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OPEN LETTER

REVISED How credible is REACH regulation without transparency, quality criteria, assurance, and control?

[version 3; peer review: 2 approved]

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Abstract

Background

The European Chemicals Agency (ECHA) has been established to act as an independent body in the context of the implementation of the Regulation on the registration, evaluation, authorisation and restriction of chemicals (REACH) (Regulation (EC) 1907/2006). Quantitative exposure estimates are required for all exposure scenarios where hazardous emissions occur using exposure measurements or exposure models. REACH regulation specifies that exposure models need to be *appropriate* and *quantitative*. Here, we evaluated the criteria for regulatory exposure models by ECHA.

Methods

The evaluation was performed by asking ECHA the criteria for exposure models.

Results

ECHA does not specify any quality criteria for regulatory exposure models or have transparency requirements. Without quality criteria and transparency, there cannot be quality assurance or control. Thus, an *appropriate* model cannot be defined. ECHA does not recognize the *quantitative* term even though the fundamental requirement for quantitative exposure assessment is quantitative uncertainty

Open Peer Review

Approval Status ✓ ✓

	1	2
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version 1 10 Apr 2025	✗ view	? view

1. **Marlene Ågerstrand**, Stockholm University, Stockholm, Sweden
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Any reports and responses or comments on the article can be found at the end of the article.

assessment.

Conclusions

As a result of these shortcomings, ECHA R.14 Guidance for occupational exposure assessment allows the use of non-physical models containing qualitative parameters based on non-accessible calibration databases and statistical evaluations. Because of the lack of transparency, non-physical model construct, and subjective input parameters, model results cannot be associated with real-world operational conditions, and quantitative uncertainty assessment is not feasible. This makes the models qualitative by definition and is not applicable to regulatory exposure modelling. This raises questions about whether ECHA has followed its regulatory mandates in implementing the REACH legislation.

Plain language summary

ECHA has a mandate to implement REACH chemical regulation in the European Union. Quantitative exposure estimates are needed for hazardous chemicals' human health risk assessment. Quantitative exposure assessment can be conducted by using appropriate exposure models. However, ECHA does not provide quality criteria for regulatory exposure models in REACH, does not require transparency from the models applied in REACH, nor does it recognize the term quantitative. It is not feasible to conduct quality control or quality assurance without quality criteria or transparency requirements. As a result of these shortcomings, ECHA R.14 Guidance for occupational exposure assessment allows the use of non-physical models containing **qualitative** parameters based on non-accessible calibration databases and statistical evaluations. This raises logical questions about whether ECHA has followed its mandates in implementing the REACH legislation.

Keywords

REACH, ECHA, Mandate, Exposure model criteria, Quantitative exposure, Qualitative exposure, Exposure modelling, Regulatory chemical safety decision-making

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This article is included in the Horizon Europe gateway.

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Author roles: Koivisto AJ: Conceptualization, Formal Analysis, Investigation, Validation, Writing – Original Draft Preparation; **Jayjock M**: Conceptualization, Formal Analysis, Investigation, Validation, Writing – Review & Editing

Competing interests: No competing interests were disclosed.

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REVISED **Amendments from Version 2**

No changes were made to the main text or Underlying Data based on the review comments. The justification was explained to the reviewer in the response letter, where we clarified that:

- In addition to transparency, other major problems are that ECHA does not follow international terminology for the quantitative exposure model and the tiered modelling approach.

- Stoffenmanager (StM) and the Advanced REACH Tool (ART) are not considered as screening-level models, in addition to many other models given in ECHA R.14, but quantitative exposure assessment models for regulatory exposure assessment under REACH legislation.

- We have repeatedly asked the Editor to change the article to "Open Letter" from "Research Article". The Editor finally did this on 6th Nov 2025.

- This work focuses on the regulatory exposure model requirements specified by ECHA. In contrast, the model evaluation for the two higher-tier models, as classified under ECHA R.14, was carried out for StM and ART in Koivisto *et al.* (2022, 2018), and the response letters by Cherrie *et al.* (2020) and Fransman *et al.* (2022) (see references, e.g., from the response letter). In the model evaluation, a systematic literature review was conducted. However, in the current study, we found no literature on the regulatory modelling criteria set by ECHA. This is why communication with ECHA is considered the most reliable and transparent source.

- In methodology, we do not know a better approach to evaluate the regulatory exposure model criteria than open and transparent discussion with ECHA.

All concerns have already been addressed in the previous version of the study and in the last review comments.

We added in the Acknowledgements a statement that "The views expressed in this article are solely those of the coauthors and may not represent those of their organizations."

Any further responses from the reviewers can be found at the end of the article

Introduction

In the registration, evaluation, authorisation and restriction of chemicals (REACH) regulation, quantitative or qualitative exposure assessment shall be performed to estimate the dose/concentration of the substance to which humans and the environment are or may be exposed (Regulation (EC) No 1907/2006 - Annex I §5.0). Exposure scenarios involving hazardous emissions require quantitative exposure estimates to support risk characterization (ECHA, 2016).

Regulation (EC) No 1907/2006 - Annex I §5.2.1 specifies that "*The exposure estimation entails three elements: (1) emission estimation; (2) assessment of chemical fate and pathways; and (3) estimation of exposure levels*". The exposure estimates are associated with operational conditions and reported in the Chemical Safety Report. With this information, chemical users can ensure that exposure is adequately controlled under operational conditions specified in the Chemical Safety Report or conditions that favor lower exposure.

The exposure assessment can be conducted using measurements or exposure modelling. Annex I §5.2.5 specifies that "*Where adequately measured representative exposure data are available, special consideration shall be given to them when conducting the exposure assessment. Appropriate models can be used for the estimation of exposure levels. Relevant monitoring data from substances with analogous use and exposure patterns or analogous properties can also be considered*". Based on the Regulation (EC) No 1907/2006 - Annex I §5.0, the requirements for the exposure model are "*appropriate*" and need to be "*quantitative*" when hazardous emissions can occur.

The European Chemicals Agency (ECHA) mandates to implement Regulation (EC) No 1907/2006 are (adopted from https://echa.europa.eu/about-us/who-we-are/purpose):

1. Carry out technical, scientific, and administrative tasks related to the implementation of the EU's chemicals legislation and policy.

2. Provide transparent, independent and high quality scientific opinions and decisions, which shall serve as the basis for the drafting and adoption of Union measures.

3. Collaborate and partner with EU bodies and Institutions, Member State authorities, as well as third countries and international organisations.

4. Provide tools, advice, and support to industry, with a particular focus on SMEs, in fulfilling their duties under chemical legislation.

