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## **Toxic Ignorance. How Regulatory Procedures and Industrial Knowledge Jeopardise the Risk Assessment of Chemicals**

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### **Abstract**

STS research has shown that processes of producing ignorance have been structurally embedded in the evaluation and regulation procedures of the tens of thousands of hazardous chemicals present on the market. What is the role of industrial actors, regulatory experts and scientific data in the institutionalisation of ignorance? Analysing two European expert panels demonstrates that institutionalised ignorance makes it difficult to justify and implement stringent regulations covering all types of population exposure. First, experts get caught up in ways of using scientific data that tend to reinforce industry's influence on the production of regulatory knowledge (and ignorance). Second, several constraints press experts to play by the rules of the 'regulatory science' game, even if this undermines their capacity to challenge the dominant rules of expertise and the relevance of data. Third, the routine functioning of regulatory science tends to favour industry-sponsored studies, while obscuring other knowledge that could have been useful for regulation. Together, these pressures illustrate the concept of *toxic ignorance*, which weaves together research on institutionalised ignorance, the political economy of science and the social study of toxics. This concept provides a fruitful way of exploring how ignorance is enacted in the public assessment of chemicals, as well as in other instances where the toxic consequences are indirect.

**Keywords:** chemical regulation, regulatory science, industry influence, expertise, toxic ignorance.

## Introduction

*Offices of the European Union in Luxembourg, March 2014.* The experts of the Scientific Committee on Occupational Exposure Limits (SCOEL) are about to return to their work: reviewing scientific knowledge in order to propose Occupational Exposure Limits (OELs) to protect workers exposed to chemicals. This afternoon's discussion focuses on the case of a well-known carcinogen, formaldehyde, and there is some tension in the air. One of the authors of an industry-funded study specifically designed to question a limit value proposed by the SCOEL (and deemed by the industry too costly, because it was too stringent), has just given a PowerPoint presentation in fairly classic scientific symposia format, presenting the methodology and main results of the study. It is time for the debate to begin. After a brief exchange with the experts, the author leaves the room. The ensuing discussion includes both consideration of the study's limitations and a comparison with a similar study conducted a few years earlier. Why does this trial feature only males (41 total), when there were eleven males and ten females in the previous one? The small number of subjects is a source of contention in both cases. As the debate proceeds, the transgressive nature of the presentation fades, and the discussions between experts resume their course. In spite of its origin and its explicitly industrial funding, this *ad hoc* study, specially designed to influence the work of the SCOEL, is to have a lasting impact on the debate around the value of formaldehyde.

Publicised mobilisations and controversies around recent scandals such as PFAS (used in, for example, non-stick cookware) or glyphosate (the world's most popular herbicide) raise political and social questions about the regulation of toxic products – questions that are at once the subject of both appropriation and development in the social sciences. The legal battle over PFAS depicted in the film *Dark Waters* (2019) is almost a textbook example of how DuPont strategies sought to sequester scientific knowledge (in the form of incomplete, partial or confidential data), resulting – for more than 60 years – in regulatory inaction (Lyons, 2007). The glyphosate affair, on the other hand, has illustrated the fact that regulatory agencies rely not on independent data, but on *ad hoc* studies designed, funded and published by industry. These studies may indeed use the standardised test protocols of 'regulatory science' – but their aim is to bring products to market (Demortain, 2013; Sismondo, 2009). As environmental issues make headlines, Science & Technology Studies (STS) work on the institutional production of ignorance in the regulation of toxics is now in the spotlight, as never before. On closer inspection, however, very little research has focused on what goes on *inside* the expert panels charged with assessing toxic chemicals – even though this is precisely where the scientific evaluation of these products is carried out.

The vignette set out above captures hitherto-neglected dimensions of the daily work of the experts who sit on chemical assessment committees. It suggests how non-scientific issues (such as the cost of compliance with worker protection measures) can influence the agenda of such panels. It also shows how data produced by the industry both flood, and guide, their daily work. In so doing, it illustrates the value of following regulatory expertise 'in the making' to understand the institutional logics that produce institutionalised ignorance in the public regulation of chemicals. Based on these premises, this article sets out to explore three main research questions: How do the expert panels in charge of assessing industrial chemicals perform their task? What sorts of toxicity data and regulatory procedures guide their activities? How does regulatory science favour certain studies and knowledge-claims even as it obscures knowledge that is absent, yet crucial to regulation? To answer these questions, we conducted ethnographic observations of the activities

of two expert panels in charge of assessing the risks of toxic substances in the European Union (EU) within the fields of occupational health and the Registration, Evaluation, Authorisation of Chemicals (REACH) framework, over a total period of two years.

In addition to showing how public regulatory expertise came to endorse those specific forms of knowledge and ignorance that are backed by the production of industrial data, we also offer an analysis of how expert committees operate in the face of these institutionalised forms of ignorance. In so doing, we identify several institutional mechanisms that serve to organise and legitimise both the proximity to the industry of these committees, and the reliance on industry data that makes this a normal (even central) dimension of regulatory activity. The expert groups we followed are, we argue, kept in a situation of *toxic ignorance*<sup>1</sup> in which they are confronted with operating rules and data constructed by and for the industry, and this makes it extremely difficult for them to implement stringent regulations covering all types of population exposure.

Our analysis contributes new insights to STS research and theory on institutionalised ignorance that has shown how organisations produce ignorance. It extends this literature by showing how expert panels, through the way they work and use knowledge, contribute to the production of specific forms of ignorance. It also highlights how the influence of industry is not limited to corruption or manipulation but includes mechanisms that are both more complex and more discreet. We start our demonstration by presenting our analytical framework and discussing how it is both in line with existing work on institutionalised ignorance, and an extension to it. We then describe our methods and data before presenting our empirical analysis. Following an overview of the two regulatory schemes investigated, we discuss the various mechanisms through which toxic ignorance plays out, within the expert panels we observed.

