Wanted: Evidence-based policy

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Introduction

Welcome to this Special Issue of EuroScientist on: Evidence-Based Policy!

Policy decisions are too often political instead of being informed by evidence-based considerations. This is obvious but not ineluctable.

In this special issue of *EuroScientist*, we first look at the art of convincing decision makers using evidence, by focusing on the example of mindfulness practice, looking at arguments that are used to entice decision makers to adopt it, in a wide range of organisations, including universities, public sector bodies, tech industries and law firms.

We also bring you an article providing an overview of the areas linked to science and research practice where policy could be more transparent–namely, the field of scientific advice and research impact.

In addition, we focus on two case studies where policy failed to align to the best available evidence. The first relates to how the policy making process left the steel industry some ample room to manoeuvre in their choice of emission limiting technology, under the 2010 Industrial Emission Directive due to be implemented in 2016 . The second example looks into how evidence based approaches–including advances in toxicology testing– could help modernise the regulations pertaining to food, drugs and chemical safety.

We then publish the insights from the European Parliament Scientific Foresight Unit, supporting the Science and Technology Options Assessment (STOA) Panel, who tell us about the novel mechanisms designed to make scientific evidence and foresight available to EP policy makers.

Find out about this topic by reading this special issue of *EuroScientist* and sharing it as widely as possible in your circles.

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Editorial

Shifting the perspective of sceptical minds

By Sabine Louët

Convincing people from all walks of society to adopt mindfulness requires evidence

To some in the science community, practicing mindfulness remains some trendy nonsense or useless hippy stuff. But the National University of Ireland (NUI) Galway is taking it very seriously. Indeed, the University is organising the *Mindful Way* conference, between 9th and 10th October 2015, to explore how best to bring the practice of mindfulness to higher education. The expectation is that mindfulness can contribute to improving overall performance of those attending the university or working there. "There are two things: either you live in a state with a mind full or you are mindful," says Lokesh, Joshi, Vice-President of Research at NUI Galway, who initiated this conference.

Mindfulness is defined as the practice of being aware of the present moment. It is credited with helping people develop mental clarity, greater focus, a greater sense of connection with others and to cultivate their well-being—be it on a personal and professional level. Stemming from Buddhist tradition, it has

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grown increasingly popular in Western countries by the work of Jon Kabat-Zinn, professor emeritus in medicine at the University of Massachusetts Medical School, who developed a mindfulness-based stress reduction (MBSR) programme.

Convincing evidence

So what did it take to convince NUI Galway's senior management to bring mindfulness to academics and students alike?

Joshi, first, pointed to mounting evidence-base related to the benefits of mindfulness—which remains, however, work in progress. Areas of research—often limited by the sample size of study participants—include studies on the effect of mindfulness, on the impact of our thoughts on brain and neuronal plasticity as well as well-being, and on the impact at biomolecular level, of stress on human bodies.

More importantly, Joshi firmly believes mindfulness can play a role in setting people up for life. As such, it fits in well with what is sees as being the fundamental educational role of the university. His view resonated with those of university leaders, who are acutely aware that current pressure imposed on students and scientists alike is not sustainable.

They know that the stress associated with the bean counting culture is not conducive to good performance. And the threat of mental illness is looming as WHO data shows, among others, that depression is due to become the biggest health burden by 2030. In addition to standard performance metrics, Joshi believes, there is therefore a need for greater recognition of the use of softer metrics like wellness indices.

To achieve greater level of wellness, mindfulness can help bring a better balance to people's lives. It can act as a catalyst for grounding people and enabling them to manage their reaction to stress. And it can help them function more effectively and in a more sustainable way. For example, by becoming less stressed, mindfulness practitioners are able to switch sooner into problem-solving mode when they encounter a difficulty.

Wider adoption

Adopting mindfulness as a practice is not limited to the university sphere, however. This is demonstrated by the broad array of speakers present at the Galway event. These range from the tech industry such as Google and the military forces, a representative of the UK parliament, entrepreneurs and members of the investment community. Despite the diversity of their background, all have one thing in common: they had to convince decision makers in their organisation of the well-founded nature of such an activity.

So how are people convinced about adopting mindfulness? "The best way to encourage decision makers to accept mindfulness, is to spend time explaining the theory and psychology behind it, and to inform them clearly about how it works," explains Thubten Gelong, a Tibetan Buddhist Monk based at the Kagyu Samye

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Ling Monastery, in Dumfriesshire, Scotland, UK, taking part of the conference. He teaches Buddhism, meditation and mindfulness internationally to organisations such as the UK's National Health Service, tech giant Google, as well as several law firms and some supermarket chain. He adds: "They are also persuaded when they hear about the evidence arising from the extensive scientific research, which has been done in recent years."

