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Systems-based analysis of the factors affecting the use of academic research in European chemical assessment and management

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ABSTRACT

Academic research provides a key source of evidence to inform chemical assessment and management. However, in practice, academic peer-reviewed ecotoxicity and toxicity studies face challenges and limitations to their use. This article presents the results of a survey that collected stakeholder perspectives from across the European regulatory toxicology system. Our data show respondents are deeply divided on the extent to which chemical assessment makes use of available and relevant evidence and academic research. Using the Socio Technical Systems (STS) model as a conceptual framework, we identify a series of system-level factors that act as barriers to the uptake and use of academic research. Whilst technical factors are well-understood in the literature our analysis moves beyond established findings and highlights that such factors are often reliant, interconnected or dependent on social factors, such as a misalignment in the goals and demands of academic and regulatory knowledge production. Overcoming the barriers to the use of academic evidence demands a coordinated, systems level approach that fully considers wider social and cultural factors. We offer some initial recommendations, suggested actions for implementation and opportunities for actors across the regulatory toxicology system to increase the uptake and use of academic research in European chemical assessment and management.

1. Introduction

The need for a modern, scientific and evidence based approach to chemical safety assessment is a long running topic of debate and research both within and outside of the regulatory toxicology system (De Bruin et al., 2021; Brack et al., 2022; Berggren and Worth, 2023). Since the 1960 s, a vast body of evidence has been curated to inform regulatory decision-making in Europe and globally (van Leeuwen and Vermeire, 2007; Syberg and Hansen, 2016; De Bruin et al., 2021). This evidence includes information on a substance's physicochemical characteristics, and (eco)toxicity in addition to its environmental fate (Fantke et al., 2023). These data are used to assess the risk and hazard of a chemical substance, and inform its management (i.e., prioritisation, authorisation, restriction etc) (Luechtefeld et al., 2016; Arp, 2018; Fantke and Illner, 2019; Kirchhübel and Fantke, 2019).

Regulatory (and policy) decision-making on the risk or hazard of a chemical substance has typically been centred on defined ecotoxicity studies, undertaken in a laboratory setting, according to specific information requirements set out in internationally accepted test guidelines by the Organisation for Economic Cooperation and Development

(OECD). These test guidelines were designed to form the basis of a harmonised approach to exposure and hazard assessment, through the use of relevant and reliable evidence, whilst also ensuring transparency and consistency of data reporting across the regulatory system. Increasingly, new forms of data are being considered for regulatory and policy decision making including new approach methodologies such as computational models, *in vitro* and *in chemico* methods, as well as contextual and real world data, such as environmental modelling, monitoring and product-specific application.

Scientists and commentators have raised concerns regarding the extent to which information on a substance hazard or risk is reported (European Environment Agency (EEA), 2019), and about the quality of the evidence provided (Lofstedt, 2014a,b; Westerholm and Schenk, 2014). In particular, there are emerging concerns that current regulatory frameworks and approaches are outdated (e.g., take a single substance approach to regulation rather than grouping substances across regulations by chemical structure or hazard), are no longer aligned with changing societal needs, lag behind scientific and technical developments, and are too slow in effectively restricting the use of harmful substances (European Environment Agency (EEA), 2019; European

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Environmental Bureau (EEB), 2022; Berggren and Worth, 2023). This is due to both a rapid increase in the capacity of industry to manufacture a variety of new and complex chemicals at growing volumes and varieties (UNEP, 2019; CEFIC, 2022; Eurostat, 2022), and an increase in the number of technologies (e.g., tags and sensors, large language models, machine learning etc) and approaches (e.g. *in silico*, *in vitro*, quantitative-structure analysis, read-across etc) used to assess and generate evidence for chemical risk assessment (Schmeisser et al., 2023; Tkalec et al., 2024). Innovation and development of these new approaches is prevalent in academic institutions (Krewski et al., 2010) and the insights from such research could and should inform chemical assessment and management.

Major pieces of UK and EU law set out the requirement for the use of all available, or relevant evidence (i.e., peer-reviewed and grey literature, scientific and industry reports). These include regulations on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and Classification, Labelling and Packaging (CLP), as well as product specific regulations on plant protection products and cosmetics, among other things (i.e., pharmaceuticals, veterinary medicines etc). However, in practice, peer-reviewed academic ecotoxicity and toxicity studies are rarely used in regulatory decision making (see Ågerstrand et al., 2014; Ingre-Khans et al., 2016; Ågerstrand et al., 2017b) and there is growing concern and scepticism amongst members of civil society, academia, and industry about the way in which chemicals are regulated, with many arguing current regulatory efforts are no longer fit for purpose (Kabat, 2017; Karlsson, 2019; Voulvoulis & Burgman, 2019; Hunt & Wald, 2020).

Increasingly, questions are being raised about the politicisation of decision-making processes, particularly in light of shifting governance structures in Europe, the United States of America and beyond. This hints toward a broader climate of regulatory uncertainty, where scientific evidence or data, including that generated by academic researchers, may be selectively interpreted or sidelined by decision makers (i.e., Member States, Commission, Regulatory agencies) in favour of economic or strategic priorities (for example see Wilson et al., 2025).

In recent years there has been a significant increase in attention to the ‘who’ and ‘what’ of (chemical evidence in) regulatory and policy decision making. Existing research has analysed issues of who is undertaking regulatory assessments (i.e., academics, industry, GLP laboratories) and thus providing knowledge (i.e. on chemical safety) and what data are considered in decision making processes (i.e. non-standard/standard toxicity tests, peer-reviewed toxicity and ecotoxicity studies, New Approach Methodologies [NAMs]) (Ginsberg et al., 2019; Carusi et al., 2022; Holden, Lee and Cavoski, 2024). To date, little attention has been given to ‘how’ evidence on chemical substances is taken up and used in regulatory decision making, and what factors act as a barrier to, or challenge the use of evidence. Previous efforts have tended to focus on technical and specific aspects of chemical regulation (e.g., processes of classification), specific groups of people (e.g., only those in government or industry e.g. Carusi et al., 2022) and specific types of data (e.g., peer-reviewed, Ågerstrand et al., 2017a,b) or methodologies (e.g., NAMs; Holden, Lee and Cavoski, 2024; Ginsberg et al., 2019).

Increasingly, “systems-thinking” approaches and frameworks (i.e., holistic descriptions on the interactive relationships and dependencies between components of a system) are called for (Glaser et al., 2008; Meadows, 2008; Muller and Giudici, 2024). A system can be defined as “any group of interacting, interrelated or independent parts that form a complex and unified whole that has a specific purpose” (Kim, 1999). For instance in the regulatory toxicology system there are people (actors) with capabilities, who work towards goals, follow processes, use technology, operate within a physical infrastructure and share certain cultural assumptions and norms (Bearth et al., submitted). Existing research has highlighted that the design or optimisation of only one area, or sub-compartment of a system (especially a complex system such as the regulatory toxicology system), in isolation will likely lead to

suboptimal outcomes, or even failure (Trist, 1981; Trist et al., 2016).

Scholars from the sub-discipline of science and technology studies (Rohracher, 2015) have emphasised the importance of understanding how these different elements of a system interact when considering ‘how’ decisions are made (Mumford, 2006; Geels, 2010; Hess and Sovacool, 2020), recognising that cultural values, power relations and social norms play an important role in enabling ethical and effective decision making alongside technical evidence (Latour, 2005; Hess and Sovacool, 2020, particularly when addressing complex challenges such as chemical risk assessment where regulatory decisions can have far reaching societal consequences (e.g., Moss et al., 2021). Insights drawn from this approach can shed light on the interplay between different parts of the regulatory toxicology system and provide understanding on the interactions and dependencies within the system to enable a more ethical, effective and holistic approach to chemical assessment and management. Therefore it is essential to analyse how decisions are made from a systems-level perspective.

1.1. Aim, objectives and research questions

In order to address the gap in the existing literature this research examines how evidence on chemical risk and hazard is taken up and used in regulatory decision making. Distinguishing itself from the narrower scientific debate (which has tended to limit itself to the technical detail and scientific process) this article also identifies the system-level barriers that hinder the use of academic research as regulatory evidence (see Table 1 and Table 2).

The Socio-Technical System (STS) model (Davis et al., 2014; Fig. 1) offers a powerful framework for understanding how decisions are made by highlighting the interconnected social, cultural, technical and economic considerations of a system (Mumford, 2003; 2006; Trist et al., 2016). By analysing ‘how’ evidence is taken up and used, we can better recognise the broader context in which decisions are made across the regulatory toxicology system, and refine decision making processes to allow for more informed and evidence-based decision making (Gorur et al., 2018; Hess and Sovacool, 2020).