### **Revisiting Institutionalised Ignorance in the Public Regulation of Toxic Substances**

STS has long been interested in the institutions, procedures and knowledge on which the control of industrial toxins is predicated (Brickman et al., 1985). A lot of research has been interested in the toxicity assessment technologies used for regulatory purposes – and on what has been called ‘regulatory science’ (Demortain, 2017; Irwin et al., 1997; Jasanoff, 1990). We propose using the concept of *toxic ignorance* – which we define as the knowledge gaps resulting from the interplay between the operating rules of expert opinion and regulatory agencies. This *toxic ignorance* both forces these agencies to limit their fields of investigation to very specific problems, and limits the types of knowledge on which they rely, because they are a hybridisation of industrial influence on the regulatory process and a quest by regulatory agencies to rely on data (regardless of provenance) to make decisions. In bringing a social sciences analysis of the production of ignorance together with the political economy of science and the politics of regulating a permanently toxic world, we see the *toxic ignorance* concept as a prism through which to study how institutionalised ignorance and ‘ignorance-based’ regulatory science are enacted in regulatory settings.

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<sup>1</sup> This expression was first coined by NGO Environmental Defense Fund, in a report that highlighted the lack of safety testing for top-selling chemicals in the US (EDF, 1997). In using this term in a social sciences analysis, we want to emphasise the social logics underlying this lack of data on toxic substances, and prevailing in expert groups as they grapple with knowledge emanating from the industry.

First and foremost, the concept of *toxic ignorance* builds on the literature on the social production of ignorance. Early research in this field has investigated how the production of knowledge and ignorance plays out in (and affects) the public regulation of toxic products. For scholars in the field, a first line of research has consisted of exploring cases where ignorance is intentionally produced and maintained by different (sometimes competing) groups of actors. A number of contributions have highlighted the role played by corporations in controlling the production (or dissemination) of potentially troublesome knowledge in the case of products such as vinyl chloride, lead (Markowitz & Rosner, 2002) and asbestos (McCulloch & Tweedale, 2008). These studies have investigated how the industry has been able to influence various regulatory processes by encouraging false controversies or through producing doubt (Michaels, 2008). They have also shown how industry has mobilised to limit the regulatory capacity of agencies in various health and environmental policies (Krimsky, 2004; McGarity & Wagner, 2008). Yet this literature has also explored how ignorance could also be a resource for administrations – especially those in charge of assessing chemicals (pesticides, industrial chemicals and even pharmaceuticals). Some studies have shown how regulatory agencies tend to use industry-fuelled ignorance ‘strategically’ to continue making decisions (McGoey, 2012, 2019), while others have explored how some organisations try to avoid uncomfortable knowledge (Rayner, 2012), or need ambiguities in order to continue functioning (Best, 2012). Though these contributions have highlighted mechanisms of wilful ignorance production, they have too often limited themselves to a reading in terms of industry or governments taking advantage of (or subverting) scientific knowledge.

Closer to what we propose here, a second line of research has investigated the mechanisms behind the unintended production of ignorance, or institutionalised ignorance. Investigating the debates over the role of pesticides in causing Colony Collapse Disorder (CCD) affecting bees, Kleinman and Suryanarayanan’s premise is that dominant approaches in toxicology contribute to an institutionalisation of ignorance. They have shown that ‘Bayer shapes ignorance production through active participation in, and contributing to, processes of knowledge production in the epistemic form that has gained broad legitimacy in academic and regulatory settings of honey bee toxicology’ (Kleinman & Suryanarayanan, 2013, p. 507). Even if industry does play a central role, it does so only indirectly, via the promotion of an epistemic form (a research perspective measuring only the effects of individual compounds at high doses) that is already present in the scientific field, promoting a focus on toxicological research in line with its interests. Therefore, all Bayer had to do in order to keep its pesticides on the market was make use of the institutional logics that contribute to producing ignorance in regulatory toxicology.

In their work on the regulatory response to chemical pollution generated by the flooding of New Orleans by Hurricane Katrina, Frickel and Edwards show how the very functioning of the administrations in charge served to generate forms of ignorance – even without the direct intervention of economic actors. When the water receded, it left behind a sludge, whose toxicity levels had to be determined; a dozen state and federal agencies were charged with assessing those risks. Although 400,000 chemical analyses were conducted, the way these agencies handled the data resulted in as much ignorance as it did knowledge. Indeed, rather than carrying out an evaluation of the risks encountered across the whole city, these administrations focused on just a few sites in which pre-existing pollution standards already existed. Chemical tests also had to concentrate on the few chemicals for which a maximum exposure limit for the population existed. As the authors put it, ‘over time, knowledge about fewer contaminants in fewer places deepens.

Simultaneously however, knowledge about greater numbers of contaminants and their potential distribution across larger land areas diminishes' (Frickel & Edwards, 2014, p. 229). Similar processes are taking place in the expert committees we observed, where the production of ignorance is a fairly direct result of institutional rationales.

Using the concept of *toxic ignorance*, we propose combining research on institutionalised ignorance with the literature on the political economy of regulatory knowledge production, thus drawing attention to the central role played by chemical companies in the production of regulatory science and data. In the late 1990s, several scholars used the example of pesticides to emphasise the actions of the chemical industry in the different facets of regulatory science – for instance the funding of research, the development and validation of regulatory tests and the management of regulatory compliance testing (Irwin et al., 1997). Since then, others have undertaken to study this 'vast economy of testing and evaluation, complete with its own infrastructures, industries and professionals' (Demortain, 2017, p. 141), investigating how industry-sponsored studies have tended to publish positive results rather than negative ones (Krimsky, 2013; Sismondo, 2008), showing how corporate funding influences the production of scientific publications. They have also analysed industry's influence on the design of regulatory tests for toxic substances (Creager, 2021) as well as on the toxicological data used for regulatory expertise (Krimsky & Gillam, 2018; McHenry, 2018). Based on the case of PFAS, Richter and colleagues have used the expression 'unseen science' to describe this industry-produced knowledge 'conducted but never shared outside of institutional boundaries' (Richter et al., 2018, p. 705). We see this as a central feature of regulatory knowledge production.