Flagging potential benefits also helps to convince decision makers. "In my experience, it is not difficult to get decision and policy makers to engage in a meaningful conversation about mindfulness," says social psychologist Jutta Tobias, an expert in organisational development, who is currently lecturer at Cranfield University School of Management, UK. This is the case, "especially if the discussion stretches beyond issues that focus on well-being alone, for example, by including cognition, executive functioning, and productivity factors," adds Tobias, who is a speaker at the conference. She recently proposed the creation of a ministry for mindfulness in the UK.

Tackling misconception

Despite all the available evidence, human nature is such that, often, there is still remnant of resistance in people's mind against the unknown. For example, one of the key areas of scepticism towards mindfulness include the fear that it might be something religious, according to Gelong.

Others worry that people get too relaxed and therefore less efficient; a myth easy to debunk. Indeed, Gelong explains, "the kind of relaxation developed through mindfulness is something dynamic and precise, not a kind of spaced out, switched off state." Another common misconception is that mindfulness and meditation are about stopping thinking. "They think one has to clear the mind, or blank out the thoughts," points out Gelong, "This is not true and actually leads to more tension."

The case of mindfulness, shows that adopting a policy to adopt its practice in an organisation may require suitable evidence and tackling myths. In reality mindfulness practice can take many guises. In her work, for example, Tobias presents mindfulness trainings as primarily behaviour change initiatives in organisations.

By contrast, others have been practicing mindfulness all along without necessarily naming it as such. "Throughout my Military life I have always attempted to focus on the 'now'," points out conference participant Lieutenant Colonel Ray Lane, who is Commanding Officer at the Irish Defence Force Ordnance School, at Curragh Camp, Co. Kildare, "I am very much influenced by understanding and analysing human behaviour patterns. This is a form of mindfulness that I have used and developed over many years."

Regardless of which way mindfulness is presented, much convincing is required before people start adopting it. No matter what, the ultimate test is for sceptics to try it for themselves!

Sabine Louët

Editor, EuroScientist

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Transparency

Policy matters: transparency is rarely a bad thing

By Arran Frood

Dealing with the lack of transparency in policy advice and impact scoring for funding

In an era where everyone in research circles is calling for greater transparency, policy decisions can appear as opaque as ever. Indeed, transparency is relevant to everything from how scientific advice is used–or whether it is used at all–to how research impact is defined. Buzzwords like 'horizon-scanning', 'benchmarking process' and 'evaluation metrics' are repeatedly brandied about by governing bodies and funding agencies alike. But this pseudo-management speak doesn't make it any clearer how policy makers really go about their business. Transparency is not enshrined in decision-making; opacity is only encouraged. But is that mere wishful thinking? Or can policy decision become more transparent in the near future? In this article, *EuroScientist* looks into how greater transparency is needed in two fields: policy-making based on evidence and research impact policy.

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Scottish failure to account for evidence

Available scientific evidence does not always inform policy making. Take, for example, the recent decision by the Scottish Government to ban the cultivation of GM crops in the country, which was not based on scientific advice. Instead, "potential wider economic ramifications" for the food and drink industry prevailed, according to First Minister Nicola Sturgeon.

The move prompted an open letter to the Scottish minister for rural affairs, Richard Lochhead, signed by 28 research organisations, including the Scotland-based Roslin Institute (creator of Dolly the Sheep), the European Academies Science Advisory Council (EASAC) and Academia Europaea. The signatories complained that the decision was political and not based on any informed scientific assessment of risk. "It is an approach to evidence that surprises and disappoints many scientists and non-scientists alike," it read.

The Herald Scotland also reported that ministers were unable to consult the Scottish Government's Chief Scientific Adviser (CSA) because the post is currently vacant; a previous CSA for Scotland, Anne Glover, left the role to become Europe's CSA. The on-off-on saga following that appointment has been previously covered in *EuroScientist*. (We also previously pondered over whether European countries need a chief scientific adviser at all.)

In the absence of a go-to person, some believe that the Scottish Government could have called a group of scientists, via the Royal Society of Edinburgh for example. This would have allowed them to evaluate the actual and perceived risks of GM crops for Scottish consumers. "The Scottish Government has admitted that its decision was not based on science," says Christine Diehl, executive director of EASAC, "Whilst we agree that scientific arguments are not the only ones that count, and that a science perspective can sometimes be outweighed by other considerations, we think the Scottish Government should have sought scientific advice in this case."

Resolving EU opacity in policy

The GM crop ban in Scotland not only highlights the need to have scientific advice at hand, but that it is *seen* as present and in the room for transparent decision-making. This very issue is being addressed by the European Commission which, in May 2015, announced the formation of the new Scientific Advice Mechanism (SAM), which is a remodeled substitute for the former EU CSA position.

Combining the strength of the EC's Joint Research Centre, as a key source of in-house scientific advice, with a "structured relationship" with scientific advisory bodies such as national academies in Member States, the new SAM will be independent and backed by a high-level group of seven scientists. They will provide advice on immediate issues such as Ebola outbreaks, as well as everything from energy to food security issues.

