

Europe's pesticide and food safety regulators

*Who do they
work for?*

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Europe's pesticide and food safety regulators – Who do they work for?

by Claire Robinson

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Declaration of interests

Claire Robinson is a freelance researcher and writer. She works for NGOs that advocate for public health and the environment.

Anthony C. Tweedale receives consultation fees from NGOs that advocate for public health.

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Summary

The European Food Safety Authority (EFSA) is charged with regulating pesticides, genetically modified (GM) foods, and food contaminants to protect public health. But some prominent EFSA regulators have conflicts of interest, holding positions in organisations that are funded by the same companies whose products they are supposed to regulate.

This report shows that over a period of many years, influential EFSA managers and regulators have been heavily involved with a US-based organisation called the International Life Sciences Institute (ILSI), which is funded by multinational pesticide, chemical, GM seed, and food companies.

Publicly funded regulators in the EFSA, as well as in US regulatory agencies, have developed a cosy relationship with ILSI. They collaborate with ILSI in workshops and conferences that work on redesigning the risk assessment processes under which ILSI member companies' products are evaluated for safety.

EFSA regulators also collaborate with ILSI affiliates in publishing papers in scientific journals. Unlike most published scientific research in the field of toxicology, ILSI papers do not report the outcomes of actual research. Instead, they propose changes to risk assessment based on the outcomes of ILSI workshops and projects, citing as their authority ILSI and other

industry-generated publications.

ILSI cultivates an image of independent scientific inquiry and constructive engagement with government-funded regulators. But its 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.

ILSI proposals are often uncritically embraced by EFSA regulators. They make their way into influential EFSA policy Opinions and Guidances on the risk assessment of pesticides, chemicals, and GM foods. In effect, EFSA is allowing industry to help design the rules of risk assessment for its products.

The presence of ILSI and other industry-affiliated people on EFSA scientific panels, combined with evidence of industry influence on EFSA policy, fatally undermines the integrity of the pesticide and food safety regulatory process.

If public confidence in the regulatory procedures for pesticides, chemicals, and GM foods is to be restored, EFSA must cease participating in privileged access meetings and projects on risk assessment with the industry it is paid to regulate. In addition, EFSA must make a 'clean sweep' of ILSI and other industry influence from its management boards and scientific panels.

Introduction

Pesticide safety regulator Angelo Moretto has resigned from the European Food Safety Authority's Plant Protection Products and their Residues (PPR) Panel, which assesses the safety of pesticides,¹ after reportedly failing to declare a conflict of interest.

EFSA launched an investigation after it emerged that Moretto was an adviser to a consultancy company, Melete Srl. Melete was founded to support companies needing to comply with REACH, an EU regulation intended to improve the protection of health and the environment from adverse effects of chemicals.² Moretto owns 17% of the shares in Melete.³

As part of its investigation, EFSA reviewed Moretto's involvement in Opinions on pesticides issued by the PPR panel. (Opinions are written into legislation if the member states vote to approve them.) EFSA decided that as there had been no written contribution, the risk of a conflict of interest was negligible and it did not need to reopen the Opinions adopted.⁴

Judging from the only report to date on the Moretto case,⁵ EFSA's investigation was inadequate. With regard to Moretto himself, it barely scratched the surface of his conflicts of interest. More importantly, EFSA has not extended its investigation beyond Moretto to address the conflicts of interest of other pesticide and food safety regulators.

Moretto is just one of several prominent EFSA officials with links to the International Life Sciences Institute (ILSI), an industry-funded group that is active in redesigning pesticide and food safety regulations in government agencies. So far, EFSA has largely overlooked the involvement of its officials in ILSI, even though ILSI represents the very industries that EFSA is charged with regulating.

This report examines Moretto's case more fully and uses it as a starting point to look at conflicts of interest of other EFSA officials. These include Alan Boobis, Milan Kováč, Diána Bánáti, and Theodorus Brock. It shows how ILSI is redesigning the regulation of toxic chemicals worldwide, making the risk assessment processes less rigorous and cheaper for industry. Finally, it considers the harmful impacts of ILSI and other industry interference in regulatory procedures.

Angelo Moretto

Moretto is involved in two projects of the International Life Sciences Institute (ILSI), an industry organisation based in Washington, DC, USA. ILSI says in response

to criticism that it is not a lobby group and is a registered charity.⁶ Whatever its technical description, ILSI is funded by multinational pesticide, agribusiness, and food firms, including ADM, BASF, Bayer, Cargill, DuPont, Kraft, Mars, Monsanto, and Unilever.⁷ Its member companies have an interest in reducing the cost and rigour of pesticide and food safety testing – and a duty to their shareholders to do so.

