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Health & Ecological Risk Assessment

Open Science in regulatory environmental risk assessment

Theo C. M. Brock,[1] Kevin C. Elliott,[2,3] Anja Gladbach,[4] Caroline Moermond,[5] Jörg Romeis,[6] Thomas-Benjamin Seiler,[7,8] Keith Solomon,[9] and G. Peter Dohmen[10]

[1]*Wageningen Environmental Research, Wageningen, The Netherlands*
[2]*Department of Fisheries and Wildlife, Lyman Briggs College Department of Philosophy, Michigan State University, East Lansing, Michigan, USA*
[3]*Department of Philosophy, Lyman Briggs College, Michigan State University, East Lansing, Michigan, USA*
[4]*Bayer, Germany*
[5]*National Institute for Public Health and the Environment (RIVM), Utrecht, The Netherlands*
[6]*Research Division Agroecology and Environment, Agroscope, Zurich, Switzerland*
[7]*Hygiene-Institut des Ruhrgebiets, Gelsenkirchen, Germany*
[8]*Institute for Environmental Research, RWTH Aachen University, Aachen, Germany*
[9]*University of Guelph, Guelph, Ontario, Canada*
[10]*BASF, Germany*

Abstract

A possible way to alleviate the public skepticism toward regulatory science is to increase transparency by making all data and value judgments used in regulatory decision making accessible for public interpretation, ideally early on in the process, and following the concepts of Open Science. This paper discusses the opportunities and challenges in strengthening Open Science initiatives in regulatory environmental risk assessment (ERA). In this discussion paper, we argue that the benefits associated with Open Science in regulatory ERA far outweigh its perceived risks. All stakeholders involved in regulatory ERA (e.g., governmental regulatory authorities, private sector, academia, and nongovernmental organizations), as well as professional organizations like the Society of Environmental Toxicology and Chemistry, can play a key role in supporting the Open Science initiative, by promoting the use of recommended reporting criteria for reliability and relevance of data and tools used in ERA, and by developing a communication strategy for both professionals and nonprofessionals to transparently explain the socioeconomic value judgments and scientific principles underlying regulatory ERA. *Integr Environ Assess Manag* 2021;17:1229–1242. © 2021 The Authors. *Integrated Environmental Assessment and Management* published by Wiley Periodicals LLC on behalf of Society of Environmental Toxicology & Chemistry (SETAC)

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INTRODUCTION

For the premarket environmental risk assessment (ERA) of regulated products (e.g., industrial chemicals, pharmaceuticals, biocides, pesticides, feed additives, genetically modified organisms), as well as for their re-registration, applicants are required to provide data and to conduct a provisional ERA according to implemented guidance as part of their market registration. Regulatory agencies evaluate whether the applicants have performed studies and the ERA in line with this guidance and request additional data and/or adjust the ERA if deemed appropriate. However, there is public skepticism toward regulatory ERA (Hunka et al., 2012; Kabat, 2017; Karlsson, 2019; Lofstedt, 2013; Voulvoulis & Burgman, 2019; Hunt & Wald 2020). Possible reasons are diverse and include:

- Conflicting opinions about what should be regarded as harm.
- Disagreements about the strength, relevance, and reliability of evidence used in ERAs.
- Distrust of experts involved in generating and evaluating such evidence.
- Perception that contradictory conclusions have been reached by different regulatory authorities and/or under different regulatory frameworks.
- Lack of transparency about the decision-making process and the evidence used.
- Growing public demand to be involved and have a say in regulatory decisions that affect them.

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Correspondence Theo C. M. Brock, Wageningen Environmental Research, The Netherlands.
Email: theo.brock@wur.nl

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Adopting Open Science in the regulatory ERA process, by making all value judgments (e.g., the definition of specific protection goals), data, and evaluation tools used in decision making accessible and transparent for the public, might help alleviate public skepticism and increase public involvement. In this paper, with a focus on regulatory ERA, we adopt the following definition of Open Science: The movement to make scientific research (including publications, basic data, and software) and its dissemination accessible to any member of the inquiring society, from professionals to citizens (Woelfle et al., 2011), under terms that enable the evaluation of the relevance and reliability of data and tools, such as models and scenarios, for their (re) use in a regulatory context.

This paper discusses goals, opportunities, and challenges that Open Science in regulatory ERA could pose. It builds on initiatives of the Society of Environmental Toxicology & Chemistry (SETAC) such as the Technical Issue Paper (TIP) entitled "Recommended Minimum Reporting Information for Environmental Toxicity Studies" (SETAC, 2019a and presentations and discussions from the special session on "Open Science in Regulatory Environmental Risk Assessment" as part of the SETAC SciCon, the virtual SETAC-Europe 30th Annual Meeting, May 3–7, 2020 (see Supporting Information Appendix SA) and a follow-up activity on this topic as part of the virtual SETAC Café Series, February 25, 2021 (see Supporting Information Appendix SB). Our objective in this discussion paper is to raise awareness of scientifically and socially relevant transparency (as defined by Elliott & Resnik, 2019) and to discuss possible initiatives to promote and facilitate the Open Science movement in support of regulatory ERA.

THE OPEN SCIENCE MOVEMENT, AN INTRODUCTION

Aim of the section

This section aims to introduce the goals and initiatives of the Open Science movement in general and to discuss its barriers and opportunities for environmental sciences.

Goals of Open Science

Several goals have been driving the Open Science movement forward. One is the concern for accelerating scientific discovery and innovation by making data, findings, and materials as accessible to others as possible. For example, this emphasis on innovation through Open Science has been a central theme of research efforts designed to respond to the novel coronavirus as quickly as possible (Kupferschmidt, 2020). Another driver for Open Science has been the desire to improve the reproducibility, reliability, and transparency of scientific findings (Mebane et al., 2019; Munafò et al., 2017; Nosek et al., 2015). In the context of regulatory ERA, another particularly important driver is the desire to be inclusive and to provide opportunities for a diverse array of scientists and other stakeholders to engage with the science that informs regulatory policy (Elliott & Resnik, 2019; Soranno et al., 2015).

