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Who are engaging in the nano-specific partner expert groups? An analysis of partner expert groups vs. expert groups

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Abstract

Background: Consultation with partner expert groups (PEGs) is an important step in updating guidance under European chemical legislation concerning nanomaterials. Here, we briefly review the differences between PEGs and the broader use of expert groups in general, and scrutinise the five closed - and one ongoing-nano-specific PEGs to investigate stakeholder composition, level of engagement and the extent to which stakeholder comments resulted in revisions being implemented in ECHA's draft guidance.

Results: Thirty-six different stakeholders were identified as having been involved in the closed PEG consultations, and an additional nine are currently involved in an ongoing PEG. For the closed PEG consultations, industry and trade associations (I&Ts) and member or associated member states (MSCAs) were the most represented groups, accounting for 15 and 13 members, respectively, whereas non-governmental organisations (NGOs) and European Union bodies (EUB) accounted for four members each. Interestingly, Academia was not represented. A total of 2700 comments were provided to ECHA's draft guidance updates. Of these, MSCAs, I&Ts, EUB and NGOs accounted for 924, 876, 771 and 126 comments, of which 678, 494, 547 and 70 were adopted by ECHA, respectively. Eight stakeholders did not provide a comment.

Conclusions: Even though EGs and PEGs are not fully comparable, we find that they hold many similarities. The nano-specific PEGs are influenced by a few very active stakeholders that have the time, resources and motivation to engage extensively while some stakeholder groups are partly or completely missing. We recommend that ECHA provides funding opportunities for less resourceful stakeholders, in order to minimise the effects of scarce funding on engagement. Furthermore, we recommend broadening the list of accredited stakeholder organisations, thereby allowing for more diversity among stakeholders involved, e.g. Academia, and that ECHA provides a justification for inclusion of the PEG members.

Keywords: Nanomaterials, Regulation, Partner expert group, Expert group, Guidance, Stakeholder influence

Background

Within the European Union (EU), new nano-specific information requirements entered into force as of 1 January 2020 [1, 2]. As pointed out by Nielsen et al. [3], established guidelines are not yet available to meet all requirements and waiving criteria. As a consequence of

the new requirements, the European Chemical Agency (ECHA) is currently updating its existing nano-specific guidance. This makes it the eighth time that ECHA has updated its guidance in order to address nanomaterials. The first guidance update in May 2012 was the "Guidance on Occupational Exposure Assessment (Chapter R.14)". Six months thereafter, the "Guidance on Characterisation of dose [concentration]—response for human health (Chapter R.8) and environment (Chapter R.10)" were updated [3]. These updates were based on advice

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provided by the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Implementation Project (RIP) on Nanomaterials 1–3 [5–7]. In 2017, “Endpoint guidance for physico-chemical properties, toxicology and ecotoxicology was updated (Chapter R.7a-c)” after consultation with partner expert groups (PEGs), the European Commission and competent authorities (CAs). Following the same procedure, ECHA “Guidance on quantitative structure–activity relationship (QSAR) and grouping of chemicals (Chapter R.6)”, and “Guidance on registration and guidance on substance identification”, was updated in 2019, in order to consider nanomaterials [4]. Chapters R.7a and R.7c’s “Endpoint-specific guidance for physico-chemical properties, toxicology and toxicokinetics” is currently undergoing a second-round update, for which there is an ongoing consultation procedure. Chapter R.7b on ecotoxicology is expected to be updated in 2021. It seems clear that an important step in the process of updating ECHA guidance is consultation with PEGs. The organisation and management of consultations with ECHA partners has been put in place to ensure stakeholder input, transparency and a broad acceptance of the guidance [8, 9].

In the following, we first provide an introductory review of the differences between the ECHA’s PEGs and the broader use of expert groups (EG) by the European Commission. Then we introduce background information on ECHA’s procedure for establishing, running and nominating experts to their PEGs and describe the methodology applied in our study, which is followed by a presentation of our results and a discussion of the implications of our findings. Lastly, we provide some concluding remarks, including some recommendations for future PEG consultations.