5. Ensure that relevant, reliable, and objective information is available for the public and interested parties.

ECHA Chapter R.14 guidance specifies exposure models for occupational inhalation exposure assessments. The Evaluation of Tier 1 Exposure Assessment Models under REACH (E-TEAM) project evaluated parts of the generic inhalation exposure estimation tools classified as tier 1 tools, including Stoffenmanager (StM), which is currently called a tier 1.5 tool (Lamb *et al.*, 2015). In ECHA Chapter R.14, the Advanced REACH Tool (ART) is similar to StM. ART is classified as a mechanistic exposure assessment tool classified as a tier 2 tool (note, ECHA does not follow the tier classification as internationally defined (e.g., Tielemans *et al.*, 2007); in ECHA, a lower tier model can produce lower exposure estimates than a higher tier model). During the past years, Koivisto *et al.* (Underlying data, section 1; (Koivisto & Jayjock, 2025)) have found fundamental flaws in StM and ART models. Both StM and ART are based on calibration factors. The calibration databases are essential for model evaluation within the International Society of Exposure Science (ISES) Europe model evaluation group. However, calibration databases are not accessible from the model developers. Based on Regulation (EC) No 1049/2001 rule 6, these documents should be available for regulatory exposure models applied in REACH regulation.

In 2024, we requested ECHA access to the calibration databases, statistical evaluation methods, and the StM model evaluation report by the Dutch Ministry of Social Affairs and Employment. ECHA informed us that no document(s) that corresponded to the description given in our application were found. The response was that "*According to Article 2(3) of Regulation (EC) No 1049/2001, the right of access, as defined in that Regulation, applies only to existing documents in possession of the Agency.*" The response raised questions about the currently used regulatory exposure models' transparency, quality criteria, assurance, and control. Such criteria are needed to establish an exposure model for regulatory chemical safety decision-making. This is one objective of the Multidimensional Integrated Quantitative Approach To Assess Safety And Sustainability Of Nanomaterials In Real Case Life Cycle Scenarios Using Nanospecific Impact Categories (INTEGRANO) (grant agreement No. 101138414) project. The requirements were discussed with ECHA between 30 May 2024 and 28 Nov 2024. Here, we have summarized the findings according to our best understanding.

ECHA communication

We sent five letters with questions about regulatory exposure model criteria, how the exposure models in ECHA R.14 guidance were evaluated, and how ECHA ensures that the exposure models comply with the "*appropriate*" and "*quantitative*" criteria. ECHA has not always provided a "yes/no" answer, and thus, the interpretation of the responses is not straightforward (Underlying data, section 2; Koivisto & Jayjock, 2025). Key questions, ECHA's responses to these questions, and our interpretations are summarized in Table 1 (Underlying data). Unfortunately, clear answers were not provided for our questions in the last letter because ECHA considered those questions to be covered by the former letters.

Results and discussion

ECHA does not specify any quality criteria for regulatory exposure models. Without quality criteria, there cannot be quality assurance or control. Thus, an "*appropriate*" model cannot be defined. ECHA does not recognize the "*quantitative*" term even though the "*quantitative exposure model*" is described implicitly, for example, by WHO/IPCS (2005). We believe that if ECHA does not follow internationally recognized terminology, it should provide its own definition (see also Underlying data, section 2; Koivisto & Jayjock, 2025).

A quantitative exposure model produces quantitative outputs using measurable variables, numerical inputs, and mathematical relationships based on physical and chemical laws (NRC, 2007; WHO/IPCS, 2005). Quantitative exposure models provide predicted exposure profiles and associated uncertainties, allowing for variability and quantitative uncertainty analysis (e.g. Simmonds *et al.*, 2022). Model accuracy and uncertainty are related to the model parametrization and how well the model construct reflects the real environment (e.g., Fryer *et al.*, 2006). Models always have qualitative components related to their application in real-world systems. Qualitative components can be, e.g., impurities in processed materials, incomplete air mixing, assumptions related to worker behavior, or sinks for emissions other than ventilation exhaust air. Qualitative components are described in the modeling result as assumptions and boundary conditions that the user needs to comply with (e.g. Simmonds *et al.*, 2022). An appropriate exposure model considers all relevant exposure determinants so that qualitative components do not significantly impact exposure estimates and the result is sufficiently precise for safety decision-making. For example, a simple near-field/far-field exposure model predictive performance for solvents (non-spraying exposure scenarios) is within a factor of 0.3–3.7 times the measured concentrations with 93% of the values between 0.5 and 2 (Abattan *et al.*, 2021). This accuracy is sufficient for regulatory chemical safety decision-making (Jayjock *et al.*, 2011). However, reporting quality defines its final applicability for regulatory chemical decision-making.

ECHA does not require transparency, which we see as violating the second mandate. Without transparency, the model construct cannot be evaluated, and the correct model application for the selected scenario cannot be ensured. For example, if model calibration databases are not available, it is impossible to ensure the database's quality or how the statistical evaluation is conducted. Transparency is a fundamental requirement for uncertainty analysis (EFSA Scientific Committee, 2018a; EFSA Scientific Committee, 2018b; NRC, 2007; Simmonds *et al.*, 2022; U.S. EPA, 2019; WHO/IPCS, 2005). For example, the U.S. Environmental Protection Agency (US-EPA) is responsible for ensuring that a model's development and use are transparent and that models developed outside of the agency must meet the same acceptability and application criteria as models developed within the EPA (NRC, 2007).

We agree that the model developers are responsible for building their models. Still, ECHA is responsible for providing acceptance criteria for the models (mandates 1 and 2) and ensuring that the models' quality meets the requirements (mandate 5). Other regulatory bodies, such as the US-EPA or European Food Safety Authority (EFSA), have established such criteria and mandated that these criteria are complied (EFSA Scientific Committee, 2018a; EFSA Scientific Committee, 2018b; NRC, 2007; U.S. EPA, 2019).

ECHA mentions that they can decide whether the assessments performed using models within the different processes are adequate. This decision addresses the model itself or the applicability of the model to the case. The decision appears to be subjective and arbitrary because it is unclear how such a decision can be made without quality criteria, transparency, or any defined understanding of what a "*quantitative*" exposure model means.

ECHA R.14 recommends using models that do not have a physical construct, are based on unknown calibration factors based on exposure measurements in different exposure groups, and contain subjective parameters (e.g., 'high transfer speed' without specifying physical values or ranges) (Koivisto *et al.*, 2022; see also a response letter by Fransman *et al.*, 2022). Because there is no physical model construct and the model contains subjective input parameters, model results cannot be associated with real-world operational conditions. For example, a

'high transfer speed' of 1 kg/min can be a high transfer speed in pharmaceutical powder handling but a low one in cement mixing. Due to the same reasons, the model uncertainties cannot be evaluated (Hesse *et al.*, 2015; Koivisto *et al.*, 2022), and thus, the results cannot be called *quantitative* exposure estimates. Non-physical models recommended in ECHA R.14 do not require information on emission rates/factors. Emission estimation is one requirement in Regulation (EC) No 1907/2006 and it is unclear if the emission estimates are always reported in Chemical Safety Reports.