ILSI has set up a body called the Health and Environmental Sciences Institute (ILSI HESI), which specializes in defining and redesigning risk assessment procedures for pesticides, chemicals, and foods. ILSI says HESI is recognized by the US government as a publicly supported non-profit organisation that is independent from ILSI. But ILSI HESI is funded by “industry members”⁸ including BASF, Bayer, Dow, DuPont, Monsanto, and Syngenta.^{9 10}

Moretto has been involved in two ILSI HESI projects:¹¹

- Agricultural Chemical Safety Assessment (ACSA), a public-private project in which industry and government scientists collaborated to develop “an improved approach to assessing the safety of crop protection chemicals” (pesticides).¹²
- Risk Assessment for the 21st Century (RISK21). Moretto is a member of the steering team of the RISK21 project on cumulative risk (the risk posed by multiple chemical exposures). RISK21 is directly financed by pesticide companies BASF, Bayer, Dow, DuPont, and Monsanto, as well as ExxonMobil and Coca-Cola.¹³ The project brings together scientists from industry and government regulatory bodies – a private-public partnership. Industry is represented on the steering team by employees of Arysta Life Science, Dow, and Syngenta. The public side is represented by government regulators from the US Environmental Protection Agency (EPA), Health Canada, the European Commission, and Germany's BfR (Federal Institute for Risk Assessment). ILSI HESI claims that a balance is maintained between public and private interests: “Each project team has one co-chair from the public sector, and one co-chair from the private sector”. But claims of balance are unconvincing when these pairings are more closely examined. The cumulative risk team consists of Moretto (the affiliation listed is his publicly funded academic position at the University of Milan, rather than his industry affiliations) and an ExxonMobil employee, Dick Phillips.¹⁴ It could be said that this is not a ‘public + private’ pairing, but ‘private + private’.

According to Moretto's EFSA declaration of interest, ILSI does not pay him a salary, but only reimburses expenses. However, in questions of conflicts of interest, EFSA needs to look beyond salaries. There are less direct

and less obvious ways in which a scientist seen as a ‘safe pair of hands’ might be rewarded by industry. Moretto’s employment history includes paid consultancy roles to industry, including ILSI funders Dow and Syngenta, and three companies embroiled in pollution scandals.¹⁵

In January 2011, Moretto was a member of the EFSA’s Pesticide Risk Assessment Peer Review (PRAPeR) Unit, responsible for the peer review of pesticides.¹⁶ It is unclear whether he is still a member, since at the time of writing, the list of members had disappeared from EFSA’s website.

Moretto has contributed to Opinions of the PPR Panel over many years. The extent of his influence cannot be evaluated by looking for written contributions, as EFSA has done. A thorough independent review of all Opinions to which he contributed should be conducted to consider whether their recommendations are in the interests of the public or of the pesticide industry.

Alan R. Boobis

Alan R. Boobis was vice-chair of the EFSA PPR Panel 2006–2009.¹⁷ He subsequently moved to the Panel on Contaminants in the Food Chain (CONTAM).¹⁸

Boobis and Moretto, in their roles as PPR Panel members, contributed to an important EFSA Opinion on pesticide data requirements,¹⁹ among many other Opinions. At the same time, Boobis was chair of the Board of Trustees and of the Executive Committee of ILSI HESI (until 2010),^{20 21} and a Trustee of ILSI²² and ILSI Europe. Since 2010 he has been a member of the board of directors at ILSI Europe.^{23 24} ILSI Europe members include many food companies, among them Kraft, Nestlé, Premier Foods, and Kellogg.²⁵

In his EFSA declaration of interests, Boobis listed his ILSI roles, adding that his involvement “has not involved any substance reviewed by EFSA”.²⁶ But as a claim of ‘no conflict of interest’, this is irrelevant. ILSI’s interests are not confined to any single substance: its member companies manufacture and promote thousands such substances. ILSI has a duty to its member companies to promote an industry-friendly climate within regulatory bodies and Boobis’s activities could be said to fulfill this role.

Boobis’s trusteeships at ILSI are unpaid.²⁷ But he is involved in at least one ILSI project for which he is paid – not by ILSI, but by its publicly funded partner, the EU. In this project on risk-benefit analysis of food and food chemicals, he carries out research funded by the EU and “coordinated by ILSI Europe”.²⁸ This appears to be a project controlled by ILSI but funded by

the taxpayer, an arrangement that is not in the public interest.

RISK21 and consultancies

Like Moretto, Boobis is involved in the ILSI RISK21 project, but he has an even more important role, as co-chair of the overall project. His affiliation is given on the ILSI website as his publicly funded academic position at Imperial College London. Following the ILSI line of ‘public + private’ pairings for each leadership role (see [Angelo Moretto](#), above), the ‘public’ Boobis is paired with an overt representative of industry, Syngenta employee Tim Pastoor.²⁹

Boobis describes the RISK21 project in his EFSA declaration of interests as a “risk assessment umbrella project with four sub-groups: dose-response, cumulative risk, exposure assessment and tiered testing strategies”.³⁰ These are topics of crucial importance in protecting public health from the effects of chemicals. As detailed below, EFSA takes at face value ILSI’s recommendations on these topics – despite the fact that they come courtesy of RISK21 funders BASF, Bayer, Dow, DuPont, ExxonMobil, Monsanto, and Syngenta.³¹

Boobis’s career includes consultancy roles for the same companies whose products the EFSA paid him to regulate, including Endura, Sumitomo Chemical, and Proctor & Gamble (the last two are members of ILSI HESI³²). He even played a role in deciding which research papers on food and chemical toxicology were published, in his former position as editor-in-chief of the scientific journal, *Food and Chemical Toxicology*.^{33 34}

Diána Bánáti

In October 2010 French MEP José Bove held a press conference to announce that Diána Bánáti, chair of the EFSA management board, was also a member of the board of directors of ILSI Europe. The EFSA management board’s considerable powers include setting EFSA’s budget, approving the annual work programme, and appointing the members of the Scientific Committee and the Scientific Panels that give Opinions on pesticides, food safety, and genetically modified crops and foods to the EU Commission. In the wake of the scandal, Bánáti resigned from ILSI. But controversially, she kept her post at EFSA.^{35 36}

