Robinson,1 Nina Holland,2 David Leloup,2 Hans Muilerman3

In September 2012 Professor Gilles-Eric Sélálini, a researcher at the University of Caen in France, published his team’s findings that a Monsanto genetically-modified (GM) maize and Roundup herbicide caused increased rates of organ damage, tumours and mortality in rats fed over a 2-year period.1 The study was significant because it followed the rats over a long-term period, with the first tumours only appearing after 4–7 months. In contrast, the safety studies carried out by GM seed companies in support of EU authorisations typically last for a maximum of 90 days.2–4 In other words, these studies are incapable of seeing long-term effects such as those found in Sélálini’s study.

Europe’s food safety agency, the European Food Safety Authority (EFSA), dismissed Sélálini’s study on the grounds of ‘inadequate design, analysis and reporting’.5 6 However, far from laying to rest public concerns about GM foods, EFSA’s review of the study1 sparked renewed accusations of conflicts of interest of the type that have plagued the agency since its founding in 2002. EFSA’s critics questioned the objectivity of its review because the agency’s original opinion that the GM maize was safe7 had led to its EU authorisation. So, in dismissing Sélálini’s study, EFSA was in effect defending its own decision. Also, EFSA has argued against the need for mandatory animal feeding trials on GM foods, adding that if they are carried out, 90 days is sufficient to see any effects.8 9 Member of the European Parliament Corinne Lepage said that, if EFSA had accepted that Sélálini’s findings had any validity, this would have been equivalent to ‘cutting the branch on which the agency has sat for years’.7

EFSA was accused by scientific organisations and individual scientists of applying double standards to studies on GM foods. They said that EFSA rejected Sélálini’s findings yet accepted less rigorously designed studies from industry as proof of safety of GM foods.10–12 In comparison with the industry studies,2–4 Sélálini’s study1:

- measured more parameters more often and over a longer period;
- tested more doses, allowing dose-response to be meaningfully analysed;
- analysed all animals for blood and urine chemistry instead of selecting 10 from each group of 20, a practice that enables bias;
- distinguished between effects caused by the GM maize, Roundup alone, and a combination of the two;
- excluded the additional ‘reference’ control diets included in industry tests. These ‘reference’ diets introduce variables from irrelevant factors, such as different growing conditions, that can mask toxicological differences arising from the genetic modification of the crop. This practice is contrary to an EU Directive that stipulates that the purpose of the risk assessment is to identify differences in the GM crop arising from the genetic modification.13

EFSA’s review of the study did not address this contentious issue of double standards.5 6

EFSA LINKS WITH INDUSTRY-FUNDED GROUPS

The Sélálini affair was the latest in a long series of controversies over EFSA’s closeness to industry. An earlier dispute involved the longstanding relationship of the chair of EFSA’s management board, Diána Bánáti, with the industry-funded International Life Sciences Institute (ILSI).14 ILSI arranges forums in which industry scientists collaborate with publicly-funded scientists from government regulatory bodies to design risk assessment methodologies for chemicals, pesticides and GM foods.15 16 ILSI is funded by the same agribusiness, food and biotechnology companies17 whose products EFSA assesses for safety.

In October 2010 Members of the European Parliament and civil society groups called for Bánáti’s resignation from the EFSA management board on which she had served since 2008. Bánáti had joined ILSI’s European board of directors in April 2010 but did not publicly report the conflict of interest before her re-election to the EFSA board later that year. In response to criticism, Bánáti resigned from the ILSI board but controversially kept her job as EFSA chair. Then, in May 2012, in a type of conflict of interest known as the ‘revolving door’, Bánáti had to resign from EFSA when she rejoined ILSI as executive director.14 18

CONFLICTS OF INTEREST IN GENETICALLY-MODIFIED ORGANISM RISK ASSESSORS

EFSA experts involved in assessing the risks of GM foods have attracted criticism for their closeness to industry. In 2010, 12 out of 21 experts on the genetically-modified organism (GMO) Panel that issued a scientific opinion that was key to the approval of a GM potato had conflicts of interest as defined by the Organisation for Economic Cooperation and Development (OECD).15 19

In 2011 the European Ombudsman ruled in favour of a complaint about Suzy Renckens, scientific coordinator of EFSA’s GMO Panel since EFSA was established in 2002. Renckens left EFSA in 2008 and went straight into a lobbying job with the biotechnology company Syngenta without any restrictions being imposed by the agency. The Ombudsman ruled that EFSA ‘failed to observe the relevant procedural rules and to carry out a sufficiently thorough assessment of the potential conflict of interest’.20–22