Lastly, *toxic ignorance* is inspired by recent work on the social study of toxic politics, which has insisted on the concrete and material *specificities* of industrial chemicals and their regulation in the course of a historic period we might refer to as 'late industrialism' (Fortun, 2012). Adopting a socio-historical perspective, Boudia and Jas (2013, 2014) have documented how the proliferation of chemicals and intensification of their use since 1945 has been accompanied by the adoption of complex administrative systems and science-based regulatory tools. The design of these devices proved immensely challenging, however. Hepler-Smith (2019) has shown how the dominant framework for assessing chemical substances – through categories, lists and classification systems, which he calls 'molecular bureaucracy' – has had pervasive consequences not just for administrative capacity to control toxic substances, but also for public health and the environment (Casper, 2003; Ross & Amter, 2010). The 'molecule by molecule' approach, Hepler-Smith shows, has made it even more difficult both to assess tens of thousands of chemicals and to regulate long-term environmental pollution. Emerging research on toxics explores the challenges associated with growing environmental contamination through the study of certain highly-polluted places (Auyero & Swistun, 2009; Spears, 2016), high-profile toxic products (McCulloch & Tweedale, 2008; Richter et al., 2018), and more transversal research (Liboiron et al., 2018; Mitman, 2004; Tsing et al., 2020). Given that such chemical pollutions have become massive and widespread (Boudia et al. 2022), we believe that the fact that the chemicals regulated are industrial toxicants (massively produced, present in our every life, yet poorly documented) is key to understanding their regulation. Our conscious use of the adjective 'toxic' in the expression *toxic ignorance* also aims to take into account the negative effects of these products in our analysis.

We believe these different lines of research can help reinforce the dialogue between institutionalised ignorance and public policy research (Paul & Haddad, 2019). Inspired by studies specifically intended to analyse the pervasive power of corporations in public policy (Aguiton et al., 2021; Henry, 2017; Henry et al., forthcoming), this article posits that the *toxic ignorance* concept is capable of offering a more explicit interrogation of interactions between industry and expert groups in the context of chemical regulation. Our hypothesis is that the strategies and action programmes of these two categories of actors develop as dialogues or interactions in response to specific problems, rather than independently of one another. It seems necessary, then, to analyse the diversity of forms of industry influence on the building of expert opinion, as well as of the vectors and processes through which power relations manifest themselves at the moment in which expert panels hosted by regulatory agencies must find solutions to the problems they encounter. Such an approach can lead to an understanding of expert opinion and assessment rules and protocols as the result of compromises worked out between industry representatives and the various regulatory bodies. Owing to the existence of specific forms of knowledge mobilised in the course of the regulatory process, the boundary between knowledge and ignorance therefore becomes more challenging to locate, making it difficult to say whether they constitute scientific knowledge, pure ignorance, or forms of knowledge explicitly negotiated between industry and regulatory agencies with the twin aims of being able to continue regulating for the agencies while also enjoying continued access to markets (for the industry).

Our analysis is based on two highly original methodological choices. The first entails conducting ethnographic observations of expert committees (see next section), making it possible to analyse both the expert report production process and the regulatory decisions made at its various stages, from the experts' initial reflections through to drafting. An analysis of the dynamics of discussions held during the sessions is also included. This method allows us to understand how the industry presence manifests itself in practice, in interactions and in the work of the experts. Since ethnographic observation is limited in time, it is in some cases supplemented by analysis of meeting minutes, which can be more closely interpreted by referring to the observed interactions. These data collection processes allow us to show how both an observed lack of usable data, and choices to use industry-supplied data, are the outcomes of both a long-term process and a search by these actors for practical solutions to the problems they find themselves facing. They also show how experts are led to seek practical solutions to their most immediate problem (the issuing of an opinion), regardless of the state of knowledge they have at their disposal.

A second methodological choice involves putting the work of the experts (as observed by ethnography) into perspective alongside the scientific data on which their work is based. It is true that ethnography is unable to explain the extent to which the work of the expert groups is embedded in historic power dynamics, which crystallise in line with the state of scientific knowledge on which these experts rely. This state of knowledge and these forms of ignorance refer to the institutionalisation of lasting inequalities, which gradually become less visible as they become increasingly self-evident (Gaventa, 1980; Pierson, 2015). As work on the notion of *undone science* has clearly shown, the distribution of knowledge and ignorance is linked to the greater or lesser presence of the political, social and economic interests capable of promoting and financing research on a given matter. It thus refers both to structuring and power relations between actors, and to their relative ability to influence scientific research. This capacity is, for example, very unevenly distributed between multinational chemical companies and national trade union

organisations seeking to document the hazards of a product (Frickel et al., 2010; Hess, 2016). The knowledge on which the experts rely largely determines the types of responses and proposals they will be able to formulate at the end of their work. Even as they strongly orient expert opinion, both the knowledge produced and the ignorance maintained obey a certain pattern. In other words, irrespective of personal orientations and inclinations, an expert intervening in the regulation of a hazardous product will find it very difficult to do so without relying on knowledge produced and funded by, and for, industry. This upstream structuring of knowledge can therefore be analysed as a manifestation of power relations – even if little evidence of it remains.