This desire to be inclusive can be looked at, described, and understood by using the Fairness Theory (Besley, 2009; Rawls, 2001; van den Bos et al., 1997). This concept postulates that a given group of people with particular interests (commonly referred to as "stakeholders" in the context of ERA) is more likely to accept a decision against their interests and/or beliefs when they feel that they have been treated fairly. People tend to believe those data supporting their pre-existing beliefs and are less likely to consider data that support alternative views (e.g., Kahan et al., 2009). These tendencies can be lessened by attending to principles of fairness in generating, communicating, and using scientific information. For an evaluation of the grade of fairness of a given decision, the Fairness Theory distinguishes between four aspects of fairness:

(1) Procedural justice: People are given a fair voice in the process.
(2) Informational justice: Full and easy access to appropriate information is ensured.
(3) Interpersonal justice: People are treated well, and they also feel this way.
(4) Distributive justice: Outcomes are distributed properly and communicated early and transparently.

Open Science most directly involves informational justice, but it is associated to some extent with all four aspects of fairness. For example, even though procedural justice is not directly covered, it can be advanced by making information (e.g., results from preregistration studies, publications, and post-publication review) available on unrestricted platforms so that all stakeholders are better equipped to make use of the tools available for public participation. It should be noted that for confidentiality reasons, it may not always be possible to make preregistration studies fully available. For companies that have invested extensive resources in collecting data, it may be financially problematic to provide complete access to this information, especially in countries that do not protect this investment. Nevertheless, summaries (and endpoints used in decision making) of these studies are usually made accessible to the public by regulatory authorities. Treating stakeholders fairly is a trust-building measure and thus supports the desire to make ERA more inclusive by promoting Open Science.

Initiatives of Open Science

Initiatives to help promote Open Science span the entire research enterprise (Table 1). Before commencing data collection, researchers can preregister their studies to promote reliability and reproducibility (Nosek et al., 2018). During the course of the research, some scientists are experimenting with "open lab notebooks" that allow others to collaborate and offer feedback on the research process in real time (Schapira et al., 2019).

TABLE 1 Examples of initiatives associated with the Open Science movement

Initiative	Example	URL	Reference
Preregistration	OSF Registries	https://osf.io/prereg/	Nosek et al. (2018)
Open lab notebooks	Open Lab Notebook Consortium	https://openlabnotebooks.org/	Schapira et al. (2019)
Data repositories	GenBank	https://www.ncbi.nlm.nih.gov/genbank/	Sayers et al. (2020)
Data sharing guidelines	FAIR principles	https://www.go-fair.org/fair-principles/	Wilkinson et al. (2016)
Preprints	BioRxiv	https://www.biorxiv.org/	Callaway (2013)
Open access policies	Plan S	https://www.coalition-s.org/	Schlitz (2018)
Open peer review	F1000 Research	https://f1000research.com/	Ross-Hellauer (2017)

A very important element of the Open Science movement is the development of repositories for making data available, together with guidelines for doing so in a way that maximizes relevance and usability of the data. For example, the FAIR Guidelines provide guidance for making data findable, accessible, interoperable, and reusable not only for human scholars but also for machines searching through information (Wilkinson et al., 2016).

Many elements of the publishing process are also changing to reflect principles of Open Science. Researchers are increasingly making preprints available online before their work is officially published (Kaiser, 2017). In addition, journals are under increasing pressure to make their articles freely available without paywalls. For example, the European Union's research framework program HORIZON 2020 requires beneficiaries in H2020-funded projects to either publish Open Access (Gold Route) or at least deposit the final peer-reviewed manuscript in an openly accessible repository after an embargo period of at least 12 months (Green Route) (EC, Directorate-General for Research & Innovation, 2016). As nearly all journals currently allow self-archiving only after 24 months, this rule strongly pushes for an increase in Open Access publishing and/or a change in policy of the major publishers.

Besides a blind peer-review policy (in which reviewers do not know the authors and their affiliation), journals are also experimenting with more open approaches to peer reviews, such as making the identity of peer reviewers and even the content of reviews openly available (Ross-Hellauer, 2017). This is already a voluntary option on the reviewer and editor platform "Publons" (https://publons.com/about/home/).

Barriers for Open Science in regulatory ERA

Pursuing Open Science in the environmental regulatory context is not without challenges. A particularly prominent concern is that preprint publications could be of lesser quality due to a lack of proper peer review. The preprint information, which might be flawed or incomplete, could influence decision makers, other scientists, and the public, even if it were never officially published by journals due to failing the final peer-review process, thereby potentially causing more harm than good. Preprint information in line with a person's own beliefs may be more readily accepted and propagated and, when deemed flawed later on, supporters might suspect conspiracy if the publication is withdrawn. Especially in the case of politically sensitive topics where accuracy matters, one might think or believe that care and precision should take priority over the speed of publication. In such cases, one might argue that scientific results should only be published after peer review that considers criteria for relevance and reliability. These concerns are especially pressing in our highly polarized political environment, in which conspiracy theories and organized disinformation campaigns hamper public-health initiatives to address COVID-19 and other diseases. Nevertheless, these dangers of preprints have to be weighed against the benefits associated with the rapid dissemination of information, which have also been apparent during the COVID-19 pandemic (Kupferschmidt, 2020). In the following section, we discuss ways of balancing these benefits and dangers.