The SAM is designed to ensure transparency, including regarding the topics it will address, the evidence provided by the academies and other bodies, as well as the final opinions of the high-level group, according to EC Spokesperson for Research, Science and Innovation Mirna Talko. "The details of the

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working modalities are however still being worked out and will be presented once SAM is set up," notes Talko.

This new mechanism is one way to bring some transparency to the commission when it comes to decisions that need scientific knowledge, according to Lidia Borrell-Damian, director of research and innovation at the European University Association, Brussels, Belgium. "This approach is becoming more common," she says, adding: "Many politicians are realising that decisions cannot just be taken based on ideology or certain political party rationale. They must take into account the existing knowledge in society."

She thinks the SAM will be important, because you need a group of very knowledgeable people to be able to make judgments and really advise to the best of their knowledge. "Policymakers and governments should seek the best scientific advice possible but be transparent about their discussions." The SAM is expected to start early operations during the autumn 2015.

Assessing the impacts

But this lack of transparency does not simply affect the day-to-day policies at EU or national level. Another major area where greater transparency is often called for is in policies governing how impact of grant proposals is defined and measured.

Europe's best pupil in this field is probably the ERC. Indeed, it publishes the minutes of the plenary meetings of its Scientific Council, the governing body that defines the funding strategy and methodologies, according to Marcin Monko, press adviser, at the European Research Council (ERC). "When it comes to the evaluation of grant proposals, the names of the review panel chairpersons are made public before the evaluation starts," Monko says. "The ERC also discloses the full composition of all 25 peer-review panels after the grant award decision is adopted."

These are surely welcome measures to curious scientists. After all, the nitty-gritty world of grant applications is where careers are forged or founded. But here the all-pervasive impact of research agenda has some scientists wondering if what's expected of them is really clear.

For a start, the definition of impact varies from country to country, between funding councils, and even individual calls. The apparent change in focus of elements of Horizon2020 towards commercialisation is also causing concern. "Impact has emerged as an extremely influential policy driver, but what one should really understand as impact still seems to be very much up for grabs," says David Budtz-Pedersen, an expert on research and innovation policies and associate professor at the University of Copenhagen, Denmark.

And when it comes to scoring impact, Budtz-Pedersen says we have seen in the UK's Research Assessment Exercise that research in the chemical and medical sciences that are closest to the market place often score higher on the final ranking. "So there still seems to be some kind of industrial company-level bias in the way UK researchers are evaluated in the impact assessments."

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Fairness and transparency

This could become a major issue for the research-centric institutes and departments that are strong in the social sciences and humanities. “Then I think the question of transparency becomes very urgent because for the people working in the social science or humanities, or even the more theoretical natural sciences, it might be quite *in*transparent what actually to list or describe as impact,” adds Budtz-Pedersen.

This is make-or-break stuff for academics. As never before, they are duty-bound to explain and quantify exactly why their projects should receive a share of the limited resources stemming from taxpayers’ funding. It’s a fair point: why should scientists be endowed with the public’s cash if their work has no value to other scientists, or cannot inform policy-makers to build a better society?

This opens the door to the whole new area of Responsible Research and Innovation (RRI) recently introduced in EU funding policies. RRI requires that scientists become more aware of their responsibility in science governance and expects them to engage with society concerning the choices and consequences of their research findings.

The human impact of assessment

Everyone wants a fair and transparent assessment system, including the policymakers who set the guidelines. Then, there is the unavoidable truth that whatever the process and level of transparency in the guidelines, decisions and judgments are made by human beings.

The trouble is that value judgments are very difficult to avoid and that some are probably implicit or subconscious. That’s the central claim of a paper entitled, Science, Policy, and the Transparency of Values, written by Kevin Elliot, a philosopher based at Michigan State University, USA, who specialises in science and ethics.

“My solution is for scientists to be as transparent as possible about the sorts of value judgments they’re making, so at least we can be aware of it and decide if we approve of the sorts of value judgments they might be making,” says Elliot. “Ideally, scientists could be 100% transparent in acknowledging whenever they make a value judgment, so the public could decide how they feel about the value judgment. But of course scientists often aren’t aware that they’re making them.”

In terms of policy makers, Elliot thinks scientists should be finding ways to require that scientists doing research on sensitive topics make their data more widely available. He cites two areas as especially important: pharmaceutical safety testing and industrial chemical safety testing.

And these are the precise areas where the EC has been dragged into controversy, namely in the regulation of bisphenol A and other endocrine disrupters. In this Special Issue of *EuroScientist*, Thomas Hartung, founder of the Evidence-based Toxicology Collaboration, at John Hopkins University Bloomberg School of Public Health, Baltimore, USA, accurately describes the issues associated with modernising toxicology tests on the basis of available evidence.

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Inherent human bias is one thing, when weighing different definitions of impact for example. But there's little excuse for a lack of transparency in areas such as making corporate safety data available and logging how elected officials use it or lose it. "It's the responsibility of the policy developers to act to the best of their knowledge," says Borrell-Damian. "But not to hide or ignore any available evidence."