### **An Ethnography of Institutionalised Ignorance in Regulatory Expert Panels**

In the course of our research, we became interested in two European schemes designed to regulate the risks associated with the use of chemicals in both the workplace and the general environment. The first is the REACH regulation, which was adopted in 2006 and governs the marketing of chemicals within the EU. The 30,000 substances within its scope are present in many products with which both employees and the general public come into contact on a daily basis – such as building materials, furniture and toys. National health agencies assess information on substances deemed suspicious on behalf of the European Chemicals Agency (ECHA). The most hazardous substances can then be subject to control measures. One highly original feature of REACH, as we shall see, is that it accords significance to economic data, which can be used to evaluate various options for the control of a hazardous product, from a cost-benefit perspective.

The other scheme we studied is that of the OELs mechanism, increasingly used in the field of occupational health within the EU. OELs are values, set molecule by molecule, above which workers should not be exposed. Once determined by regulatory authorities, OELs are incorporated into national and European regulations to govern occupational exposure. The European Community (and then the EU) have encouraged the use of limit values since the 1970s, and in 1990, a group of experts was charged with setting these values: this was the Scientific Committee on Occupational Exposure Limit (SCOEL). Whether they target occupational risks or the marketing authorisation of more widely used chemicals, such mechanisms place strong emphasis on expert scientific opinion, and involve various committees, both national (in France, OEL and REACH committees in the French regulatory agency ANSES) and European (SCOEL and ECHA).

This research is based on various types of materials. We conducted an initial ethnographic observation from within the French REACH committee (responsible for evaluating chemicals under REACH regulation), whose monthly meetings we were able to observe between May 2013 and June 2014. Another study was carried out, covering five SCOEL meetings held between March 2014 and March 2015. Ethnographic observation of these committees was conducted as non-participant observation. They accepted our presence as observers and we were able to bear witness to all the discussions, using a field notebook to record our observations. The observation of the REACH committee was facilitated by our agreement that we would share our insights with the experts (which we did, in October 2014). Our observation of the SCOEL committee was in turn facilitated by the fact that these were its final months of operation prior to a new directive reorganising its operations coming into force in 2015. At the time, the committees' chairs did not require ethical approval but did ask us to keep confidential business information and companies' names to ourselves. Interviews were then carried out with experts sitting on these committees and



with actors whose activities are directly related to those of these groups – namely industrial representatives and civil servants from relevant administrations. Lastly, we analysed the minutes of their meetings, as well as other scientific and regulatory documents, in order to understand the scientific and institutional landscape in which our observations were taking place.

## **1. Tackling the slowness and scarcity of scientific evaluation: how routine expertise came to rely on companies**

In the panels whose activities we observed, the availability of relevant toxicity data was a regular problem that could – surprisingly – always be solved, thanks to the framework in which they operate. Because of the need to set dozens of limit values as efficiently as possible, the SCOEL regularly relies on industrial data. The REACH procedures, however, simultaneously generate ignorance about a massive number of *substances* and knowledge on a limited number of their actual *uses*. These limits end up guiding the cases in which experts can effectively conduct their evaluations, even though this sometimes leads them to exclude dangerous substances whose uses are less documented, or for which regulatory derogations have been obtained.

### ***1.1. Relying on industrial knowledge to ‘rationalise’ the setting of OELs***

The use of industrial data was not implemented at the inception of the SCOEL. Analysis of the first years of the committee’s operation in charge of setting OELs at European level clearly shows how scientific experts and the European administration gradually came to turn to industry-related experts and scientists as a result of the difficulties they faced in acquiring scientific data to support proposals for limit values. Prior to the formal establishment of the SCOEL in the 1995 Directive, the European Commission had set up a more informal Scientific Expert Group (SEG), which had begun work on the development of limit values at European level. Early on, the committee’s minutes reflect the Commission’s desire to streamline and accelerate the process by reaching out to industry. Two years after the committee’s creation, collaborations with an industry-related association were already in the pipeline:

‘Possible mechanisms [of accelerating the establishment of limit values] include joint preparation of criteria documents with Member States or ECETOC [an industry-funded scientific organisation] [...]. Offers have been received from industry and from ECETOC for a representative to explain additional data on certain substances to the SEG. [...] ECETOC will provide criteria documents on 1,3-butadiene, styrene, methylmeth[yl]acrylate and n-butoxyethanol to the SEG.

Concern was expressed with regard to the objectivity of evaluations conducted by an industrial organisation. The SEG agreed that all criteria documents are considered for their individual merits and decisions on whether they could be used as a principal reference or as supplementary data would be taken on a case-by-case basis’. (Minutes SEG, 16<sup>th</sup> meeting, 14-15 Dec 1993).

This initial proposal for collaboration with industry thus gave rise to a discussion between experts regarding the specific risks and difficulties of setting up such relationships. However, as collaboration with the industry became more regular, these precautions gradually disappeared and

the primary objective of speeding up the expert opinion process was soon lost amid interminable scientific controversies.

The example of setting an OEL for 1,3-butadiene shows how this group of experts found itself trapped between ignorance and lack of data, and how the participation of ECETOC ended up delaying the very process it was supposed to accelerate. This case reflects a twofold shift in how the work of this expert group was conceived. The first shift involved outsourcing some of the scientific work to experts working with the industry. A year after it was commissioned, a first ECETOC report was submitted to the SCOEL; it was then discussed at the December 1993 meeting. The second shift entailed inviting industry-related experts to SCOEL meetings. This proposal from ECETOC was initially refused but then accepted, and industry scientists began presenting their work to the SCOEL experts. In March 1995, two ECETOC representatives took part in a SCOEL meeting ‘to provide additional information on butadiene’ (Minutes of SEG’s 21<sup>st</sup> meeting, 20-21 March 1995). Over the following years, there were regular discussions involving ECETOC experts during SCOEL meetings mainly on whether 1,3-butadiene was a carcinogen (a point that would have an impact on how the experts would go about setting the limit value). This controversy continued into 1999, when the SCOEL set its first limit value for this chemical. However, because of the lengthy negotiation process that had led to the adoption by the European Commission of a few limit values for certain carcinogens, it was only in 2017 that this OEL was definitively adopted.