A wide variety of other concerns have been raised. One worry is that calls for greater transparency could be misused to hamper good science and good decision making. For example, a number of commentators have argued that the new proposal against "secret science" put forward by the U. S. Environmental Protection Agency (USEPA, 2018a) could prevent the agency from making use of important scientific findings (Fineberg & Allison, 2020; Malakoff, 2019). The proposal would give the EPA authority to only rely on studies that are made sufficiently available to the agency and the public. Critics have worried that the proposal could exclude important studies from consideration due to privacy concerns, for example, related to patients' medical data (Thorp et al., 2019). Some companies also worry about the potential for transparency initiatives to complicate their protection of confidential business information.

Others have raised the concern that transparency initiatives could be exploited by special interest groups to harass scientists with whom they disagree, by slowing the scientists down with endless requests for information (McGarity & Wagner, 2010) or by accusations of possible conflicts of interest when the results were obtained in research projects (co)funded by, or in collaboration with, the private sector even when this information was fully disclosed. Similar harassment of scientists by interest groups

may result from governmental funding if the research question is driven by value-laden policy preferences. For example, research concerning the consequences of ecological side effects of the use of pesticides may be perceived differently when funded by the Ministry of Agriculture or the Ministry of the Environment, even if advocacy is avoided in the scientific output. Some commentators argue that judging science by its funder should be discouraged, but scientists should disclose potential conflicting interests (Mebane et al., 2019), whereas others contend that information about funding can impact the credibility of research (Resnik & Elliott, 2013).

Some commentators have also worried that Open Science initiatives have the potential to focus primarily on issues relevant to the scientific community while neglecting the information needs and concerns of other stakeholders (Elliott & Resnik, 2019). Also, it should be noted that some stakeholders (e.g., nongovernmental organizations [NGOs]) and most members of the public do not have the time and resources to handle large databases.

Opportunities for Open Science in regulatory ERA

Fortunately, there are many opportunities to move Open Science forward, despite these challenges. Transparency in science can take many different forms, with varying goals, audiences, content, and avenues for disseminating information; thus, there are many ways to adjust Open Science initiatives to alleviate concerns (Elliott, 2020). For example, in response to the concern that preprints could contain faulty information that misleads decision makers, the prominent biology preprint server bioRxiv decided not to host preprints in most areas of clinical research; instead, a separate site, medRxiv, was developed with more stringent policies for screening papers (Kaiser, 2017). In general, preprint information should be spread and used with caution and accompanied with sufficient "warning" information. Further efforts are needed to design strategies for lessening the dangers associated with preprint servers and for identifying situations in which those dangers cannot be reduced to an acceptable level. Many of the concerns about violating patient privacy and disclosing confidential business information can also be addressed by designing policies with appropriate safeguards.

Some of the most important opportunities for moving Open Science forward in the environmental regulatory context involve efforts to make meaningful information more readily available to different stakeholders. We need to recognize that different stakeholders will want different kinds of information and may need that information to be provided in different ways (Elliott & Resnik, 2019). Data communication must be differentiated for different audiences. When talking about "the public," we should be aware that this is an extremely heterogeneous population that cannot be addressed appropriately in a single way. The majority of the "general public" will never read original scientific papers, even if they are made openly accessible beyond paywalls. So, a challenge is to transparently filter the relevant information out of the overwhelming quantity of data and then condense it in a manner that is meaningful to specific audiences. This filtering and condensing will likely need to be done by a range of different individuals and organizations (e.g., NGOs, community leaders, and community-engaged scientists) that understand the concerns of particular audiences and have built relationships of trust with them. Thus, meaningful Open Science requires developing systems through which information can flow in usable ways to different audiences (Elliott, 2020).

A variety of innovative strategies for reaching specific audiences are currently being explored. Some government agencies have developed strategic partnerships to analyze and interpret the data available to them in ways that serve specific community needs. For example, the U.S. National Aeronautics and Space Administration (NASA) has collaborated with the U.S. Agency for International Development (USAID) to help local governments use NASA data for predicting national disasters (Schumann et al., 2016), and NASA has worked with a Health and Air Quality Applied Sciences Team (HAQAST) to help communities use NASA data to answer their questions about environmental health threats (Holloway et al., 2018).

Community-based participatory research (CBPR) projects and citizen science initiatives have also given many community members the opportunity to learn about and contribute to scientific research that matters to them (Cavalier & Kennedy, 2016; Roy et al., 2012). For concerned community members who do not have the time to engage in CBPR or citizen science, science journalists and NGOs also have important roles to play in making scientific information available in meaningful ways (Elliott, 2019). In addition, corporations have recently been taking steps to make more information about their products available to the public, especially in the environmental regulatory context (see Section "Open Science in Regulatory Era and Stakeholder Involvement").

THE PROBLEM FORMULATION STEP IN REGULATORY ERA

Aim of the section

This section aims to clarify how problem formulation frames the ERA process and provides context on how value judgments and data that underlie regulatory ERA procedures are used (e.g., selection of specific protection goals; remaining uncertainties in adopted decision schemes). This is important to gain trust in, and alleviate skepticism toward, regulatory ERA.

