EuropeanLawOpen

Response to the reviewers’ comments:

**Reviewer: 1**

Comments to the Author
This is an excellent and fascinating article with great writing and research. Its findings about the epistemic power of economic actors and how entrenched they have become over the years are profoundly troubling. It is difficult to find fault with it. True, it is long, but as a whole it is a coherent analysis, and I could not find any unnecessary idling. The manuscript should be published as it is.

To fulfill the task of a critical reviewer, I would however like to raise a few questions for the authors to consider.

1. What is exactly “a new socio-legal lens”? The notion of a socio-legal perspective could be perhaps opened up a bit. Now it seems to be the opposite (or an alternative) to “doctrinal” to criticise the epistemic foundations of the court’s jurisprudence. Could a socio-legal perspective open into something more?

*Thank you for raising this. We forgot to set a ‘comma’ after ‘new’. We offer a new perspective to the current discussion, which uses a socio-legal lens. So, it should say ‘a new, socio-legal lens.’ We corrected that.*

1. The authors are right noting that in implementation ”economic actors enjoy an advantage in terms of access to regulators vis-à-vis public interest group ” (p. 13). The other side of the coin, which could perhaps be clarified here is that many NGOs seem to prefer influencing in the legislative stage (because they think that the most fundamental issues are settled here) and run out of resources and steam when the legislative process comes to an end.

*Indeed, the relationship between economic actors and NGOs is more balanced in the legislative phase, due to both institutional efforts to encourage NGOs participation (see fn 30 on page 13) and to the features and context of the decision-making process (higher political salience, involvement of the EP, less technical nature). We explain this at p. 14, in particular fn 33. As we are focussing on the institutional dimension, we do not closely consider the internal motivations of NGOs (or economic actors) for choosing to engage in the legislative rather than the implementation phase.*

1. The authors have widely read and engaged with the literature, so it is again difficult to suggest new literature. Perhaps R Joosen’s article “Persuading the independent: understanding why interest groups engage with EU agencies” in Interest Groups & Advocacy (2021) might be worth a look.

*Thank you for the suggestion, we have read it and added a reference on p. 11 (n 22).*

1. The suggestion of extending review to public forums is a good idea. However, the authors note that “scientific assessments rely widely on the evidence generated, sponsored, and presented by the regulated industry” (p. 17). The industry also think that they own the studies, which complicates the implementation of a more public and inclusive review. Perhaps E Korkea-aho and P Leino-Sandberg’ article “Who Owns the Information Held by EU Agencies? Weed Killers, Commercially Sensitive Information and Transparent and Participatory Governance” Common Market Law Review (2017) may be worth a look.

*Yes, thank you for pointing this out, this is indeed an important aspect. We address it in fn 245 and have added a reference to Korkea-aho and Leino Sandbeg’s article there.*

1. A tiny detail: Busuioc’s first name on p. 28 fn 83 is Madalina.

*Thank you for flagging this, we have corrected the name.*

1. The problem that the authors describe here relate to the influential role of economic actors and how the court’s in many ways suboptimal jurisprudence has only helped entrench their power. I suppose that the question remains whether we should even try to fix the way in which the courts operate? It might be too late in the political process anyway. Is there anything to be done to fix the power of economic actors earlier on in the process? This is probably a question for another article though.

*Indeed, this is not the focus of our paper. However, our response to the question you raise is that the Court’s review probably should be more limited and that indeed other solutions within the regulatory process and even before that are necessary.*

**Reviewer: 2**

Comments to the Author
The heart of this paper is an unconventional (and critical) reading of the unintended effects of EU judicial review of risk regulation. The main argument - the approach taken by the CJEU in its consolidated case-law strengthens the epistemic power of economic actors, that is their ability to influence the regulatory process - is clearly formulated, based on an accurate analysis (Sections 2-3) and developed in a convincing way. It is perhaps not really illuminating, but certainly interesting and capable of affecting future research on EU law. The socio-legal method used by the authors is coherent with the research question. The paper is clearly of publishable quality.

I have, however, two remarks.

1. First, I find Section 1 not fully developed. The two points made by the authors (economic actors play an important role in the regulatory process both as lobbyists and as applicants in authorization procedures) are reasonable and sound, but they hardly support the general conclusion that EU processes of risk regulation are largely dominated by economic actors (and characterized by a ‘minoritarian bias’). The reader may be intuitively in agreement with the authors, but the general conclusion is more asserted than really demonstrated.

*Our general conclusion is not that EU risk regulation processes are dominated by economic actors, but rather that there is a risk of such dominance, and that such risk is tangible (p. 18). In order to substantiate our conclusion, we refer to the empirical findings of political science and interest group scholars, who show that economic actors enjoy an advantage in terms of access to the regulatory process and at times also in terms of actual influence, especially in the implementation phase. We however also acknowledge the presence of legislative safeguards and of institutional efforts to rebalance the participatory gap between economic actors and NGOs. Taken together, these elements lead us to the conclusion that there is a risk of a minoritarian bias in EU risk regulation, but we do not make an empirical claim as to its existence.*

1. Second, while the authors are fully convincing in their critique of the approach taken by the CJEU, the pars construens is somehow impressionistic. The authors provide some useful functional suggestions to correct the current inclination to entrench the economic actors’ power at the expense of other relevant actors, but this is far from being ‘a normative vision for EU judicial review in risk regulation’. As in Section 1, even in Section 4 there is an asymmetry between the specific points that are made and the way in which the general conclusion is formulated.

