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Risk-risk tradeoffs: what should we do in Europe?

Ragnar Lofstedt* and Anne Schlag

King's Centre for Risk Management, Department of Geography, King's College London, London WC2R 2LS, UK

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Risk-risk tradeoffs occur when a regulator focuses on decreasing one particular risk in one area which leads to another risk appearing elsewhere which was not originally considered. These risk-risk tradeoffs abound all around us and are frequently ignored by regulators. In this article we firstly, examine why risk-risk tradeoffs are often ignored. Secondly we summarize some of the criticisms to the use of risk-risk tradeoffs and then we look at the phenomenon via a number of European based case studies. In the final section of the paper we put forward a series of recommendations to help regulators to be better equipped in dealing with risk-risk tradeoffs.

Keywords: risk-risk tradeoffs; regulation; risk management; Europe

1. Background

The so-called risk-risk tradeoff occurs when a regulator focuses on decreasing one particular risk in one area which leads to another risk appearing elsewhere which was not originally considered. An example of this phenomenon was the US decision to halt the logging of large tracts of the Pacific Northwest to protect the spotted owl which in turn led to cellulose being imported from less sustainable sources such as Siberia or Brazilian eucalyptus plantations (Graham and Wiener 1995). The concept builds on risk-risk analysis developed by the late Lester Lave (Lave 1981), and in the words of Graham and Wiener requires policy-makers and regulators to:

> … evaluate in weighting the comparative importance of target risks and countervailing risks when hard choices must be made. (Graham and Wiener 1995, 19)

These risk-risk tradeoffs abound all around us. They are referred to as side effects in medicine (taking a specific pharmaceutical drug may lead to other health problems), to collateral damage in the military (the killing of terrorists in Afghanistan also leads to the killing of innocent civilians). Over the years, there have been a multiple number of studies discussing the prevalence of risk-risk tradeoffs (see for example Gayer, Hamilton, and Viscusi 2000; Graham and Wiener 1995; Hrudey 2009; Krupnick and Cropper 1992; Viscusi, Magat, and Huber 1991; Viscusi et al 1994)

Risk-risk tradeoffs have been and are frequently ignored by regulators, even though over the years there have been a number of studies stating that they need to be properly and systematically addressed (e.g. Adler 1992; Marchant and Mossman 2004; Whipple 1985). There are many current examples of this. One example, if we

*Corresponding author. Email: ragnar.lofstedt@kcl.ac.uk

are to phase out all substances having possible endocrine disrupting effects based on uncertain science, something that has been proposed by a number of members of the European Parliament (e.g. Westlund 2012, 2013), what are the alternatives to them, in line with the substitution principle? A number of expert workshops show that the alternatives have been much less studied and analysed and, as a result, there is even more scientific uncertainty associated with them (e.g. FAO/WHO 2010).

In this article we, shed further light on the use and understanding of risk-risk tradeoffs based in part on a number of informal interviews with regulatory officials in a number of European countries. In the next section, we examine some of the key reasons why risk-risk tradeoffs are presently ignored and in Section 3 we summarize some of the criticisms and responses to the risk-risk tradeoff paradigm. Section 4 discusses the status of risk-risk tradeoffs today and in Section 5 we focus on the use of risk-risk tradeoffs through the lens of a number of case studies. In the final part of the essay, we offer some recommendations for the European Commission and other bodies active in the broader area of regulation on how they can best avoid risk-risk tradeoffs.

2. Why are risk-risk tradeoffs not properly understood and accounted for?

One would expect that in an era of almost instant communication, the growth of smart phones and the evermore comprehensive and detailed internet search engines that regulators and other stakeholders would better able to avoid risk-risk tradeoffs. The digital age, one could assume, would lead to more informed and less ignorant policy-makers. This has not occurred. There are a number of key reasons why risk-risk tradeoffs often continue to be ignored, all of which need careful academic attention.

2.1. The problems of unscientific decision-making

Firstly, risk-risk tradeoffs are products of incomplete, often rushed and non-evidence-based, decision-making. Regulations are often suggested or pushed through too quickly without properly taking account all the possible consequences, often driven by media which tend to amplify certain risks (Kasperson et al. 1988; Pidgeon, Kasperson, and Slovic 2003). Similarly, in many cases stakeholder and/or political concerns receive precedence over evidence-based policy-making (Lave and Males 1989) which is sometimes referred to the ‘risk of the month concern’. These incomplete decisions are often made following regulatory scandals, when public trust in regulators is often low (Löfstedt 2005). One classic example is following the BSE (Mad Cow disease) scandal in the UK, when regulators in England decided to replace multiple-use surgical equipment for removing tonsils from patients with single-use surgical equipment as they were concerned about spreading Variant Creutzfeldt-Jakob disease (vCjD) from patient to patient. During the time the short ban was in place, it led to several hundred cases of excess bleedings and one patient dying. After less than a year the ban was revoked, as regulators realized that there was a real risk of patients suffering from single-use surgical equipment while with multiple use there was only a statistical and not a proven risk of possible vCjD spread (BBC News 2001).

2.2. The growth of bounded specialization

Over the past 40 years or so, there has been a growth of bounded specialization within the regulatory discipline itself (Krier and Brownstein 1992). That is, as regulatory issues become increasingly complex, regulators themselves focus on dealing with a particular risk issue at hand, blinding the policy-makers from the risks that may abound outside his/her specialty area (Graham and Wiener 1995). These problems are compounded by the fact that, for example, in many cases special interest groups focus on single source pollution end points rather than the broader environmental problem at hand (Viscusi 1998). Hence, rather than having the Swedish Chemicals agency (SCA) trying to achieve a so-called 'toxic free' society by the year 2020, policy-makers there should take a broader picture and focus on the real chemical and food risks affecting the Swedish population, be it every day food poisonings caused by salmonella or being exposed to dioxin in fatty fish caught in the Baltic Sea (see Lofstedt 2014 for a discussion).