Value judgments underlying problem formulation

Problem formulation is the initial stage where the ERA is framed (Devos et al., 2019; EFSA PPR, 2010; Gray, 2012; Norton et al., 1992). This includes the identification of the protection goals, description of the pathways whereby the intervention or the product could affect those protection goals, and the articulation of testable risk hypotheses. This is

followed by identifying the data and information needed to test those hypotheses to develop adequate decision schemes to be used in regulatory ERA. General protection goals found in legislation (policy protection goals) underlying ERAs for regulated products are often broad and generic. One example is the protection of biodiversity found in most jurisdictions. Biodiversity, however, can be defined in different ways, for example, alpha, beta, and gamma biodiversity (Whittaker, 1972) and genetic, species, functional, and community biodiversity (Swingland, 2001). These policy protection goals thus must be made operational (i.e., definition of specific protection goals) on basis of a dialog between risk managers who have the democratic mandate to make policy decisions (Selck et al., 2017) and risk assessors who develop risk assessment schemes for regulatory ERA (Devos et al., 2015; Nienstedt et al., 2012). This includes a definition of the components of the environment that are valued and should be protected. In certain frameworks, not only environmental entities are considered when defining specific protection goals, but also economic and social costs. For example, in current specific protection goals for agricultural pesticides in the EU, population-level and community-level effects on nontarget terrestrial invertebrates are allowed in pesticide-treated in-crop habitats if followed by ecological recovery within the growing season, whereas in off-crop habitats, population-level effects on nontarget organisms due to pesticide exposure generally are not accepted (EFSA SC, 2016a, 2016b). In environmental protection goals in ERAs conducted under auspices of the European Chemicals Agency (ECHA) and the European Medicines Agency (EMA), the recovery option as described above for pesticides is a priori not considered. In addition, the results of the ERA in these frameworks may feed into a regulatory benefit and risk assessment, where other information on the product (efficacy, human safety, economic considerations) may be considered. Consequently, what is regarded as an environmentally "acceptable" impact is clearly subjective, context-dependent, and based on socioeconomic criteria outside the realm of natural sciences (Brock et al., 2006; Holt et al., 2016; Sanvido et al., 2012; Sarewitz, 2004). Openness in the stakeholders that were involved in the problem formulation phase, a transparent description of all information and criteria that underlie the final definition of the specific protection goal used in ERA schemes, the handling of remaining uncertainties, as well as the procedures for a benefit and risk assessment by risk managers and policymakers, are important to increase trust in regulatory decision making.

Transparent procedures that explain how to translate policy protection goals into operational protection goals are not always available for ERAs conducted for different legislative frameworks. It often is implicitly assumed that laboratory toxicity data for a limited number of test species and standardized extrapolation methods (e.g., standard assessment factors) suffice to derive predicted no-effect concentrations (PNECs) or regulatory acceptable concentrations (RACs) not in conflict with general protection goals. Ideally, this needs to be verified (e.g., by appropriate field studies or expert knowledge elicitation) and remaining uncertainties identified.

Value judgments and the definition of specific protection goals: An example from an EU perspective

In the EU, the described procedures for defining specific protection goals are more advanced in ERAs for products related to the human food chain such as pesticides and genetically modified organisms (GMOs). For that reason, a GMO example is presented below (Figure 1).

To operationalize general protection goals such as the protection of populations and biodiversity of nontarget species, the concept of ecosystem services has been very

Stressor of concern:	Insecticidal Bt Cry protein produced in GM plant
Policy protection goal:	Sustainability of populations of non-target organisms and biodiversity in agroecosystem
Specific protection goal:	A) Biological control of pests in agricultural fields during cropping season B) Food-web support for insectivorous birds and mammals that forage in agricultural fields C) .....
Assessment endpoint:	A) Abundance of predatory lady beetles in agricultural fields B) Total abundance and biomass of arthropods in agricultural fields C) .....
Measurement endpoint:	A) Mortality, growth and reproduction of lady beetle in laboratory feeding assay at worst-case exposure conditions B) Monitoring of abundance and biomass of arthropods in experimental field plots with the GM and non-GM crop C) .....

FIGURE 1 Example of steps in problem formulation of Bt Cry protein in a genetically modified (GM) plant to evaluate possible impact of the ecosystem service biological control of insect pests (e.g., aphids) provided by lady beetles and food-web support for insectivorous birds and mammals

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helpful (Devos et al., 2015; Maltby et al., 2017; Munns et al., 2015; Nienstedt et al., 2012) as well as the concept of assessment and measurement endpoints (USEPA, 1998). For example, in agroecosystems, one of the specific protection goals is the protection of the ecosystem service "biological control of pests" within the agricultural field during the cropping season (Figure 1).

In this case, abundance (attribute to protect) of lady beetles, a group of important predatory insects contributing to biological control (entity to protect), could serve as one of the assessment endpoints. A possible pathway to harm would be that the lady beetles are killed or reduced in population growth after exposure (here, consumption) to the stressor of concern (e.g., a Bt protein produced by insecticidal Bt-transgenic crop plants). To test whether planting of a Bt-transgenic plant causes harm to this protection goal, one could conduct feeding studies where lady beetles and other selected surrogate test species representing valued nontarget species in the receiving environment are exposed to various doses of the Bt protein that include realistic and reasonable worst-case values. If survival and/or reproduction (measurement endpoint) are unaffected, the risk of planting Bt plants to nontarget lady beetles can be regarded as negligible.

This process apparently involves several choices to be made to ensure the regulatory relevance of the ERA procedure, including:

(i) Which entities (e.g., birds, nontarget arthropods, nontarget plants crop plants, endangered species) of the environment should be protected?
(ii) What is the attribute (e.g., individual, population, functional group) of the entity that should be protected?
(iii) Over which temporal and spatial scale does the entity need to be protected?
(iv) Which are the most plausible pathways (exposure routes) to harm and what is the exposure assessment endpoint to be assessed (e.g., ecotoxicologically relevant concentration and spatiotemporal dimension of exposure)?
(v) Which (surrogate) species, measurement endpoints, and exposure regimes are assessed?
(vi) What effect is regarded as unacceptable from an environmental and socioeconomic point of view and should the potential for recovery be considered?
(vii) What are the remaining uncertainties of the ERA decision schemes in achieving sufficient protection in relation to the specific protection goals defined?