Expert groups and partner expert groups

There has been a lot of research into the organisation and use of expert groups (EGs) in the European Union, see e.g. [10–23]. EGs are less well-defined and cover expert consultations in different contexts, whereas PEGs are solely focussed on supporting ECHA in their preparation of guidance documents within the scope of Europe’s chemical legislation [24]. Thus, the general mandate of a PEG is to ensure that an amendment, revision or new guidance is scientific/technically discussed, taking due account of the particularities of all concerned stakeholders and other ECHA partners. Also, issues such as workability, enforceability, efficiency and proportionality may be addressed, in order to ensure the necessary buy-in from all ECHA partners. In addition, the PEG should strive for consensus [9, 24]. This raises the question of whether research findings with regard to EGs also hold true for ECHA’s PEGs.

As we show throughout this study, EGs and PEGs have many similarities although they also hold important differences.

The first study that we have been able to identify on EGs is from 2008 by Gornitzka and Sverdrup [16], who looked into the configuration of EGs of the European Commission. Based on information from the their database of Commission EGs, they discovered that EGs are unevenly distributed among policy fields and are subject to sectoral differences, with the vast majority of EGs being set up by the three European Commission’s Directorate Generals (DGs) on Research, Environment and Enterprise. Nevertheless, there has been an increasing use of expert groups within all the DGs since 2000, and their employment have become a permanent feature of the EU governance system [16].

Gornitzka and Sverdrup followed up on this work in 2011 and 2015 by studying the informational foundation in EU decision-making, examining patterns of participation in EGs under the European Commission. Based on an analysis of a dataset covering all of the EU Commission EGs (1237 to that point), Gornitzka and Sverdrup [17] found that officials from national governments were the predominant actors in EGs, in order to provide information to the European Commission. Their study supported the hypothesis that patterns of participation in EGs are affected by routines, habits and an element of path-dependency. Gornitzka and Sverdrup also studied the participation of interest groups (NGOs, social partners/unions, consumer organisations) and business in the European Commission’s EGs [18]. A positive correlation was found between the institutionalisation and the maturity of the DG in managing their portfolios, aligned with a higher tendency for them to include interest groups. Furthermore, the more organised the interest groups were in a DG’s policy domain, the more the DG opened up for participation of societal actors in the policy process [18]. After having analysed which organisational factors influence these actors’ involvement, they revealed that interest groups and businesses are highly involved in the EG system, but the extent to which these actors engage differs greatly, and there is no “one overall logic” to how the Commission approaches the inclusion of societal actors. The representation of interest groups in EGs has recently been studied by Vikberg [23], who ended up suggesting that political logic drives the accessing of specific and diffuse interests and that the relative access between the two might be subject to path dependencies. With diffuse interests, Vikberg referred to the interests of groups “*whose constituencies are larger and less well defined*” than for specific interests [23]. Further, they found that specific interests gain more access than diffuse ones when considering the overall use of EGs. However,

in certain policy areas, diffuse interests have more access to EGs (e.g. in regional and social policy) [23].

The presence of business and the role of corporate actors in the European Commission's EGs have been subject to intense political discussion and scrutiny for decades. Back in 2008, the Alliance of Lobbying Transparency and Ethics Regulation (ALTER-EU) expressed concern that the EG system lacked transparency, and the EGs seemed to be dominated by business representatives in many key public interest policy areas [10]. The criticism continued, and in 2011, the European Parliament froze the budget for EGs and established a list of conditions for their reopening, leading to the Commission committing itself to complete an EG reform [12]. Approximately at the same time, Rasmussen and Carroll scrutinised data generated throughout one decade on stakeholder participation in the European Commission's online consultations and found strong indications of business dominance—or what they termed “upper-class” dominion [22]. However, they pointed out that the degree of dominance was likely to vary from consultation to consultation. In addition, Gornitzka and Sverdrup found no evidence that the overall patterns of participation were the consequence of “agency capture” by strong corporate actors [18]. In contrast, it was found that the presence of business in expert groups seemed to be balanced by participation by consumer organisations, NGOs and/or social partners/unions, but that this interaction was kept separate from the DGs' interaction with member states' ministries.

One year prior to the findings of Gornitzka and Sverdrup, Chalmers published an interesting study. Based on an analysis of the composition of more than 800 EGs, and an investigation into whose interests were being represented in these EGs and corresponding interest organisations, the author argued that EG membership often relates to superior resources, EU-level interests and existing institutionalised ties to decision-makers [14]. He noted that the European Commission relied substantially on external stakeholders to provide decision-making advice on highly technical matters and that EG membership was more a “*story of capital and capture*” than addressing the European Commission's need for expertise [14].