2.3. The role of globalization

National regulators focus primarily, if not solely, on national risk problems rather than international ones. Today, there is a growing globalization of manufacturing capacity be it cars or cement, yet in the environmental, food and pharmaceutical areas, we either have national or at most regional (e.g. EU) regulations and not global ones (Haas, Keohane, and Levy 1993; Majone 1996). In other words, by putting forward tough regulations in one nation, for a certain manufacturing sector, the risk in question is often simply 'exported' to another nation, at times leading to an increased overall risk due to inadequate regulations there (Daly 1993), sometimes referred to as a 'risk transfer' (Graham and Wiener 1995). Environmental regulations are overall considerably tougher in Europe and North America than the rest of the world. As a result, the globalization of manufacturing capacity and the export of jobs to China and elsewhere have led to greater environmental destruction on a global scale than had those jobs stayed in Europe or North America (Falkner 2008; Scharpf 1995).

Because of these three key reasons, risk-risk tradeoffs are presently not properly understood by European regulators, policy-makers and stakeholders. In doing informal interviews for this paper, for example, we saw a number of examples of the 'silo mentality'. Regulators at the Swedish Food Agency (SFA), for example, were unable to come to an agreement on how to best regulate chemicals with their colleagues at the SCA. SFA wanted to use a strict risk analysis approach while the SCA preferred using hazard classifications (Lofstedt 2014). The reason for these differences came down to the fact that the two Agencies had different political mandates.

Not all academics active in the risk area, however, believe that there are risk-risk tradeoffs and that something actually needs to be done about them. This is discussed in the next session.

3. Critics to risk-risk tradeoffs

There has been some academic debate regarding the merits of risk-risk tradeoffs. One group of critics argue that the proponents of risk-risk tradeoffs either fail to

provide good examples to support their case or that the examples the proponents use are incorrectly labelled as risk-risk tradeoffs when they are actually not (Hansen and Tickner 2008; Hansen, von Krauss, and Tickner 2008). One case that Hansen et al. raise as 'not a good example' is the risk-risk tradeoff of increased highway fatalities caused by less effective brake linings that came on the market following the ban of asbestos brake linings. They note that this is a bad example as there is not enough evidence provided for this risk-risk tradeoff. Similarly, Hansen et al. argue that the possible risk-risk trade-off occurring when workers become injured or killed cleaning up hazard waste sites is 'hypothetical' as there are no data/statistics available with regard to occupational death or injuries associated with waste site remediation.

In a reply to this article and the subsequent commentary, Graham and Wiener dismiss the arguments made by Hansen, von Krauss, and Tickner 2008 arguing that:

> … Hansen et al. do not show that few risk-risk tradeoffs are 'real'. On the contrary, their own data show that many such cases are worthy of policy attention. The criteria that Hansen et al. use for selecting their sample and for characterizing the cases within their sample are problematic … Moreover Hansen et al. are simply incorrect in their dismissal of several cases. (Graham and Wiener 2008a, 472)

For example, with regard to the above-mentioned brake lining example Graham and Wiener argue that not only did Hansen et al. ignore the longer discussion on this case study in Graham and Wiener (1995, 15) but also the extended discussion in the federal court decision on the same topic that was highlighted in Graham and Wiener namely (*Corrosion Proof Fittings vs US EPA, 947 F.2d 1201* (5th Cir. 1991)). In other words, the whole discussion of bad examples and scientific misinterpretations, according to Graham and Wiener, simply do not add up (Graham and Wiener 2008a, 2008b).

Other critics of risk-risk tradeoffs argue that its proponents are biased against environmental regulation. In other words, the critics argue, the proponents want less rather than more regulation (Steel 2015). At the root of this claim is an in-depth analysis by Revesz and Livermore who note that on the whole, proponents of risk-risk tradeoffs focus solely on the risks of these tradeoffs thereby ignoring ancillary benefits (Revetz and Livermore 2008, 55–65). There is some truth to this argument. A number of the proponents of risk-risk tradeoffs have focused more of their attention on the risk aspects rather than the possible benefits (e.g. Sunstein 1996; Viscusi 1996). As Cass Sunstein argues in the forward to Graham and Wiener's seminal book:

> If government imposes environmental regulation on companies, it may decrease some environmental risks. But these very regulations may increase other environmental risks or shift risks to other areas. (Sunstein 1995, viii)

Reading this quote, there is no mention of unintended ancillary (secondary or supplementary) benefits or even consideration of such benefits. That said, the main proponents of risk-risk tradeoffs do acknowledge the importance of ancillary benefits as well. As Mendelson and Wiener argue:

> …analysis should include all important impacts-both quantitative and qualitative, both intended and ancillary (including both ancillary harms and ancillary benefits). (Mendelson and Wiener 2014, 513)

This point has been made repeatedly by a number of the key proponents (e.g. Graham and Wiener 2008a, 2008b; Stern and Wiener 2006, Wiener 1998, 2002, 2006) so it is

unfair to brand all the research on risk-risk tradeoffs as ways to reduce regulation, even though most of the studies to date may have focused more on the risks rather than benefits (e.g. the case studies in Graham and Wiener 1995 focused on ancillary risks rather than ancillary benefits). One important note, however, is to what degree regulatory agencies themselves consider ancillary risks more or less than ancillary benefits. One would hypothesize that regulators would want to play up ancillary benefits and downplay ancillary risks. As past research shows, regulators (and here we refer to career civil servants rather than political appointees) by their very nature want to regulate, some more emphatically than others (for a personal account see, for example, Vallianatos and Jenkins 2014).