Milan Kováč

Milan Kováč is another ILSI-linked member of the

EFSA management board. His positions at ILSI are:

- 2002–2011 (now): ILSI Europe – Member of the board of directors, non-industry member
- 2001–2011 (now): Member of the board of trustees of ILSI Global – Washington, USA, non-industry member from board of directors of ILSI Europe.³⁷

Kováč is a member of the scientific advisory board of the European Food Information Council, an organisation that is largely funded by food companies. Members include Cargill, Cereal Partners, Coca-Cola, Danone, DSM Nutritional Products Europe Ltd., Ferrero, Kraft Foods, Mars, McDonald's, Nestlé, PepsiCo, Pfizer Animal Health, Südzucker, and Unilever.³⁸

Theodorus Brock

Theodorus Brock is a member of the EFSA PPR Panel and a former member of the EFSA Working Group on Ecotoxicological Effects. He is a senior research scientist in ecotoxicology at Alterra, an institute connected to Wageningen University in the Netherlands. Alterra receives public funding from the Dutch government to carry out research to “scientifically underpin the environmental risk assessment procedure for pesticides”. Brock helps design these studies. Since 1991 Brock has worked as a consultant to the chemical industry on toxicological risk assessment. His clients include Bayer, Cheminova, Dow Agrochemicals, BASF, Syngenta, Monsanto, Feinchemie Schwebda GMBH, and Makhteshim-Agan.³⁹

Brock says that the funding he receives from these companies goes directly to Alterra. But this does not reassure, since Brock is an employee of Alterra.⁴⁰ In other words, the money that Brock earns in his work for the chemical industry goes to Alterra, which then pays Brock. In this context, Alterra could be seen as playing the role of a money-laundering facility.

In addition, this financial arrangement means that Brock's pesticide industry clients are funding an institute (Alterra) that helps design regulations for their pesticide products.

Since 1995 Brock has been an “active”,⁴¹ if unpaid, member of the Society of Environmental Toxicology and Chemistry (SETAC), a scientific society with extensive industry backing. He is a former president of SETAC Europe and former chair of the SETAC/EU Workshop on Linking Aquatic Exposure and Effects in the Registration Procedure of Plant Protection Products.

Brock describes SETAC in his EFSA declaration of

interests as a public body. But its “partners” include chemical and petrochemical companies 3M, BP, DuPont, Eastman Chemical Company, ExxonMobil, Shell, S.C. Johnson & Son, Syngenta, and Unilever – as well as ILSI.⁴²

EFSA Opinion teaches industry to bend regulations

EFSA has the reputation among some NGOs of being unduly biased towards industry. This view is supported by a 2007 PPR Panel Opinion⁴³ on pesticide assessment data requirements. The Opinion is examined here as an example of how pro-industry bias in pesticides regulation can endanger public health.

As then members of the PPR Panel, ILSI-affiliated regulators Boobis and Moretto were among the contributors to this Opinion. The Opinion is one of many that EFSA investigators reportedly decided was not compromised by Moretto's conflict of interest as it included no written contribution from him.⁴⁴

Data requirements are crucial to pesticide risk assessment. They stipulate the tests that industry has to perform on a pesticide it is putting forward for approval. It is in the public's interest that these data requirements are rigorous, but industry has consistently lobbied to weaken them. Weak data requirements save industry time and money spent on testing, while allowing it to move products more quickly and cheaply to market.

The Opinion suggests ways in which industry can manipulate the toxicological data requirements of the current pesticide regulation, 91/414. These include negotiating away the need for a study, substituting a required study with another, and even submitting a “reasoned argument” about the effects of combined toxins instead of doing actual tests.

In detail, the Opinion recommends that industry should be allowed to:

- “submit a reasoned scientific argument as to why a particular study is not needed. Handling of such cases will generally be assisted by dialogue between the notifier [industry] and regulatory authority at an early stage in the approval process.”⁴⁵
- use “alternative methods” than those specified in the data requirements to address an aspect of the risk assessment⁴⁶
- use “fewer but more informative studies”⁴⁷
- address the problem of combined toxicity, where two or more active substances are co-formulated in

the same product”, by “reasoned argument” rather than by actual tests⁴⁸

- omit the prenatal developmental toxicity study in the rat under certain conditions⁴⁹
- conflate one or more tests rather than doing individual tests, as a way of reducing the number of studies carried out⁵⁰
- make certain histopathological examinations (microscopic analysis of tissue) in carcinogenicity studies optional, in the interests of “flexibility”.⁵¹

In short, the Opinion encourages industry to negotiate away data requirements stipulated by a democratically established regulation. Taken together, these proposals follow a trend of making the data requirements less rigorous and cheaper for industry – at the expense of public health and the environment.

There is no suggestion that Moretto or Boobis were solely or even chiefly responsible for the views in this Opinion. Contributors include the entire PPR Panel.⁵² The point is that the presence of industry-affiliated people on the Panel, combined with an industry-friendly result in the form of the Opinion, casts doubt on the integrity of the pesticide regulatory process.