More recently, Moodie investigated how the European Commission responded to the criticism and demands for reforms on the way it uses EGs [21]. Openness towards such criticism is a prerequisite for improving and avoiding complacency in the system. Using an online register of EGs, semi-structured qualitative interviews and desk-based research into European Commission documents, Moodie found that the European Commission was not resistant to change, as illustrated by the introduction of

reforms aimed to increase transparency and openness in EU decision-making [21]. However, the study underlined that the issue of expert use in the Commission is an everlasting problem and that it must be ensured that EGs remain open and transparent—and be monitored—to prohibit the domination of vested sectoral interests.

While there has been a lot of research into the organisation and use of EGs in the European Union [10–13, 15–21, 23], there has been little or no focus on the role and use of PEGs in European chemical regulation and the development of the guidance. In this study, we use elements of stakeholder analysis (SA) to investigate the PEGs that have been organised to date on nanomaterials, in order to understand their composition, level of engagement in the consultation process and the extent to which they have been able to influence the final outcomes of the consultation process.

ECHA's consultation procedure for guidance and PEGs

ECHA has published two procedure documents describing its approach to guidance consultation. The first was published in 2008 [8], and an updated version was published in 2020 [9]. According to the latter, PEGs are supposed to be composed of experts in a specific subject, chosen from various stakeholders and interested parties as well as “institutional interested partners,” referring to member state competent authorities (MSCAs) and to the European Commission. These experts are consulted on technical content issues regarding draft amendments, revisions or new guidance. The PEG consultation includes the circulation of the draft amendment, revisions or new guidance by ECHA amongst PEG members, the submission of comments made by PEG members to ECHA and, finally, arranging a meeting—if deemed necessary—to resolve issues that cannot be solved in writing. Based on the input received, ECHA prepare a consolidated final draft of the amendment, revision or new guidance, which is then sent for a concluding consultation with the European Commission and the MSCAs to ensure agreement and harmonised implementation by all authorities. The latter consultation follows the “silence gives consent” principle, but if consensus cannot be reached, the majority opinion will be followed; however, both majority and minority opinions (and their justifications) are incorporated into the guidance, thereby specifically making the reader aware of a lack of consensus [9].

Accredited stakeholder organisations (ASOs) and institutional interested parties are invited to nominate experts to given PEGs. There are currently 144 ECHA ASOs, 76% of which are industry associations, 8% environmental NGOs, 7% animal welfare NGOs, 3% academic associations, 3% consumer associations and a further 3% trade unions [24]. ECHA can also invite individual experts

to participate in the PEGs [25]. Note that ECHA uses a grouping of ASOs different from the one used in our analysis. Eventually, it is up to ECHA to define the number of experts and their required expertise or experience in its invitation to nominate experts. Criteria for ECHA's selection of nominated experts include scientific and technical expertise to address the amendments, revision or new guidance in the fields covered by the nominating organisation, and that they have experience in similar regulatory processes or cross-cutting issues of relevance, such as other relevant legislation and different scientific disciplines. ECHA strives to strike a balance between scientific and technical expert knowledge, practical knowledge of the field and industrial sectors, a balance between experts nominated by MSCA and stakeholder organisations as well as geographical distribution and gender [9].

With the aim of keeping the process open and transparent, all draft documents sent for consultation at the different stages are published on ECHA's website together with the composition of the PEGs, comments made by PEG members and ECHA's brief response to all of these PEG comments. The latter includes an indication of whether the comments were accepted or specifies the reasons why they were only partly implemented or fully rejected. This allows stakeholders not directly involved, such as third countries and other interested parties, to follow the progress of work closely and to comment using a standard form provided on ECHA's website [4].

The consultation procedure for guidance, of which the PEGs are part, is inspired by the RIPs [5–7] that the European Commission developed after REACH was adopted back in 2007, whereby all relevant parties in the guidance process were involved from an early stage. According to ECHA, this led to general endorsements in the vast majority of cases, thereby ensuring that the final guidance documents were acceptable to all [8].

Materials and methods

Stakeholder analysis (SA) is a set of tools used to identify stakeholders, assess their interests, agendas and mutual relationships and reveal various stakeholder attributes, such as importance and influence [26]. Even though the stakeholder concept is far older, Freeman formulated his “Strategic management: A stakeholder approach” in 1984 [27]. Since then, many SA approaches have been proposed in the literature [28–30]. The different approaches have different scopes and angles. Some of them focus on business management, some on conflict management and others on environmental management or other scopes [31–34]. In common is that all of the approaches collect data on stakeholders and assess how to manage or account for them.