In examining some of the regulatory impact analysis done by the Swedish authorities with regard to promoting ever stronger chemical controls based on precautionary and substitution principles, for example, it is clear that these authorities downplay the risks and highlighted the benefits. In its regulatory impact analysis of its 2013 Government Bill on Chemicals, the Swedish Ministry of the Environment notes with regard to benefits of the bill:

> The main social benefits of further developed chemical control policy has concern the reduction in negative effects on human health and the environment. (Swedish Government Bill 2013, 124 [translation by first author])

It goes on to say with regard to the costs of the proposed regulations:

> Tougher regulations can in many cases stimulate innovation and in the long term assist companies which are forward looking with regard to producing chemicals to gain competitive advantage. Also by phasing out the use of dangerous substances some companies can reduce the costs of protecting workers from those active in the production process …. (Swedish Government Bill 2013, 125)

In this rather non-rigorous discussion without any facts or references, it is clear that possible risk-risk tradeoffs are not addressed nor considered (for further discussion on Swedish chemical control policy see Lofstedt 2014). Hence, one can argue that it is therefore justified for researchers to examine the risks to a greater degree than the benefits as regulators themselves will most likely play down the risks (for an excellent discussion see Dudley 2012).

4. What is the status of risk-risk tradeoff research today?

After the publication of the seminal Graham and Wiener book, a number of academics including Cass Sunstein and Kip Viscusi as well as public policy think tanks such as AEI-Brookings Joint Centre for Regulatory Studies argued that regulatory agencies needed to take into account risk-risk tradeoffs (e.g. Sunstein 1996; Viscusi 1996). These pleas were picked up by politicians and it became a popular item of discussion especially during the 105th and 106th US Congresses (1997–1999) where there were attempts at regulatory reform under the so-called Gingrich revolution (Revesz and Livermore 2008). Although these proposed initiatives never became law, it was highlighted by the OMB in 2003, at a time when Dr John Graham was the Administrator for Office of Information and Regulatory Affairs (OIRA), when it noted that 'decreasing one risk may increase a countervailing risk' (OMB 2003).

In Europe, most of the discussion surrounding risk-risk tradeoffs have taken place in the pharmaceutical sector (Eichler et al. 2013). One issue of importance is risk-risk tradeoffs with regard to personal patient–physician interactions. Do doctors

and patients view the risks in the same way? A number of studies show that these groupings have different mindsets (Arnardottir 2013; Arnott et al. 2012; Johnson et al. 2010; Lenert, Markowitz, and Blaschke 1993), leading pharmaceutical regulators to conclude that:

> it could be argued that patient's risk-risk trade-offs are likely to be asymmetrical (or biased) as those of physicians or perhaps regulators-only in the opposite direction. (Eichler et al. 2013, 909)

As a result, medical regulators going forward need to take into account patients' and doctors' views when assessing risk-risk tradeoffs of various pharmaceutical products. The most well-known medical example of risk-risk tradeoffs being discussed in the public domain occurred when HIV activists persuaded pharma regulators to give them access to certain anti HIV/Aids drugs that still were in the experimental/developmental stages in the 1980s (Carpenter 2010).

Outside the pharmaceutical sector, risk-risk tradeoffs are acknowledged but less discussed. One study examined UK public willingness to trade-off the possible risks associated with nuclear power plants with that of climate change, and although a high number of the British public would be willing to accept nuclear power in such circumstances, most of the public saw climate change and nuclear power more or less equally problematic. Rather, the UK publics would prefer to use renewable energy sources to solve the climate change issue (Pidgeon et al. 2008). Within European policy circles, European and US-based academics repeatedly raise the importance of risk-risk tradeoffs (e.g. Graham and Hsia 2002; Löfstedt 2013; Wiener et al. 2011). Policy-makers that the first author interviewed, for example, were aware of the concept with some of them finding it important while others ignoring it. One senior Swedish civil servant noted:

> Yes I understand the concept of risk-risk tradeoffs. It is rather quite logical and rational. But to be honest I don't necessarily adhere to it. If my Minister wants a bill passed regarding the phase out of a certain chemical I will do everything I can to get the bill passed whether it is completely sensible or not. I am loyal to my Minister. (Interview with author November 2013)

On the opposite side of the argument, one UK civil servant noted:

> We take pride in being as evidence based as possible in our Department and, as result, we follow the discussion regarding risk-risk tradeoffs with keen interest. It is in everyone's interest that regulations are as robust as possible and a better understanding of risk-risk tradeoffs should help us achieve this goal. (Interview with author October 2013)

In discussion with civil servants and politicians, however, one issue that was repeatedly raised was the lack of European risk-risk tradeoff examples. The Graham and Wiener book, which contained no less than 9 case studies were all American based. Similarly, the examples used by Viscusi and others where US based. In the next section, I provide 3 concrete European examples.