Conflicts of interest in members of EFSA’s management board and expert panels were among the issues that prompted the European Parliament to postpone approving the agency’s 2010 expenditures.23 24

In 2012 the European Court of Auditors issued its report on the conflicts of interest policies at four European agencies, EFSA among them. The Court concluded that, while EFSA’s policies were among the most advanced, none of the agencies ‘adequately’ managed conflicts of interest.25

EFSA REWRITES CONFLICTS OF INTEREST POLICY

In 2011, under pressure from the European Parliament,26 EFSA rewrote its ‘independence policy’.27 While the new rules contain improvements, some conflicts of interest are still allowed.28 In 2012 EFSA renewed eight expert panels, giving an opportunity to see how its new policy worked in practice. Improvements were noted. Some experts with conflicts...
of interest, notably with ILSI, are no
longer on the panels. Some who remain
have given up their ILSI involvement,
though others have not. Other conflicts of
interest, such as receiving research
funding from industry, are still evident.28

Conflicts of interest on EFSA's manage-
ment board are permitted by a loophole in
EFSA's founding regulation, which
states that four members 'shall have their
background in organisations representing
consumers and other interests in the food
chain'.29 'Other interests' are interpreted by
EFSA and EU authorities as including
industry interests. However, the presence of
industry figures on EFSA's management
board is unacceptable. EFSA does not
have the power to change the founding
regulation, which is the responsibility of
the EU institutions.

CONFLICTS OF INTEREST INFLUENCE
GMO POLICY

Conflicts of interest are particularly serious
when they leave a permanent mark on how
technologies and products are regulated. In
such cases, even if an expert with a conflict of
interest is removed, their work remains
behind them. In 2012 the term of office of
GMO Panel chair Harry Kuiper expired.
Kuiper had occupied this position since
2003, during which time he was involved in
Kuiper's research on GM food.28

Even the design of EFSA's GMO risk
assessment standards was influenced by an
ILSI task force headed by a Monsanto
employee. They are based on the concept of
comparative assessment, a rewording of the
controversial concept of 'substantial
equivalence'. Substantial equivalence
assumes that GM crops are equivalent to
non-GM crops and do not require rigor-
ous safety assessment.15

Currently, in the EU, substantial equiva-
ience must be measured, but the analysis
is confined to known basic components of
the GM food such as protein and fats.
Unexpected changes such as novel toxins
or allergens are likely to be missed.
Though currently, whatever the outcome of
the analysis, a full risk assessment is
required, a new Regulation30 adopted in
February 2012 via the EU Commission's
opaque comitology process still makes the
weak comparative assessment the basis
and guiding principle of the risk
assessment.12

EFSA must bear responsibility for the
inadequacy of the comparative assessment
because it has never defined the degree of
similarity that a GM crop must have to a
non-GM crop to qualify as equivalent. Also,
when differences are found in the GM crop,
EFSA often dismisses them as being within
the normal range of variation and/or as not
biologically relevant. Yet EFSA has not
properly defined these concepts. It allows
industry to define the normal range of vari-
ation based on an ILSI database of historical
crop varieties grown in differing condi-
tions.13 15 An EFSA opinion allows industry
to define biological relevance on a case-by-case
basis.34

These tactics mask or dismiss differ-
ences in the GM crop arising from the
genetic modification process—even
though identifying such differences is the
purpose of the risk assessment as defined in
an EU Directive.13 The risk is that sub-
stantial equivalence may be assumed even
though there are unexpected toxins or
allergens in the GM crop. Unexpected
allergens could sometimes be exposed by
rigorous animal feeding trials, but these
have hitherto not been mandatory. EFSA's
opinion arguing that feeding trials are not
always necessary contained large amounts of
text lifted from an ILSI report.15

EFSA's flawed assumptions of the substan-
tial equivalence of GM foods were thrust
into the spotlight by Séralini’s 2012 study.1
Earlier, Monsanto had carried out a 90-day
feeding trial with the same maize in support of
its application for regulatory authorisa-
tion. Differences were found in the GM-fed
rats,2 but EFSA concluded that they were
‘of no biological significance’15 and the EU
authorised the maize in 2004.