Subjective models can produce nearly any outcome, which can be seen in their predictive performance. For example, StM and ART predictability is in the range of 100 000 fold (Lamb *et al.*, 2015) and 21 000 fold (Lee, 2023), respectively. See Koivisto *et al.* (2022) for a more comprehensive list of performance studies. Spinazzè *et al.* (2017) showed how lower-tier models (European Centre for Ecotoxicology and Toxicology of Chemicals - Targeted Risk Assessment (ECETOC-TRA) and StM) produced lower exposure estimates than higher-tier model ART. The reason for this is not known because of the model's characteristics; The magnitude and direction of the uncertainty introduced by the models cannot be assessed (Hesse *et al.*, 2015; Koivisto *et al.*, 2022). Koivisto *et al.* (2022) stated that combining the model's high uncertainties with subjective interpretation of exposure taxonomy, a tiered approach using, e.g., ECETOC-TRA, StM, and ART can produce nearly any outcome. Currently, such subjective models are useful only to obtain compliance with REACH regulations, but they will not give information on workers' exposure and safety or provide helpful information on the effect of exposure determinants on workers' exposure levels.

ECHA does not provide numerical criteria for model performance. According to our understanding, neither other institutes, such as the US-EPA and EFSA, offer numerical criteria for exposure models. However, NRC (2007), a guidance document for US-EPA, specifies that if the model has been shown to produce erroneous results (false positives or false negatives), it should lead to a rejection of that model. ASTM D5157-19 provides numerical standards for indoor air quality models under well-specified conditions. A well-mixed model and a near-field/far-field model complied with the criteria by ASTM D5157-19 (Arnold *et al.*, 2017).

ECHA has not formally evaluated the exposure models for compliance. The regulatory exposure models specified in ECHA R.14 were incorporated after expert discussions with as yet unidentified stakeholders. In fact, ECHA could not provide answers on who were the stakeholders in this process. They could not give the model quality criteria or how the evaluation was conducted. There appears to be no transparency criteria.

ECHA or the ECHA committees can reject an exposure model for regulatory exposure assessment. The rejection is usually based on undefined expert judgement applicable to the case at hand rather than explicit generic criteria. It is unclear how the evaluation is conducted because, according to ECHA, they do not formally evaluate the exposure models for compliance. Also, an assessment by ECHA using unspecified, generic criteria without explicitly defined quality criteria is not a technically rational approach, especially if the evaluation reports are not available for review.

ECHA can update its Guidance depending on the scientific outcomes from the ISES strategy 2020–2030 for exposure models (Schlüter *et al.*, 2022). ECHA also monitors scientific development in international organizations such as the ISES group, the Society of Environmental Toxicology and Chemistry (SETAC), and the Organisation for Economic Co-operation and Development (OECD). However, ISES does not provide regulatory guidance or perform regulatory exposure model evaluations because they do not have a mandate. ECHA relies on "stakeholders" to implement the regulatory guidance, but ECHA's contribution and responsibility are unclear. This is dramatically different from the practices of EFSA and US-EPA, which have established guidelines with quality criteria, have established a quality management system, and conduct self-reviews to improve their processes (EFSA, 2024; NRC, 2007; U.S. EPA, 2019). Considering that we have found fundamental flaws in the highest tier models of the ECHA R.14 Guidance and that ECHA has not addressed those flaws for the past 6 years, we are not convinced that ECHA will ever actively develop its regulatory Guidance.

Conclusions

ECHA has not developed quality criteria for regulatory exposure modelling, and thus, quality control is based on unspecified expert judgments. The details on which these judgments were made are unavailable to any independent scientific investigator. Indeed, ECHA does not require transparency from exposure models, which is in stark contrast to other chemical regulation bodies. Also, ECHA does not follow international terminology for exposure sciences, and thus, the interpretation of ECHA Guidance is not straightforward. These facts allow ECHA to recommend using qualitative exposure models in quantitative exposure assessment.

In contrast to the above ECHA practices, we decided in the INTEGRANO project to follow the US-EPA guidance for the regulatory exposure models, ensuring their global applicability.

We recommend that ECHA adopt the quality criteria, assurance, and control for regulatory exposure modelling from US-EPA and EFSA. Harmonization is a step towards globally accepted regulatory exposure assessment. Afterward, the ECHA Chapter R.14 exposure models should be objectively evaluated for compliance with these criteria. We see this as necessary to ensure the transparency of all models used for regulatory compliance.

Ethics and consent

Ethical approval and consent were not required

Institutional review board statement

Not applicable.

Informed consent statement
Not applicable.

Abbreviations

ART	The Advanced REACH Tool
ASTM	American Society for Testing and Materials
EC	European Commission
ECETOC-TRA	European Centre for Ecotoxicology and Toxicology of Chemicals - Targeted Risk Assessment
ECHA	The European Chemicals Agency
EFSA	The European Food Safety Authority
E-TEAM	Evaluation of Tier 1 Exposure Assessment Models under REACH
EU	European Union
INTEGRANO	Multidimensional Integrated Quantitative Approach To Assess Safety And Sustainability Of Nanomaterials In Real Case Life Cycle Scenarios Using Nanospecific Impact Categories
ISES	The International Society of Exposure Science
OECD	The Organisation for Economic Co-operation and Development
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SETAC	Society of Environmental Toxicology and Chemistry
SME	Small and Medium Eterprises
StM	Stoffenmanager
US-EPA	The United States Environmental Protection Agency

Data availability statement
The communication emails are available in Underlying data (anonymized).

Data availability
Underlying data
Zenodo: Underlying data for "How credible is REACH regulation without transparency, quality criteria, assurance, and control?" https://doi.org/10.5281/zenodo.15095459 (Koivisto & Jayjock, 2025):

- Section 1, History of StM and ART evaluation
- Section 2, ECHA communication letters
- Section 3, ECHA review comments and responses
- Table 1, Answers extrapolated from ECHA communication Letters

Acknowledgments
We are grateful for ECHA revisiting the manuscript (Undelying data, section 3; Koivisto & Jayjock, 2025).

The views expressed in this article are solely those of the coauthors and may not represent those of their organizations.

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Version 3

Reviewer Report 10 January 2026

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✔ **Marlene Ågerstrand**
Stockholm University, Stockholm, Sweden

I am satisfied with the changes implemented by the authors. The revised manuscript effectively addresses a relevant topic that warrants increased scholarly attention, and I appreciate the authors' efforts to highlight this issue for a wider readership.