Guided by the STS model, and using the European regulatory toxicology system as a case study for analysis, this article addresses the following research questions:

Table 1
Acronyms.

Acronym	Term
ARRIVE	Animal Research: Reporting of In Vivo Experiments
BPA	Bisphenol A
CLP	Regulation on the Classification, Labelling and Packaging of substances and mixtures
CRED	Criteria for Reporting and Evaluating ecotoxicity Data
CREED	Criteria for Reporting and Evaluating Exposure Datasets
Defra	Department for the Environment, Food and Rural Affairs
ECHA	European Chemicals Agency
EDC	Endocrine Disrupting Compound
EFSA	European Food Safety Authority
EU	European Union
GLP	Good Laboratory Practice
HSE	Health and Safety Executive
NAM	New Approach Methodologies
NGRA	Next Generation Risk Assessment
OECD	Organisation for Economic Co-operation and Development
PEWS	Priority Early Warning System
PFAS	Per- and polyfluoroalkyl substances
RAC	Committee for Risk Assessment
REACH	Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals
RMOA	Risk Management Options Analysis
TG	Test Guideline
UK	United Kingdom
WFD	Water Framework Directive
WoE	Weight of Evidence

Table 2
Definitions and terminology.

Term	Definition
Academic research	Any distinct line or piece of evidence (i.e., <i>in vivo</i> , <i>in vitro</i> , <i>in silico</i> , population studies, modelled and measured exposure data etc) across all chemical groups, which may come from studies conducted according to official guidelines (e.g., OECD) or from non-standard methodologies, which is derived from white literature (i.e., peer-reviewed academic publications) only.
Chemical assessment and management	Regulatory and/or policy decision making processes, across all lines and/or pieces of evidence, chemical groups and legislation, for the protection of people and the environment.
Evidence	Any distinct line or piece of relevant evidence (i.e., <i>in vivo</i> , <i>in vitro</i> , <i>in silico</i> , population studies, modelled and measured exposure data etc) across all chemical groups, which may come from studies conducted according to official guidelines (e.g., OECD) or from non-standard methodologies, and includes that which is derived from white literature (i.e., peer-reviewed academic publications), grey literature (i.e., governmental, non-governmental, inter-governmental agency reports) and/or black literature (i.e., confidential and/or industry studies and reports).
Elements (of the regulatory toxicology system)	The people, processes, culture, goals, technologies (i.e., data) and infrastructure of the regulatory toxicology system.
Regulatory toxicology system	A group of interacting, interrelated and independent elements and/or components of regulatory toxicology that form a complex and unified whole with the specific purpose to protect the environment and human health from exposure to harmful and hazardous substances (i.e., chemicals, drugs, pesticides, food, consumer products). This includes but is not limited to those involved in decision making in regulatory or policy contexts, regulatory toxicologists, risk assessors and risk managers, academics, scientists, consultants and researchers, as well as non-governmental organisations and charities from various sectors, across regulatory silos, all playing their own role in the generation, synthesis, evaluation and management of scientific data for regulatory and policy making decisions (Gluckman, 2018).
Social factors	Factors that primarily relate to the people (actors), culture, and goals of the regulatory toxicology system.
Technical factors	Factors that primarily relate to the technology (data), processes and infrastructure of the regulatory toxicology system.

1. What are stakeholder perspectives on the uptake and use of evidence in European chemical assessment and management?
2. Which factors act as a barrier to, or challenge the uptake and use of academic research in European chemical assessment and management?

This article answers these questions by integrating the experience and perspective of different groups of stakeholders from across the European regulatory toxicology system. This case was selected due to the global importance of the European regulatory toxicology system (Vogel, 1995; Bradford, 2020), its large knowledge base (Berggren and Worth, 2023), and the growing volume and diversity of chemicals on the European market (EEA, 2023), alongside its comprehensive and wide-reaching regulatory framework. Whilst this study focuses on the perspectives of stakeholders from the European regulatory toxicology system, the findings may exist in other settings and jurisdictions and are therefore of relevance to a global audience.

2. Methodology

To address these research questions we gathered data on the perspectives of stakeholders from across the European regulatory toxicology system. We first piloted the survey (April 2024) with key experts (N = 4) from the field of environmental toxicology, policy and research, and amended it in light of their feedback. This included feedback on the specificity and definition of key terminology, survey design, and identification of predetermined factors considered to limit the uptake and use of academic research in European chemical assessment and management. A survey was designed and hosted on the online survey software Qualtrics (<https://www.qualtrics.com>) for 12 weeks (3rd May 2024 – 19th July 2024). The survey was launched and promoted online using social media (i.e., X, LinkedIn). Active promotion of the survey (using QR codes, posters, word of mouth) was undertaken at the 2024 Society of Environmental Toxicology and Chemistry (SETAC) Europe Annual Meeting in Seville. SETAC annual meetings aim to bring together experts from across the regulatory system to share knowledge, discuss challenges and foster collaboration on environmental issues, and it was anticipated that attendees to the meeting included an array of potential participants from (but not limited to) academia, regulation, industry and government. Additionally, the survey was distributed to approximately 10,000 members and subscribers of the SETAC Globe in the form of a short article (Jones, 2024) in May 2024.

2.1. Data analysis

The survey collected stakeholder perspectives on the uptake and use of *evidence* (including academic research) in European chemical assessment and management (see [supplemental material 1](#)). The survey consisted of a series of Likert-scale questions, multiple choice and free text responses and was designed to understand stakeholder perspectives on the reliability, transparency and adequacy of the use of evidence in regulatory decision making. It was also designed to identify system-level factors that act as a barrier to, or challenge the uptake and use of academic research as evidence. In particular, the survey asked respondents to reflect on their experience in the regulatory toxicology system and *provide an example where possible* in open ended free text boxes. This allowed more detailed understanding of the factors stakeholders perceive to be most important or significant.

Information gathered in the free text boxes of the survey was coded for qualitative analysis with the software tool NVivo (version 14.24.2, <https://www.lumivero.com>). A codebook detailing the overall structure and example codes can be found in [supplemental material 2](#). These are used to support thematic analysis of the data and are discussed in more detail throughout the remainder of this article. Quantitative data from the survey was imported into excel for analysis. No statistical analysis was undertaken as we do not consider the sample size suitable to be

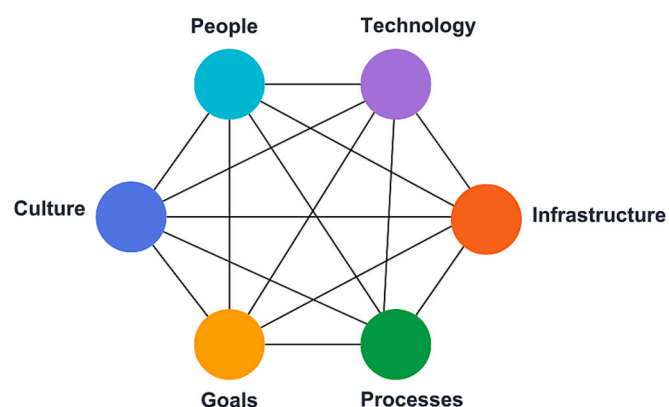


Fig. 1. Socio-Technical Systems (STS) model as conceptualised by Davis et al., 2014. Represented visually as a hexagon, with six interconnected (lines) elements (circles): goals, culture, people, technology, infrastructure and processes. The model emphasises how changes in one area of a sub-system can impact others.

reliable or meaningful in answering the research questions. Although the sample size was limited, we observed a high degree of thematic saturation across survey responses indicating that key dimensions and perspectives were consistently represented and are considered robust.

3. Results

62 individuals participated in the survey. Only those that considered their work relevant to European (i.e., EU or UK) chemical assessment or management were asked to complete the survey ($N = 58$; see Fig. 2), with 4 participants excluded. Participants were asked to select which of the four main elements of the regulatory toxicology system they primarily worked in (i.e., Academia [14 %], Consultancy [17 %], Industry [24 %], Government [38 %]; Fig. 2a), and the scale of decision making of their work (i.e., Regional [47 %], National [22 %], International [31 %]; Fig. 2b). Respondents from all sectors considered their work to relate to the regional scale (i.e., EU) (Fig. 2c). This includes half (50 %) of those that work in non-governmental organisations (NGOs) or health charities (i.e., 'Other'), 43 % of Industry, 63 % of Academia, and 70 % of Consultancy. While less than a third of respondents from Government (32 %) considered their work to be at the regional scale. No respondents (0 %) from Industry or Consultancy considered their work to relate to the national scale (i.e., member state) with the majority of participants from Industry (57 %) working at the International (i.e., global) scale.