Beyond the case of this particular product, the SCOEL’s debates during its first decade of operation show an evolution towards increasing prominence of industry-sourced knowledge as well as an industry presence in the debates that gradually became more regular. Parallel to the debates on 1,3-butadiene, various issues relating to the role of companies were addressed within the committee. For example, in 1995 there was an offer of service from industry in connection with the SCOEL’s work on 2-methoxypropanol, demonstrating the attention paid by industry to the work of this expert group. The committee’s response reveals the precautions taken at the time: ‘The SEG considered that it was necessary to examine the comments in the light of all available information before deciding at the next meeting whether a recommendation for further reading could be given’ (Minutes SEG 24<sup>th</sup> meeting, 12-13 Dec 1995). At the following session, discussion of the possibility of integrating external experts to the working groups set up within the SCOEL showed an attentiveness to possible conflicts of interest that might arise out of this situation (Minutes SEG 25<sup>th</sup> Meeting 14-15 March 1996).

Despite these misgivings, the following meeting (July 1996) welcomed industry representatives for the first time. Specifically, representatives from the mining industry came to discuss limit values for nitrogen dioxide. After that, the number of cases handled directly by the industry gradually increased. In 1997, nickel and nickel compounds were on the agenda, as well as hexavalent chromium – for which the criteria document was presented during the meeting by its industry-sponsored authors. Without drawing up an exhaustive list of the products for which the industry either educates or provides additional information, after about ten years of operation a very clear shift in the committee’s functioning can be discerned. This committee had originally been intended to bring together the independent experts responsible for scientific investigation of the creation of limit values, yet here it was, gradually becoming a forum for negotiating with industry on worker protection policies to be put in place at European level. From 1999-2000

onwards, the majority of substances discussed at SCOEL meetings were processed with the help of the affected companies, and there was less and less debate on precautions to be taken in relation to these industry reports, as the minutes of meetings for the year 2000 show clearly.

This routine working with industry is quite common in the case of OELs as well as in occupational risk management more generally, which actually primarily concerns employers. The use of limit values began earlier in the United States, where Threshold Limit Values (TLVs) are issued by the American Conference of Governmental Industrial Hygienists (ACGIH). These were then integrated into federal regulations, which have long been produced and used by hygienists working in industry as pragmatic exposure management tools (Henry, 2021; Murphy, 2006; Sellers, 1997). The case of SCOEL shows how the shift of limit values from the world of business into the world of regulation occurred via a transfer of industrial knowledge into the regulatory space, while rendering the origin of this knowledge less visible (Corn, 1989; Salter, 1988). This situation is fairly similar to the one analysed by Kleinman and Suryanarayanan (2013) in the CCD case (mentioned above); they examined how Bayer's influence over regulation involves modifying the modes of production of legitimate scientific knowledge in toxicology.

### ***1.2. Regulatory procedures that generate both knowledge and ignorance***

The SCOEL situation is not an isolated case. This gradual internalisation of the value (or even necessity) of working with industry can be analysed as one of the elements facilitating this way of doing things – which has become commonplace in producing public policy at European level (Robert, 2012), as the REACH system illustrates. Over a period of more than 40 years, several dozen European regulations had been awaiting evaluation by public experts of thousands of molecules – a task they were unable to perform since they lacked the necessary data. By the end of the 1990s, Europe's record on chemical control was appalling. Unable to either force companies to provide them with the necessary toxicity studies or conduct them themselves, the public authorities had managed to evaluate just a few dozen of the tens of thousands of substances. The European Commission decided, at this point, to overhaul the chemical regulatory framework. The distinguishing feature of the new REACH system is that it reverses the 'burden of proof' by forcing companies to share data on their chemicals. In so doing, it institutionalises regulatory procedures that generate both knowledge and ignorance. At the point of 'registration', companies share with the authorities general information about the *substances* they market. However, at the time of 'evaluation', what the experts are asked to assess are specific *uses* of these chemicals.

Across all the expert sessions that we were able to observe, experts regularly expressed concern about the 'generic' nature of the dossiers submitted by the industry. For example, when trying to assess the risks of nickel salts, widely used in the metallurgical industry, one of the experts said of this recurring difficulty:

**Expert 1:** 'Once again, our difficulty here is that we have to conclude with a high level of detail, on the basis of the very generic information provided in the registration dossiers. Anything about the uses that we might want to evaluate is scarcely mentioned in the dossiers. These elements are known to companies, but we only have the conclusions of their evaluations, and they are under no obligation to provide us with any more'. (Fieldwork notes, REACH committee, 2013).

This situation is the result of how the registration procedure functions. Companies are allowed a great deal of leeway in preparing their dossiers – a freedom that translates into the possibility of selecting those studies that seem to them most appropriate to describing the various toxicity endpoints (skin and eye irritation, acute toxicity, etc.) that they have to document. Though any chemical is characterised by the plurality of its uses and forms, the media in which it is transformed and the purities in which it circulates (different formulations can include various hazardous additives), the registration procedure allows companies to disappear these singularities. The functioning of registration mechanisms, which are typical of contemporary ‘molecular bureaucracies’ (Hepler-Smith, 2019), blatantly illustrates how a regulatory procedure designed for sharing data ends up institutionalising the production of ignorance.

As they tried to evaluate the different nickel salts, experts were to discover that even when useful studies were available, many uses were purely and simply excluded from the scope of REACH. In the same meeting, they realised that they were unable to assess the situation of miners involved in nickel extraction – even though a great many of these workers were contaminated by these compounds:

**Expert 2:** ‘We are well aware that nickel has to be extracted prior to reaching the various applications of these salts. Yet all this is completely excluded from REACH?’

**Expert 3:** ‘98% of nickel matte is extracted by a French company in New Caledonia. Yet REACH applies only in the European Union... Everything that has to do with occupational exposure in New Caledonia is therefore not covered by REACH’. (Fieldwork notes, REACH committee, 2013).