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Chemical regulation

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Version 2

Reviewer Report 15 December 2025

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✔ **Peter Egeghy**
Center for Computational Toxicology and Exposure, Research Triangle Park, USA

The change of designation from "Research Article" to "Open Letter" has addressed and allayed my concerns.

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Exposure modeling

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 19 August 2025

https://doi.org/10.21956/openreseurope.22833.r57503

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Marlene Ågerstrand
Stockholm University, Stockholm, Sweden

The authors highlight a major concern: the lack of transparency in the calibration databases for two screening-level models. By pressing ECHA for greater openness, the authors provide an important public service. Robust and transparent exposure models are essential for managing chemical risks to health and the environment, while open data fosters innovation, supports academic research, and advances the development of safer, more sustainable chemical solutions.

My concern with this paper is the categorisation as a “research article”. A research article is a detailed, structured report of an original scientific study. It typically presents a specific research question, explains the methods used to investigate it, presents data collected during the study, and analyses that data to draw a conclusion. A commentary, on the other hand, is a shorter, more opinion-driven piece that does not present original research data. Instead, it offers expert insight, interpretation, or critique on existing research, current trends, or issues in the field. Their purpose is often to stimulate discussion, guide interpretation, or provide context for ongoing debates.

In the present case, the lack of a systematic approach to how the data have been analysed is making it difficult to categorise it as a research article. The authors could have used qualitative document analysis, which is a valid research approach involving systematic examination of texts to identify patterns, themes, and meanings. However, the paper fails to deliver on both the methodological rigour and performance expected for such a study. A clear description of the analysis process, particularly how the documents were examined, coded, and interpreted, is absent. This absence pushes the work closer to an informal commentary rather than a robust research article.

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Regulatory toxicology, EU chemical regulation

I confirm that I have read this submission and believe that I have an appropriate level of

expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 19 Aug 2025

Antti Joonas Koivisto

We thank the reviewer for valuable comments. These comments did not lead to changes, which are justified below. The authors highlight a major concern: the lack of transparency in the calibration databases for two screening-level models. By pressing ECHA for greater openness, the authors provide an important public service. Robust and transparent exposure models are essential for managing chemical risks to health and the environment, while open data fosters innovation, supports academic research, and advances the development of safer, more sustainable chemical solutions.
Response: *Transparency is a fundamental requirement when applying modelling results to real-world systems. Underlying assumptions, model boundaries, and parameterisation must be reported so that the model result can be applied accordingly. However, this is only one primary concern regarding the exposure models given in ECHA R.14.*

Other major concerns are that ECHA allows use of qualitative exposure models in regulatory exposure assessment under REACH and claims that the qualitative exposure models result in quantitative exposure estimates. Accuracy and uncertainty assessment are not possible for models without a physical construct (e.g. mass-balance), applying subjective parameters, and without transparency. Such models are qualitative models that are not applicable for tiered exposure modelling, such as screening the highest exposure potential under reasonable worst-case conditions. Stoffenmanager and the ART are not classified as screening-level models but quantitative exposure models for regulatory exposure assessment under the EU health and safety regulations Directive 98/24/EC—risks related to chemical agents at work and Directive 2004/37/EC—carcinogens or mutagens at work (Cherrie et al., 2020; Schlueter and Tischer, 2020; Schlüter et al., 2022; Schlüter and Spinazzè, 2023). For example, Stoffenmanager is claimed to be directly applicable to (https://oshwiki.osha.europa.eu/en/themes/stoffenmanagerr-smart-chemicals-management-and-business-continuity; Accessed 19 Oct 2025):

- *Directive 98/24/EC - risks related to chemical agents at work of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)*
- *Directive 2004/37/EC - carcinogens or mutagens at work of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) Directive 89/391/EEC)*
- *Regulation (EC) No 1907/2006 - REACH of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency. Occupational exposure assessment (Chapter R.14) (23/08/2016) of the REACH technical Guidance on Information Requirements and Chemical Safety Assessment*
- *Regulation (EC) No 1272/2008 - classification, labelling and packaging of substances and mixtures of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No*

1907/2006 (Text with EEA relevance)
Additional legislation (only latest list mentioned):
- *Directive 91/322/EEC - indicative limit values of 29 May 1991 on establishing indicative limit values by implementing Council Directive 80/1107/EEC on the protection of workers from the risks related to exposure to chemical, physical and biological agents at work.*
- *Directive 2019/1831 - indicative occupational exposure limit values of 24 October 2019 establishing a fifth list of indicative occupational exposure limit values pursuant to Council Directive 98/24/EC and amending Commission Directive 2000/39/EC*

The biological agents legislation directly applicable to Stoffenmanager® is:
- *Directive 2000/54/EC - biological agents at work of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC)*

My concern with this paper is the categorisation as a "research article". A research article is a detailed, structured report of an original scientific study. It typically presents a specific research question, explains the methods used to investigate it, presents data collected during the study, and analyses that data to draw a conclusion. A commentary, on the other hand, is a shorter, more opinion-driven piece that does not present original research data. Instead, it offers expert insight, interpretation, or critique on existing research, current trends, or issues in the field. Their purpose is often to stimulate discussion, guide interpretation, or provide context for ongoing debates.

Response: *We agree. This article was supposed to be published as an Open letter and not a Research article. We ask the editor to change the article to "Open Letter" from "Research Article". We repeat this request to the Editor.*

In the present case, the lack of a systematic approach to how the data have been analysed is making it difficult to categorise it as a research article. The authors could have used qualitative document analysis, which is a valid research approach involving systematic examination of texts to identify patterns, themes, and meanings. However, the paper fails to deliver on both the methodological rigour and performance expected for such a study. A clear description of the analysis process, particularly how the documents were examined, coded, and interpreted, is absent. This absence pushes the work closer to an informal commentary rather than a robust research article.