3.1. Perspectives on the uptake and use of evidence in European chemical assessment and management

In general, our data show that survey respondents from the European regulatory toxicology system are deeply divided on the extent to which they agree chemical assessment makes use of available and relevant evidence. Data from the Likert scale responses suggest this lack of consensus could partly be attributed to differences in perspective on issues of reliability, adequacy and transparency of evidence. For instance we find that over three quarters of respondents from the Government (86 %; $N = 19$) and Consultancy (80 %; $N = 8$) agreed (i.e., somewhat or strongly) that the uptake and use of evidence is reliable

(Fig. 3a), however less than two thirds of respondents from the Government (64 %; $N = 14$) agreed that the uptake and use of evidence is adequate (Fig. 3b) while just over a quarter of respondents from Consultancy (30 %; $N = 3$) agreed that it is transparent (Fig. 3c). Interestingly, 63 % of respondents from Academia ($N = 5$) agreed that the uptake and use of evidence is reliable (Fig. 3a) and adequate (Fig. 3b) whilst the same number disagreed (i.e., somewhat or strongly) that it was transparent (Fig. 3c). No respondents (0 %; $N = 0$) from NGOs or health charities agreed that the uptake and use of evidence is transparent (Fig. 3c).

All respondents were asked to what extent they agreed that 'European chemical assessment makes use of all available and relevant evidence' (see Table 1 for definition). Overall, almost half of all respondents (43 %, $N = 25$) agreed (i.e., strongly or somewhat) that European chemical assessment makes use of all available and relevant evidence, with the majority of respondents from industry (71 %, $N = 10$) and government (59 %, $N = 13$) agreeing (Fig. 3). Some of these respondents noted that in most cases it is in fact a "requirement of the legislation". However, commented that "what may not be known is whether other (industry) studies exist which have not been made available to regulators". No respondents from academia (0 %, $N = 0$) and only 20 % of respondents from consultancy ($N = 2$) agreed that European chemical assessment makes use of all available and relevant evidence (Fig. 3).

We find that survey respondents are also divided on the uptake and use of academic research in European chemical assessment and management. Our data shows that around a third of respondents from the Government (36 %; $N = 8$), Consultancy (40 %; $N = 4$) and Industry (36 %; $N = 5$) disagreed that the uptake and use of academic research is reliable (Fig. 4a). Less than half of all respondents agreed that the uptake and use of academic research is adequate, except for Industry where 57 % agreed ($N = 8$) (Fig. 4b). While we also find differences in opinion between sectors on the extent to which they agree that the uptake and use of academic research is transparent (Fig. 4d). For instance 55 % of respondents from Government ($N = 12$) agreed that it is transparent in contrast to 20 % and 25 % of respondents from Consultancy ($N = 2$) and Academia ($N = 2$), respectively (Fig. 4d).

When asked to what extent they agreed 'European chemical

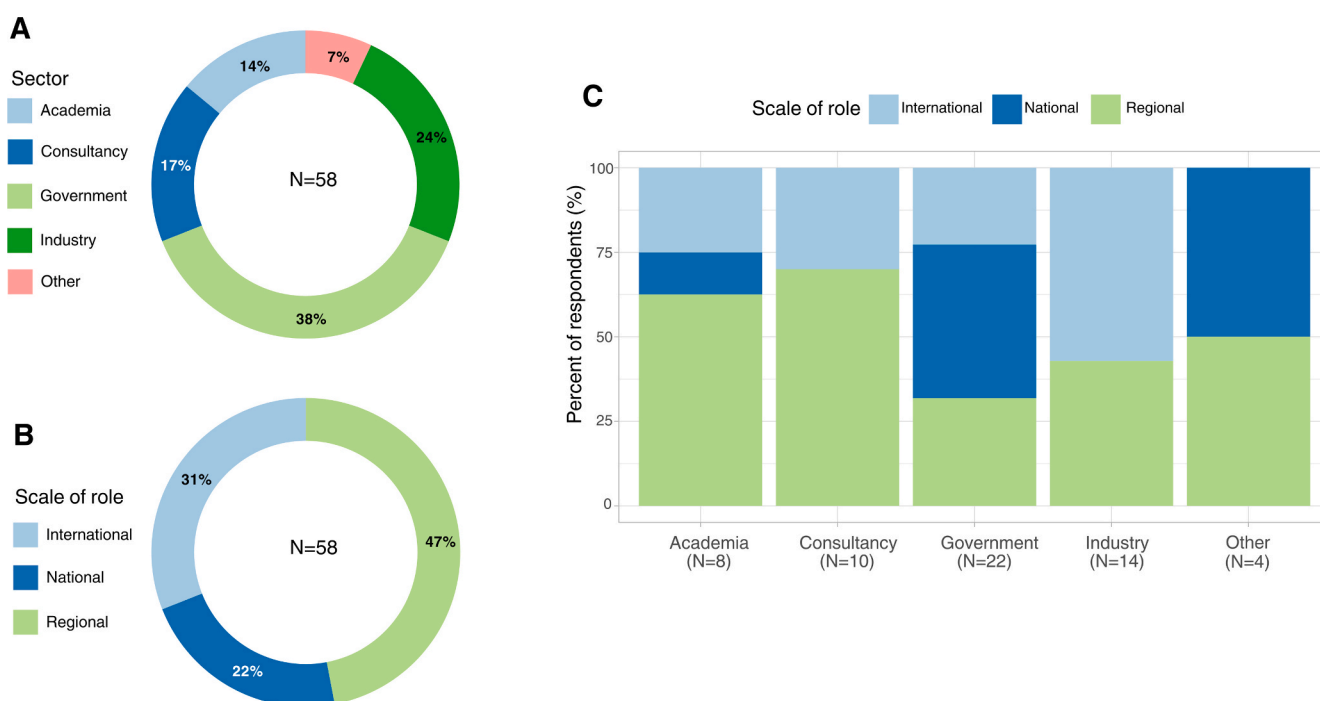


Fig. 2. Demographic information of survey respondents, including the % breakdown of respondents by sector of work (A), the geographical scale of decision making their work primarily relates to (B) and the % breakdown of sector of work by geographical scale (C).