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Case Studies

Nerves of steel: carte blanche to Europe's atmospheric polluters

By Dino Trescher, Stefano Valentino, Luuk Sengers

A classic example of how evidence-based policy does not prevail to the detriment of EU citizens' health

A new European environmental Directive designed to protect EU citizens against fine dust emissions is unlikely to be very effective. Indeed, it appears that the Industrial Emission Directive 2010/75/EU, also called IED, has been weakened due to industry pressures. The aim of the IED was to prevent or reduce as much as possible environmental pollution by fine dust emanating, among others, from industrial facilities. The trouble is that the very industries such Directive is designed to regulate have had tremendous amount of influence on how it will ultimately work.

The Directive expects industry to apply the best available techniques (BAT) to reduce fine particles emissions. But, in the case of steel production, industries alone are left to decide how much efforts they

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are to invest in environmental protection. In this article, *EuroScientist* publishes the conclusion of a collaborative investigation by a team of European journalists. It reveals how little evidence-base has been taken into account to inform policy in this instance, following a year-long policy-making process.

Using the best available techniques to reduce industrial emissions is key. Indeed, among all industrial emissions, fine dust is one of the most dangerous for health as it is carcinogenic. Comprehensive European and international studies confirm that air pollution significantly increases the risk of lung cancer.

This means that air pollution has to be taken seriously. "There is no known safe level of air pollution," says Francine Laden, epidemiologist at the Harvard School of Public Health in Boston, Massachusetts, USA, and IARC working group member on this topic. Her working group at IARC, which is the cancer research agency of the World Health Organisation (WHO), branded outdoor air pollution as carcinogenic for humans in late 2013. And there is no evidence of a threshold for such harmful effects. Therefore, prolonged exposure to these particles can lead to lung cancer as well as respiratory and cardiovascular illnesses. The European Environment Agency (EEA) claims this dust has been responsible for the deaths of an estimated 430,000 people in 2011 alone.

Estimates of health impact

Germany has been hit the worst by the atmospheric pollution caused by industry between 2008 and 2012, the EEA notes. Indeed, the country lost an estimated €58 million based on costs associated with healthcare (by social security and individuals), sick leave and the death of family members contributing to household income. Then, the UK is right behind Germany with losses totaling €40 million and followed by France and Italy, each with €23 million in estimated losses.

Based on 2013 estimates by EPER, the EU Pollutants Emission Register, the energy sector is the largest emitter of this dust (935,000 tons). Following behind is Europe's steel industry, with about 200,000 tons. The EU, in a bid to alleviate the problem, adopted the IED directive in 2010 to regulate such industrial emissions. Steel producers are expected to comply with the regulation by 2016.

Even though the largest share of fine dust is generated by domestic heating, which accounts for 30%, industrial emissions account for around 17%, with the steel industry being one of the major emitter of particulate matter in the air we breathe. In Europe, particular matter levels are often above the safety levels set out by WHO. Each ton of fine particulate matter in the atmosphere represents an estimated additional €23,000 in costs for all of Europe's health services combined.

Regulatory farce

To better understand the dynamic of the convoluted policy-making path, let's take the example of how the IED Directive has worked out in the case of the steel industry. The Directive states that, by 2016, national governments will have to renew permits for steelworks and other industrial installations. Permit renewal

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will depend on companies adopting the best available technology (BAT) on the market to reduce fine particulate matter as well as other pollutants.

Therein lies the rub. According to the new regulation, companies themselves decide what the BAT actually is. In reality, these industries do not necessarily choose the technology proven to be the most innovative and efficient.

At the end of a year-long process, European policy makers have approved general rules to compel European industries to pollute less. But those such as the steel industry have now been left to decide both how and by how much emissions should be reduced. Metaphorically speaking it is akin to telling a motorist: you must stop at the red light, but you can turn it off if you'd like. Giants of the steel industry have managed to strip the new rules bare, by applying much of their weight to influencing technical working groups, according to an informed participant of the policy process who wished to remain anonymous.

Evidence-based policy?

To understand how we came to this situation, it is useful to examine how the policy process works. Legislators gave the task of defining the Best Available Technologies to a number of committees known as "technical working groups". Each industrial sector, such as steel, chemicals, food, thermoelectrical energy, has its own dedicated group. "The idea is to avoid definitively fixing technical criteria in normative texts, given that they are prone to become obsolete over time," explains an environmental policy officer at the European Commission.

Instead, the EU adopted a more flexible approach, allowing criteria to keep up with improvements in technology without having to pass through long parliamentary procedures, each time. These committees are meant to review the most effective technologies regularly and impartially, before adding them to a list sent to the European Commission for approval. The list is then added to the annexes of the Directive. The Directive itself becomes binding for each sector four years after the Commission's decision containing the recommended technologies has been adopted.