As these exchanges suggest, the extraction of nickel matte is a particularly significant mode of exposure. The problem raised by these experts stems from the fact that, unlike registration, the evaluation concerns *uses* likely to affect EU citizens, rather than *substances* (such as nickel sulphate, for example). Since New Caledonia is only a French-administered territory, any exposures happening there are excluded from REACH. In this case, even though the company extracting the nickel is French, exposures linked to the matte extraction cannot be included in expert analyses.

The reason for certain *uses* being excluded from REACH can often be put down to political and diplomatic compromises – signalling a willingness to relax the obligations imposed on the chemical industry. Another example of this is DEHP, a massively used plasticiser from the phthalate family (Boullier, 2019). This endocrine disruptor has, in theory, been prohibited under REACH since 2015. Certain *uses* are nevertheless excluded from the scope of the regulation – in particular when it is used as a component of manufactured goods produced abroad and imported into the EU. The US government secured this exception to the application of the regulation during REACH negotiations, accusing it of creating technical barriers to trade. Risks linked to the exposure of European citizens to the many imported products containing such plasticisers (PVC floors, shower curtains, plastic sandals) are consequently excluded from regulatory assessments.

These examples point to the ‘institutional logics’ that produce ignorance (Frickel & Edwards, 2014) – in particular the simultaneous production of knowledge and ignorance by regulatory

procedures. The case of nickel salts illustrates how regulatory procedures produce both ignorance, by sharing generic data on thousands of *substances* (registration), and knowledge, on a limited number of *uses* that fall within the scope of REACH (evaluation). As provided by the law, chemical registration procedures are usually designed in such a way as to force companies to provide generic information, on a chemical-by-chemical basis (Hepler-Smith, 2019), on the tens of thousands of toxic substances present on the market. This generic information on *substances*, however, can become problematic in the context of risk evaluation by expert panels, which requires measurement of exposures to those chemicals for specific *uses*. Multiple exemption categories (negotiated during the drafting of the law) push experts to focus on uses that are not at the heart of the chemical industry's activities, deliberately narrowing the scope of the potentially infinite number of assessments they could have conducted.

## **2. Industry-sponsored data at the heart of expert opinion**

As routine activities were built up, and reforms in the field of industrial chemicals adopted, it gradually became self-evident that expert opinion would have to rely on companies. In this section, we look at how expert opinion and regulation operate within this regime. In the example of OELs, observation of how the expert groups operate shows that it seems impossible to thwart the existence, within the expertise framework, of industrial research organised exclusively for the purpose of modifying existing regulations. Within REACH, toxicological and economic data are entirely produced by companies, and as such, often impossible to counter-evaluate. In both cases, experts are required to use toxicity studies that meet the standards of regulatory toxicology (i.e. experiments following the OECD guidelines for chemical assays). In practice, they are consequently bound to rely either on the industry-sponsored studies included in regulatory dossiers or on *ad hoc* studies prepared by companies to answer specific questions raised during regulatory assessments.

### ***2.1. The effects of upstream industrial formatting***

The setting of OELs pushes experts up against substantial difficulties related to the centrality of industrial data in the process of constructing limit values. In general, OELs decline gradually over time, in line with the accumulation of scientific knowledge about a given chemical product (Hansson, 1998). With advances in knowledge derived from toxicology and epidemiology, it is easier to produce more protective values. During the SCOEL observation period, however, it was possible to observe discussions concerning two values considered by the industry to be too low, in relation to which the economic actors produced new data that was impossible for the experts to get around. Ultimately, the outcome was a weakening of the regulation (Boudia et al., 2022).

The first such case is aniline. The SCOEL published an initial report on this substance in 2010, proposing an OEL of 0.5 ppm/mm<sup>3</sup>, based mainly on a scientific study dating from 1961. The industry then funded a new, human experimental study (Käfferlein et al., 2014), and one of its conclusions is that an OEL of 2 ppm/mm<sup>3</sup> is sufficiently protective for workers:

‘Our results on the controlled exposure to airborne aniline [show] that the current threshold limits of aniline in air (2 ppm) and urine (1,000 µg/l) adequately protect workers from

aniline-induced cyanosis via the formation of Met-Hb. Overall, our results contribute to the setting of exposure limits at the workplace' (Käfferlein et al., 2014, p. 1425).

At that March 2014 meeting referenced in the vignette at the start of the introduction, the chairman used the following words in introducing the study: 'We have a dispute with industry. They submitted a research report which says that, based on human studies, SCOEL's OEL is too low. I think OEL should be at 2 ppm, but we have to wait until this study is published.' Several points were discussed at the next meeting, leading to the experts proposing to increase the OEL from 0.5 to 2 ppm/mm<sup>3</sup>. Some experts insisted that this new study failed to address the carcinogenic risk, and expressed criticisms regarding certain aspects of the protocol. For example, why was the pilot study (with two male and two female volunteers) based on experimentation over a period of eight hours, when the final study (ten male and nine female volunteers) was based on an exposure of just six hours? The chairman's answer: 'They did what they could'. Despite numerous debates about this study's arguments, the new limit value of 2 ppm was neither challenged nor discussed at any point.

Formaldehyde is another product that was discussed with a view to increasing its limit value. In this case, the SCOEL report was adopted in 2008, setting the OEL over an 8-hour average at 0.2 ppm, with a 15-minute short-term exposure limit (STEL) set at 0.4 ppm. This was based in part on an industry-funded experimental human study involving ten men and eleven women. Considering this value too low, the companies affected then financed a new experimental study in which scientists (from the same laboratory) directly criticised the SCOEL OEL (this is the study described in the vignette of the introduction). In their conclusion, they wrote: 'We disagree with SCOEL's interpretation of results obtained in our previous study' (Mueller et al., 2013, p. 115). The study method is explicitly designed to build a new OEL:

'41 male volunteers were exposed for 5 days (4 h per day) in a randomised schedule to the control condition (0 ppm) and to formaldehyde concentrations of 0.5 and 0.7 ppm and to 0.3 ppm with peak exposures of 0.6 ppm, and to 0.4 ppm with peak exposures of 0.8 ppm, respectively' (Mueller et al., 2013, p. 107).