As a way of acquiring a thorough understanding of the stakeholders represented in the nano-specific PEGs, and their influence on guidance revisions, elements of a top-down SA are conducted. Generally, SA encompasses four steps: (1) stakeholder identification; (2) stakeholder interests; (3) stakeholder importance and influence and (4) a stakeholder strategy plan [29]. However, as the scope of this study is on PEG members' influence on ECHA's revised guidance documents, only steps 1 and 3 are considered herein. Furthermore, we substitute step 4, the stakeholder strategy plan, with a discussion of our own observations, including general recommendations for future PEG consultations.

Stakeholder identification

As recently highlighted, Bendtsen et al. show how the application of SA within an environmental management and regulatory setting is hampered by inconsistent use of the term ‘stakeholder’ and that many studies using it do not properly define it [34]. To avoid confusion, we define the term ‘stakeholder’ as “Any member of ECHA's nano-specific PEGs”.

Stakeholders were identified from ECHA's lists of stakeholder composition for the six nano-specific PEGs previously described, as well as from comments provided on the guidance documents. This information is and has been made publicly available online by ECHA. To assess the stakeholder composition of nano-specific PEGs and the corresponding represented institutions, members were divided into five groups: member states and associated countries' competent authorities (MSCA); industry and trade associations, including trade unions (I&T); non-governmental organisations (NGOs); European Union bodies (EUB) and academia (Academia). In addition to the five stakeholder groups, a group named “Other” was established, to include anonymous comments provided as a stakeholder termed *Unknown*. However, *Unknown* is not as such considered a separate stakeholder in the analysis.

Stakeholder influence

Measuring or assessing the influence of stakeholders is no easy task and comes with several inherent issues, such as a potentially biased evaluation and a lack of transparency in the assessment stage [35, 36]. Dür distinguishes between three different approaches to measuring the influence of different interest groups, namely process-tracing, attributed influence and gauging the degree of preference attainment [35]. According to Collier, process-tracing is the “*systematic examination of diagnostic evidence selected and analyzed in light of research questions and hypotheses posed by the investigator*” [37] or in other words, the examination of the sequence of

events leading to the final results or outcome. The second approach, attributed influence, is common within environmental management and regulation SAs [34]. Stakeholders or experts are typically via questionnaires or interviews, are asked to assess “influence” according to how they perceive the stakeholders. This approach can be both qualitative or (semi-)quantitative. The last approach, i.e. gauging the degree of preference attainment, is a retrospective method, whereby the interests and agendas of stakeholders are compared to the investigated result or outcome [35]. In this paper, we apply a variant of “gauging the degree of preference attainment” by comparing ECHA’s initial drafts sent out to PEGs on nanomaterials, with the final guidance adopted by ECHA, the European Commission and the MSCAs.

When analysing stakeholder attributes such as “influence” in a SA setting, it is important to define the term [34]. In this paper, we refer to influence as the ability to suggest and argue in favour of specific amendments to ECHA’s initial draft guidance that are eventually adopted. To analyse the influence that PEG members have had on the final outcome of nano-specific guidance revisions, we completed an analysis of the comments provided to ECHA’s initial draft guidance with the amendments that were eventually implemented in the guidance revisions. ECHA’s responses to each of the individual stakeholder comments were furthermore scrutinised, and the comments’ status according to ECHA—“Adopted/Partially adopted”, “Dismissed” or “Not applicable (n/a)” —was recorded.

Results and discussion

Stakeholders in nano-specific PEGs

In total, 36 stakeholders were identified from the closed nano-specific guidance consultations. By simple observation of nano-specific PEG member composition, it is evident that 13 members—or a little more than one-third (~36%)—of the PEGs represent MSCA. However, the largest group represented is the I&Ts, constituting 15 members, or approximately 42% of the nano-specific PEGs. Both NGOs and the EUBs are represented by four members each (~11%), and Academia is not represented at all (0%). Mirrored against the composition of the 144 ASOs, which do not encompass MSCAs, nano-specific PEG composition and ASO composition seem to reflect each other well.