All these questions require (value) judgments. A more detailed discussion on these questions, with a focus on regulatory ERA by the European Food Safety Authority (EFSA), can be found in EFSA SC (2016a, 2016b, 2016c), Boesten (2017), and Rico et al. (2016). Laying the problem formulation open will enhance the transparency and reproducibility of the regulatory decision-making process by making the choices and their underlying values explicit and by placing the data and information used into context. This is in line with Regulation (EU) 2019/1381 (EC, 2016) on the transparency and sustainability of the EU risk assessment in the food chain that comes into force on March 27, 2021. This Regulation has several objectives, such as to (1) ensure better transparency of the EU decision-making cycle and (2) enhance sustainability through stronger involvement of Member States in risk assessment work of EFSA.

THE USE OF RELEVANT AND RELIABLE DATA AND WEIGHT-OF-EVIDENCE APPROACHES IN REGULATORY RISK ASSESSMENT

Aim of the section

One of the goals of Open Science is to make publications, raw data, and software of scientific research accessible. However, the use of this information in a regulatory ERA context requires an evaluation of its relevance and reliability. This section aims to increase the awareness of environmental scientists to a priori consider criteria for relevance and reliability when publishing their research.

Overall framework of data assessment in ERA

As stated before, a transparent and systematic evaluation of reliability and relevance of all data used is needed to increase trust in the results of regulatory ERA. Depending on the goal of the assessment and the amount of data available, data may be used in a straightforward way according to guideline requirements, or a weight-of-evidence approach may be needed (Figure 2).

In the context of regulatory ERA, reliability is the inherent quality of an exposure and/or effect value of an environmental stressor in a test report or publication. In recognition

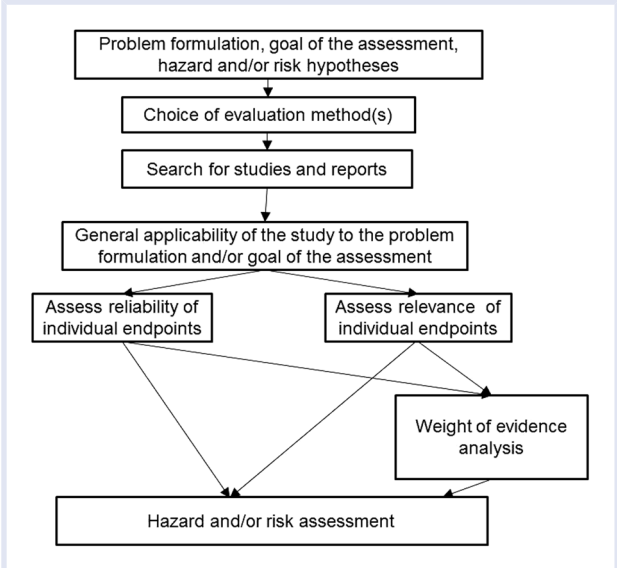

FIGURE 2 Overall framework for data assessment within a hazard or risk assessment (adapted from Moermond et al., 2017)

of differences in terminology between Eurasia and North America as well as the Northern and Southern Hemisphere, the terms "reliability" and "quality" are used interchangeably in this paper to refer to how well a study was conducted.

Assigning a study or measurement endpoint a high reliability score at least requires a clearly described study design that can be repeated independently. A high reliability score also reflects the way the study procedures (covering experimentation, monitoring, and modeling) were performed and the complete reporting of the results to provide evidence of the reproducibility, accuracy of the findings, and reanalysis of the data if needed (definition of reliability based on Moermond et al., 2017 and Klimisch et al., 1997). As such, reliability should not be confused with relevance. Reliability concerns the quality of a study, and the reliability of the results of this study is the same for every assessment in which it is used. In contrast, the relevance of that endpoint depends on the purpose of the assessment and relates to the (specific) protection goal and the hazard or risk hypotheses tested (see Section "Problem Formulation," above). Thus, relevance encompasses the extent to which data, tools, and tests are appropriate to the problem formulation for a particular hazard identification or risk characterization (Klimisch et al., 1997; Rudén et al., 2017). The published literature and reports may provide many studies and data on a certain regulated substance. These data can be quite heterogeneous in detail, relevance, and reliability, and may provide conflicting information. A weight-of-evidence (WoE) approach aims to deal with this and is discussed at the end of this section.

Assessment of reliability

In many risk assessment frameworks, all available data should be used for the risk assessment. This applies to studies performed by (or on behalf of) industry under good laboratory practice (GLP), theses, or reports in the gray literature, and peer-reviewed scientific papers. All these sources could provide valuable information, but they may vary in design of the study, methodology, quality, and level of detail reported. Regulators have the responsibility to make sound and verifiable decisions and should evaluate each study for reliability in accordance with scientific principles, regardless of whether they were conducted in accordance with GLP and/or standardized protocols or not (Warne et al., 2018). Studies performed under GLP often provide highly reliable results, but adherence to GLP does not necessarily mean that a study is well-designed and addresses the correct question. A GLP study aims to guarantee that it is completely documented and that the protocol of the study was followed (Mebane et al., 2019). Non-GLP studies from scientific literature may lack the information necessary for evaluating their reliability, resulting in a lower reliability score or even be "unassignable" according to the Klimisch or CRED (Criteria for Reporting and Evaluating ecotoxicity Data; Moermond et al., 2016, 2017) terminology, and thus may be less usable in regulatory ERA. However, if studies from the scientific literature are found to be reliable and relevant, they should be included in the ERA. For some EU regulatory frameworks (e.g., REACH, Water Framework Directive, and authorization of pharmaceuticals) a less reliable non-GLP study may be selected by regulators as the most appropriate study on which the conclusions are based, even if a more reliable (but less critical) GLP study is present in the dossier (Moermond et al., 2016). This, however, is not always acceptable to all stakeholders and ideally should be subjected to a WoE analysis (see below).