The issue of formaldehyde was on the agenda for several meetings after March 2014, and the experimental study was the subject of many discussions and requests for clarification. In the absence of any epidemiological data demonstrating a link between exposure to low doses of formaldehyde and the occurrence of cancer, one of the experts suggested setting a new OEL of 0.3 ppm, deriving this from toxicological studies carried out on animals. The experts gradually agreed to set a new limit value of 0.3 ppm (and 0.6 for the STEL) on the basis of a twofold justification that persists in the final report, adopted in 2016. One was based on animal studies (due to the lack of epidemiologically confirmed dose-response relationships at low doses) and the other on the industrial experimental study presented to the experts (Bolt et al., 2016).

These examples show that industry influence must be taken into account way beyond both what happens for each expert individually, and the discussions held within the actual committee meetings. Across the examples analysed, it was the companies' work upstream of expert opinion that structured both the knowledge and the ignorance framing the different options for expert intervention. As Kleinman and Suryanarayanan state, 'ignorance is the result of undoable science,

[...] undoable by certified scientists following the established epistemic form' (Kleinman & Suryanarayanan, 2013, p. 508). As described in the case of the effects of pesticides on bees, it is very difficult to intervene 'downstream' once the scientific knowledge has been generated in a way that makes it difficult to address certain issues. This pervasiveness of industrial data (or data formatted in the industry's own interest) makes stringent regulations less likely to be imposed.

## ***2.2. The effects of delegation and economisation***

REACH committee experts always conduct a detailed evaluation of the data present in the registration dossiers. They seem systematically astonished by both the age and the poor quality of data provided by companies. According to them, these data are inadequate to assessment of the chemical under review – as illustrated by the case of this solvent, for which all studies provided were more than 40 years old:

**Expert 4:** 'On questions of metabolism [...] we really don't have a lot. If there was more information, we could try to think about it.'

**Expert 5:** 'One old thesis has been provided, which dates back to the 1970s'.

**Expert 4:** 'Forget it, the 1970s are long gone!'

**Expert 5:** 'The problem is that most of the substances being evaluated were studied a long time ago. Old studies are all we have.'

**Expert 4:** 'Okay, but it's 2013, I'm not interested in 1970. So either we have data and we can talk, or we have no data and we're stuck.' (Fieldwork notes, REACH committee, 2013)

For Expert 4, the data in the registration dossiers fails to meet current scientific standards. Similar objections come up almost incessantly in each case, and relate to the length of time the studies have been in existence, their level of detail and the diversity of available data. Experts are obviously allowed (even encouraged) to rely on data other than that contained in the dossiers prepared by companies, such as papers published in academic journals, but independent (i.e. non-industry-sponsored) studies scarcely exist. Why is this? First, because toxicity testing can be extremely expensive. Nowadays, the costs of carcinogenicity testing for a single chemical are in the range of \$2-4 million (Jacobs & Hatfield, 2013), making it inaccessible for non-industrial actors who have thousands of compounds to assess. Second, because these studies have to comply with the 'gold standard' protocols of regulatory toxicology, often criticised as outdated (Demortain, 2013). This explains how regulatory science can be both *undone* and *unseen* (i.e. unpublished confidential studies), as a result of 'unequal distributions of power and resources' and 'knowledge access and protection that are codified in rules, regulations and laws' (Richter et al., 2018, p. 15). The actors most likely to fund these studies are those who will benefit from their continued marketing – which is why chemical companies are so central to the political economy of regulatory toxicology (Irwin et al., 1997).

During our observations, experts' dependence on industrial data was more visible still when they were consulted on measures that could be applied to control chemicals whose risks were already known. In this situation, experts can compare the costs and benefits of different control options, based on economic data (e.g. employment costs and health benefits) that they have only partial

access to. We observed them being compelled to ‘collaborate’ with companies; this is what happened with one of the above-mentioned compounds, nickel sulphate:

**Nickel Institute representative:** ‘At the outset, [the REACH committee experts] really had refused any dialogue with the industry, saying that they wanted to maintain their neutrality, they did not want to be influenced. And then it was them who came back to us, saying they wanted relevant information for their analyses. So we began this collaboration by providing them with data that could be useful, such as commodity chain studies and economic [impact] studies’ (interview with a representative of the Nickel Institute, 2012).

Using this data, experts were able to embark on the evaluation of several regulatory measures. For nickel sulphate, three options were compared. The studies provided by the Nickel Institute showed the devastating effects of overly restrictive control measures on the industry: were nickel sulphate to be banned in bathroom fittings, the resulting cost of relocating this industry would amount to €29 billion – and the loss of up to 150,000 jobs. According to one expert we interviewed, the experts had ‘no other way of working than to rely on this industry data’ (interview with an economist at ANSES, 2013). Because they were unable to counter-evaluate the industry figures, most of the economic expertise was delegated to industry. This led the committee to favour the least ambitious regulatory option, which entailed simply making the existing voluntary exposure limits mandatory. These last examples offer an outstanding illustration of the effects of the institutionalised outsourcing of both toxicological and economic data production to companies, and contribute to documenting the consequences of the contemporary economy of regulatory science production (Demortain, 2017).

## Conclusion

Previous STS research has looked at both the intentional and the non-intentional production of ignorance in the public regulation of toxic substances. Building on this literature, we identified various mechanisms that make it extremely difficult for the expert panels in charge of conducting regulatory risk assessments to support the adoption of stringent provisions, such as protective exposure limits or bans of chemicals – even for the most toxic products. Through our case study, we intended to contribute to discussions on how the production and uses of ignorance are structurally embedded in policy processes (Paul & Haddad, 2019).