*We have reformulated previous section 4, shortening it (and splitting it up) and further sharpening the argument. It is true that we do not provide a fully-fledged normative vision. This is however not the main goal of our article. As we explain both in the Introduction and in sections 4 and 5 (the edited version), these two last sections merely aim to sketch out constructive ideas for reform, which should be further investigated in future research. We believe that there is enough substance in our argument to claim that we at least are pointing to (‘sketch out’) a new normative version for the Court’s review of regulatory science. See in particular (new) pages 78-79 of the main file.*

1. My suggestion would be to rethink a bit the relevance of Sections 1 and 4 in the overall structure of the piece. They certainly enrich the paper, but there is no need to present them, respectively, as a necessary premise and development of the argument. The important part of the article is, my opinion, the critique of the CJEU case-law presented in Sections 2-4. It is in these Sections that the authors shed new light on EU judicial review of risk regulation, offer an innovative interpretation and set the direction for future research. And it is this part that deserves to be immediately presented to the reader as the main contribution given by the authors in this piece of work.

*We have shortened section 1 and restructured and shortened the previous section 4 streamlining the argument.*

**Reviewer: 3**

Comments to the Author
This is an excellent article. It is original and such a pleasure to read and it would make a terrific contribution to EU Law Open! It is without hesitation that I recommend it to be published almost as it is.

I have only some minor comments, and I would leave it to the discretion of the authors and editors to consider how to implement them.

1. While the article is extremely clear and well-written, it would greatly benefit by being shortened. In certain parts, the article is redundant and in others it engages in an almost apologetic justification of what is doing. In this way the main arguments may be lost. By shortening it, the article will be more daring, to the point and powerful. I offer couple of examples where words could be cut, but I am sure that by an attentive reading the author(s) could easily spot other redundancies and unnecessary passages.

a. On p. 85 the author(s) writes: ‘The Court has maintained its approach despite a longstanding critique from different corners including academics, international bodies and the Court’s Advocate Generals, with the latter developing what we believe are at least legally defensible alternative interpretations.’ This was already well explained on p. 26. You don’t need to repeat.
b. On p. 19, the last two sentences can be left out as they do not add much to the main reasoning (The above discussion does not prove the actual existence of a minoritarian bias in EU risk regulation. Yet, it confirms that such risk is present.)

c. On p. 44 the author(s) write: ‘ This shows that the Court holds regulatory science to account by scrutinizing the agency’s use of evidence but does so only with respect to the scientific studies invoked by the industry applicant.’ You could leave this type of conclusions at the end of the section. You could also just delete as it is stated also elsewhere.

d. On p. 50 you write: ‘This is problematic, considering the epistemic power exerted by economic actors in EU risk regulation, and the ensuing risk of a minoritarian bias highlighted in section 1. It is even more problematic when read in conjunction with the intensified review, whereby the Court sometimes borders dangerously close to substitution of judgement. In other words, the Courts’ more stringent review of EU risk regulation mostly benefits those actors, i.e. the regulated industry, who already enjoy a dominant position in the regulatory process.’ You do not need all these words, particularly because the idea is already well explained at the beginning of the paper. The above can be said in one sentence.
e. Ftn 237 is redundant when it describes Scott and Sturm, which was amply discussed earlier.
f. Etc.

*Many thanks for these suggestions and the generosity of the reviewer. We have implemented some of these suggestions. We did not shorten where we felt that such shortening would have made our argument more difficult to follow. Overall, we went through the whole draft once more and shortened the language where necessary.*

1. On p. 17 the author(s) explain that there are ‘legal safeguards’ ‘in place to ensure scientific quality.’ Further corroborating the main thesis of the article, the author(s) may add that such safeguards have also been partly criticized for being skewed in favor of economic actors. For example, the application of OECD Good Laboratory Practices (and the Klimish criteria) by regulatory agencies such as EFSA, can be deployed to de facto exclude independent studies from risk assessments  (on this see Claire Robinson and others, “Achieving a High Level of Protection from Pesticides in Europe: Problems with the Current Risk Assessment Procedure and Solutions” (2020) 11 European Journal of Risk Regulation 450, particularly at pp.456-58)

*Thank you for the suggestion. We do refer to Robinson’s work and have added a reference in fn 54 to corroborate the point made also by Abbott and Lee.*

1. Fn 79 starts with ‘who on several occasion …’ I would not start a footnote in such a way.

*Thank you for flagging this, we rephrased the sentence.*

1. I find section 4A (Internal critique) rather peripheral to the main thesis and, I would consider removing or shortening it. In some parts, it is also not very persuasive. In particular, I would be hesitant in engaging in a discussion of ‘legal certainty.’ While the Court may have displayed some incoherence, I question whether this could be equated to ‘undermining legal certainty.’ My impression is that such reasoning would be distracting and overall risk weakening the principal line of argumentation of he paper.

*We have shortened the part on the internal critique and moved it up as a summarizing section at the end of section 3 (case law analysis). We have also removed references to legal certainty as we agree that this is a rather strong claim.*

1. Subsection 4(c) titled ‘Caveats and limits ..’ from p 83 onwards introduces an important proposal of the paper. I would discuss these proposals under a different heading.

*We agree and moved that part under a ‘new’ section 5 ‘What way forward for CJEU review of regulatory science?’.*

1. There are couple of typos (e.g. p. 65 ‘This approach it complemented’ should be ‘This approach is complemented’).

*Thank you for flagging this. We language checked the whole paper one last time.*

Besides these minor comments, as mentioned, the paper is extremely interesting and well argued. To the best of my knowledge, this is the first time the relationship between judicial review and epistemic power of different actors in the European legal system is discussed, and discussed with such rigor. Chapeau to the author(s)!

*Thank you!*