Different tools exist to aid the assessor in systematically and consistently assessing the reliability of a study. Several approaches have been suggested in the literature, for example, CRED (Moermond et al., 2016), the USEPA evaluation guidelines for published studies (USEPA, 2011; 2015; 2018b), SciRAP (Molander et al., 2015; for aquatic toxicity fully based on CRED), ToxRTool (Schneider et al., 2009; Segal et al., 2015), SIFT (Beasley et al., 2015), Environment Canada (Breton et al., 2009), Australian and New Zealand criteria for evaluation of aquatic toxicity data (Hobbs et al., 2005), and so forth. For an overview, see Moermond et al. (2017).

Assessment of relevance

For every new question or risk hypothesis, relevance of a study needs to be re-assessed, whereas the reliability conclusion stays the same (see above). For instance, the amount of bioconcentration may be irrelevant when determining a PNEC or RAC based on direct ecotoxicity but is very important when determining the risk for secondary poisoning. Thus, relevance aspects can only be determined if the purpose of the assessment is known and the problem formulation is clearly defined (see Section "Problem Formulation"). Although GLP studies do not secure their relevance per se, these studies often meet relevance criteria when procedures are followed in line with data requirements, OECD guidelines, and guidance documents that underlie a specific regulatory framework. However, peer-reviewed scientific literature may also provide very relevant information for evaluation of hazard and/or risk. A systematic approach with a scoring system may be used to assess relevance. A more detailed discussion on aspects of relevance of data used in ERA is presented in Rudén et al. (2017).

Weight-of-evidence assessment

Expert judgment is usually required to evaluate the reliability and relevance of studies, particularly those that are non-guideline. Making the assessment of reliability and relevance of data and studies as transparent as possible is key to increase public trust in the ERA process.

In a WoE approach, all available studies, also those where methods and results are incompletely reported, are included in the analyses. A WoE gives weight to individual studies depending on their quality and relevance (van der Kraak et al., 2014). These weights are then combined for use in decision making. In a systematic WoE approach, weights may be assigned in the form of numerical scores. Complete

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and transparent descriptions of the reasons for assigning scores to reliability and relevance of the studies are needed to facilitate discussions between experts and/or stakeholders. When the dataset consists of many studies, a graphical display of the scores helps to identify the general trend in a line of evidence and possible outliers (e.g., Hanson et al., 2019; van der Kraak et al., 2014). A systematic WoE approach relies on a set of clear criteria to characterize reliability and relevance of the studies used. To perform this in a transparent and consistent way, these criteria should be developed a priori. Depending on the goal of the assessment and the types of studies analyzed (e.g., toxicity, fate and exposure, field, or laboratory), these sets of criteria may be different.

Currently, there is some guidance on the conduct of a WoE assessment (Ågerstrand & Beronius, 2016; ECHA, 2016; EFSA SC, 2017; EFSA and EBTC, 2018; Suter et al., 2017a, 2017b). Several papers using WoE have been published (Becker et al., 2017; Bridges & Solomon, 2016; Bridges et al., 2017; Dekant & Bridges, 2016; Dekant et al., 2017; Hanson et al., 2019; Solomon & Stephenson, 2017a, 2017b, 2017c; Stephenson & Solomon, 2017a, 2017b), but approaches are different, sometimes due to the nature of the question (risk hypothesis) and the assessment goal(s). Currently, there is no harmonization of approaches within and between legal frameworks. However, there is general agreement in the regulatory community that regulatory and management decisions should be data-driven, transparent, and without bias. In the spirit of Open Science, the reasons for the assignment of scores for quality of the study and relevance of the results should be clearly described.

OPEN SCIENCE IN REGULATORY ERA AND STAKEHOLDER INVOLVEMENT

Aim of this section

Within the context of this discussion paper, an important goal of stakeholder engagement is to alleviate public skepticism toward regulatory ERA and help improving environmental decision making. This section aims to increase the awareness that all stakeholders involved in regulatory ERA play a role in achieving this by promoting Open Science and by transparent communication.

Stakeholder involvement in regulatory ERA

Human activities such as the production of goods and food have an impact on the environment. We want the benefits (e.g., available, affordable, and healthy products), but potential negative side effects on the environment should be avoided or at least minimized. The avoidance or minimization of side effects usually comes at some costs. In the end, it is a political, societal decision how much of the benefit is wanted or needed and at which costs. As explained in the sections above, to take appropriate and informed decisions, openness in value judgments and transparency in the relevance and reliability of data underlying decision making are crucial.

Ideally, various stakeholders should be involved in this: Governmental regulatory authorities responsible for assuring that the political decisions are implemented, and official guidance documents are used, the private sector as producers of the desired goods and associated ERA data requirements, academia contributing to scientific knowledge on ERA, and NGOs as critical observers of processes and regulatory decisions. The following subsections shortly describe their roles and perspectives with respect to Open Science.

Governmental regulatory authorities

On the basis of the respective legal requirements, governmental authorities are responsible for developing guidance documents on ERA. It is important to involve the relevant stakeholders at least before and after the drafting of the guidance to make use of the combined knowledge to produce scientifically sound guidance documents that can be used in practice and organize public consultation on the draft guidance for improvement, increasing acceptance by the stakeholders, and gaining trust from society. Open science and transparent decision making are crucial for both points.