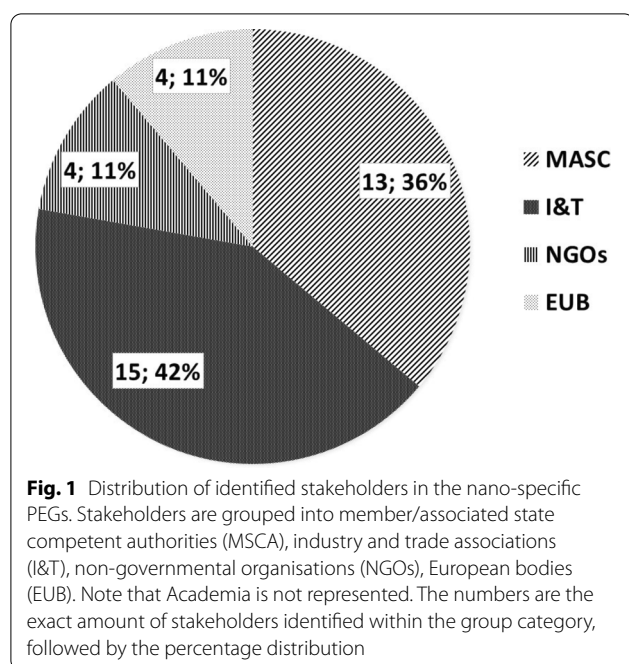
For nano-specific PEGs, NGOs are solely represented by four members, thereby supporting the statement made by Rasmussen and Carroll that there might be an “upper-class” domination for at least some of the EU consultation procedures [22]. In contrast, Chalmers found NGOs to be well-represented in the Commission’s EGs [14]. This could be due to the fact that the author studied

broadly defined EGs, which are different from PEGs that consist of experts associated with the ASOs of ECHA and which are involved in guidance updates and revisions [24].

To become a member of an ASO, organisations can apply, but only if they fulfil a set of requirements: it is legally based in the EU/EEA; it has activities at the EU level; it has a legitimate interest in the work areas of ECHA; it is representative of its field of competence; it is a non-profit organisation; it represents more than individual companies and it is registered on the EU Transparency Register [38]. The latter requirement applies only to stakeholder organisations that wish to be observers at committee and forum meetings. Thus, becoming an ASO should be possible for a broad range of stakeholder organisations. Currently, the list comprises 144 members of where I&T, NGOs and Academia accounts for 79%, 18% and 3%, respectively [25]. In this regard, we recommend ASOs to submit potential experts that could be involved in the PEGs so that ECHA has a more diverse set of ASO expert representative draw on. Also, more stakeholders representing Academia should seek influence by applying to become members of the ASO list. This could be accomplished by advertisements and by reaching out to potential ASOs and urge them to apply and engage. Also, to support the ECHA’s need for input it is pivotal that the ASOs appoint experts that actively engage and comment.

As observed and pointed out by Gornitzka and Sverdrup, there are major differences in the configuration of the EGs and a remarkably unevenly distribution among them in different sectors and policy domains [16]. This might explain the differences between our findings for the nano-specific PEGs and the observations for EGs done by Chalmers [14]. The full member distribution composition is presented in Fig. 1, and the full member lists are provided by ECHA [4]. Also, a short description of each of the identified stakeholders can be found in Table 1.

It is worth noting that Academia as such is not represented among PEG members. Some might be indirectly represented, for example, by ECOPA, but in being so, they serve a specific cause and are thus not representatives of independent research. Recently, Krik and Gornitzka tested the hypothesis that the European Commission’s EG system has become subject to what they termed “scientization”, i.e. the increased authority of research-based knowledge in policymaking [19]. They did not find signs of substantial “scientization”, which might be in line with our observation of Academia representatives, or lack of the same for the nano-specific PEGs. However, we argue that PEGs and PEG consultations rely very much on scientific and technical knowledge and



might thus be an example of what Krik and Gornitzka termed “scientisation” [19].

We find that I&Ts is by far the most represented stakeholder group in the nano-specific PEGs, which is consistent with the findings offered by Chalmers for EGs [14] (Fig. 1). This unbalanced stakeholder representation in the EGs has previously been noted by ALTER-EU [10] and more recently by Gornitzka and Sverdrup [18], leading them to express concern about the significant presence of lobbying interests in EGs. For the nano-specific PEGs, MSCAs are almost as well represented as I&Ts (Fig. 1), and thus there is a detrimental difference between the overall EG composition observed by Chalmers [14] and the nano-specific PEGs. Our observations are more in line with the findings provided by Gornitzka and Sverdrup [17, 18], which observed a biased informational foundation of EGs towards input from officials of national administrations.