5. Risk-risk tradeoff case studies

There are a number of case studies we could choose from to explore risk-risk tradeoffs. In order to get as broad a set as possible, we decided to pick 3 different cases studies: one energy case, and then cases from the plant/crop protection products

(pesticides) and pharmaceuticals/biotechnology sectors, respectively. We chose these case studies on two primary criteria: firstly, the familiarity of the case in question and secondly, the broader policy relevance. All three case studies have direct policy relevance, of which case study 3, that of Tysabri, has received much attention from policy-makers on both sides of the Atlantic. In addition, independently, we have worked on all three cases at some point in our careers.

5.1. *A risk transfer example – closing the Barseback nuclear power station*

Nuclear power has long been a contested issue in Sweden, especially in the 1970s and 1980s when elections were won and lost depending where one stood on whether to phase out or keep Sweden's nuclear reactors working (e.g. Anshelm 2000; Lofstedt 1993; Sahr 1985; Vedung 1980, 1991). In 1976, for example, the Social Democrats failed to gain a majority in the elections and lost control of the Swedish parliament for the first time in 44 years because of a strong showing of the anti-nuclear Center Party. Similarly, following the 1979 Three Mile Island accident, the decision was taken to hold a 'nuclear' referendum in Sweden which resulted in a call for the nation's 12 nuclear reactors to be phased out by 2010 at the latest (Lofstedt 1993; Sahr 1985). In 1986, the Chernobyl disaster, which was first detected outside the then Soviet Union by monitoring equipment at the Forsmark nuclear power plant in Sweden, spread radiation over southern Lapland and the Swedish province of Gastriksland. This disaster caused concern among Swedish policy-makers, leading to the then Energy and Environmental Minister, Birgitta Dahl, pledging to close down two nuclear reactors by 1996 (Löfstedt 2001). However, this pledge was quickly forgotten in the early 1990s as Sweden was facing a recession that held the attention of policy-makers instead. Having said this, the future of Sweden's nuclear power came back to the forefront in the 1994 election campaign when the then leader of the Social Democratic opposition, Ingvar Karlsson, noted that should he be elected that he would stand by the promise to phase out all of 12 nuclear reactors by 2010 and start the phase out within the next election period (in line with Dahl's pledge). The results of the 1994 election gave the Social Democrats 45% of the seats. With their hand forced by the need to build a ruling coalition with the Center Party, they stood by their campaign promise and announced that the phase out of nuclear power would begin in 1995 or 1996 (Anshelm 2000).

In their initial negotiations, they decided to target two reactors at the Barseback site located in southern Sweden some 20 km away from Malmo (and 30 min away from Copenhagen, Denmark via the bridge across the Oresund straight). Although these two nuclear reactors were as safe as any of the other nuclear reactors in Sweden, they were picked for two main reasons: firstly, they were small compared to the other Swedish reactors (615 MW each) and secondly, and more importantly, they were built in the 'wrong' place. They were located too close to major cities (most notably Copenhagen and Malmo) and the antinuclear Danes were especially opposed to them (for a discussion see Löfstedt 1996). Hence, by closing them, rather than reactors at Ringhals or Forsmark nuclear power stations the authorities hoped that they would be able to make amends with senior Danish policy-makers.

The Swedish utilities were highly opposed to the closure of Barseback arguing that it would be better to use the money that the Swedish state would be paying Sydkraft (now part of the EON group) to compensate for the closure of Barseback, to make nuclear power stations in the Baltic area safer (such as the massive Ignalina

reactor in Lithuania which is based on the same design as the ill-fated reactor at Chernobyl). Anticipating this outcry, the then Social Democratic Prime Minister Goran Persson and the Center Party leader Olof Johansson wrote an opinion editorial noting:

> For us the introduction of ecologically sustainable society is not utopian, nor something that is built on a Sorgard romanticism where modern technology has played out its role. Rather, we are convinced that the restructuring of Sweden will lead to the birth of new technologies that will lead to greater employment opportunities throughout the country. (Persson and Johansson 1997, 4)

The Social Democrats and their allies then announced that an upcoming energy bill would provide plenty of government funds to help develop such a sustainable society. These funds were discussed in the Swedish Government 1997 Energy Bill when it noted that Barseback 2 would only be closed down if the electricity lost from this reactor could be replaced by energy conservation measures and investments in renewable energy sources (Swedish Government Bill 1997). To make this happen, the Swedish government set aside 3.5 billion SEK (1997) in subsidies designed to yield energy savings and new renewable energy production equivalent to 4 TW-hours per year (Löfstedt 2001) and established the Swedish Energy Agency to oversee it.

After some foot dragging and legal battles, the first Barseback reactor was closed down in November 1999. Sydkraft (now part of the German Eon group), the owner of the Barseback nuclear power plant, received a generous compensatory deal. The utility was awarded funds to cover the cost of shutdown as well as increased generating capacity from nuclear reactors at Ringhals (owned by the public utility Vattenfall). The combined cost for the Government in terms of compensation for lost capacity at Barseback at the time of the closure was between 5.9 and 8.4 billion SEK (Sydkraft 1999).

At the time of closing Barseback 1 in 1999, the Swedish government commissioned two boutique consulting companies to see if the subsidies allocated from the 1997 Energy Bill were having an effect and whether, therefore, the second reactor could also be closed. These two consultancies concluded independently that the subsidies would not be enough to compensate the electricity lost from Barseback 1 (COWI 2000; Miljoteknik 2000). In its reply to the two consultancy reports, the Swedish Energy Agency agreed with the findings of the consultants but advocated a mid-2001 closure in any case as they felt that the energy market had changed significantly since 1997 (Swedish Energy Agency 2000). If renewables and energy conservation measures could not replace the electricity generation capacity lost with the closure of Barseback 1, where did it come from instead? Of the 4TWh lost from the closure of Barseback 1 only 1–1.5 TWh was replaced from the combination of renewable energy sources and energy conservation. Rather, the majority of it was replaced with coal-generated electricity most of it coming from Denmark. As Sydkraft pointed out, just after the closure of Barseback 1 in the period from 1st December 1999 until 6th February 2000 more than 100 GW hours of coal-generated electricity per week was imported from Denmark to Sweden (Sydkraft 2000).