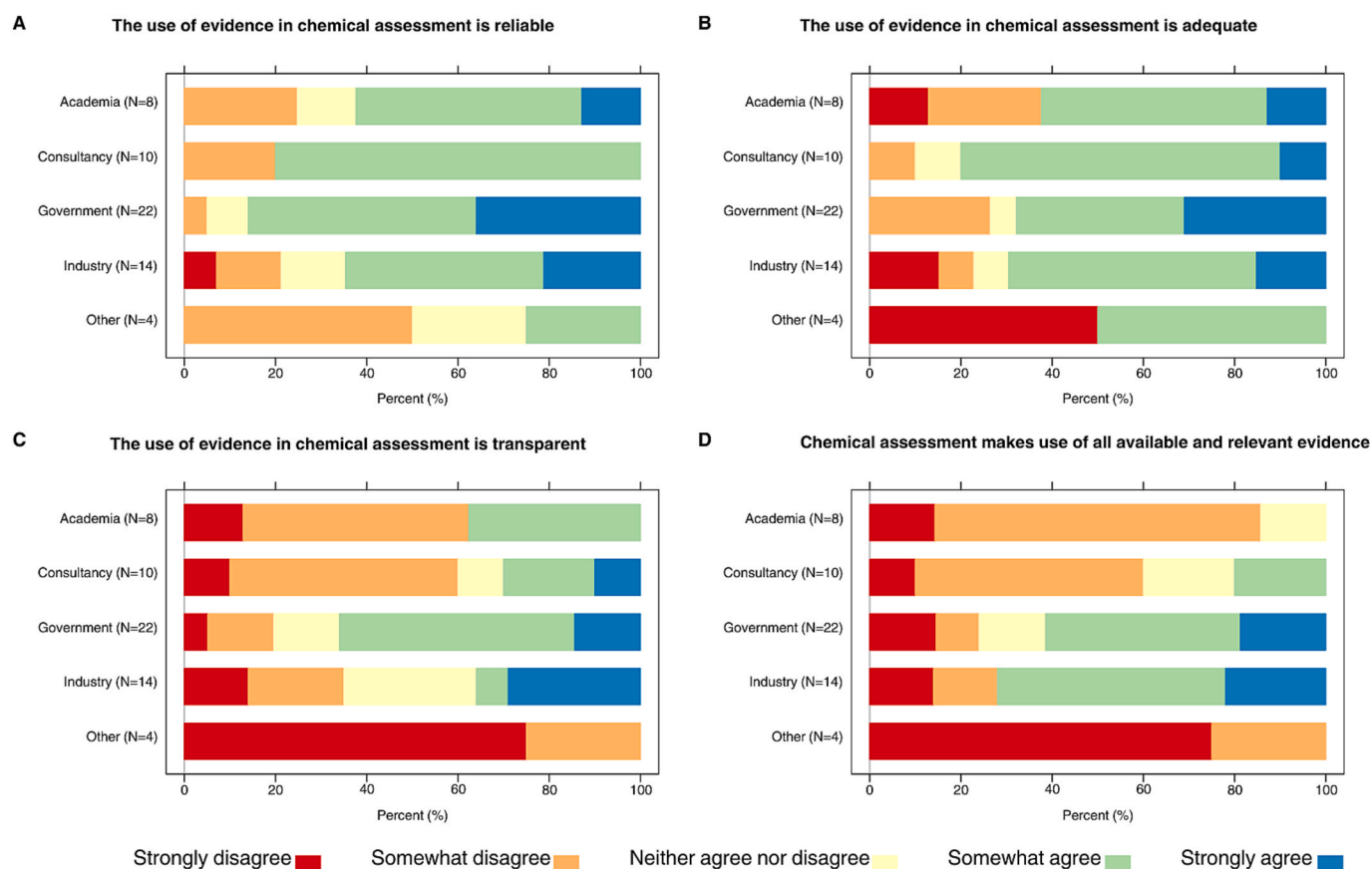


Fig. 3. Likert scale responses on the uptake and use of evidence in European chemical assessment and management. Responses shown with regard to agreement on the use of evidence in European chemical assessment and management being reliable (A), adequate (B) and transparent (C) along with agreement on the uptake and use of all available and relevant evidence (D).

assessment makes use of all available and relevant *academic research*' (see Table 1 for definition), only 38 % of respondents (N = 22) agreed. In fact, a high proportion of respondents from academia (75 %, N = 6) and consultancy (70 %, N = 7) somewhat or strongly disagreed that chemical assessment makes use of all available and academic research (Fig. 4). In contrast, more than three quarters of participants from industry (79 %; N = 11) agreed (i.e., strongly or somewhat), whilst almost half (41 %, N = 9) of respondents from the government agreed that chemical assessment makes use of all available and relevant academic research (Fig. 4D).

One respondent from consultancy believed that "academic research provides the largest body of work for addressing the true ecological impacts of contaminants (i.e., population and community level effects)" and that "regulatory agencies do not make good use of this information". However our data suggest that respondents believe that academic research should not be considered "reliable by default", unless it conforms to regulatory standards. Respondents to our survey suggest that this is because data and records that support academic publications are "not verified independently with an underlying quality system", while "typically, neither the peer reviewers nor the readers have access to a sufficient degree of data" to "adequately assess reliability [of academic research] according to existing and validated procedures (e.g., Good Laboratory Practices)".

Analysis of the free text responses (N = 46) suggests that depending on the regulation, the uptake and use of academic research can vary, with a governmental respondent noting "remarkable differences in the state of play across sectors". It was mentioned frequently that in the case of pesticides, "appropriate published literature [including academic] is searched for" and reviewed for relevance and reliability. A respondent explained that in the EU this happens at the active substances renewal

stage (every 10 years) or where adverse data are reported, however notes that "there is scope for more frequent consideration of such evidence".

In general, a respondent from the government believed that the uptake and use of academic research in regulatory decision making is "insufficient", however, argued that academic data are often "not sufficiently robust, replicable or transparent" to enable regulatory authorities to establish reliability. A respondent from the government or regulatory authority felt that academic research is "not really suitable for providing endpoints for chemical risk assessment" but could be used more to question or support a risk assessment decision (e.g., demonstrate exposure routes not covered), provide evidence on environmental fate, or supply data that could be considered relevant (e.g., data from chemicals in the same group).

3.2. Factors affecting the uptake and use of academic research in European chemical assessment and management

Respondents were asked to select up to three factors from a pre-determined list (see Fig. 5) that they consider most important to the uptake and use of academic research in European chemical assessment and management. This was used to gain insight into how actors from across the regulatory toxicology system perceive different factors, and to identify which factors are considered most important (i.e., % vote). As respondents were not asked to rank their choices, the overall % vote represents the proportion of respondents that considered the challenge important but not which challenge they considered to be most important. An overview of the participants' ranked responses can be seen in Fig. 5.

Overall, we find some consensus on the factors considered most

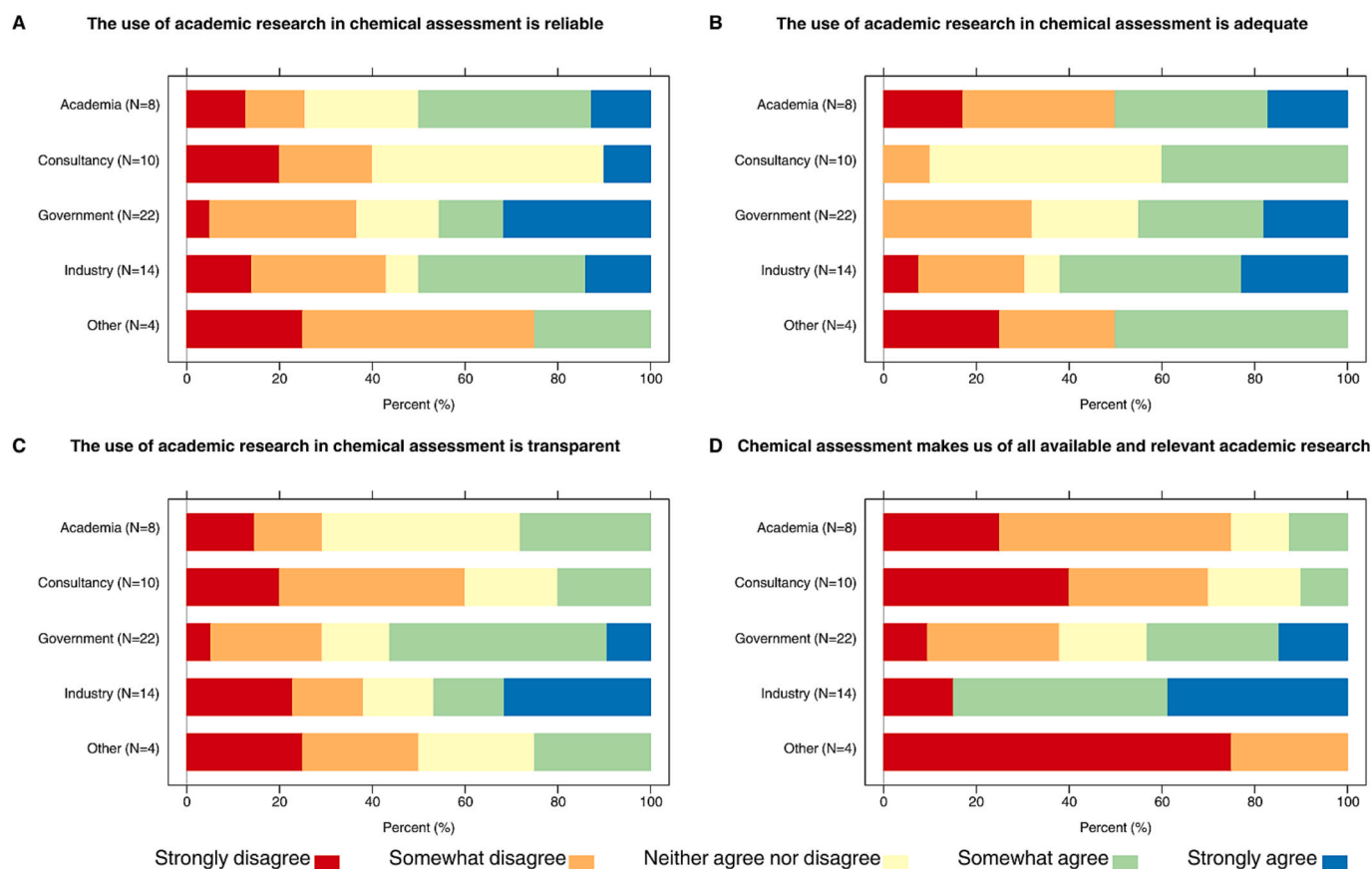


Fig. 4. Likert scale responses on the uptake and use of academic research in European chemical assessment and management. Responses shown with regard to agreement on the use of academic research in European chemical assessment and management being reliable (A), adequate (B) and transparent (C) along with agreement on the uptake and use of all available and relevant academic research (D).