Séralini’s team obtained Monsanto’s
raw data and re-analysed it. They found
signs of liver and kidney toxicity in the
GM-fed rats.16 They conducted their
2012 study as a direct follow-up to
Monsanto’s study to see what happened when the
study period was extended to 2 years and found
that they escalated into serious organ
damage.1 The findings showed that
EFSA’s view that the differences in the
GM-fed rats were not biologically signifi-
cant was incorrect. The study highlighted
serious shortcomings in EFSA’s risk assess-
ment of GM foods, as was noted by
Members of the European Parliament,
who called for reform.37

EFSA PROMOTES INDUSTRY CONCEPT
TO ASSESS CHEMICALS RISK

In the area of chemicals, as with GM foods,
EFSA’s closeness to industry has resulted in risk
assessments methodologies of
questionable scientific rigour. In its review
of conflicts of interest at EFSA, the Court of
Auditors criticised EFSA's handling of the
concept of the threshold of toxicological
concern (referring to it as an anonymous
'concept').25 This concept has been
promoted for years by industry groups such as
ILSI18 39 to assess the risk of chemicals on
which little or no toxicological testing has
been done. Chemical industry consultancy
Cantox defines the threshold of toxicolo-
gical concern as a level of human intake
or exposure considered to pose ‘negligible
risk, despite the absence of chemical-specific
toxicity data’.40

A less reassuring explanation for why
industry favours the concept emerged from
interviews with proponents. By waiving
targeted toxicological testing, the
threshold of toxicological concern enables
substances to be fast-tracked through the risk
assessment, cutting time to market
approval from as much as 4 years to as
little as a few months. The concept also
allows inadequately tested chemicals to
remain on the market if expected expos-
ures are below a level deemed safe on the
basis of an assessment that depends
heavily on assumptions.41

In 2012, EFSA's scientific committee
published an opinion recommending the
use of the threshold of toxicological
concern in the risk assessment of chemi-
cals in food.42 The opinion stated that an
exposure level of 0.15 μg per person per
day is acceptable for genotoxic substances
(substances that damage DNA, possibly
giving rise to cancer and birth defects).42
EFSA's opinion contradicted its own pre-
vious opinion which stated that it is
current practice to assume that there is no
safe level of exposure for genotoxic sub-
stances.43 It also undermined the pesticide
Regulation, which forbids approval of
genotoxins.44

The impartiality of the 2012 opinion is
in doubt, since 10 of the 13 members of
the EFSA working group on the threshold
of toxicological concern had a publishing
history favouring its use or had previously
advocated its use. Eight had formal links
with ILSI.45

EFSA UNDERMINES PESTICIDES LAW

A public health protection democratically
established in an EU pesticides Regulation of
2009 was undermined by EFSA. The
Regulation made clear that pesticides must
no longer be assessed only on the basis of
industry tests. It stipulated that studies from
the 'scientific peer-reviewed open lit-
erature' had to be included in the dossier
that industry submits to regulators in
support of pesticide authorisations.44
The Regulation marked a breakthrough. For the first time the large body of evidence on pesticide risks in the peer-reviewed literature would inform risk assessments. This would almost certainly result in restrictions or bans on some pesticides.

However, EFSA effectively extracted the Regulation’s teeth. The agency issued a guidance document to help industry evaluate the reliability of studies from the peer-reviewed literature for possible inclusion in the dossier. EFSA gives as its first and main criterion of reliability the Klimisch classification, derived from a paper by employees of the chemical company BASF. Klimisch et al state that only tests performed according to Good Laboratory Practice (GLP) rules, the type of tests that industry performs to support regulatory authorisations, are reliable without qualification. Studies from the open literature, which generally do not use GLP, are categorised as unreliable by Klimisch et al.47

Thus EFSA gave industry an excuse to exclude almost any peer-reviewed study from its dossier. It steered pesticide risk assessment in the opposite direction to that intended by the Regulation.

INDUSTRY TESTS ITS OWN PRODUCTS FOR SAFETY

A factor that compromises the independence of the regulatory process is that industry tests its own products for safety. This system lies outside EFSA’s control as it is laid down in EU law. Yet it encourages bias. Reviews of the scientific literature on products such as tobacco,48 49 the plastics industry tests its own products for safety. This could be done to improve the rigour of its scientific decision-making and to gain public trust.