The closure of Barseback 1 was driven by the desire of the Social Democratic Party to secure power within the Swedish Parliament. They did so by playing the antinuclear card to portray themselves as architects of an ecological society. The reality, however, showed that the closure of Barseback 1 produced results counter to

the expressed goals, at a huge cost to Swedish tax payers (Löfstedt 2001). The consequences of this phase out strategy, at least in the short term, was in effect the replacement of nuclear-generated electricity with coal-generated electricity leading not only to greater CO_2 emissions but also to higher levels of acid rain much of which were deposited in south Swedish forests. In sum, this was not only an expensive risk transfer but an inferior one.

5.2. *Neonicotinoids – leading to worse outcomes for the bees*

Since the late 2000s, a group of novel insecticides classed as neonicotinoids have come under increasing scrutiny over their environmental impacts, especially over their effects on bees' health. Used as systemic pesticides, neonicotinoids are a class of neuro-active insecticides chemically similar to nicotine. They have become the most widely used class of insecticides with a global market share of over 25% (Van der Sluijs et al. 2013). Relatively safe for humans and other vertebrates with less toxicity than previously used organophosphate and carbamate insecticides (Tomizawa and Casida 2005), they are focused on targeting pests that feed on crops selectively. Generally used as seed treatments rather than sprayed across crops, they can reduce the amount and frequency of pesticide applications (Fairbrother et al. 2014).

However, a range of studies already suggested links between the use of neonicotinoids and adverse ecological effects, including honeybee colony collapse disorder (CCD), the reduction of wild bee density and bumblebee colony growth, and loss of insectivorous birds due to a reduction in insect-prey populations (e.g. Cresswell 2011; Girolami et al. 2012; Hallmann et al. 2014; Rundlof, Andresson, and Bommarco 2015; UNEP 2010).

In 2012, due to increasing demands from some stakeholders and Member States, the European Commission asked EFSA to assess the safety of some uses of three of the most widely used neonicotinoids (clothianidin, imidacloprid and thiamethoxam), in response to growing concerns about their impact on bees.

Industry provided additional data to respond to the concerns. Field studies which allowed testing under realistic environmental conditions showed that neonicotinoids had no significant effect on honeybee health. As such, it seemed that under 'realistic field conditions' neonicotinoids do not pose an unacceptable risk to bees. In contrast, research conducted in controlled laboratory settings exposed the risks of neonicotinoids for bee health.

Triggering a wave of media attention, Whitehorn et al.'s (2012) study published in *Science* showed a severe negative impact of 'field relevant' doses of imidacloprid on bumblebee colonies (Whitehorn et al. 2012). Researchers argued that neonicotinoids are bioavailable to pollinators for most of the year due to their wide application, persistence in soil and water and potential for uptake by succeeding crops and wild plants (Van der Sluijs et al., 2013). Neonicotinoids can be present in honeybee hives causing a wide range of adverse effects in their colonies (Cresswell 2011; Decourtye et al. 2004).

In 2014, the self-appointed Taskforce on Systemic Pesticides published a series of papers in the journal *Environmental Science and Pollution Research,* assessing the impact of neonicotinoids on biodiversity and ecosystems, concluding that neonicotinoids pose a serious risk to a broad range of non-target invertebrates (The Task Force on Systemic Pesticides 2014; Van der Sluijs et al. 2014).

Yet, while some academic research has suggested that neonicotinoids have strong negative effects on bees (Rundlof, Andresson, and Bommarco 2015; Whitehorn et al. 2012), there is no scientific consensus as to whether these effects would happen to the same extent in realistic field situations. Laboratory studies have been criticized for giving bees unrealistically high doses of neonicotinoids and for not providing any other choice of forage. Regular daily feeding of chemicals for a prolonged period of time likely differs from intermittent exposures to nectar and pollen in the field (Cresswell et al. 2014). In turn, this may make such studies less relevant to real-life exposure in the field than researchers propose (United States Department of Agriculture 2014).

As the scientific evidence resulting from field vs. laboratory studies was contradictory, it could thus be used to support already existing views. The gaps in understanding meant that different policy conclusions could be drawn according to the weightings given to the scientific findings and to those of different interest groups (Godfray et al. 2015). A polarized political debate clouded in uncertainty ensued.

EFSA concluded that neonicotinoids can pose an *unacceptably high risk* to bees, arguing that the industry-sponsored science, upon which regulatory agencies' claims of safety relied, could not demonstrate the absence of certain risks. EFSA's scientists were unable to finalize risk assessments for some authorized uses, identified a number of data gaps and also highlighted that the risk to other pollinators should be further considered (EFSA, January 2013a). That said, in many cases the European Commission itself has not had a problem in authorizing the use of a number of bio pesticides.

Yet, Rimkute (2015) suggests that *extra efforts were taken by the commission (and followed by EFSA) to justify the inclusion of studies proving a risk and excluding studies suggesting that there was no risk* (Rimkute 2015, 10). Rimkute is critical that EFSA's conclusions relied almost exclusively on laboratory research (from academic scientists), excluding a notable amount of evidence from field research (conducted by industry).