important to the uptake and use of academic research in European chemical assessment and management (Fig. 5). Expertise and resources (time, financial, personnel) were considered important in affecting the uptake and use of academic research across all sectors on average (47 %), but particularly by those in NGOs or health charities (100 %) and Academia (75 %). Goals and demands of academia, regulation and industry (40 %), and legislative processes and design (40 %) were considered important in affecting the uptake and use of academic research, as were regulatory needs and requirements (57 %). In particular those from the government (55 %), industry (57 %) and consultancy (70 %) considered regulatory needs and requirements to be important with more than half of respondents from each sector identifying them as a barrier. In contrast, interests and values (e.g., financial, political) (14 %) along with personal beliefs, values and assumptions (10 %) were not considered important overall, however they were ranked highly among certain sectors. For instance 75 % of respondents from NGOs or health charities considered interests and values to be a barrier whilst approximately a third of respondents from industry considered personal beliefs, values and assumptions (36 %) and mistrust between actors and sectors (29 %) to be a barrier. Interestingly, 38 % of respondents from academia considered knowledge exchange systems and infrastructure to be barriers, despite no respondents from academia (0 %) considering relationships between agencies, actors and institutions to be barriers to the uptake and use of academic research in European chemical assessment and management. This suggests that academic respondents struggle with the practical aspects of accessing and sharing research, rather than the relational or collaborative aspects.

Respondents were given the opportunity to explain their choice with anecdotal evidence and examples in open-ended free text boxes. These data allowed for more in-depth understanding of factors and thematic

analysis of coded responses. We identified seven key themes from analysis of coded responses (Table 3), and mapped these on to the STS framework (Davis et al., 2014; Fig. 1). Where appropriate factors that respondents considered as barriers to the uptake and use of academic research were combined when similar themes emerged. We then used the STS framework to aid the identification of additional factors beyond those previously listed (Fig. 5) and map these on to the STS model, while also exploring the interdependencies between different parts of the system (see Fig. 6). These included a range of social and technical considerations. The following sections explore these themes in more detail.

3.2.1. Technology: Issues of relevance and reliability of academic data as scientific evidence

Evidence (including academic research) must fit strict criteria, set out by the regulatory framework, for authorities to move forward with legal certainty. Our data suggests that evidence from academic research is perceived as unfit for use in processes of chemical assessment because its purpose is not relevant, or it is not considered to be reliable. Regulatory guidelines (i.e., OECD) and guidance (i.e., European Commission) set out which data can be used to support regulatory assessments. These include standards of replicability, reproducibility and robustness considered reliable for use in regulatory processes (i.e., number of replicates, number of test concentrations/doses, analytical verification of exposure conditions, statistical analyses).

It was frequently mentioned that academic research does not always meet the standards of reliability (compared to OECD guidelines or regulatory guidance) needed for regulation. For instance, a respondent from industry reported that while academic studies state they followed OECD guidelines, they often do not, or they “modify the experiment in

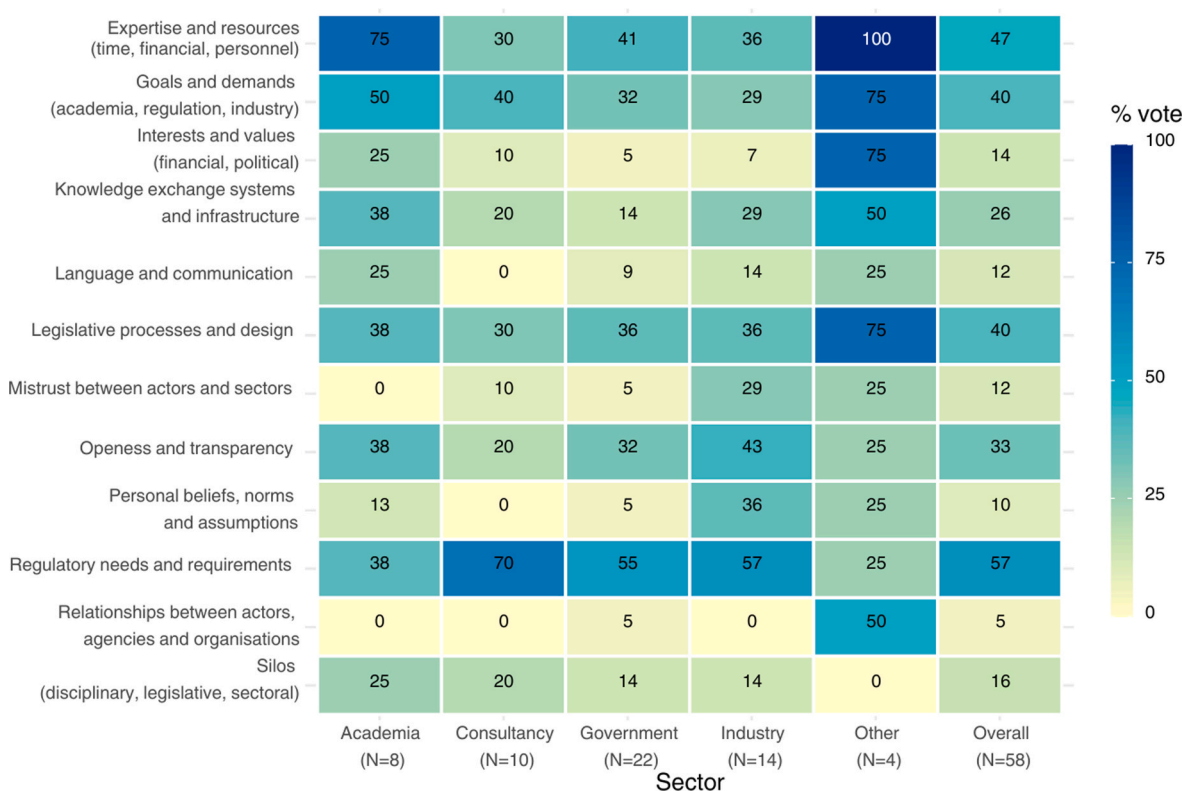


Fig. 5. Heatmap of factors respondents identified to be a barrier or challenge to the uptake and use of academic research in European chemical assessment and management. Numbers in each box represent the percentage of respondents that selected a factor to be a barrier, and not the ranked order therefore the sum of each row will likely be greater than 100.

Table 3
Themes matched to STS framework (Davis et al., 2014).

Element of the STS framework	Theme
Technology	Issues of relevance and reliability of academic data as scientific evidence
Goals	Misalignment in the goals and demands of regulatory knowledge production
Processes	Restrictions in the design of legislative structures processes
People	Lack of expertise and resources of actors in the regulatory system
Infrastructure	Lack of infrastructure for knowledge exchange and effective communication
Technology	Issues of availability, accessibility and transparency of scientific data
Culture	Role of bias, interest and cultural values in regulatory decision making

some way with unknown outcome” and “never document key criteria”. If key elements of the study methodology are missing (e.g., insufficient blank control), or are not reported then regulators can not ascertain whether the data are reliable (i.e., compare results with those of studies according to regulatory guidelines). A respondent from industry raised the challenge that “academics often lack the financial resources that would enable them to deliver studies as per the OECD guidelines” and that the required level of quality assurance (QA) and quality control (QC) comes at a significant cost to academics. Particularly those early in their career or in small groups, where funding opportunities may be more limited and highly competitive. They explained that such guidelines are “very demanding” (e.g., number of replicates necessary, specificity of test concentrations, analytical verification of exposures) which makes a fully fledged OECD study “extremely costly”.

Our data suggest that academic researchers are often not familiar

with the relevant policies, legislation or guidance documents to which their research could be applied. The “research may not ‘fit’ neatly” into the mould of standard (regulatory) data and is therefore disregarded. Weight of Evidence (WoE) assessments are a method in which different lines of evidence (including academic research) can be evaluated and used as evidence in a regulatory decision, so long as they are considered relevant and reliable. It was explained that this “can be a useful approach for recognising a wide range of literature and improving transparency and consensus building”, whilst it is considered particularly useful within a regulatory context where there is a high reliance on evidence from typically heterogeneous or incomplete data sources, “for example in endocrine disruption regulation”. Those from industry and government noted that this allows academic studies that do not follow OECD test guidelines (which is common) to still have a place in the assessment, however a respondent from consultancy noted that they had seen (in the past) relevant studies only taken as “supporting information” (i.e., in a WoE assessment) and not as key information, due to a lack of alignment “with the regulatory processes or requirements”.