The Opinion’s proposals would add to the existing failures of the regulatory chronic toxicity testing protocol, which include:

- no testing at realistic exposure levels
- no dosing at critical developmental windows
- no testing of chemical mixtures
- killing the animals before they have a chance to develop the disease caused by the dosing.⁵³

How industry influences EFSA regulators

While the 2007 PPR Panel Opinion shows EFSA’s pro-industry bias, it also shows how industry influences EFSA policies on pesticides.

The PPR Panel suggests that industry could jettison the 1-year dog study and the mouse carcinogenicity study that form part of the data requirements for pesticides assessment under current law. EFSA says the mouse carcinogenicity study “does not provide any additional contribution to risk assessment” on top of the same study done on a second rodent species, usually the rat.⁵⁴

The PPR Panel cites as its authority for this argument a 2006 paper by ILSI HESI task force leader and then Syngenta employee, John E. Doe.⁵⁵ Moretto and Boobis are co-authors of this paper. Doe, like Moretto and

Boobis, is involved in the ILSI HESI RISK21 project, as the industry representative of one of the teams working on risk assessment. He is paired with Doug Wolf of the US EPA.⁵⁶ EFSA does not mention ILSI’s industry backing in its favourable citation.⁵⁷

In his paper, Doe published the recommendations of an ILSI HESI task force he headed on toxicity testing for pesticide regulatory assessment.⁵⁸

Doe’s task force on pesticide regulatory assessment was one of several set up by ILSI HESI under its Agricultural Chemical Safety Assessment (ACSA) project. ACSA, like other ILSI projects, was a public-private project in which industry and government scientists collaborated to develop “an improved approach to assessing the safety of crop protection chemicals” – in other words, to redesign pesticide risk assessment.^{59 60} The Doe paper was published as part of this project.⁶¹ Three ‘sister’ papers were also published in scientific journals in 2006 by other ILSI HESI task forces. All four papers were co-authored by ILSI and other industry scientists together with scientists from government regulatory bodies in the US and Europe. All proposed detailed changes in the way pesticides are tested for safety.^{62 63 64}

Doe’s co-authors on his toxicity testing paper include employees of Syngenta, Bayer, Monsanto, DuPont, and BASF, as well as affiliates of ILSI. The public sector is represented by employees of the European Commission and the US Environmental Protection Agency (EPA).⁶⁵

Origins of the mouse carcinogenicity study argument

Doe gives as a source for his recommendation to jettison the mouse carcinogenicity study a paper on pharmaceuticals regulation by Van Oosterhout (1997). The paper was published in the controversial chemical/pharmaceutical industry-sponsored journal *Regulatory Toxicology and Pharmacology* (RTP). RTP was one of several industry-linked outfits that were investigated by a US Congressional Committee in 2008 over their role in the Food and Drug Administration (FDA) decision allowing the toxic chemical bisphenol A in infant formula and other foods.^{66 67 68}

Van Oosterhout says in his study that regulators never act on mouse tumour findings, so there is no point in industry doing the test.⁶⁹

Doe also cites another paper on pharmaceuticals regulation by Monro (1993), which concludes that tumours in mice are irrelevant to human risk assessment and that the mouse carcinogenicity test should be abandoned. But Monro’s study was sponsored by the pharmaceutical company Pfizer.⁷⁰

Industry links apart, there may be good scientific reasons to jettison the mouse carcinogenicity study. Van Oosterhout argues that mice are less sensitive than rats in carcinogenicity studies and add little to the data.⁷¹ And given the age of the mouse carcinogenicity study, it is possible that independent toxicologists could come up with more sensitive, up-to-date, and relevant testing methodologies.

But both EFSA and the industry-affiliated authors it cites only seem interested in one half of the equation – throwing out the mouse study and, at best, having other tests stand in for it. They do not mention the other half – putting forward a more rigorous alternative. Both EFSA and industry put forward the animal welfare argument that getting rid of the mouse study would reduce the number of animals used in pesticide testing.⁷² But the public may well conclude that another factor briefly mentioned by both parties – saving “resources” (money) – is the driving force.^{73 74}

Interestingly, neither EFSA nor industry mentions studies by independent scientists that argue for the specific usefulness of mice in research on cancer causes and treatments.^{75 76}

As well as throwing out the mouse carcinogenicity study, EFSA also recommends getting rid of the important multi-generation reproduction study, which is designed to find out if exposing animals to a pesticide affects their offspring. EFSA wants to substitute a less rigorous “extended one-generation study”.⁷⁷ Again, EFSA cites ILSI HESI as its authority, as well as a paper by Cooper,⁷⁸ the leader of an ILSI HESI task force.⁷⁹

What is needed is an open and transparent debate among independent scientists (who would be paid from public funds to do the job) regarding the best and most sensitive methods of testing for a required endpoint. What is unacceptable is for EFSA to argue for jettisoning studies in lockstep with industry interests.

ILSI's latest recommendations for redesigning risk assessment

ILSI-affiliated authors are prolific, generating a large number of published scientific papers each year. But unlike most published papers in the field of toxicology, ILSI-generated papers do not report actual laboratory research findings. Instead, they report the outcomes of ILSI workshops. These workshops invariably recommend changes to risk assessment procedures, citing as their authority other ILSI workshops and papers.

Below is an analysis of the recommendations of just

two of these papers, selected at random, giving the ILSI and other corporate affiliations of some of the authors.

McGregor, D., A. Boobis, et al. 2010. Guidance for the classification of carcinogens under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS). Crit Rev Toxicol 40(3): 245-285.