Regulatory authorities also are responsible for the evaluation of the registration dossiers and other relevant information such as public literature or environmental monitoring data. They will do this by applying the approved guidance documents. All the information should be checked for relevance and reliability, ideally by using the same criteria for the different studies, as a basis for weighing and integrating all the evidence (see Section "The Use of Relevant and Reliable Data and Weight-of-Evidence Approaches in Regulatory Risk Assessment"). If necessary, this is then followed by an analysis of the remaining uncertainties. Finally, the summary data and ERA conclusions will be compiled and transferred to the open domain (open access, publicly available). In some jurisdictions (e.g., the European Union, https://ec.europa.eu/info/about-european-commission/service-standards-and-principles/transparency/consultations_en and the USA, www.epa.ie/pubs/consultation/), the documentation of public consultations is also made publicly available, a valuable addition in the process to transparency.

Applicants (private sector)

Companies intending to bring regulated products into the market are primarily responsible for generating the data legally required for registration and authorization. They can generate the required data themselves or they may commission and finance specialized institutes for doing so. Any generation of data relevant for the risk assessment for humans or the environment as part of product registration must follow special legal requirements (e.g., GLP) to ensure that data are generated in compliance with the rules, that data are verifiable, and that all documents and raw data will be archived. In addition, they are obliged to provide any knowledge they are aware of, which may be relevant for the safety assessment of their product. In addition, they often

support product stewardship on a voluntary or mandatory basis. Product stewardship schemes support the environmentally sound management of products and materials over their life (see e.g., https://www.environment.gov.au/protection/waste/product-stewardship).

All relevant data must be fully disclosed to the regulatory authority. However, even though regulatory authorities evaluate these data and make their risk assessment decisions as well as a summary of the basic data provided by industry open to the public, concerns have been raised that not all data are completely accessible to everybody, potentially reducing trustworthiness. These data, however, represent a significant value to companies that invested a lot in the development of an innovation and the associated safety-relevant information. Protecting these studies from unauthorized use by competitors is necessary so as to not undermine the interest of companies investing in innovation. This needs to be balanced with the public's interest in relevant health and environmental safety information.

Ideally, applicants who aim to place a regulated product on the market should be supportive of revealing data generated for registration purposes to foster an open dialogue. This may be done on dedicated websites by revealing not only summary data on substances that have been evaluated by regulatory authorities but also by including on-demand, noncommercial access to the full study reports behind these summaries. First initiatives to open their studies to the public have already been started voluntarily by some companies (see e.g., https://www.cropscience.bayer.com/transparency-crop-science or https://agriculture.basf.com/global/en/business-areas/crop-protection-and-seeds/services/regulatory-data-transparency/studies-overview.html).

In support of Open Science, and in building trust in the data underlying ERA, these studies can then be used for the purpose of furthering scientific knowledge and debate.

Academia

Academia should be the institution for developing scientific knowledge also beyond directly applied science. Academia is also the dominant source of scientific publications and should thus be the biggest contributor to and beneficiary of Open Science.

Academic research often contributes to the foundations of ERAs, even if these data may not be directly applicable to the respective regulatory risk assessments. Government-funded research is often considered as without conflict of interests. However, academic research also largely depends on available funds and resources by other parties. These could be research programs directly or indirectly funded by the private sector. In the latter case, a "conflict of interest" issue may arise. It should be noted, however, that in many countries, applied research programs are promoted in which co-funding by the private sector is mandatory for government funding. It may help to increase trust in these co-funded studies if the research projects are made transparent and results, including all underlying data, are made available in open access publications. However, some evidence indicates that it is difficult to mitigate the lack of public trust associated with private-sector funding, even with transparency initiatives (Besley et al., 2017, 2019).

In academia, successful career paths are related to number and impact of publications. To enhance trust, Open Science also needs to be open with regards to the different—intentional and unintentional—biases that are part of the system academia are operating in. Hanson et al. (2018) and Martin et al. (2019) argued that environmental studies showing a lack of effect are less often reported in the open literature, in part due to the preference of scientific journals and academics for "exciting, sensational" manuscripts with a high potential for citations.

As part of the Open Science and Transparency initiatives of the regulatory authorities (see above, "public consultations"), they request input from stakeholders and particularly from academia on their draft documents. However, feedback by academia on public consultations appears to be limited, most likely due to lack of time and resources. Further engagement of academia in the public consultation process is desirable, but for this to happen, a system for recognizing the time and efforts invested is required.

NGOs

NGOs can play an important role by critically attending ERA processes and evaluations and by providing additional opinions, thus constituting a critical counterbalance of commercial or political interests. This is also true when it comes to defending the environment, which has no commercial lobby.

As NGOs rarely perform their own scientific research, they largely depend on published studies and open data to fulfill their tasks such as surveillance and information of the public. Accordingly, NGOs are a primary beneficiary of open data, and it is also important that they gain access to all relevant environmental data to be able to critically review developments based on scientific facts.

However, NGOs must also contribute to Open Science by following the same principles of open science and transparency when publishing their reports or initiating their campaigns. In this context, it is also important to clarify the role of scientific evaluations and value-driven judgments.

Further direct engagement of NGOs in the public consultation process and in scientific meetings and workshops that aim to improve ERA decision schemes is highly desirable.

OPEN SCIENCE IN SETAC

For SETAC, Open Science is not only an effort to share data properly with the scientific community, other stakeholders, and the larger public, but the Society rather strives to make it an integral part of environmental sciences, to further recognize scientific research as a benefit for society (Table 2). This follows SETAC's mission statement, "Environmental Quality through Science." As one of the major professional organizations for environmental sciences, SETAC can play an important role in fostering Open Science. The acceptance of science and science-based

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TABLE 2 Major SETAC initiatives associated with the Open Science movement

SETAC Initiatives	URL
SETAC Declaration on Open Science	https://www.setac.org/page/open-science-declaration
SETAC Journal Data Transparency Policy	https://cdn.ymaws.com/www.setac.org/resource/resmgr/Publications_and_Resources/SETAC-data-transparency-poli.pdf
SETAC TIP "Recommended Minimum Reporting Information for Environmental Toxicity Studies"	https://cdn.ymaws.com/www.setac.org/resource/resmgr/publications_and_resources/SETAC_TIP_EnvTox_Info.pdf
SETAC Declaration on Research Integrity	https://www.setac.org/page/Integrity-Declaration

conclusions relies on trust, and Open Science should help to increase trust, as outlined in the sections above, with reference to the Fairness Theory. As a tripartite professional organization, SETAC can facilitate this process.