Our analysis began with a presentation of the concept of *toxic ignorance*, which we propose to use to study the difficulties of regulatory assessment of toxic substances. With this concept, we sought to weave three strands together: STS research on institutionalised ignorance, which has shown that ignorance could be the result of institutional logics associated with risk assessment (Frickel & Edwards, 2014; Kleinman & Suryanarayanan, 2013); insights from work on the political economy of science, which has shown increasing industrial clout in the production of knowledge (Irwin et al., 1997; Sismondo, 2009), and the social study of toxic politics as a result of weak regulations (Boudia et al., 2021; Liboiron et al., 2018). While existing research has often studied these institutional mechanisms at the level of regulatory agencies, our contribution strove to dig deeper, by looking more precisely at the routine functioning of expert panels through *in-situ* observations



aimed at documenting how expert groups perform their tasks, and what types of regulatory procedures and toxicity data they have to deal with.

Our ethnographies of two European expert panels proved particularly useful for understanding how ‘ignorance-based’ regulatory science is enacted in regulatory settings. First, from a methodological and analytical perspective, we have shown the relevance of studying the activities of experts themselves and of observing their ways of working and using data. Kleinman and Suryanarayanan have already demonstrated that ‘the EPA accepts ignorance as a necessary result of the use of an institutionalised epistemic form and resource constraints’ (Kleinman & Suryanarayanan, 2013, p. 506). Based on this, we were able to analyse the dynamics through which experts came to accept this situation. Although the push to involve industry came from the public authorities (in our case the European Commission), we have shown how the working modalities of the expert panels gradually resulted in them integrating data provided by industry-funded organisations (such as ECETOC and the Nickel Institute) so that they could carry out their work more efficiently within a limited timeframe. While we acknowledge that the issue of expertise is thoroughly addressed in the STS literature, this article calls for future research to focus on the daily activities of experts (including industry scientists and private consultants as well as scientists sitting on regulatory panels) rather than on the functioning of ‘regulatory science’ at an agency level. This could provide a fruitful entry point for STS research to explore how uses of scientific data in expertise can reinforce industry’s influence on the production of regulatory knowledge.

Second, in analysing the work of the experts, we paid particular attention both to the rules structuring their work (which both allow them to ask certain questions and prevent them from asking others) and to the functioning of the organisations (mainly agencies) in which they operate. Thus, we were able to observe the web of constraints that forces them to accept the limitations of their work and play by the rules of the ‘regulatory science’ game. Existing research has already shown that the functioning of regulatory agencies, in itself, leads to both the production of ignorance and to regulatory inaction: ‘the production of knowledge about identified risks and the production of ignorance concerning potential risks are not only mutually constituted, their coproduction within risk assessment frameworks is structured in ways that, on a policy level, helps to legitimate regulatory inaction’ (Frickel & Edwards, 2014, p. 229). Our case helped us go further by showing how the experts deal with these constraints as well as how these limitations are little discussed and ultimately accepted in their day-to-day work. Even when panel members clearly perceive the shortcomings of regulatory procedures, they remain more or less obliged to accept them if they are to carry out their work successfully. These arrangements weaken the experts’ capacity to question or challenge either the rules of expertise or the relevance of the data on which their opinions are based.

Third, our analysis documents how the routine functioning of regulatory science tends to favour industry-sponsored studies, while obscuring knowledge that could have been useful for regulation – for instance, studies on chronic exposures or cocktail effects linked to exposure to multiple chemicals. As shown in previous studies, ‘the picture of ignorance that emerges from this analysis stands in sharp contrast to more narrowly drawn depictions of ignorance as the conspiratorial result of powerful corporate and government actors purposefully manipulating or subverting scientific research’ (Frickel & Edwards, 2014, p. 229). However, while existing research have illustrated how the principles of ‘risk assessment’ tend to narrow the questions asked by regulators, we have

shown that the experts often depend on unpublished, and sometimes confidential, *ad hoc* studies prepared by the industry that public experts are unable to circumvent. In this situation, the experts of the SCOEL and REACH committees are all the more likely to formulate opinions in line with companies' interests. Beyond the limits of risk assessment, we have consequently shown that the industry's own considerable capacity (in terms of financial and human resources, as well as toxicological and socio-economic expertise), together with that of the regulatory intermediaries they mobilise (e.g. the Nickel Institute), structurally produce biases in the knowledge available for regulatory purposes. In the end, the role played by corruption or manipulation is dwarfed by that of the political economy of regulatory knowledge, which legitimises this situation of institutionalised ignorance, skewed in favour of industrial interests.

Through these examples, we wanted to offer a more accurate description of this institutionalised form of knowledge (which, since it is formatted and even biased by industry needs and objectives, is fairly close to ignorance) that is serving as the basis for regulatory expertise. The *toxic ignorance* concept can help us avoid reducing the analysis of industrial clout to inadequate data, while also rendering visible the biases generated by industry-formatted data in expert assessments and regulatory procedures. In addition, it makes it possible to move beyond the knowledge/ignorance dichotomy to show the extent to which use of this type of knowledge/ignorance is problematic in terms of its effects on chemical regulation policies; it limits the experts' scope for action. As we have tried to show, gaining access to expert groups in a bid to understand their inner workings is likely to provide us with a better grasp of the endemic tensions which constrain regulatory choices. Their social and political implications could (or should) perhaps discourage society from entirely delegating these choices to expert bodies and complex bureaucratic procedures – at least for as long as regulatory science remains this close to being corporate science. The notion of *toxic ignorance* could also be used in contexts other than the regulation of chemicals, particularly in cases where toxic consequences are indirect – as in the cases of land occupation, loss of biodiversity in ecosystems, and the systemic consequences of climate change.

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