Nevertheless, applying the precautionary principle and in line with public opinion and NGO lobbying – in April 2013 – Member States voted for a two-year suspension of several uses of these three neonicotinoids. Eight Member States (including the UK) voted against the motion, while four abstained. The UK's environment minister, Lord de Mauley responded to the use suspension:

> Having a healthy bee population is a top priority for us but we did not support the proposal because our scientific evidence doesn't support it. We will now work with farmers to cope with the consequences as a ban will carry significant costs for them.

Adding to the issue was a leaked memo by Henk Tennekes (from the International Union for the Conservation of Nature (IUCN)), which implied that a group of scientists from the IUCN affiliated with the task force (who had conducted the academic studies) agreed – in advance of obtaining the data – on the research papers to be published to demonstrate the negative impact of neonicotinoids on insects, birds and other species. It appeared that *Beegate* was deliberately engineered on the basis of questionable evidence by the IUCN, headed by one of the co-founders of the Dutch WWF and funded by the EU (Miller 2015). Miller suggests that some scientists and EU authorities, were colluding, meaning that business and farming interests stood little chance. The European Crop Protection Association (ECPA-representing many

of the companies producing crop protection products) argued that this memo discredits the task force on systemic pesticides set up by IUCN.

However, Tennekes responded (Volkskrant 2014):

> if we do not ban neonicotinoids, we will be on the threshold of an ecological catastrophe. Entire ecosystems will collapse due to insects going extinct. Of course there was a campaign plan, and the participants knew that. I get that some see this as an unscientific approach but in this situation I think it is entirely justifiable.

To date, the link between neonicotinoids and honeybee decline is far from clear, with a range of other factors coming into play (Neumann and Carreck 2010). Moreover, the European Academies Science Advisory Council (EASAC (European Academies Science Advisory Council) 2015) criticizes the focus on honeybees arguing that it has distorted the debate around neonicotinoids, as their widespread use may have a damaging impact on a wide range of organisms (such as bumblebees and butterflies) which aid pollination and natural pest control, as well as on biodiversity.

However, although it is difficult to present a definite analysis at this stage, the costs of the EU moratorium on neonicotinoids are already becoming evident. The unintended consequences of applying the precautionary principle in this case are risk-risk tradeoffs. It is still unknown whether the EU ban has succeeded in diminishing pesticide risk to bees per se. Rather, there appears to be a negative risk transfer based on uncertain and highly polarized science.

The unintended consequences of removing neonicotinoids meant that other possibly more harmful products were being used instead. One of the advantages of neonicotinoids is that they are less environmentally damaging than many older pesticides (such as pyrethroids) as they are generally used as seed treatments rather than sprayed. While environmentalists urge the transition to pollinator-friendly alternatives rather than neonicotinoids for the sake of sustainability of ecosystems, alternatives can have worse outcomes for bees and other pollinators. Carreck (2015) argues that the ban could do more harm than good, as farmers would now spray crops multiple times with older pesticides that may be more harmful to wildlife, including bees.

The ban also means that certain pests are returning. In Germany, the European Union's biggest rapeseed producer, the Deutsche Bauernverband warned that there now is significant damage to young rapeseed plants from insects (e.g. flea beetles) which growers are unable to control due to the EU ban on neonicotinoids (Agrimoney 2014). In the UK, farmers are reporting significant crop damage to oilseed rape because of the ban on neonicotinoids. The moratorium has already caused huge damage to European agriculture – it is estimated that the costs to British farmers alone are over £600 million (Booker 2014). The National Farmers Union is strongly concerned by the extent of oilseed rape crop damage resulting from the lack of availability of neonicotinoids last autumn (AHDB (Agriculture and Horticulture Development Board) 2015). Overall losses from cabbage stem flea beetle in the current oilseed rape crop in England and Wales (the first to be sown without the chemicals) are judged to be 5%, equating to an estimated 22,000 ha of lost crop (AHDB (Agriculture and Horticulture Development Board) 2015).

By conducting a detailed risk-risk analysis incorporating these tradeoffs prior to their decision-making, the EU Member States might have been able to avoid such negative economic and environmental outcomes. Existing scientific research, be that driven by industry funding or environmental ideology, was obfuscated by

predetermined objectives. It now remains to be seen whether the current moratorium will be upheld in the light of the environmental and economic risks it has introduced.

5.3. *Learning by listening: Tysabri*

In late 2004, Tysabri[1], a drug produced by Biogen Idec and Elan, was fast track approved by the US FDA for patients with relapsing forms of multiple sclerosis (MS) following 1 year of clinical trials. At the time that the drug was US FDA approved. Its press release noted that:

> This innovative treatment for multiple sclerosis represents a new approach to treating MS – exciting news for patients with this serious disease … while we eagerly await long-term results from ongoing clinical trials, we have reason to believe that Tysabri will significantly reduce relapses in MS. (FDA 2004, in Institute of Medicine 2014, 54)

FDA provided accelerated approval for Tysabri as it took the view at the time that the new drug provided substantial benefits to patients with the disease. Four months after the accelerated approval, the drug was voluntarily withdrawn from the US market by the US sponsor (Biogen Idec) because of 3 cases of the rare but life-threatening Progressive Multifocal Leukoencephalopathy (PML), a rare opportunistic viral brain infection, among patients taking Tysabri. FDA began questioning itself – whether it had been wise to grant accelerated approval, as it had been done on the basis of 1 year of clinical trial data rather than the usual two. At the time, US FDA did not feel that it had a scientific understanding of the magnitude of the risk to patients taking Tysabri. In addition, FDA wanted to clarify whether there were any possible and identifiable risk factors that would help explain why some patients got PML and others did not. If these risk factors could be scientifically proven, it would help FDA make a decision to allow the remarketing of the drug with clear warning labels.