Chalmers and Gornitzka and Sverdrup observed a large number of NGOs represented in the EGs [14, 18]. This is not the case for nano-specific PEGs, as they were only represented by four members. Furthermore, it is important to keep in mind that NGOs represent a broad range of interests with possibly markedly different agendas, thus making this group very heterogeneous [36]. As an example, environmental NGOs tend to focus on environmental protection and public health, while animal rights NGOs tend to focus on limiting the use of animal tests. Like the NGOs, I&Ts might have conflicting interests within the group. The underrepresentation of NGOs

could potentially be problematic, though, as decisions might be taken by a majority vote during a given PEG consultation, if no consensus can be reached, according to the EHCA consultation procedure for guidance [9]. As a consequence, this might lead to oppression of the underrepresented despite the position of the minority being recorded and included in the guidance, again according to the consultation procedure.

Lack of transparency in PEG member selection

In the main, it is somewhat unclear from the ECHA’s guidance consultation records why the different stakeholders in nano-specific PEGs have been granted a seat by ECHA. This lack of transparency was also addressed by Field, who determined that the compositions of EGs are often a result of previous individual correspondences, and individuals who have had previous dealings with the European Commission are more likely to be made aware of the opportunity to participate in an EG [15]. This notion is strongly supported by Gornitzka and Sverdrup, who stress that getting a seat in an EG is often a matter of “*routines, habits and an element of path-dependency*” [18]. As stressed by Gornitzka and Sverdrup, and supported by Vikberg, there might be different reasons behind the inclusion or exclusion of various stakeholders in EGs, which in turn may or may not be related to technical expertise [18, 23]. In relation to this point, Metz points to the fact that EGs serve more purposes than just providing expert knowledge to the Commission or its agencies [20]. For nano-specific PEGs, we observe that many of the stakeholders are represented in all or most of them, indicating that the tendencies observed for EGs might also hold true for PEGs. With this in mind, providing a brief justification for the selection of individual PEG members would greatly enhance the transparency of the selection process.

Stakeholder influence on revised guidance documents

A total number of 2700 comments were provided by the nano-specific PEG members. The full overview of comments provided by all nano-specific PEG members includes: total number of comments provided, total number of comments adopted or partially adopted, total number of comments dismissed, number of comments neither dismissed nor adopted and the adoption rate in percentage, all of which are provided in Table 2. The same data for the individual nano-specific PEGs are provided as supplementary information, Additional file 1: Table S1–5.

Overall, MSCAs provided 924 comments, European bodies provided 771 comments, I&Ts provided 876 comments, NGOs provided 126 comments and Academia was not represented (Table 2). Thus, MSCA provided the

Table 1 Short description of the institutions represented by the 36 identified nano-specific PEG members

MSCA	Description
Austria	The competent authority of Austria
Belgium	The competent authority of Belgium
Denmark	The competent authority of Denmark
Finland	The competent authority of Finland
France	The competent authority of France
Germany	The competent authority of Germany
Italy	The competent authority of Italy
Lithuania	The competent authority of Lithuania
Netherlands	The competent authority of the Netherlands
Norway	The competent authority of Norway
Poland	The competent authority of Poland
Sweden	The competent authority of Sweden
United Kingdom	The competent authority of the United Kingdom
European bodies	
DG Env	The Directorate-General for Environment is the European Commission department responsible for EU policy on the environment [39]
DG Grow	The Commission's Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs is responsible for EU policy on the single market, industry, entrepreneurship and small businesses [40]
ECHA—European Chemicals Agency	The European Chemicals Agency. Responsible for the administration of the Registration, Evaluation, Authorisation and restriction of CHemicals (REACH) regulation; the Classification, Labelling and Packaging (CLP) regulation and the Biocidal regulation in the European Union. Based in Helsinki, Finland [41]
JRC—Joint Research Centre	The Joint Research Centre (JRC) is the Commission's science and knowledge service, which provides independent scientific advice and support to EU policy. Situation in Ispra, Italy [42]
Industry and trade associations	
CEFIC—European Chemical Industry Council	The European Chemical Industry Council is a not-for-profit organisation that represents large, medium and small chemical companies across Europe, directly providing 1.2 million jobs and accounting for 14.7% of global chemical production. CEFIC is based in Brussels, Belgium [43]
CheMI—European Platform for Chemicals Using Manufacturing Industries	A European platform for downstream users of chemicals in the manufacturing industry. CheMI members consist of 18 industry associations, ranging from the tyre and rubber industry, to the toy industry. Based in Brussels, Belgium [44]
ECETOC—European Centre for Ecotoxicology and Toxicology of Chemicals	Founded in 1978 to provide industry with a scientific forum within the field of ecotoxicology and toxicology of chemicals. Financed by 52 leading companies. Based in Brussels, Belgium [45]
ECPA—European Crop Protection Association	An association of the crop protection industry in Europe, situated in Brussels, Belgium [46]
EFCC—European Federation for Construction Chemicals	EFCC represents construction chemical companies and associations in Europe. Communicates the industry's voice for European Union institutions and other public authorities. Based in Brussels, Belgium [47]
EFfCI—European Federation for Cosmetic Ingredients	A European trade association for manufacturers of synthetic and natural ingredients for the cosmetics and personal care industry. Based in Brussels, Belgium [48]
ETRMA—European Tyre & Rubber Manufacturers' Association	The voice of the tyre and rubber industry within Europe. Located in Brussels, Belgium [49]
ETUC—European Trade Union Confederation	A trade union with a special focus on workers' rights. Based in Brussels, Belgium [50]
ETUI—The European Trade Union Institute	An umbrella organisation for European trade unions. An independent research and training centre of ETUC. Based in Brussels, Belgium [51]
EuPC—European Plastics Converters	A European trade association for the plastic conversion industry. Based in Brussels, Belgium [52]