Prevent conflicts of interest

EFSA’s conflicts of interest policy must be tightened to remove loopholes. Its founding regulation must be rewritten to exclude people with links to industry. EFSA experts, who currently work on a voluntary basis, should be paid.

Sanctions for experts and staff who breach public trust through conflicts of interest should be defined in European law. The laws of some member states include sanctions such as temporary bans on holding public office and the withholding of salary.56

EFSA, like other organisations, is unable to police itself on conflicts of interest. An independent body should oversee EU agencies.

Establish a code of scientific practice

The reasoning behind EFSA’s opinions on certain substances should be clarified by establishing a code of scientific practice for risk assessments. This would set out in a clear and transparent way how EFSA experts search for and evaluate scientific evidence, increasing the transparency and replicability of EFSA’s decision-making and enhancing public confidence. It is not acceptable to exclude studies from the peer-reviewed literature because they do not adhere to GLP rules.

The code could draw on methodologies from evidence-based medicine for reviewing large bodies of data of different types and translating them into decisions, such as the Navigation Guide57 and the Cochrane Collaboration.58

Improve transparency and accountability

EFSA must make accessible all data and information on which it bases risk assessments. EFSA’s opinions should be independently peer-reviewed.

Ensure wider participation in decision-making

Risk assessment should take into consideration social, economic and ethical factors. While those aspects are outside EFSA’s remit, EFSA should broaden the expertise on its expert panels to include, for example, embryologists, endocrinologists, neurodevelopmental scientists, ecologists and soil biologists.

CONCLUSION

While EFSA has made progress on addressing conflicts of interest, it has much to do to improve the rigour of its scientific decision-making and to gain public trust.

Funding

The authors received no funding (beyond employment salaries) for their work on this paper. Corporate Europe Observatory receives funding from the Adessium Foundation, Isvara Foundation, Polden-Puckham Charitable Foundation, RH Southern Trust, Sigrid Rausing Trust, J M Goldsmith Foundation, Misericor, Human Earth Foundation and Environmental Investigation Agency. Earth Open Source and GMWatch receive funding from individual donors and in 2012 from the Isvara Foundation. GMOseralini.org receives funding from individual donors and support from non-profits. Pesticide Action Network Europe receives funding from trusts and foundations, including the European Endocrine Health Initiative.

Competing interests

CR is employed at Earth Open Source, GMWatch and GMOseralini.org. NH and DL are employed at Corporate Europe Observatory. HM is employed at Pesticide Action Network Europe.

Provenance and peer review

Commissioned; externally peer reviewed.

To cite

Robinson C, Holland N, Leloup D, et al. J Epidemiol Community Health Published Online First: [please include Day Month Year] doi:10.1136/jech-2012-20185

REFERENCES

5 European Food Safety Authority (EFSA). Review of the Seralini et al. (2012) publication on a 2-year rodent feeding study with glyphosate formulations and GM maize NK603 as published online on 19 September 2012 in Food and Chemical Toxicology. EFSA J 2012;10:2910.
6 European Food Safety Authority (EFSA). Final review of the Seralini et al. (2012a) publication on a 2-year rodent feeding study with glyphosate formulations and GM maize NK603 as published online on 19 September 2012 in Food and Chemical Toxicology. EFSA J 2012;10:2986.
7 Lepage C. OGM: l’EFSA a manqué à une déontologie élémentaire [GMOS: EFSA breaches basic ethical code]. Le Nouvel Observateur 7 October 2012.

Robinson C, et al. J Epidemiol Community Health Month 2013 Vol 0 No 0

10 European Network of Scientists for Social and Environmental Responsibility (ENSSER). Questionable biosafety of GMOs, double standards and, once again, a "shooting-the-messenger" style debate. 2011.


19 Corporate Europe Observatory (CEO). Approving the GM potato: conflicts of interest, flawed science and fierce lobbying. 2011.

20 Then C. Head of department moves from European Food Safety Authority (EFSA) to biotech company within two months [press release]. 2010.


22 Diamandouros PN. Draft recommendations of the European Ombudsman in his inquiry into complaint 775/2010/ANA against the European Food Safety Authority. 2011.


26 Trollope K. MEPs call for clear timetable from EFSA for concrete measures on credibility: EU Food Policy. 2011.

27 European Food Safety Authority (EFSA). A policy on independence and scientific decision-making processes of the European Food Safety Authority. 2011.