By September 2005, the sponsor had done extensive research on the safety of Tysabri and, based on this information, requested FDA to reauthorize the use of the drug (Institute of Medicine 2014). FDA took this information into account and began conducting its own review into the drug focusing specifically on how big the risks of PML actually were to patients taking Tysabri. Was Tysabri a risk superior product in terms of preventing MS relapses vis-à-vis PML or did the risk-risk trade-off not really exist? At the same time as this Review was being conducted, MS patients themselves complained about the initial decision to withdraw the drug in the United States arguing that the regulators were far too risk-averse. They felt the drug was highly effective, compared to the other drugs available in its class, and when a FDA advisory committee met in March 2006 to discuss its Review on the future of Tysabri with other experts, two dozen patients testified that the drug should come back on the market. Those testimonies, as well as surveys showing that a majority of MS patients would either probably or definitely use the drug should it come back on the market, as it was more effective than similar drugs in the area (Calfee 2006), persuaded the Agency to put Tysabri back on the market in June 2006, albeit with some restrictions (Institute of Medicine 2014). As the Deputy Director for Clinical Science and Acting Deputy Director of Office of Drug Evaluation 1, CDER, FDA Dr. Robert Temple noted:

> … while patients plainly understood the risk that contracting PML could be fatal, they provided 'powerful personal testimony' in favour of reintroducing Tysabri. In response, FDA allowed marketing of Tysabri to resume, accompanied by an extensive risk mitigation plan that included requirements for strict labelling and safety information; controlled distribution; and a prospective, observational post marketing study, following at least 5000 patients for 5 years. (Temple in Institute of Medicine 2014, 29)

Interestingly, surveys carried out 6 years after the market introduction showed that patients felt that the Agency overstated the risks of getting PML by taking Tysabri compared to the risks of MS relapse when not taking the medicine (Miller, Karpinski, and Jezewski 2012). One of the reasons for this was that the patients felt that too much of the discussion surrounding Tysabri was on the risks associated with PML and that there was not enough discussion on the benefits of the drug. In other words, they felt that the benefit–risk communication regarding Tysabri was unbalanced (Institute of Medicine 2014).

Unlike the FDA, EMA did not put Tysabri on fast track approval in 2004 at the time when FDA did. After examining the PML data, and noting that in fact Tysabri was in many cases a better MS drug than the other ones on the market, it decided in Spring 2006 to authorize the approval of the drug albeit with some restrictions and warnings that Tysabri can cause PML. Since the reintroduction in the US and the approval in Europe in 2006, there have, as of September 2013, been some 401 cases of PML worldwide caused by Tysabri.

Tysabri is an example of how regulators can change their minds over time as the scientific uncertainty is reduced. The product was withdrawn in 2004 as a precautionary measure. The sponsor and the regulators were surprised to find PML amongt the patients taking it as it is such a rare disease. With time, however, as the regulators began understanding under what conditions the MS patients taking Tysabri developed PML they took the view that in a risk-risk tradeoff sense the reauthorization of Tysabri made sense.

The studies done by the sponsor noted that patients were at increased risk of getting PML if patients:

- Had in the past been infected by the John Cunningham Virus;
- Had been taking Tysabri for more than 2 years;
- Had received certain other medicines that could weaken one's immune system before starting Tysabri;
- Or more importantly had a combination of all three.

In so doing the regulators, assisted by the sponsors, were able to help minimize the risks of patients getting PML when taking Tysabri. Throughout the whole re-authorization process as well as afterwards, the sponsor worked with regulators, patients and others, sharing the knowledge they had gained and in so doing decreased the scientific uncertainty around the drug. As Dr Carmen Bozic, Senior Vice President, Global Development at Biogen noted:

> Every time we learned something new, we should share it with the regulators, we would share it with prescribers and patients, and we did it through multiple avenues, with the label being the primary approach. (Bozic in Institute of Medicine 2014, 58).

At the end of the day, Tysabri was a risk superior product.

6. Conclusions

Risk-risk tradeoffs are all around us. They are caused by everything from unscientific decision-making to the growth of bounded specialization. They are found in a number of regulatory sectors ranging from energy to pharmaceuticals. Some of these risk-risk tradeoffs lead to risk inferior and expensive outcomes. In some cases, however, when all the parties are able and willing to work together in an evidence-based fashion one can successfully address risk-risk tradeoffs as was the case with Tysabri.

7. Recommendations

What is needed to reduce the number of risk-risk tradeoffs that-policy makers take, and going forward how can we help ensure that regulators and policy-makers are better equipped to avoid risk-risk tradeoffs? In this final section of our paper, we put forward a number of recommendations.