This paper recommends:

- Classifying carcinogens under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS). Industry likes harmonization of chemicals risk assessments across the globe because it saves money and resources in testing. This is not dangerous in itself, but the paper uses the system to ‘level down’ the carcinogenicity risk assessment of one chemical by cherry-picking the most reassuring evaluation of its safety (the EU’s), dismissing another evaluation (Japan’s) that views it as more risky.
- Adopting carcinogenicity risk assessment methods developed by ILSI.
- Identifying the mode of action (MOA), the biochemical process by which an adverse effect is created. This is a dangerous distraction, as for many known toxic chemicals, the mode of action is still unknown. For example, it is known that the widely banned pesticide DDT causes eggshell thinning and decreased numbers of birds of prey and that it works by endocrine disruption, but the mechanism of action is still debated. It can take decades to find out a chemical’s MOA. Delaying regulatory action on a chemical until a MOA is known suits industry but puts public health at risk. It is not yet clear that ILSI intends to insist on delaying action until an MOA is identified, but this is a likely outcome of its preoccupation. In addition, the emphasis on MOA gives industry room to negotiate away cumulative effects on the grounds that the different chemicals have different MOAs. This argument has already crept into EFSA views on risk assessment.⁸⁰ Its danger is that it ignores interaction between different MOAs and the problem of cumulative stress from chemicals with different MOAs.
- Establishing whether a MOA is relevant to humans. This gives industry and its allies the chance to dismiss worrying findings on the claimed grounds that they are not relevant to humans – as in the case of the German ministry BVL’s response to Professor Andrés Carrasco’s findings that glyphosate causes malformations in frog and chicken embryos.^{81 82} Industry also uses this argument to dismiss mouse carcinogenicity findings, as detailed above.⁸³

McGregor’s co-authors include current and former

representatives of ILSI (Boobis among them), petrochemical companies BP and ExxonMobil, chemical companies Solvay and Syngenta, chemical products company S.C. Johnson, and pharmaceutical company Nycomed.

Carmichael, N., M. Bausen, et al. 2011. Using mode of action information to improve regulatory decision-making: An ECETOC/ILSI RF/HESI workshop overview. *Critical Reviews in Toxicology* 41(3): 175–186.

This paper recommends “broader uptake and use of the MOA concept”, citing ILSI workshops as its authority. The benefits to industry are made clear: “Setting up a repository of accepted MOAs and associated guidance concerning appropriate data to support specific MOAs for critical effects would facilitate categorization of chemicals and allow predictions of toxicity outcomes by read-across.” This will lead to the industry-friendly outcome of “reduction of toxicity testing in animals” – saving industry time and money.

Favouring “read-across” predictions of toxicity over actual toxicological testing is potentially dangerous and operates against the public interest. In addition, Carmichael’s paper, like McGregor’s, puts forward MOA as a way of questioning the relevance of toxicological findings to humans.⁸⁴

Carmichael is a former ILSI ACSA task force leader⁸⁵ and Bayer employee.⁸⁶ Co-authors of his paper include ILSI’s Michelle Embry; former ILSI ACSA task force leader and former Syngenta employee John Doe; and employees of Syngenta, BASF, and AstraZeneca.⁸⁷

It remains to be seen to what extent these and other ILSI recommendations will make their way into EFSA’s regulatory policies. However, it is clear that through ILSI, industry is making strenuous efforts to influence EFSA policy.

ILSI database for regulators

As another tool in its ‘redesigning risk assessment’ box, ILSI is setting up a “Developmental Toxicity Database” for the use of “public health researchers and regulators”.⁸⁸ While it may be tempting to assume that this is an act of charity on ILSI’s part to help hard-pressed regulators, it should be seen in the context of ILSI’s parallel development of the Crop Composition Database to assist regulators of genetically modified crops (see [How ILSI designed EFSA’s GM crop risk assessment process](#), below). Clearly, this initiative represents an industry

attempt to define and control the risk assessment of developmental toxins by controlling the information that is put into the process.

EFSA praises ILSI proposals for redesigning pesticides regulation

There is no suggestion that EFSA tries to hide ILSI’s industry links. On the contrary, the EFSA PPR Panel uses its Opinion to proudly promote ILSI HESI’s “proposals for radical changes to data requirements” of pesticides regulation.⁸⁹ Equally, it sees nothing wrong with citing in support of these proposals the four ILSI sister papers⁹⁰ by ILSI HESI task force leaders Doe, Carmichael (an employee of Bayer⁹¹), Barton (US EPA⁹²), and Cooper (US EPA⁹³).

The PPR Panel praises ILSI’s proposals as “emerging developments in scientific understanding” and examples of “the way in which scientific understanding on risk assessment for plant protection products is currently evolving”.⁹⁴

It would be more accurate to substitute for “evolving” the words, “being directed by industry”, as these developments appear to have little to do with an emerging independent scientific consensus or with public health protection – but everything to do with industry’s needs.