Some respondents from consultancy and government believed that not following standard guideline protocols has the benefit of providing additional information relevant to the legislation (e.g., to understand toxicological properties or mechanisms). For instance, a study may focus on answering a specific research question that does not directly align with the requirements of the regulatory risk assessment (e.g., exposure levels not representative of the natural environment), present field monitoring data (e.g. use of eDNA), or promote the use of new methods and approaches (e.g., sub-organismal biomarkers). It was suggested by a respondent from academia that “academic research provides the largest body of work for addressing the true ecological impacts of contaminants (i.e., population and community level effects)” and that “regulatory agencies do not make good use of this information”. However, methods of risk assessment and regulatory decision-making are clearly set out in law, and typically rely on the use of specific processes (e.g., single

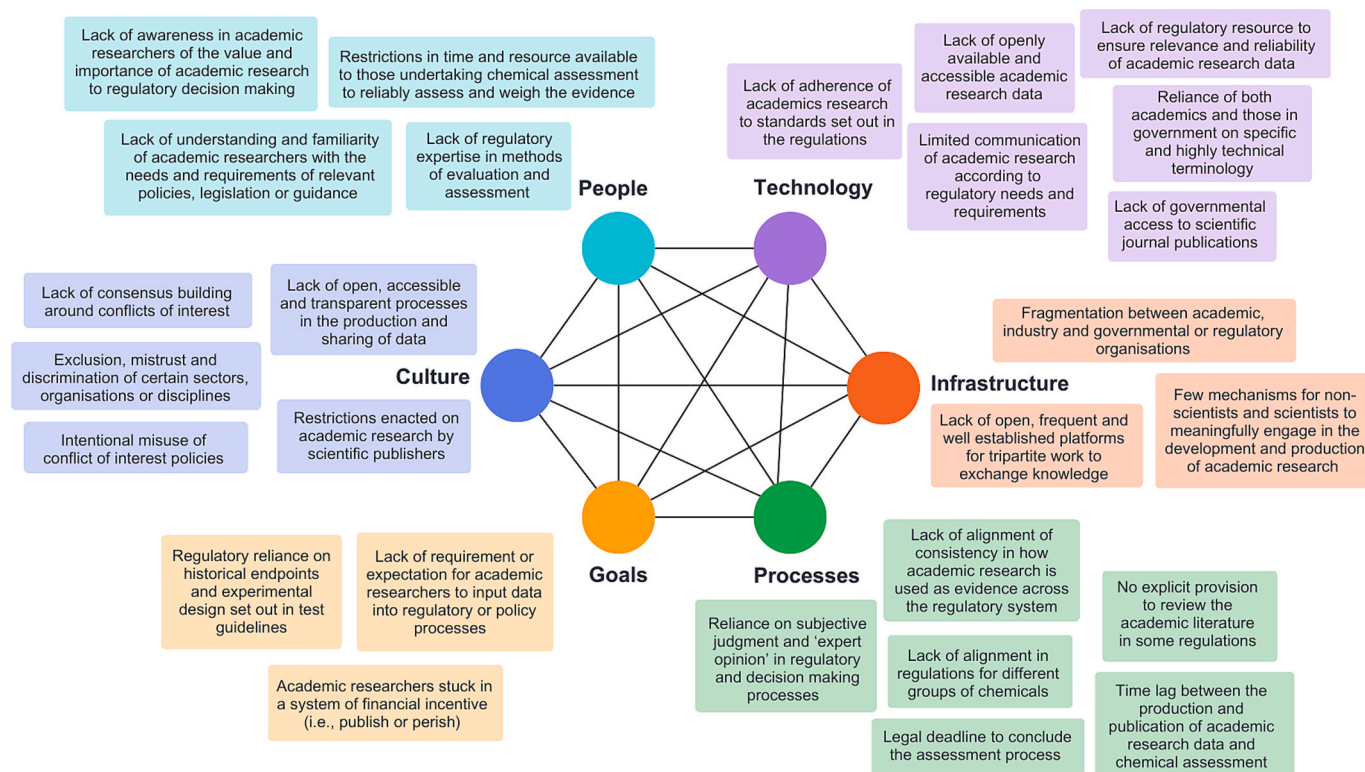


Fig. 6. Factors (N = 27) identified within the themes that emerged (N = 7) from participant free text responses, mapped on to the hexagonal STS model framework (Davis et al., 2014).

substance assessment) and endpoints (e.g., growth, reproduction, survival) set out within the guidelines. Thus the introduction of data from new or alternative methodologies and approaches “can get messy”.

3.2.2. Goals: misalignment in the goals and demands of regulatory knowledge production

Our data suggest that there is possibly “something of a mismatch” between the goals and demands of academic and industry knowledge production, which might not always coincide with that of regulation. Academic research is considered by respondents across the regulatory toxicology system to be at the “forefront of science”, and thus its goals are typically about driving “innovation”, “anticipating future need” and bringing new “knowledge and insight” to the scientific research community. Typically this is in the form of a scientific journal article or publication. In contrast, it was the perception of survey respondents from across industry and government that the goals of industry knowledge production are “aligned” with those of regulatory authorities. For instance, a respondent explained that regulatory authorities “focus on compliance of data with regulatory requirements” and internationally recognised standards, while industry aims to use scientifically robust data, with a “focus on standard studies [reported] according to e.g., OECD test guidelines, to deliver information that fulfill regulatory data requirements”. Thus the goals of academic and industry knowledge production are different.

Almost a quarter of respondents (20 %; N = 12) noted that academic researchers are “stuck in a system of financial incentive” which, historically, has pushed the community to publish as many scientific journal articles as possible. Some in industry and government noted that the pressure to “publish or perish” is a “major issue for how academic research is regarded by other stakeholders”. For instance, it was suggested in our data that “academic achievement [is] judged by number of publications, not quality of work”, and thus there is little incentive or demand for academics to align research with regulatory needs or requirements.

It was frequently mentioned that these “fundamental objective differences” between the goals and demands of academic research (i.e., pushing boundaries of knowledge for societal gain) and regulatory requirements (i.e., focus on standard studies and compliance with regulatory guidelines) can result in a lack of uptake and use of academic research by regulatory authorities. Furthermore, it was reported that in general, it is not a requirement or expectation of an academic’s role to input or submit evidence into formal and informal policy processes (i.e., consultations, calls for evidence, RMOAs), whilst “time and resource pressures plus the lack of outreach from regulators limits academic input”.

3.2.3. Processes: restrictions in the design and structure of legislative processes

Our data suggests that a lack of harmonisation and consistency in approach across the regulatory system can impact how academic research is taken up and used. Respondents from industry and consultancy highlighted that data requirements within the “risk assessment process are not fully aligned” between different regulations (i.e., REACH, CLP, BPR etc) for the different families of chemicals (i.e., biocides, pesticides, industrial chemicals, cosmetics etc), with committees (i.e., risk assessment committee for biocides/pesticides) often working “in isolation”. This means a substance can be rejected or restricted under one set of regulations but approved without restriction in another. For instance, it was mentioned that the requirements for how data and evidence (including academic research) are used is “clearly laid out” in EU pesticide and biocide legislation. This was attributed by a governmental respondent to extensive and clear guidance within the pesticide regulation on how to assess different lines of evidence, and a “high level of scrutiny on the completeness, relevance and reliability of evidence ensured by existing EU regulations and EFSA guidance”. In contrast, a different respondent from the government explained that for other compounds, such as industrial chemicals there is “no explicit provision to systematically review the scientific literature” (e.g., under EU

REACH). It was mentioned that in some cases this can result in “lots of evidence” not being used due to the design of regulations, with one respondent explaining how “flea and tick treatments that were approved based on minimal use... are now not minimal use but [are] still on the market despite evidence that they are detrimental to biodiversity”.

Respondents from academia and consultancy argued that the uptake and use of evidence, including academic research, in chemical assessment are in part dependent on “who is involved in bringing the data together”. The reliance on subjective judgement is considered an issue. A consultant explained that there are many situations in the legislative process that require “expert opinion” and an academic shared their concern that expert opinion when called for, “does not always come from those who are best placed to advise on a particular issue or subset of chemicals”, but rather from a more “generalised perspective”, such as those in policy teams who are not experts in chemical testing or effects assessment but can provide their opinion or judgment. It was reported by a consultant that in the EU, “assessments often fall down to a single key result or value (based on regulatory workflows) which may run counter to the broader weight of evidence”. It is thought that the reliance on expert judgment can thus “enable a pass or fail decision which can have significant implications for chemical assessment”.