The trouble is that these committees are almost exclusively made up of representatives from the companies facing regulation and from governments supporting these companies in the name of national interest. Their presence in high numbers dwarfs the number of civil society representatives taking part in the process. In addition, independent scientific advisers are nowhere to be seen. Indeed, EU nomination rules do not include their mandatory participation, as confirmed by the confidential list of the members of the committee on steel obtained in the course of this investigation.

Indeed, the technical working group on iron and steel industry includes 94 participants from industry, 113 representatives of Member States, 18 from the EU Commission and 6 participants from environmental Non-Governmental Organisations (NGOs) and private research organisations. "The [European Environmental Bureau] is one of only three NGOs involved. Member States have a strong say. It is worrying that these have also been infiltrated by industry operators," says Christian Schaible, senior policy officer for Industrial Production at the Brussels-based European Environmental Bureau (EEB).

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Hapless technology

In 2012, the steel committee adopted what they called the "best" technology in the sector. The committee minutes obtained during this investigation reveal how industry representatives successfully applied pressure on the committee's secretariat, which is there to guarantee the impartiality of the decision-making. "Steelmakers' heavy lobbying aimed to kill the strengthening of the [Best Available Technology]-based permitting requirements under the Industrial Emissions Directive," says Schaible. He adds that they pursued an implementation delaying tactic as "they wanted to start the review all over again after the Directive was published."

"Discussions between the secretariat and members of the committee were mostly divided around the issue of the sinter plants. These are the most polluting pieces of apparatus in integrated steelworks [present in] the most common type of steel plants," says Sebastian Plickert, an engineer working for the unit Resource Conservation, Material Cycles, Mineral and Metal Industries at the German Federal Environment Agency in Dessau, Germany, who was part of the committee. Integrated steelworks, he says, are responsible for 84% of the total particulate matter emissions of all steel plants in the EU. And such sinter plants are responsible for about 50% of the dust produced by steel plants. Technically, sinter plants are called agglomerators; they transform raw iron into a material optimised for use in blast furnaces.

The secretariat of the committee on steel had initially proposed the adoption of baghouses, equipped with bag filters, an innovative technology that directly captures dust as it is emitted. Thus, reducing dust emissions down to less than 15 milligrams per cubic meter of treated air. The method is already used in Germany and by Tata Steel in the Netherlands. Experts like Plickert, consider it to be applicable to every steelworks prepared to make the necessary investment of around €23 million on average.

But the steel industry does not share this opinion, pointing to the crisis hitting their sector. They blame energy costs and competition from producers outside the EU, particularly from China, which are not subject to the same environmental regulations. "All this created a situation where many plants are not profitable anymore and so they can hardly afford a further raise of the environmental costs, which are already quite high," argues Thorsten Hauck, head of the department for iron making process technology at the VDEh-Betriebsforschungsinstitut (BFI), a research institute for steel-making technology in Düsseldorf, Germany.

Exceptions

In this context of economic pressure, "the steel industry coalition successfully called for keeping a technique known as electrostatic precipitation, in the list of Best Available Techniques for dust abatement," at the decisive stage of the policy making process, according to Plickert. He points out that the technique has already been adopted by the majority of European steelworks. But he also says that it is outdated and almost three times less efficient than bag filters with fine dust emissions of 40 milligrams per cubic meter remaining in the exhaust gases–much higher than the 15 milligrams per cubic meter obtained with baghouses.

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Eurofer, the Brussels-based European federation of steel producers, claims that these limits did not go against the Directive. Excluding electrostatic precipitators from the BAT options for existing sinter installations would not have been in line with the definition of BAT in the Industrial Emissions Directive, according to Danny Croon, environment director at Eurofer. He believes the Directive defines technologies in the broadest sense, including which technologies are to be used and how the installation is designed. What is more, the Directive allows for more efficient technology to be waived, should its adoption incurs costs that are disproportionate to its environmental benefits.

A waiver within the document approved by the technical committee allows steel plants to keep on using electrostatic precipitation whenever bag filters are not applicable. "This wording of the waiver in the committee's decision is so vague, though, that it protects steelworks from the need to invest in bag filters without any real restriction, as long as the state authorities shy away from conflict," counters Plickert.

Because of this decision, 3,800 tons of additional particulate matter will therefore enter the atmosphere, according to the same experts. To put this figure in context: this amount of emissions represents less than 1% of the fine particulate matter emitted in Europe–as such emissions remain dwarfed by domestic heating and vehicle emissions. Yet, the extra dust emitted by the European steel industry has a potential total estimated cost of €524 million, over six years. It is a sum greater than the €460 million that steelworks without bag filters would have to invest.

What's next?

The Best Available Technologies list for a given sector will only become definitive after validation by a supervisory committee formed uniquely by representatives of national governments. This investigation demonstrates that EU policy leading to collective binding decisions remain the fruit of a consensus and decisions aligned with national governments priorities.