This Opinion is not unusual in its enthusiasm for ILSI proposals. Another PPR Panel Opinion, this time on assessment of cumulative and synergistic risks of pesticides, cites ILSI as its authority for the reassuring conclusion that pyrethroid pesticides are unlikely to have a synergistic toxic effect at low levels of exposure.⁹⁵

Regulators at the EFSA and the World Health Organisation even held a conference supported by ILSI Europe in 2005 on risk assessment of genotoxic (damaging to DNA) and carcinogenic (cancer-causing) substances.⁹⁶ The following year, in 2006, EFSA held a colloquium on cumulative risk assessment of pesticides to human health – and cited in its summary report ILSI’s “Useful frameworks and guidances ... for determining mode of action”. Attending the colloquium were ILSI affiliates Alan Boobis and Andras Szoradi, along with employees of Syngenta and Bayer. Another participant was a representative from Exponent,⁹⁷ a company that, according to one investigative report, “is known for its scientific research on behalf of corporate clients facing product liability concerns.”⁹⁸ Notably absent were any representatives from NGOs or the general public.

The fact that EFSA sees its alliance with industry as normal and even desirable is a sign of how far Europe's pesticide regulation has shifted from its rightful alignment with the public interest.

ILSI collaborations with regulators condemned

ILSI's involvement with regulators in Europe, the US, and internationally has come under heavy criticism from independent scientists and NGOs.

2006: ILSI barred by WHO from setting standards on food and water

In January 2006 the World Health Organisation (WHO) decided that ILSI can no longer take part in WHO activities setting microbiological or chemical standards for food and water because of its funding sources. ILSI's status was downgraded following a letter to the WHO from the Natural Resources Defense Council, Environmental Working Group, United Steelworkers of America, and other groups, protesting against its role in setting standards.

Jennifer Sass, senior scientist at the US's National Resources Defense Council, wrote in the letter on behalf of the groups 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."⁹⁹

2007: US EPA scientifically weakened by partnership with ILSI

In 2007, Jennifer Sass of the National Resources Defense Council testified before a Congressional Committee that due to budget cuts, the US Environmental Protection Agency (EPA) was "spiralling into an increasingly weak scientific state" and was "increasingly reliant on data supplied by the very industries that it regulates". Sass's chief example of "a relationship that has demonstrably compromised the quality of EPA's scientific inquiry" was EPA's relationship with ILSI. Sass said that such partnerships had developed into little more than opportunities for the regulated industry to redesign EPA's scientific analysis and risk assessment.¹⁰⁰

2010: US scientists condemn regulators' links with ILSI and RISK21

In 2010, the participation of US government regulators in an ILSI RISK21 workshop was condemned by

the Natural Resources Defense Council and the Environmental Defense Fund. In a letter to scientific advisor to the US EPA Paul Anastas, Jennifer Sass of the NRDC wrote, "Because this is a meeting fully funded by industry and comprised largely of industry scientists on scientific topics for which the industry has a financial stake in the outcome, having regulators participate and even co-lead meeting planning and the meeting discussions is an obvious conflict and misuse of our publicly-funded scientists."

Sass noted that ILSI was one of a few "corporate-membership groups" which "have relied upon similar industry-driven workshops in which government officials have participated, and in some cases which government has financially supported, to challenge chemical regulations; to share their anti-regulatory views; and to give workshop outcomes – in line with their interests – a veneer of credibility and independence."

Sass said that industry has a right to hold its own meetings to discuss risk assessment but that public funds should not be used to send government regulators to such meetings. Also, regulators should not meet with industry in a forum unless the process is public and all stakeholders, including NGOs, are involved.¹⁰¹

2011: WHO collaborates once more with ILSI

In February 2011 in Paris, ILSI HESI held a workshop with the World Health Organisation (WHO) on the risk assessment of chemical mixtures. Pesticide Action Network (PAN) Europe wrote to the director of WHO, Dr Margaret Chan, protesting against the collaboration. Hans Muilerman of PAN Europe wrote: "The topic is right but the cooperation with ILSI HESI is very wrong... there is no reason to distinguish [ILSI HESI] from any other industry lobby club... Allowing ILSI HESI a cooperation with WHO/OECD is a grave mistake. It allows influence of industry in developing public risk assessment methodologies, which is unfair and simply wrong. Either you have a stakeholder meeting with a balanced representation of all powers, or you have a meeting of independent regulators."¹⁰²

How ILSI designed EFSA's GM crop risk assessment process

ILSI has been influential in designing EFSA's risk assessment process for genetically engineered (GM) crops. This was highlighted by a report by the NGO TestBiotech,¹⁰³ which revealed close links between ILSI and the EFSA's GMO Panel.

Harry Kuiper, chair of the EFSA GMO Panel, has been a leading scientist at ILSI since 2003. Just before he joined the EFSA, he worked for an ILSI task force. A Monsanto employee, Kevin Glenn, heads this task force and all other members are representatives from large biotech corporations (Cargill, Monsanto, Renessen, Dupont/Pioneer, Bayer CropSciences, Syngenta, and Dow AgroSciences). Even after starting work at EFSA, Kuiper has remained active in ILSI. Other EFSA GMO Panel members have also worked for the ILSI task force.

TestBiotech says the collaboration between ILSI and the GMO Panel experts has had a marked effect on EFSA guidelines for the risk assessment of GM crops. A concept developed by ILSI, “comparative assessment”,¹⁰⁴ was implemented as a starting point for EFSA’s risk assessment.¹⁰⁵ Under comparative assessment, if no significant differences are found in the comparison of certain basic components, such as carbohydrates and protein, then the GM crop is said to be as safe as its non-GM counterpart and no further in-depth investigations of its safety, such as rigorous animal feeding trials, are required.