Our data also highlight a frustration in respondents on the timing of legislative processes, with one respondent from the government noting “issues with time lags between evidence production and implementation of assessments”. Another explained that if academic research is published very late in a regulatory process, it is “more difficult to include it and assess it fully”, particularly “when there are legal deadlines to conclude the process”. The respondent argued that governmental authorities “want to make good regulations that can be implemented in a pragmatic way, and to do so using the best evidence available” but “cannot wait years and years for ‘perfect’ or ‘complete’ evidence to materialise”. It was acknowledged that the chances of an academic correctly determining which substances would be most helpful to research, “sufficiently in advance of the time” at which it would be of use to the regulatory process, “is very difficult”.

3.2.4. People: lack of expertise and resources of actors in the regulatory system

Our data also suggest that it can be a challenge for regulatory bodies to keep track of all relevant, published and unpublished data. It was reported that in the UK, “most Defra and HSE staff do not have access to scientific papers and are not up to date (or unable to keep up to date) on relevant literature”, with most relying on the Prioritisation and Early Warning System (PEWS) to alert them of emerging risks and hazards. It was also reported by a UK governmental respondent that there is not enough capacity or expertise (both in quantity and specialism) in methods of evaluation and assessment “to be able to incorporate it (academic research) to its full potential”. For instance, a respondent from the government explained that they had seen examples in the pesticide regulatory system of peer-reviewed publications that could not be properly evaluated due to a lack of required expertise to assess the reliability or adequacy of toxicological studies for inclusion in a regulatory risk assessment. Previous research has also suggested that UK authorities lack the regulatory capacity, oversight and expertise post-Brexit to keep pace and are thus slow in making regulatory decisions (Jones and Burns, 2024).

Resources and expertise, along with the consideration of time was highlighted in our research to be a key factor affecting the uptake and use of academic research in European chemical assessment and management. For instance, respondents from across sectors stated that reviewing scientific literature for WoE assessments is a time-intensive task. It was suggested in our research that “it takes more time (for regulatory authorities) to quality assess a peer-review (academic) study than to assess a contract lab report”, and resources do not always stretch far enough to allow an extensive review or meta-analysis to be undertaken. It was acknowledged by a respondent from the government that

regulatory authorities do not always have enough resources to review, evaluate and quality assess the data in a “satisfactory way”, and when time is limited or financial resource is lacking “a short cut may be taken and peer reviewed studies ignored”.

3.2.5. Technology: issues of availability, accessibility and transparency of scientific data

Our results suggest that it is difficult for academic researchers, industry and regulatory authorities to engage when it is hard to locate, obtain and understand potentially useful data. From a governmental respondents point of view (i.e., that of the regulating agency or authority), if relevant scientific data are not freely available (i.e., commercially sensitive, behind a paywall, require a subscription, need to request full text) it makes regulatory assessment very challenging, with academic research often discarded, or given a lower weight (i.e., Klimisch score; Klimisch et al., 1997) on this basis. It was argued that this is the case for both commercial or industry data, and academic data. Such data are only available to those who have access. If data are restricted for commercial (e.g., issues of confidentiality) or financial (e.g., cost of access to academic journal publications) reasons, regulators and risk assessors are then reliant on scientific data that have been published open access (e.g., free of charge). However, representatives from consultancy, industry and the government explained that even if an article is open access, academic publications often lack transparency in the thorough description of methods (e.g., exposure condition, test concentration, statistical analysis), and results (e.g., raw data are not usually accessible, data presented only in graphs and figures) whilst study protocols are usually not described in sufficient detail (for inclusion in regulatory processes) or are missing. This makes it challenging for actors to understand if data for use in regulatory assessments “have been cherry picked and if the statistics have been conducted correctly”.

For committees like the Committee for Risk Assessment (RAC), it is reported that “the methodology is of critical importance”, with documentation and reconstruction key to GLP processes. A respondent explained that when methodological details are missing, regulators cannot ascertain whether the data are reliable. A respondent from the government stated that they “aim to use all reliable and adequate academic research in regulatory assessments” but sometimes the level of reporting or the types of endpoints used means the data cannot be used, or used with limitation. A consultancy representative noted that this is largely because “academic publications are not typically produced with regulatory needs in mind” so are “prone to missing out key requirements” or have an inadequate study design. Whilst peer-reviewed reporting guidelines for academic writing exist (i.e., CRED, Moermond et al., 2016; CREED, Merrington, Nowell and Peck, 2024; ARRIVE, du Sert et al., 2020), it is reported that academics do not always communicate essential information according to the guidelines, and thus studies are often rejected, given less weight, or repeated by a contract research organisation (CRO) under good laboratory practices (GLP). A respondent from industry argued that the demands on academics to publish their work (i.e., “publish or perish”) and restrictions enacted by scientific journal publishers (i.e., word count, contribution, structure etc) can mean detail necessary for regulation is often missing. A respondent from the government explained that regulators do their best to obtain the necessary data by following up with lead or contact authors; however the data is not always provided, and can slow down the regulatory process.

3.2.6. Infrastructure: lack of structures for knowledge exchange and effective communication

For academic research to be taken up and used in regulatory processes, researchers and academics need the opportunity to communicate and share new, existing and emerging evidence with regulatory agencies and authorities. This was reported as a “fundamental challenge”, particularly by those early in their academic career who lack the relationships or contacts needed to overcome institutional or

organisational barriers.

Our data suggests that there are “very few mechanisms for non-scientists and scientists to communicate meaningfully” within the regulatory toxicology system. In particular it was suggested that there is a lack of platforms for “open, tripartite work that could enable the exchange of knowledge beyond the ‘affiliation’ of scientists”. A respondent from the EU shared that it has become “almost impossible” to have a scientific debate and exchange between sectors, highlighting that whilst “we all attend conferences” it is “quite rare for regulators, academia, industry and consultancy to engage”. It was reported by a representative from an NGO that Defra, the UK policy lead, “meets with NGOs and business on a regular basis to discuss the chemical work programme and priorities however there is no equivalent academic fora”. A respondent from industry argued that limited pathways of communication across sectors ultimately “leads to slower uptake of new methods and new evidence, as well as sub-standard and often unworkable proposals”.

A clear theme which emerged from the data is that regulatory authorities and agencies need to be better at communicating the regulatory needs, processes and requirements to researchers and academics. For instance, a respondent from consultancy explained that when they worked for a regulator supporting regulatory dossiers on persistent organic pollutants (POPs) “there was an expectation that data gaps would be filled by new research”. Such gaps were never really communicated to the academic research world and there was an expectation that it was “all meant to happen by osmosis”.

Our data also suggest that how academic research is communicated can impact its use in regulatory processes. For instance the language (i.e., style of writing) and terminology of different sectors can act as a barrier to the uptake and use of academic research. Academic writing is often highly technical and uses specific terminology “not easily accessible to those outside the area of expertise”. Whilst they did not provide an example, a respondent from academia felt “that because non-scientists do not understand the academic literature because of its technical nature they are unwilling to support its findings or recommendations in case they have misunderstood it”. Respondents from industry and the government also suggested that the language (i.e., geographical) in which research or evidence is shared can also limit its use. For instance, a respondent from the government noted that their “literature searches are generally restricted to English language publications” and that despite more than 200 languages spoken across Europe (including 24 official languages in the EU), there remains a “bias towards publications in English”.

3.2.7. Culture: role of bias, interest and cultural values in regulatory decision making

Finally, responses to our survey suggest that each sector has its own beliefs, assumptions and norms, including academics. It is reported that these can “play an active part” in the polarisation of discussions between different sectors on the uptake and use of evidence in regulatory processes. For instance, some respondents felt that industry scientists are often, and increasingly excluded (in the EU) from projects that seek to develop new methods and new types of evidence. It was the belief of several respondents that the European Partnership for the Assessment of Risks from Chemicals (PARC) has failed to involve any representatives from the chemical industry. This is despite one of the primary objectives (of PARC) being to “strengthen the networks which bring together actors specialist in the different scientific fields contributing to risk assessment”, with PARC’s website specifically seeking involvement (at the time of writing; May 2025) of “industry associations and companies involved in the production, use and disposal of chemicals” (PARC, 2025).