Response:*This work focuses on the regulatory exposure model requirements specified by ECHA. Model evaluation was carried out for StM and ART in Koivisto et al. (2022, 2018), but this work was ignored. This is explained in the Underlying data "History of StM and ART evaluation". ECETOC-TRA, EMKG-EXPO-TOOL, MEASE, EASE, etc. models based on multipliers and subjective selections have a similar structure to "more sophisticated" StM and ART, which fail in quantitative exposure assessment. Thus, these models are qualitative as well. We also request that "the ECHA Chapter R.14 exposure models should be objectively evaluated for compliance with these criteria [referring to US-EPA and EFSA]." We wrote in the "History of StM and ART evaluation" that "E-TEAM reports have not evaluated the models' theoretical backgrounds at the scientific level. There are no independent evaluation reports from StM and ART other than Koivisto et al. (2022, 2018) in which scientific issues were laid out but not responded to." We see that "...but not responded to"*

holds because Cherrie et al. (2020) and Fransman et al. (2022) did not address the scientific parts in their response letters. We extracted all the information related to exposure models criteria within the REACH regulation from ECHA and presented the results transparently. Feel free to propose a better approach which is more systematic. Terminology was discussed within ISES Europe, and this discussion is followed here. Unfortunately, the terminology study has not yet been published, but we can provide the proposals. However, that is irrelevant if ECHA uses its terminology without following international definitions or providing its own definitions. See also the comments for Peter Egeghy. References Cherrie, J.W., Fransman, W., Heussen, G.A.H., Koppisch, D., Jensen, K.A., 2020. Exposure Models for REACH and Occupational Safety and Health Regulations. IJERPH 17, 383. https://doi.org/10.3390/ijerph17020383 Fransman, W., Arnone, M., Borghi, F., Cattaneo, A., Cavallo, D.M., Cherrie, J.W., Franken, R., Galea, K.S., van der Haar, R., Heussen, G.A.H., Jensen, K.A., Koponen, M., Koppisch, D., Kromhout, H., Luo, Y.-S., McNally, K., Säämänen, A., Spinazzè, A., van Tongeren, M., Vanoirbeek, J., Verpaele, S., Vetter, D., Viegas, S., Warren, N., 2022. Response Letter to Koivisto et al . 'Evaluating the Theoretical Background of STOFFENMANAGER® and the Advanced REACH Tool.' Annals of Work Exposures and Health 66, 543–549. https://doi.org/10.1093/annweh/wxac001 Koivisto, A.J., Jayjock, M., Hämeri, K.J., Kulmala, M., Van Sprang, P., Yu, M., Boor, B.E., Hussein, T., Koponen, I.K., Löndahl, J., Morawska, L., Little, J.C., Arnold, S., 2022. Evaluating the Theoretical Background of STOFFENMANAGER® and the Advanced REACH Tool. Annals of Work Exposures and Health 66, 520–536. https://doi.org/10.1093/annweh/wxab057 Koivisto, A.J., Jensen, A.C.Ø., Koponen, I.K., 2018. The general ventilation multipliers calculated by using a standard Near-Field/Far-Field model. Journal of Occupational and Environmental Hygiene 15, D38–D43. https://doi.org/10.1080/15459624.2018.1440084 Schlueter, U., Tischer, M., 2020. Validity of Tier 1 Modelling Tools and Impacts on Exposure Assessments within REACH Registrations—ETEAM Project, Validation Studies and Consequences. IJERPH 17, 4589. https://doi.org/10.3390/ijerph17124589 Schlüter, U., Arnold, S., Borghi, F., Cherrie, J., Fransman, W., Heussen, H., Jayjock, M., Jensen, K.A., Koivisto, J., Koppisch, D., Meyer, J., Spinazzè, A., Tanarro, C., Verpaele, S., Von Goetz, N., 2022. Theoretical Background of Occupational-Exposure Models—Report of an Expert Workshop of the ISES Europe Working Group "Exposure Models." IJERPH 19, 1234. https://doi.org/10.3390/ijerph19031234 Schlüter, U., Spinazzè, A., 2023. Understanding the limitations and application of occupational exposure models in a REACH context. Journal of Occupational and Environmental Hygiene 20, 336–349. https://doi.org/10.1080/15459624.2023.2208188

Competing Interests: No competing interests were disclosed.

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Peter Egeghy
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The article titled “How credible is REACH regulation without transparency, quality criteria, assurance, and control?” argues that ECHA may not be in compliance with its regulatory mandates for implementing the REACH legislation. This argument is based on (1) REACH Regulation (EC) No 1907/2006, Annex I, §5.0 requires quantitative exposure estimates to support the risk characterization, (2) ECHA allows the use of non-physical models containing qualitative parameters based on non-accessible calibration databases, and (3) the authors contend that “the fundamental requirement for quantitative exposure assessment is quantitative uncertainty assessment.” The article is well written, and both authors are well respected with strong reputations in the area of human exposure modeling.

One of the main issues that the authors discuss is the lack of transparency that arises form the use of non-accessible calibration databases for two particular screening-level models: Advanced REACH Tool (ART) and Stoffenmanager (StM). Indeed, many regulatory organizations are prohibited, or at least highly discouraged, from using models that are not fully transparent with publicly accessible algorithms and training data. A lack of transparency undermines the legitimacy of any decisions that rely on those models. The authors are providing the public and other stakeholders a great service by pushing ECHA towards greater transparency and accountability.

This article is important to the scientific community because robust exposure prediction models are critical to managing the human health and ecological risks posed by chemical substances. Moreover, open access to data encourages research and innovation within the chemical industry and academia. Full transparency allows researchers to build upon existing knowledge, leading to the development of safer and more sustainable chemical products and processes.

The article is categorized as a “research article,” but despite following the standardized structure of a research article, it more closely resembles a commentary. The Methods of the investigation consisted of sending five letters to ECHA asking specific questions about criteria for use of the models for regulatory purposes (i.e., registration of chemical substances to ensure that the risks associated with their use are properly managed). While there is an abundance of published articles that evaluate available lower-tier models for occupational exposure [which can be accessed through Google Scholar with search term "‘evaluation’ AND (‘Advance Reach Tool’ OR ‘Stoffenmanager’ OR ‘Ecetoc TRA’"), the authors have not performed a comprehensive evaluation of those articles.

It appears that many of the criticisms of in the current manuscript were previously published by the authors (Koivisto, Jayjock, Hämeri, et al., 2022 [Ref 1]) and that the criticisms were elaborately refuted by the developers of the models (Fransman, Arnone, Borghi, et al., 2022 [Ref 6]). While the authors of the current manuscript cite their previous article multiple times, they fail to acknowledge the rebuttal while repeating the criticisms.

One of the key criticisms levied by the authors is that the (screening level) models accepted by ECHA fail to meet the definition of a "quantitative" exposure model. According to the authors a quantitative exposure model must not only rely on measurable inputs and mathematical relationships based on physical and chemical laws but must also allow for quantitative uncertainty analysis. The latter requirement does not appear to be aligned with internationally recognized terminology. For example, the seminal textbook by Rappaport and Kupper (2008)[Ref 5] makes no mention of a requirement for uncertainty analysis. Both ART and StM are referred to as "quantitative exposure models" in the scientific literature (e.g., Lee, Lee, and Kim, 2019 [Ref 4]). The citation provided by the authors of the current manuscript to support their contention of the fundamental requirement for quantitative uncertainty assessment (Simmonds EG, Adjei KP, Andersen CW, et al., 2022) acknowledges that quantification of model-related uncertainty is not consistent across scientific fields and presents a concept of uncertainty that is much more expansive than in the current manuscript. Likewise, Fryer et al. (2006) [Ref 2] describe four broad categories of uncertainty in exposure modeling, namely scenario uncertainty, model uncertainty, parameter variability, and parameter uncertainty.