TestBiotech shows that the document published by EFSA to explain why animal feeding trials are not necessary was partly plagiarized from an ILSI paper.^{106 107 108}

To help regulators follow its prescribed system of risk assessment for GM crops, ILSI set up the Crop Composition Database, a databank of industry tests that compare the composition of GM plants with those of plants derived from conventional breeding. ILSI presents this database as “an essential part of the safety assessment of new crop varieties” and as a “useful resource” for “regulatory scientists” in the field of GM crops.¹⁰⁹

ILSI’s term “comparative assessment” is a flagrant renaming of the widely discredited concept of “substantial equivalence,” developed in the early 1990s by the Organization for Economic Cooperation and Development (OECD). Substantial equivalence has been much criticized by independent scientists as scientifically inadequate.¹¹⁰ “Comparative assessment” avoids using the same controversial terminology but has the same meaning, as ILSI itself states in a 2004 paper:

This comparative assessment process (also referred to as the concept of substantial equivalence) is a method of identifying similarities and differences between the newly developed food or feed crop and a conventional counterpart that has a history of safe use.¹¹¹

The problem with the comparative assessment

approach from the public health point of view is that you only find what you are looking for. Unexpected changes that occur in the plant as a result of the GM process will be missed. Such unexpected effects could be revealed by rigorous nutritional and toxicological testing on animals. But it appears that industry’s aim was to encourage EFSA to set a policy that accepts a finding of no significant difference in the comparative assessment as justification for avoiding doing such rigorous testing.

Due to ILSI’s influence, GM crops are less rigorously investigated than they would have been if EFSA had not based much of its safety assessment on the concept of “comparative assessment”. EFSA must require GM companies to acknowledge the established scientific fact that GM and conventionally bred crops are different and that in-depth toxicological and nutritional studies, not superficial comparisons, are necessary.

ILSI has also taken control of the environmental risk assessment for GM crops. It has set up a body called the Center for Environmental Risk Assessment (CERA) to “develop and apply sound science to the environmental risk assessment of agricultural biotechnologies”. CERA has its own “GM Crop Database” which claims to give environmental safety information about GM crops.¹¹²

ILSI’s projects and databases on GM crops are direct parallels to its ‘redesigning risk assessment’ projects and Developmental Toxicity Database on chemicals.

Dangers of industry involvement in regulation of hazardous products

Some may argue that there is no danger in allowing industry to involve itself in the regulatory procedure because it is a rigorous scientific process that cannot be manipulated. But this would be naive in the extreme. Bias can creep into scientific inquiry in many ways, from the initial decisions of which question to ask and which endpoint to look for, to selection of methodology, choice of experimental animal and exposure route, length of study, and other factors.

The tendency to bias in industry-sponsored studies on risky products and technologies is well documented. The best known example is tobacco industry studies, which successfully delayed regulation for decades by manufacturing doubt and controversy about the effects of smoking and

passive smoking.¹¹³ More recently, studies sponsored by the pharmaceutical and mobile phone industry have been shown to be more likely to portray their products in a favourable light than non-industry-funded studies.^{114 115 116}

Fewer comparisons of industry vs. independent studies have been performed for chemicals (including pesticides), but in four such reviews the same relationship is found: industry sponsorship is more likely to find favourable results, while the independent literature finds both safety and risk.^{117 118 119 120}

As the IBT fraud in the 1970s–1980s (which brought into question 15% of all pesticides in the US) and the Craven Labs fraud in the 1990s showed, industry tests can be biased. This is true whether or not they use Good Laboratory Practice (GLP), a set of rules instituted by regulators to try to combat industry fraud. GLP, in spite of frequent claims by industry and regulators, is a management tool and not a guarantee of ‘good science’. But because regulatory agencies worldwide require GLP, only industry’s GLP-compliant toxicity data is ever used in risk assessments – excluding more rigorous and up-to-date independent science.^{121 122}

There are examples of industry pressure, fraud, and bias in pesticides approvals processes worldwide:

- In 2006 in the US, union leaders representing thousands of scientists and risk managers with the US Environmental Protection Agency (EPA) sent a letter to EPA Administrator Stephen Johnson objecting to imminent agency approval for more than 20 neurotoxic pesticides, which they said violated the precautionary principle mandated by the Food Quality Protection Act. In their letter, the union leaders warned Johnson about political pressure from industry to allow high tolerances of these pesticides.¹²³
- During the public consultation on the proposed release of Bt brinjal (aubergine) in 2010 in India, the former managing director of Monsanto India, Tiruvadi Jagadisan, said that Monsanto broke regulatory rules and “used to fake scientific data” submitted to government regulatory agencies to get approval for its herbicides in India.¹²⁴
- In December 2010, a leaked memo¹²⁵ revealed that the US EPA was aware that the neonicotinoid pesticide clothianidin poses risks to honeybees, yet it allowed Bayer to use the pesticide on corn, wheat and other staple food products.¹²⁶ In the face of similar regulatory inaction by the EU authorities, some member states have brought in their own bans and restrictions.¹²⁷

Case study in industry bias and regulatory failure: bisphenol A

Pro-industry bias in regulatory procedures is exemplified by the case of the chemical bisphenol A (BPA), a plastics ingredient widely used in food packaging.