In essence, the steel mills are entitled to flag up the need to protect their profitability when faced by new requirements for environmental protection. However, the steel industry should not decide on its own types of technologies that are required for environmental protection. In this context, there are renewed expectations of the new Scientific Advice Mechanism, whose creation was recently announced by the EC, to help shift the balance towards greater evidence-base to inform policy in future Directives.

Stefano Valentino, Italian journalist based in Brussels, Belgium.

Dino Trescher, German science journalist, based in Berlin, Germany.

Luuk Sengers, is a Dutch investigative journalism trainer, based in Utrecht, The Netherlands.

This investigation as performed with the support of Journalismfund, enriched thanks to contributions gathered through the Mobile Reporter platform.

Photo credit: Billy Wilson

Case Studies

Evidence-based safety science is nigh

By Thomas Hartung

Modernising toxicology tests could help improve the safety of new drug approval and better clinical practice

Translating the evidence provided by science into policy has always been challenging. This is particularly true when integrating scientific evidence into safety sciences.

As surprising as it may appear, most of the tests that are currently used in the decision-making process used for the approval of new food, drugs and chemicals by regulatory agencies worldwide have not all been validated. Current test methods for prediction of hazardous effects, experts agree, are not always adequate to ensure the safety of consumers exposed to medicines and other chemicals. Today, pressure is mounting on industries and food and drug regulators worldwide to improve the safety of consumer products and bring regulatory batteries up to date with modern science.

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The solutions may lie in following principles used in evidence-based medicine (EBM). EBM relies on a core tool, namely systematic reviews. These have been developed for clinical research to add rigour to appraisals of the value of evidence presented in past studies. Reviews of the available literature on a given topic are at the heart of decision-making in science. They answer questions like: What do the studies on a specific topic collectively indicate? Systematic reviews constitute therefore a standardised approach for addressing this question.

Their advantages is that they yield transparent, robust conclusions. And they provide a convenient means for scientists and regulatory decision-makers to gain a condensed snapshot of the literature findings on their topic of interest.

Today, EBM principles need to be adopted in safety sciences like toxicology–a field known as evidence-based toxicology (EBT). Ultimately, adopting EBT principles will yield fully validated safety testing methods into the regulatory approval process for new drugs, food and chemicals.

The dawn of modern toxicology

Transparency, objectivity and consistency are the three principles of EBM, collectively referred to as the Cochrane principles. The use of these criteria has strengthened the scientific foundation of decision-making in clinical medicine and healthcare. The idea was to assess the bearing of available evidence on healthcare questions in a structured way.

Moreover, bestowing such EBM approach to previous studies inevitably encouraged improvements in the design and reporting of new studies. As a result, clinical research has undergone a fundamental improvement in quality in the last few decades. This has led to an increased transparency and rigour in all aspects of research, from study design to reporting of the outcomes.

While EBM and systematic reviews are well established approaches in clinical medicine, traditional narrative reviews are still the norm in toxicology. While such reviews still have their place, they lack many of the features of a systematic review. Besides, they are prone to author bias in selecting, synthesising and interpreting studies under review. Consequently, these traditional practices can compromise decision-making.

Fortunately, this situation is now changing. Prominent agencies around the world, including the European Food Safety Authority (EFSA), the US National Toxicology Program (NTP), and the US Environmental Protection Agency EPA with its Integrated Risk Information System (IRIS program), have embraced the systematic review framework. Already early applications of such reviews are focusing on hazard identification and risk assessment, as well as test method performance. What is more, applying systematic review to test method performance offers opportunities to provide a new and more robust framework for assessing evidence in the contentious area of toxicology tests validation.

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Shift from medicine to toxicology

Historically, the translation of evidence-based approaches from medicine to toxicology has already been underway for a decade. Around 2005 as the term EBT emerged. Together with colleagues, we noted the potential value in translating evidence-based assessments of diagnostic measures in medicine to assessments of test methods in toxicology. We went on to further elaborate the conceptual underpinnings of EBT and coordinated the first international conference on EBT, held in Italy in 2007.

This led one of us–Thomas Hartung – to later found the Evidence-Based Toxicology Collaboration (EBTC). This is an initiative based at Johns Hopkins University Bloomberg School of Public Health, located in Baltimore, Maryland, USA. It aims to advance EBT and gather all the international EBT efforts under one roof. The collaboration has brought together stakeholders from government, non-governmental organisations, academia and industry to accelerate the transition of toxicology from expert judgement-based narrative to evidence-based science.

The collaboration ultimately aims to address directly all the challenges of translating EBM principles to toxicology and to reach consensus on draft of a primer and handbook of EBT and systematic reviews in toxicology. This information will then be disseminated among the members of the toxicology community, while taking the lead to write systematic reviews in chemicals' and test performance assessment under the newly developed guidelines.