The authors seem to overlook the fit-for-purpose nature of lower-tier screening level models like ART and StM. The usefulness of these models lies in the ability to apply them in data-limited situations, such as the registration of new chemicals. For these models, accuracy is less important than producing conservative estimates to ensure health protection. As described in Schlüter et al. (2022) [Ref 3], higher-tier, mass balance-based models are able to provide a more refined quantitative estimate of exposure, but at a far higher cost (e.g., for input data) and far more limited applicability.

Specific comments:

Introduction, 1st sentence: the phrase "shall be to make" is awkward. An awkward first sentence can bias a reader.

Introduction, 2nd paragraph: These three elements refer to exposure assessment across the lifecycle of a chemical whereas this manuscript is focused on occupational exposures.

Introduction, 3rd paragraph: The first four items of the bulleted list do not seem relevant to this manuscript.

Introduction, 4th paragraph: The last sentence states that calibration databases are required to be available under REACH regulation. What fraction of available lower-tier models make the calibration database available?

Introduction, 5th paragraph: Please explain why the authors relied on responses to questions from ECHA rather than on the multitude of REACH-related model evaluations available in the scientific literature.

Results, 1st paragraph: It is not clear what is meant by "ECHA does not recognize the 'quantitative' term". Also why cite a source that only "implicitly" defines "quantitative exposure model" when there are numerous sources that explicitly define the term?

Results, 5th paragraph: The definition of "quantitative exposure model" should come much earlier

in the manuscript.

Results, 5th paragraph: The paragraph is about uncertainty, yet the final two sentences refer to “accuracy,” which, as the authors know, is a related but different concept.

Results, 6th paragraph: The text presents an example of how a transfer speed can be high on one context yet low in another. Perhaps it is this context-related relativity that forces the reliance on subjective input parameters in screening-level models.

Results, 7th paragraph: The last sentence states that models like StM and ART “will not give information on workers' exposure and safety or provide helpful information on the effect of exposure determinants on workers' exposure levels.” I do not think that is the purpose of these models and that it may not be fair to criticize a model (or category of models) for not being able to do something for which it is not intended.

Results, 8th paragraph: In the second sentence, I believe that he authors intended the affirmative (i.e., “do offer”) rather than the negative (“do not offer”). Otherwise this statement would contradict the last sentence of the third paragraph in the Results section.

Results, last paragraph: Please provide a citation for the ISES strategy for exposure models.

Disclaimer: *The views expressed in this peer review are those of the author and do not necessarily represent the views or the policies of the U.S. Environmental Protection Agency.*

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Is the work clearly and accurately presented and does it cite the current literature?
Partly

Is the study design appropriate and does the work have academic merit?

Partly

Are sufficient details of methods and analysis provided to allow replication by others?
Yes

If applicable, is the statistical analysis and its interpretation appropriate?
Not applicable

Are all the source data underlying the results available to ensure full reproducibility?
Yes

Are the conclusions drawn adequately supported by the results?
Partly

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Exposure modeling

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 30 Jul 2025

Antti Joonas Koivisto

We thank the reviewer for the valuable comments.

The article is categorized as a “research article,” but despite following the standardized structure of a research article, it more closely resembles a commentary.

With the Editor, we agreed to publish the manuscript as Open Letter rather than a Research Article.

I sent a separate message to the Editor The Methods of the investigation consisted of sending five letters to ECHA asking specific questions about criteria for use of the models for regulatory purposes (i.e., registration of chemical substances to ensure that the risks associated with their use are properly managed). While there is an abundance of published articles that evaluate available lower-tier models for occupational exposure [which can be accessed through Google Scholar with search term "'evaluation' AND ('Advance Reach Tool' OR 'Stoffenmanager' OR 'Ecetoc TRA'"), the authors have not performed a comprehensive evaluation of those articles. We agree, this is not related to the quality criteria for exposure models. Also, the Underlying Data, Section 1, “*The history of StM and ART evaluation”*, reveals that there are no other evaluation studies than ours. See justification from Table R1. Table R1 can be added to the Underlying Data, Section 1, to support our statement. **Table R1.** STOFFENMANAGER® and ART evaluation studies. Developmental studies can be found from (Koivisto et al., 2022a). Last updated Dec 2024. **Study Investigation** Hesse et al. (2015) Theoretical evaluation of STOFFENMANAGER® concept Hesse et al. (2015) Uncertainty

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It appears that many of the criticisms of in the current manuscript were previously published by the authors (Koivisto, Jayjock, Hämeri, et al., 2022 [Ref 1]) and that the criticisms were elaborately refuted by the developers of the models (Fransman, Arnone, Borghi, et al., 2022 [Ref 6]). While the authors of the current manuscript cite their previous article multiple times, they fail to acknowledge the rebuttal while repeating the criticisms. We have explained this thoroughly in Section 1 of the Underlying Data. We add the reference.

One of the key criticisms levied by the authors is that the (screening level) models accepted by ECHA fail to meet the definition of a “quantitative” exposure model. According to the authors a quantitative exposure model must not only rely on measurable inputs and mathematical relationships based on physical and chemical laws but must also allow for quantitative uncertainty analysis. The latter requirement does not appear to be aligned with internationally recognized terminology. For example, the seminal textbook by Rappaport and Kupper (2008)[Ref 5] makes no mention of a requirement for uncertainty analysis. The latter requirement is an outcome of the first requirement; i.e., quantitative uncertainty assessment is possible for physical models, and their boundaries can be assessed. In the ISES Europe, we made a systematic evaluation of exposure terminology. The ISES Europe proposal was that “A quantitative exposure model is a mathematical representation that estimates the magnitude, frequency, duration, and route of exposure to a chemical. It combines information on the frequency, mode, and magnitude of contact with contaminated media to yield a quantitative value of exposure associated with quantitative uncertainty.“ We could not have access to Rappaport and Kupper. Both ART and StM are referred to as “quantitative exposure models” in the scientific literature (e.g., Lee, Lee, and Kim, 2019 [Ref 4]). Yes, as explained by Koivisto et al. (2022) StM and ART are called by different names without justification (See e.g. Table 1 in Koivisto et al. 2022). The citation provided by the authors of the current manuscript to support their contention of the fundamental requirement for quantitative uncertainty assessment (Simmonds EG, Adjei KP, Andersen CW, et al., 2022) acknowledges that quantification of model-related uncertainty is not consistent across scientific fields and presents a concept of uncertainty that is much more expansive than in the current manuscript. Likewise, Fryer et al. (2006) [Ref 2] describe four broad categories of uncertainty in exposure modeling, namely scenario uncertainty, model uncertainty, parameter variability, and parameter uncertainty. We agree. We added