Hundreds of peer reviewed published studies show significant effects of BPA at low doses, with over 30 showing significant effects below the predicted “safe” dose. The evidence that BPA poses a danger to public health is strong. It has been found in human blood and tissues, including in human foetal blood, at levels higher than those causing adverse effects in mice. An epidemiological study shows that that BPA is related to ovarian disease in women.¹²⁸

But industry studies on BPA have reached diametrically opposite conclusions. While 94 of 104 (90%) of government-funded published studies on bisphenol A reported significant effects at low doses, no industry-funded studies (0 of 11) report significant effects at the same doses. A 2005 review of studies on BPA found that source of funding is highly correlated with positive or negative findings.¹²⁹

A 2009 review authored by 30 scientists blamed regulatory fixation on Good Laboratory Practice (GLP) for the BPA debacle. The scientists criticized the US FDA and the EFSA for deeming two industry-funded studies that adhered to GLP to be superior to hundreds of independent non-GLP studies funded by the US National Institutes of Health and similar agencies in other countries.¹³⁰

The authors pointed out that there is simply no data from GLP studies on many of the toxic effects observed in independent studies on BPA, such as some adverse effects on the female reproductive system. This is because those effects have not yet made their way into the outdated regulatory testing system. In other words, the reason the effects are not found in GLP studies is not because the chemical is safe, but because those effects are not looked for. The authors added that there is a large literature on neurotoxic effects and behavioral abnormalities caused by low doses of BPA which are not capable of being detected by current GLP studies conducted for regulatory purposes because of their outdated methodologies.¹³¹

The authors argued that the chemical industry-sponsored GLP studies on which the agencies based their decisions are incapable of detecting low-dose endocrine-disrupting effects of BPA and other

hormonally active chemicals. They stated that the FDA and EFSA “mistakenly assumed that GLP yields valid and reliable scientific findings (i.e., ‘good science’).”

The authors stated that the main factors determining the reliability of scientific findings are independent replication and use of the most sensitive and up-to-date tests – neither of which is an expectation of GLP. They concluded, “We are not suggesting that GLP should be abandoned as a requirement for industry-funded studies. We object, however, to regulatory agencies implying that GLP indicates that industry-funded GLP research is somehow superior to NIH-funded studies that are not conducted using GLP.”¹³²

EFSA continues to rely for its risk assessment of BPA on the few industry studies adhering to GLP guidelines that found no adverse effects. Based on these studies, EFSA refuses to take decisive action restricting its use.^{133 134} The EU Commission announced in November 2010 that it would ban BPA from babies’ bottles but would not extend the ban to materials such as the linings of food and drinks cans as there was no scientific evidence to support such a move.^{135 136}

The regulatory prejudice against open scientific literature and in favour of industry OECD- and GLP-standardized studies has forced the public to live with many more years of exposure to potentially dangerous levels of BPA.

Conclusions and recommendations

The independence of EFSA’s risk assessment processes on pesticides and food safety has been seriously compromised by its close involvement with industry, chiefly represented by ILSI.

EFSA must make a ‘clean sweep’ of ILSI- and other industry-affiliated people from its boards and Panels. It should reform its conflicts of interest rules to exclude people with unpaid as well as paid roles in industry organisations.

EFSA Opinions and Guidances issued during the tenure of ILSI-connected people on the PPR, CONTAM, and GMO Panels must be reviewed for pro-industry bias by independent experts on toxicology and public health, as well as representatives of the general public. The independent experts and public representatives must be paid solely from public funds to do this work – a doubling-up of expense made necessary by EFSA’s failure to ensure its independence.

It is not enough to identify specific written contributions to Opinions and Guidances by individual panel members, as EFSA did regarding Moretto. The reviewers should consider whether the recommendations in EFSA Opinions and Guidances are in the best interests of public health and the environment – or in the best interests of industry. Until this process is complete, the recommendations of EFSA Opinions and Guidances should not be adopted as EU regulations. Those that have already been adopted must be re-examined.

EFSA should ban its scientific panel members from working for industry while they are employed to work for the public and should pay them well enough to ensure that they do not need to seek industry funds. Also, rules should be implemented to banish the ‘revolving door’ syndrome, whereby someone passes straight from a job with industry to EFSA.

EFSA should not be taken in by industry-generated claims that suitable scientific expertise is only to be found in the industry sector and that industry interests are unavoidable. EFSA should recruit its scientific advisers from the ranks of toxicologists, ecotoxicologists, and public health experts in the public sector who have not received relevant industry funding.

Further, EFSA should favour scientists who are actively doing research in toxicology, embryology, epidemiology, ecology, and other fields directly relevant to public health and the environment. Many of these people are engaged in far more advanced and relevant scientific work than that practised by industry toxicologists, who still use the same outdated and insensitive methods developed almost a hundred years ago by the pharmaceutical industry.^{137 138 139} Care should be taken to exclude people who seldom see the inside of a laboratory but who specialize in helping industry get its products onto the market and keep them there.

Industry is entitled to hold its own meetings, as is EFSA. But it is not acceptable for EFSA regulators to collaborate with industry people in forums and projects that exclude other stakeholders, such as the public and NGOs. EFSA could hold multi-stakeholder meetings that are open to public representatives, NGOs, and industry. This would ensure that the discourse between EFSA and all stakeholders, including industry, is transparent.

Until these measures are implemented, the public cannot have confidence in EFSA’s regulatory processes.

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