Next steps

We believe that one of the first applications of EBT could be in validation of safety assessment methods. EBT and systematic reviews can serve as key tools to help accelerate transition of new safety technologies into a quicker qualification stage. In addition, this approach can give confidence to the regulators to start using these technologies for regulatory decision making. With their emphasis on transparency, objectivity, and consistency, evidence-based approaches offer a tremendous potential to transform and modernise toxicology.

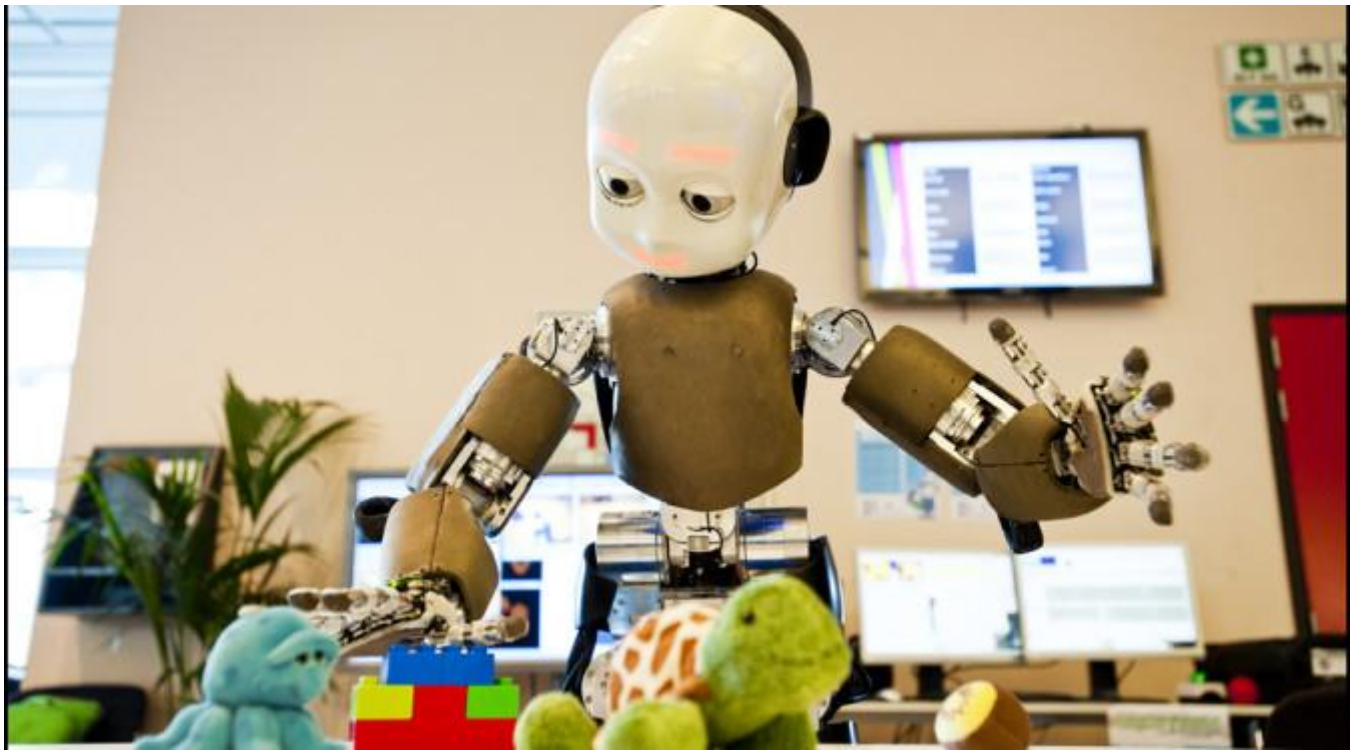
Thomas Hartung

Founder of the Evidence-Based Toxicology Collaboration (EBTC)

This article has been co-written with contributions from EBTC colleagues including: Katya Tsaioun, Director EBTC, Martin Stephens, Founding Director EBTC, and Sebastian Hoffmann, Research Staff, European Affairs EBTC, at the Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland, USA.

Photo credit: John Hopkins University

Regulator's Perspective



Scientific foresight, new in the EU Parliament science advice toolkit

By Theodoris Karapiperis and Lieve Van Woensel

A science policy ecosystem based on sound scientific evidence and oriented towards the future

The European Parliament has its own source of strategic advice, based on sound scientific evidence, in all policy areas affected by developments in science and technology. This advice is provided by the Science and Technology Options Assessment (STOA) Panel, which is supported by the European Parliamentary Research Service (EPRS). Together they strive to turn the science-policy interface into a future-oriented science-policy eco-system. There, scientists and policy-makers are in dialogue with all relevant stakeholders, including industry, NGOs and society as a whole.

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The advantage of creating such an eco-system, is that scientists and policy-makers are less likely to overlook important consequences of their choices. This matters, for example, with respect to the potential of industry to turn scientific results into innovative products. Or for the acceptance of new products and services by society. And this, even if these products only arrive in the distant future. In this article, we will explain why STOA believes in the power of an inclusive approach when defining policy options for techno-scientific issues.