Fryer et al. (2006) reference.
The authors seem to overlook the fit-for-purpose nature of lower-tier screening level models like ART and StM. The usefulness of these models lies in the ability to apply them in data-limited situations, such as the registration of new chemicals. For these models, accuracy is less important than producing conservative estimates to ensure health protection. StM and ART are classified as higher-tier models, not screening-level models. One criterion for an adequate exposure model, as established by the Dutch Social Economic Council (Koivisto et al., 2022) and the OECD (ENV/CBC/MONO(2021)28), is that ≤10% of the modelled exposure estimates can exceed the measured exposure level. This criteria is not complied by StM or ART for which the the modelled 75th/90th percentile of the exposure distribution falls below the measured exposure level in >10% of the cases (e.g. Lamb et al. (2015); Riedmann et al. (2015); Landberg et al. (2017); Landberg et al. (2018); van Tongeren et al. (2017); Lee et al. (2018); Lee et al. (2020); Lee et al. (2023); Spinazzè et al. (2017). Similarly, Tier 1 models are shown to fails this criterion (e.g. Noij et al. (2023; Tijdschrift voor toegepaste Arbowetenschap 2023;36(3)); Savic et al. (2023; 10.1093/annweh/wxad001); Spinazzè et al. (2017); van Tongeren et al. (2017); Landberg et al. (2018); Riedmann et al. (2015); Lamb et al. (2015)). StM or ART does not comply with the ASTM D5157-97 numerical criteria (we did not confirm this for Tier 1 models) (Koivisto et al. 2022). It is a misleading statement that these models would produce conservative estimates if they do not meet the minimum numerical criteria for an exposure model. This was also addressed in Koivisto et al. (2022), which Fransman et al. (2022) did not deny. This demonstrates how vital quality criteria is for exposure and risk communication. As described in Schlüter et al. (2022) [Ref 3], higher-tier, mass balance-based models are able to provide a more refined quantitative estimate of exposure, but at a far higher cost (e.g., for input data) and far more limited applicability. Emission is the point of departure for exposure and must be reported in the chemical safety report (REACH regulation - Annex I § 5.2.1). Emission is a minimum requirement for predictive exposure assessment under various conditions and establishing conditions of use for chemical manufacturing and use (see e.g., https://doi.org/10.12688/openreseurope.19498.1; https://doi.org/10.12688/openreseurope.19658.2). Suppose the emission assessment is considered too high cost, and ECHA allows the use of non-physical models that do not require information on emissions. In that case, it is recommended to use these user-friendly models. What is a more refined quantitative estimate of exposure?

Specific comments:

Introduction, 1st sentence: the phrase “shall be to make” is awkward. An awkward first sentence can bias a reader. The sentence was revised.

Introduction, 2nd paragraph: These three elements refer to exposure assessment across the lifecycle of a chemical whereas this manuscript is focused on occupational exposures. Yes, this is correct. No changes were made.
Introduction, 3rd paragraph: The first four items of the bulleted list do not seem relevant to this manuscript. We refer to these mandates in the main text. No changes were made.
Introduction, 4th paragraph: The last sentence states that calibration databases are required to be available under REACH regulation. What fraction of available lower-tier models make the calibration database available? To the best of our knowledge, none of the

calibration databases is currently available. No changes were made.

Introduction, 5th paragraph: Please explain why the authors relied on responses to questions from ECHA rather than on the multitude of REACH-related model evaluations available in the scientific literature. The objective was to understand the criteria by ECHA for exposure models applied in the REACH regulation. Please see more from the Underlying Data section 1, which discusses the objective model evaluation, and Table R1. No changes were made.
Results, 1st paragraph: It is not clear what is meant by "ECHA does not recognize the 'quantitative' term". Also why cite a source that only "implicitly" defines "quantitative exposure model" when there are numerous sources that explicitly define the term? ECHA considers a model result quantitative if the units are correct physical dimensions. Similarly, Fransman et al. (2022) state that the model is quantitative if it produces correct dimensions (here: mg/m3). This is not a sufficient criterion as explained in the main text and Underlying Data, Section 3, ECHA review comments and responses. We would be grateful if you could provide an explicit definition for "quantitative exposure model". We added a citation to Underlying data, section 2; Koivisto & Jayjock, 2025).

Results, 5th paragraph: The definition of "quantitative exposure model" should come much earlier in the manuscript. We agree, we moved this to the second paragraph in Results and discussion.

Results, 5th paragraph: The paragraph is about uncertainty, yet the final two sentences refer to "accuracy," which, as the authors know, is a related but different concept. We agree. We added "Model accuracy and uncertainty are related to the model parametrization and how well the model construct reflects the real environment (e.g., Fryer et al., 2006)."

Results, 6th paragraph: The text presents an example of how a transfer speed can be high on one context yet low in another. Perhaps it is this context-related relativity that forces the reliance on subjective input parameters in screening-level models. See Marquart et al. (2008) for context-related relativity. No changes were made.

Results, 7th paragraph: The last sentence states that models like StM and ART "will not give information on workers' exposure and safety or provide helpful information on the effect of exposure determinants on workers' exposure levels." I do not think that is the purpose of these models and that it may not be fair to criticize a model (or category of models) for not being able to do something for which it is not intended. This is the purpose of StM and ART (See e.g. Schlüter et al. 2022; https://doi.org/10.3390/ijerph19031234). They state that "*STOFFENMANAGER® and ART are well-established and accepted tools that are used for regulatory risk assessments, e.g., for REACH or in the context of the EU occupational health and safety directive 98/24/EC (ref to https://doi.org/10.3390/ijerph17020383)*". No changes were made.
Results, 8th paragraph: In the second sentence, I believe that the authors intended the affirmative (i.e., "do offer") rather than the negative ("do not offer"). Otherwise this statement would contradict the last sentence of the third paragraph in the Results section. Negate is correct. We clarified the sentence as "According to our understanding, neither other institutes, such as the US-EPA and EFSA, offer numerical criteria for exposure models."

This does not contradict the third paragraph in the Results section because there are other criteria related to uncertainty assessment. If the model result, including uncertainty, yields compliance, then the result can be considered sufficiently accurate.
Results, last paragraph: Please provide a citation for the ISES strategy for exposure models. This was added.

Competing Interests: No competing interests were disclosed.

Reviewer Report 25 July 2025

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The paper critically examines the credibility of the EU's REACH regulation for chemical safety, particularly occupational exposure modelling, arguing that it lacks sufficient transparency, quality criteria, assurance, and control mechanisms. The authors build their case by analyzing data access issues, inconsistencies in regulatory practices, and weaknesses in currently used exposure tools. The authors address a timely and under explored issue within EU chemical regulation, and with their work, they could contribute to improved policy accountability and scientific robustness.