Some in industry cite an “abuse and intentional misuse of conflict of interest” as reasons for their exclusion, which is used with the aim to “exclude, marginalise and silence industry scientists”. For instance, it was explained by a respondent that EFSA’s stringent rules on the declaration and conflicts of interest have led to “unusable and not fit for

purpose” types of evidence and methods for risk assessment, as industry scientists are increasingly excluded from projects or expert panels. This perceived fragmentation between academic, industry and governmental representatives and authorities is reported by one industry representative as detrimental to scientific progress, “hindering knowledge exchange” and “thus depriving the whole system to make optimal use of knowledge available in different sectors”.

Our data also suggest that some individuals within the regulatory system may have a preconceived assumption of what it is like to work in another sector “without having any real experience or understanding”, and thus may trust or distrust certain sectors more. For instance, a respondent from academia suggested that the onus of industry-funded research is “clearly on finding a rationale to dismiss any detected effect” be that through the use of historical endpoints, a lack of true evidence synthesis, or only “considering endpoints and tests one by one in isolation, at the expense of detecting patterns across the whole body of evidence”. This sentiment was supported by a respondent from consultancy who perceived a lack of trust in industry by regulators, NGOs and to a lesser extent academics to be largely attributed to a lack of openness, transparency, and so called “cherry picking” of data.

A governmental representative acknowledged that more “independent” research (i.e., free of bias and conflict of interest) is necessary to ensure regulatory agencies have taken into account “all possible information on the substance before concluding on its hazard assessment”. However a respondent from the government cautioned against the use of academic research, stating that in their opinion it is clear that some academics use their research to gain attention in an “unbalanced manner”. A respondent from industry explained that “scientific quality standards vary and sometimes academics with relatively low norms with respect to reproducibility and adherence to scientific methods are very vocal and influential advocates of their work”, noting that they had experienced some in academia advocating for inclusion of their own theory or method, including “flawed or poor quality approaches, into EFSA regulatory guidance documents”.

4. Summary, recommendations and opportunities

This article has gathered and analysed stakeholder perceptions on the uptake and use of evidence, including academic research in European chemical assessment and management (question 1), and has also identified stakeholder views on the factors considered to be a barrier to the uptake and use of academic research as evidence (question 2).

On question 1, data from our research suggests that there is a general lack of consensus on the uptake and use of academic research as evidence within European chemical assessment and management. Actors across the regulatory toxicology system that responded to our survey hold divergent views on the utility and role of academic research data in European chemical assessment and management. In particular, there is a divide in opinion on whether academic research can provide necessary and suitable forms of evidence for regulatory decision making (e.g., chemical risk assessment). Research suggests that academic research can, and does contribute useful knowledge on aspects beyond the regulatory domain (i.e., environmental monitoring, fate) (Backhaus and Trier, 2015), however, it is acknowledged in our research that evidence (whether academic or not) must be robust, reliable (i.e., reproducible) and relevant to regulatory concern, whilst being gathered and reported in a form that fits the needs of policy.

Despite the contrast in perspectives that we identify in our data on the acceptance, utility and role of academic research in regulatory processes, we find general consensus between actors on what they consider the most important factors to its uptake and use (question 2). These factors incorporate different elements of the regulatory toxicology system (i.e., people, processes, culture, goals, technologies (i.e., data) and infrastructure) and touch on various aspects of the evidence cycle (i.e., knowledge production, documentation and reporting, accessibility and retrieval, screening and evaluation, see Gluckman, 2018).

Table 4

Recommendations, actions, opportunities and the actors responsible for driving change within the regulatory toxicology system to increase the uptake and use of academic research in European chemical assessment and management.

Recommendation	Suggested actions for implementation	Opportunities	Actors responsible
Promote the adoption of FAIR (Findable, Accessible, Interoperable, Reusable) and Open Access (OA) principles across academic research to enhance transparency, replicability, and regulatory use.	● Encourage the publication of data and detailed methods (e.g. via electronic supplementary materials, preprints, and open research platforms; ● Standardise metadata through guidelines; ● Facilitate non-academic access to journal articles via institutional subscriptions and free tools like Google Scholar.	Widespread implementation of these practices will support regulators, foster collaboration, and maximise the accessibility and utility of academic research.	Scientific journals; Academic researchers.
Establish incentives and recognition frameworks that actively reward scientists for contributing to regulatory-aligned research and for moving across academia, government, and industry throughout their careers.	● Create opportunities for academic researchers to participate in formal and informal policy processes – including joint appointments, secondments, advisory roles; ● Support independent, high-quality research that considers wider societal and environmental implications beyond regulatory compliance.	Cross-sector experience of academic researchers enhances policy relevance by bridging knowledge gaps, aligning diverse priorities, and accelerating the translation of research into practice.	Funding bodies; Universities and academic research institutions.
Establish sustained, cross-sector collaboration between academia, regulatory bodies, and industry to align research with policy needs, increase transparency in regulatory timelines, and accelerate the uptake of academic evidence.	● Leverage science-policy networks (e.g., SETAC, PARC) to facilitate ongoing dialogue across sectors; ● Support the collection and curation of policy-relevant data; ● Follow co-design and co-participation approaches to ensure regulatory toxicology research is collaboratively shaped, socially relevant, and policy-informed; ● Implement targeted and timely evidence calls.	Academic participation in regulatory discussions will support research that is responsive, impactful, and ready for integration into regulatory assessments and innovation pipelines.	Science-policy networks. Government and regulatory agencies; Industry and business; Academic researchers.
Develop inclusive, multi-sector knowledge exchange platforms that foster trust, transparency, and shared understanding through open, and sustained dialogue across academia, industry, government, and non-scientific actors.	● Develop shared, cross sector and interdisciplinary supervision models for PhDs and research; ● Engage in policy and industry fellowships to facilitate movement between sectors, ensuring knowledge exchange and professional development. ● Design funding mechanisms to support these initiatives.	Integrating these elements and establishing clear processes for identifying, disclosing, and managing conflicts of interest will create a more inclusive, collaborative, and dynamic environment for engagement across academia, policy, and industry.	Funding bodies. Universities and academic research institutions; Science-policy networks; Government and regulatory agencies; Industry and business; Academic researchers.

Our analysis of participant free-text responses highlights a series of themes (Table 3) that incorporate a range of system-level factors and considerations (Fig. 6). The inclusion of social, (i.e., people-based) factors distinguishes this research from the narrower scientific debate which has tended to limit itself to understanding the technical aspects (i.e., data requirements, reporting). Whilst the technical relevance, reliability, and transparency of data are critical components in the uptake and use of evidence, our research highlights that social factors (e.g., actors, goals, culture) are equally as important, and moreover, technical (i.e., science-based) factors are often reliant, interconnected or dependent on social processes.

For instance, whilst issues of relevance and reliability of academic data as scientific evidence are considered in this research to be a technical barrier (i.e., they are largely process based and deal with technical or scientific data), its production, interpretation and application to regulatory decision making exhibit social dimensions (i.e., competing goals and demands, restrictions enacted on academic research by scientific publishers, regulatory reliance on historical endpoints, lack of familiarity with regulatory needs and requirements, time lag between evidence production and chemical assessment; see supplemental material 3). Furthermore, whilst structures and systems for knowledge exchange and effective communication are considered in this research to be a social process (i.e., they are largely led by people within an organisation or infrastructure), effective knowledge exchange relies on both social and technical considerations.

Inter-dependencies, –connection, and –reliance of factors both within and across socio-technical elements of the regulatory toxicology

system are identified in all themes that have emerged from our data (see supplemental material 3). Thus, we consider it particularly important when considering ‘how’ multiple streams of evidence can be taken up and used in chemical assessment and management, that the factors and themes identified in this research are considered not in isolation but holistically across the regulatory toxicology system. Future research should develop system-level solutions, strategies or enablers for the uptake and use of academic research in European chemical assessment and management. Here we set out a series of initial recommendations and opportunities that we consider a useful first step (see Table 4).

Whilst the factors identified in our paper are not exhaustive, we consider them to be a crucial step in the development of a coordinated, systems-based approach to the uptake and use of evidence in European chemical assessment and management. Though the focus of this research is on the perspectives of those in the European regulatory toxicology system (i.e., the UK and EU), we believe the findings of this research are likely to be applicable to other jurisdictions and global settings, and invite further research to see whether and how these factors play out across other scales and jurisdictions.

Author statement

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CRediT authorship contribution statement

Lowenna B Jones: Writing – review & editing, Writing – original draft, Visualization, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Charlotte J Burns:** Writing – review & editing, Supervision, Methodology, Conceptualization. **Kathryn E Arnold:** Writing – review & editing, Supervision, Methodology, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

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Data availability

Data will be made available on request.

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