In-house expertise

EPRS is the European Parliament's in-house research department and think tank with a mission to "assist Members in their parliamentary work by providing them with independent, objective and authoritative analysis of, and research on, policy issues relating to the European Union" and to "increase the capacity of Members and committees to scrutinize and oversee the European Commission and other executive bodies throughout the EU policy and legislative cycle."

STOA was established in 1987 to carry out the European Parliament's Technology Assessment activities. It provides Members of the European Parliament (MEPs) and committees with expertise in all policy areas with a significant science and technology component. All together, STOA is governed by a panel of 24 MEPs, appointed by eight committees and assisted by a secretariat within the Scientific Foresight Unit of EPRS.

STOA's role is to follow all aspects of EU policy with a relevance in science and technology. The Panel publishes Technology Assessment studies addressing "medium- to long-term, complex and interdisciplinary problems relating to the impact of [S&T] developments on society". Between 2009 and 2014, STOA produced 24 studies.

One [recent study] (http://www.europarl.europa.eu/stoa/cms/home/publications/studies), dated January 2015, looks into risks and opportunities raised by the current generation of network services and applications as well as options for longer-term security and privacy improvements in connection with mass surveillance. Two other studies, published in March 2015, look at technology options for deep seabed exploration and for learning and teaching technologies, respectively.

STOA also organises events "in which politicians and representatives of [the] scientific [community] and of society as a whole … discuss … [science and technology] developments of political relevance". Recent events focused on the transition towards sustainable and livable urban futures and how technology can contribute to improving patients' health literacy, among others.

Evolving role

Going one step further since 2014, STOA has taken on the challenge of helping Members and committees to take into account possible long-term unintended consequences of legislation on society. Hence, STOA's

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traditional role of providing committees and Members with sound evidence on techno-scientific issues was then strengthened through a new emphasis on the long-term future dimension of its research.

This focus has been implemented through a new approach, called 'Scientific Foresight', which systematically involves social scientists, in addition to natural scientists and technical experts. Indeed, this approach encompasses all aspects of techno-scientific trends to be investigated, including social, economic and ethical aspects.

This led, for example, to the publication of and EPRS report 'Ten technologies which could change our lives', prepared by the Scientific Foresight Unit (STOA), in January 2015. This opus analyses emerging technology trends with potential unintended/unexpected impacts on society. This practice will continue with regular techno-scientific horizon-scanning reports to inform priority setting by the STOA Panel and parliamentary committees.

Wisdom of many

Similarly to the approach of the new Scientific Advice Mechanism developed by the European Commission, the STOA Panel relies, for the governance of STOA activities, on a wide range of expertise, involving professionals with diverse backgrounds. Thus, speakers in STOA workshops are always chosen to represent the full range of relevant expertise and viewpoints.

STOA also regularly invites committees and Members to propose topics to be assessed, as a valuable input to inform their discussions and choices. The STOA Panel selects the proposals it wants to turn into STOA projects according to well-defined criteria, grouping them into five priority areas.

These include Eco-efficient transport and mobility (how can this be ensured for an ever-increasing population?); Sustainable management of natural resources and modern energy solutions (how can the world secure the necessary resources for the future?); Potential and challenges of the Internet (what is the future for e-government, social networks, cloud computing and the Internet-based collaborative economy?). They also include Health and new technologies in the life sciences (the quest for 'perfect life': what can we do to improve people's health?) and Science policy, communication and global networking (how can STOA help to 'join the dots' with scientists across the globe?).

Future steps

STOA aspires to maintain a robust capacity to provide comprehensive and authoritative options for the appropriate policy response to current and future developments in science and technology. To do so, it relies on a panoply of tools, such as Technology Assessments, techno-scientific trends monitoring and Scientific Foresight. This capacity should firmly anchor STOA in the agenda-setting phase of the policy cycle.

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And STOA is designed to help MEPs to conceive legislative pathways consciously chosen in a way to reach desirable outcomes in the long-term. This has been traditionally done through presentations of interim and final study outcomes to the STOA Panel and parliamentary committees. It will be extended in the future to include personalised contacts with MEPs to discuss long-term scenarios and their implications for current legislative work, in the context of Scientific Foresight studies.

In essence, STOA has been developing the capacity to play a well-defined role in the EU policy cycle and has invested a lot of efforts in effectively communicating the available evidence at the 'science-policy interface'. In the past few years, STOA has developed novel ways of communicating the outcomes of studies and workshops as well, making ample use of the social media, such as blog posts on the EP Think Tank, video clips summarising studies for non-experts and live tweeting during events. This activity has helped raise awareness of STOA activities among the wider public, which has responded favourably to this new way of interacting. After all, communicating science and technology issues and making them understandable to society at large is an important part of STOA's mission.

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Legend: "The iCub presented on the occasion of European Research Leadership in Robotics, a 2012 exhibition in the European Parliament, organised by STOA."

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