I have some suggestions for how the paper could be improved:

While I sympathise with the author's frustration, they still need to maintain professional and objective language. As it is now, the paper borders on advocacy, which is rarely an advantage in such cases. There is also passive voice that needs to be removed.

Consider making some language edits to improve clarity and precision, especially in the results and discussion sections. Some sections are wordy and repetitive rather than providing a logical order to the text.

The first sentence of the introduction is missing a word: 'performed'?

The paper lacks a systematic methodology section, so the text reads more like an anecdotal regulatory critique than a structured evaluation. A clear method section is important if you want to provide an unbiased critique and address institutional failure.

Different abbreviations appear in the text without explanation and, in some cases, without justification, for example: ISES Europe model, INTEGRANO and E-TEAM.

The statement is not sufficiently clarified, nor is the process by which the authors arrived at it: 'ECHA does not recognise the "quantitative" term...'

The text would benefit from presenting counterarguments to balance the critique.

Conclude the paper by listing your recommendations for ECHA and the EC.

There are also places where modifiers are misplaced, for example:
'Such models can produce nearly any outcome...' Which model is being referred to here?

'There appears to be no transparency criteria.' What lacks transparency criteria?

'This is one objective of INTEGRANO.' The preceding sentence reads, 'Such criteria are needed to establish an exposure model for regulatory chemical safety decision-making', and I assume this is not Integrano's objective.

Is the work clearly and accurately presented and does it cite the current literature?
No

Is the study design appropriate and does the work have academic merit?
Yes

Are sufficient details of methods and analysis provided to allow replication by others?
No

If applicable, is the statistical analysis and its interpretation appropriate?
Not applicable

Are all the source data underlying the results available to ensure full reproducibility?
Yes

Are the conclusions drawn adequately supported by the results?
Partly

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Regulatory toxicology, EU chemical regulation

I confirm that I have read this submission and believe that I have an appropriate level of expertise to state that I do not consider it to be of an acceptable scientific standard, for reasons outlined above.

Author Response 30 Jul 2025

Antti Joonas Koivisto

The paper critically examines the credibility of the EU’s REACH regulation for chemical

safety, particularly occupational exposure modelling, arguing that it lacks sufficient transparency, quality criteria, assurance, and control mechanisms. The authors build their case by analyzing data access issues, inconsistencies in regulatory practices, and weaknesses in currently used exposure tools. The authors address a timely and under explored issue within EU chemical regulation, and with their work, they could contribute to improved policy accountability and scientific robustness. We thank the reviewer for the valuable comments.

I have some suggestions for how the paper could be improved:

While I sympathise with the author's frustration, they still need to maintain professional and objective language. As it is now, the paper borders on advocacy, which is rarely an advantage in such cases. There is also passive voice that needs to be removed.
Response: We aim to explain the situation as clearly as possible to make an objective picture of the current situation in ECHA. In a previous study by Schlüter et al. 2022 (DOI: https://doi.org/10.3390/ijerph19031234), we balanced the text, which led to misinterpretations by other authors and ECHA. Removing passive voice can lead to misinterpreting the message of this manuscript. Unfortunately, we prefer to give as realistic a description of the situation as possible, but feel free to propose changes in passive sentences so that the message remains transparent and objective.

Consider making some language edits to improve clarity and precision, especially in the results and discussion sections. Some sections are wordy and repetitive rather than providing a logical order to the text.
Response: We moved the description of the quantitative model to the second paragraph.

The first sentence of the introduction is missing a word: 'performed'? The sentence was revised.

The paper lacks a systematic methodology section, so the text reads more like an anecdotal regulatory critique than a structured evaluation. A clear method section is important if you want to provide an unbiased critique and address institutional failure.
Response: This article was supposed to be published as an Open letter and not a Research article. We ask the editor about this. I'm not sure what a better approach is than having a transparent discussion with ECHA. Terminology was discussed within ISES Europe, and this discussion is followed here. Unfortunately, the terminology study has not yet been published, but we can provide the proposals.

Different abbreviations appear in the text without explanation and, in some cases, without justification, for example: ISES Europe model, INTEGRANO and E-TEAM.
Response: We agree. We had an abbreviation table, but it was removed from the online version. This was added once more. We were unable to identify abbreviations without justification. For example, "*The calibration databases are essential for model evaluation within the ISES Europe model evaluation group.*" Should justify the use of the ISES Europe model evaluation group.

The statement is not sufficiently clarified, nor is the process by which the authors arrived at

it: 'ECHA does not recognise the "quantitative" term...'
Response: ECHA did not answer this. ECHA mentioned that “It is worth noting that a significant portion of the European scientific community has identified ART and Stoffenmanager as quantitative exposure models (Fransman et al., 2022).” (Underlying data, section 3). However, Fransman et al. (2022) state that the model is quantitative if it produces correct dimensions. This is not a sufficient criterion for quantitative assessment. No changes were made.

The text would benefit from presenting counterarguments to balance the critique.
Response: We can add, for example, that if one divides the postal code by the shoe number and multiplies it by the occupational exposure limit value, it does not produce a quantitative exposure estimate, regardless of whether the dimensions are correct. However, this type of argument is not very constructive, because it should be clear to the scientific community. No changes were made.

Conclude the paper by listing your recommendations for ECHA and the EC.
Response: This has been listed in the conclusions as “*We recommend that ECHA adopt the quality criteria, assurance, and control for regulatory exposure modelling from US-EPA and EFSA. Harmonization is a step towards globally accepted regulatory exposure assessment. Afterward, the ECHA Chapter R.14 exposure models should be objectively evaluated for compliance with these criteria. We see this as necessary to ensure the transparency of all models used for regulatory compliance.*” No changes were made.

There are also places where modifiers are misplaced, for example:
'Such models can produce nearly any outcome...' Which model is being referred to here?
Response: We clarified that such models are subjective models.

'There appears to be no transparency criteria.' What lacks transparency criteria?
Response: Calibration databases, their calculation methods, and the StM evaluation report. These were listed in the Introduction. No changes were made.

'This is one objective of INTEGRANO.' The preceding sentence reads, 'Such criteria are needed to establish an exposure model for regulatory chemical safety decision-making', and I assume this is not Integrano's objective.
Response: INTEGRANO’s objective is to establish a mechanistic exposure model applicable for regulatory chemical safety decision-making in indoor environments. For that, we need to know what criteria have been established for exposure models, because a regulation that can be conducted by using arbitrary methods is not useful. No changes were made.

Competing Interests: No competing interests were disclosed.