The global strategic goals of SETAC (2018) include "Advancing Science" and "Science-based Decision Making" as key aspects of the Open Science movement. Furthermore, the Europe Geographical Unit (SETAC Europe) approved striving for Open Science in their 2018 to 2020 strategic planning (SETAC Europe, 2017).

In 2020, SETAC issued its "Declaration on Open Science" to fully support the movement. The declaration follows the definition by the Center for Open Science: "Show Your Work. Share Your Work. Advance Science. That's Open Science" (https://www.cos.io/). It calls for adhering to the FAIR principles of Open Data and advocates for communicating the body of knowledge as well as the way of interpreting data in decision making. This resonates well with the Fairness Theory's focus on informational and distributive justice. The SETAC journals *Environmental Toxicology & Chemistry* and *Integrated Environmental Assessment and Management* require a Data Accessibility Statement through their Data Transparency Policy (SETAC, 2019b). They award Open Research Badges to papers with complete and openly accessible raw data and/or materials, which accords with evidence indicating that these badges encourage data sharing (Kidwell et al., 2016).

In 2019, SETAC published a Technical Issue Paper (TIP) on the "Recommended Minimum Reporting Information for Environmental Toxicity Studies" (SETAC, 2019a). This TIP is intended to be a guide to Open Data and Open Science, to help scientists advancing science and science-based decision making with their work. The TIP covers all relevant aspects of data reporting, from study design over test subjects to data analysis and disclosures.

The majority of current SETAC initiatives toward Open Science focus on communications within the scientific community. Although this is an important initial step, it may not be sufficient to build trust between risk assessment experts, stakeholders, and the public at large. This provides an opportunity for SETAC to explore more innovative mechanisms for making scientific information usable for multiple communities, as discussed above (Elliott & Resnik, 2019). Initially, SETAC could recommend that the criteria for reporting recommendations become requirements (at least in the scientific journals associated with SETAC), but a broader range of initiatives merit consideration.

CONCLUSIONS

Open Science and open data are important to increase transparency. This is a key aspect to increase trust in ERA processes and acceptance of regulatory decisions. This should outweigh its perceived risks such as potential misuse, "cherry-picking" or misinterpretation of data, and reusing data without giving credit to the original sources. Nevertheless, there are certain limits to "openness" due to legitimate concerns about security, safety, privacy, and commercial value. However, these should not hinder the proper sharing of data used in decision making.

The Open Science movement cannot depend solely on the efforts of individual researchers; we need to develop systems that incorporate the work of scientific societies, regulatory agencies, journalists, NGOs, and other institutions. Multistakeholder professional societies (e.g., SETAC) can play a key role to strengthen the trust in regulatory ERA by (i) taking further actions (sessions, workshops, TIPs) to support the Open Science initiative in environmental sciences, (ii) facilitating training on good reporting requirements for environmental studies to support regulatory ERA, (iii) promoting that reporting criteria move from recommendations to requirements, and (iv) developing a communication strategy for stakeholders not actively involved in the professional societies to build trust in science-based environmental risk assessment.

Adoption of the principles of Open Science as espoused in this paper will greatly improve the assessment of quality of data and relevance of findings. It will also facilitate the conduct of WoE assessments and streamline regulatory decision making. Every regulatory assessment needs a complete, transparent, and publicly available documentation of the decisions made during the risk assessment process, including value judgments (e.g., on specific protection goals), assessment tools, evaluations of studies as well as all underlying data, scores, and choices used in the WoE procedure. Even when datasets and methodologies are the same, risk assessors often arrive at different conclusions. As science is not black and white, the same often holds for risk assessment. Transparency and public accessibility of discussions and decisions are thus essential. Besides this, the use of harmonized methods among

countries, frameworks, and assessors is needed to share and use results of ERAs between assessors and regulatory frameworks, respecting differences in underlying specific protection goals, and consequently the regulatory relevance of data. Tools that include extensive guidelines for reliability and relevance evaluation may facilitate this process. Risk assessors, regardless of whether from government, scientific institutions, contract labs, industry, or NGOs, need to be regularly educated. Short courses, trainings, and webinars (e.g., organized by regulatory authorities and/or professional organizations) may contribute to this.

To increase the reliability of papers in the scientific literature, good reporting of the materials and methods used and of results, including underlying data, is essential. A large number of papers still lack the information needed to assess their reliability or recalculate their results. Both authors and reviewers may benefit from using a systematic reporting checklist during the publication process. Well-reported studies will be cited more often and can be used for regulatory risk assessment. In addition, quality research that shows the absence of treatment-related effects at environmentally relevant exposure levels should be sufficiently valued and appreciated by scientific journals.

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DATA AVAILABILITY STATEMENT

Data are available upon request from the corresponding author (theo.brock@wur.nl).

SUPPORTING INFORMATION

APPENDIX A. Program and abstracts special session on Open Science in Regulatory Environmental Risk Assessment as part of the SETAC SciCon, the virtual SETAC-Europe 30th Annual Meeting, May 3–7, 2020.

APPENDIX B. Program virtual SETAC Café Series, February 25, 2021.

ORCID

Theo C. M. Brock http://orcid.org/0000-0002-1842-1597

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