7.1. Increasing the transparency behind risk management decisions

Over the past 15 years or so, policy-makers, NGOs, journalists and others have been pushing certain European risk assessment agencies such as the European Food Safety Authority to become more transparent in how they make their scientific decisions (Corporate Europe Observatory 2011, 2012; Robinson et al. 2013). These individuals are worried that EFSA and similar bodies have been captured by industry or special interests and therefore their decisions need to be carefully examined and monitored (Corporate European Observatory 2012). What is interesting to note, however, is that academics, NGOs, stakeholders and others do not, to the same degree, ask the risk managers themselves to make their decision-making processes transparent. This needs to be addressed. In many cases, risk managers make non-evidence-based decisions, thereby, at times, leading to unnecessary risk-risk tradeoffs, without justifying the reasoning behind their decision-making, as discussed in a powerful Head of National Food Agencies report (Heads of National Food Agencies 2012). In other words, when risk managers make unscientific decisions, such as ignoring the underlying independent risk assessment, they should be asked to explain their reasoning behind that decision. As HoA themselves note:

> The risk management process should be transparent, consistent and fully documented. Decisions on risk management should be documented so as to facilitate a wider understanding of the risk management process by all interested parties. (Heads of National Food Agencies 2012)

7.2. Regulators and policy-makers need to become better communicators of uncertainty

One of the key tools to help eliminate risk-risk tradeoffs is for regulators and policy makers to become better communicators of uncertainty. There is a belief in some policy circles that all kinds of scientific uncertainties are bad. This is not necessarily the case. As we saw with the Tysabri case, research indicated that patients are willing to tolerate high levels of scientific uncertainty when the benefit to risk ratio is large (Schwartz and Woloshin 2011). Furthermore, scientific uncertainty can and should be better structured for policy-makers, the publics and concerned stakeholders (Fischhoff

and Davis 2014). If we are able to simplify or categorize scientific uncertainty, this will not only help policy-makers to get a firm grasp of them but also lead the publics and stakeholders to better understand where the missing variables are (Fischhoff and Davis 2014; Institute of Medicine 2014). As Fischhoff and Davis argue:

> … communicating scientific uncertainty requires both simplifying and complicating normal scientific discourse. On the one hand, the uncertainties that it addresses must be reduced to their decision-relevant elements. On the other hand, the uncertainties that scientists fail to mention must be uncovered. Which uncertainties to subtract and add depends on the decisions that the communications are meant to serve. (Fischhoff and Davis 2014, 13664)

Developing so-called mental model procedures, an evidence-based risk communication tool, and using other decision science methodologies will assist regulators to categorize uncertainty (Casman et al. 2000; Fischhoff et al. 2006). As Fischhoff and Davis note:

> Communicating uncertainty requires identifying the facts relevant to recipients' decisions, characterizing the relevant uncertainties, assessing their magnitude, drafting possible messages, and evaluating their success. (Fischhoff and Davis 2014, 13670)

Mental models, done properly, address these issues (Morgan et al. 2001).

7.3. The importance of evidence-based policy-making on the member state level

Member State regulators need to better understand possible European consequences of pushing for ideologically based regulatory decisions in their home markets. Taking un-scientific regulatory decisions, be it arguing for the phase out of all human-made chemicals in Sweden or lobbying for the phase out of nuclear power in parts of Europe, which is of concern to Austria, will enable the regulator and or politician in that country to win 'green brownie' points in the home market but it could have significant economic consequences in other parts of Europe (Lofstedt 2011). What needs to happen is twofold: Firstly, national policy-makers should help push regulatory agencies within the member states to work together to identify what risks should be prioritized based on scientific evidence and why. It makes little sense, for example, for the SFA and the Swedish Chemical Agency to use different definitions of the precautionary principle as well as different risk analysis methodologies. This ensures that regulators are looking at the wrong regulatory issues, such as the then Swedish Environment Minister's decision to sue the European Commission for the delay in bringing forward the criteria to regulate endocrine-disruptors in specific EU legislation, rather than attempting to reduce radon levels in schools or warning children and women of childbearing age of the dangers associated with consuming fatty fish from the Baltic Sea (Lofstedt 2014). Secondly, the European Commission should be encouraged to bring together the Member State regulators on an annual basis for an evidence-based policy-making summit, where the purpose would be to help Member State regulators understand the broader economic consequences of their domestic actions. This summit should be arranged by the Secretariat General and held in Brussels.

7.4. Avoiding path dependencies and sunk cost biases

One reason why risk-risk tradeoffs occur is because in many cases political parties, pressure groups or regulatory agencies are set in their own ways. They have taken stances on certain (usually emotive) issues and have gained a reputation for doing so. When this occurs, it is difficult to change to a new policy trajectory. If a political party has in the past won elections for being anti-nuclear power, for example, it is difficult to expect that political party to become pro nuclear power even though the science may be supporting such a switch. Similarly, anti-nuclear campaign groups will unlikely become pro nuclear as they have placed so much time and effort (sunk cost) being anti-nuclear. In other words, history matters as developed policy trajectories are difficult to reverse (Hacker 2002; Kahneman 2011; Pierson 2004; Tversky and Kahneman 1974). A case in point is the Barseback example. The politicians achieved a very expensive, risk inferior outcome based on the Social Democrats working with the Center Party. The Social Democrats knew that in order to get an agreement with the Center Party, it had to show an ability to phase out nuclear reactors even though it made little economic or environmental sense. Going forward, regulators and policy-makers need to first recognize path dependency and sunk cost bias when negotiating with other parties and secondly, ensure that such un-scientific reasons are quickly taken out of the negotiations. When that is not possible, the negotiating party needs to find other bodies to work with – e.g. in the case of Barseback, the Social Democrats should never have contemplated opening negotiations with the predictable anti-nuclear Center Party.

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Note

1. Although Tysabri is arguably a US-based case study as the decision was taken in the US to take it off the market before it was approved in Europe, it is treated as a European case study as European regulators have repeatedly used it as an example of a classical risk-risk tradeoff (e.g. see Eichler et al. 2013)

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