Table 1 (continued)

MSCA	Description
Eurometaux—European Association of the Metals Industry	An umbrella association of non-ferrous metals producers and recyclers in Europe [53]
FEPA—Federation of European Producers of Abrasives	An association representing more than 80% of the producers of abrasive products within Europe, including SMEs and international companies, and the abrasives' national associations including their members. Based in Paris [54]
IMA—European Industrial Minerals Association	An umbrella organisation bringing together more than 500 European companies and associations specific to individual minerals. Situated in Brussels [55]
NIA—Nanotechnology Industries Association	The advocacy organisation of the nanotechnology industries. NIA cooperates with stakeholders and regulators on national, European and international levels and is based in Brussels [56]
SME United—Crafts & SMEs in Europe	The former UEAPME. An employers' federation of craft SME firms. They encompasses national cross-sectoral craft and SME federations, European SME branch organisations and associate members [57]
NGOs	
ECOPA—European Consensus Platform for 3R Alternatives to Animal Experimentation	An international not-for-profit organisation representing people from academia, animal welfare movements, governments and industry. Members include several European countries' national platforms on alternative testing methods. They are based in Belgium and comply with Belgium law [58]
EEB—European Environmental Bureau	A network of local, national and international environmental citizen organisations. Based in Brussels, Belgium [59]
HIS—The Humane Society International	An NGO working for animal rights and protection. Based in multiple global headquarters [60]
PISC—PETA International Science Consortium	A science consortium that coordinates scientific and regulatory expertise to advance the development, use and global regulatory acceptance of the best in silico and in vitro testing approaches [61]

Note that Academia is not represented

most comments, even though there is somewhat equal weight to comments provided by the member states, the European bodies and the industry-related stakeholder representatives.

Members providing the most comments were the industry representative CEFIC, the European Commission's Joint Research Centre (JRC) and the European Commission's Directorate-General for Internal Market Entrepreneurship and SMEs (DG Grow), accounting for 345, 335 and 332 comments, respectively. It is interesting to note that whereas CEFIC represents I&Ts, the latter two represent EU bodies. Together, their comments account for more than one-third (~37%) of the total comments provided.

As observed from the composition of the nano-specific PEGs, NGOs are not well represented. This is also true when it comes to the number of comments provided. NGOs account for less than one-twentieth (~4.7%) of the total amount of comments provided (Table 2). The limited number of comments afforded by NGOs, or those not providing comments at all, might reflect that in general they are very pleased with the draft version of the updated guidance—in contrast to stakeholders that have provided hundreds of comments and suggested revisions.

However, it might also be a reflection of a lack of time, resources, prioritisation or motivation [62]. Also, of the 36 members represented, eight (~22%) did not provide any comments. Out of these, seven represented I&Ts. The reason why they did not engage more actively in the consultation process is a matter of speculation, but again it might be due to a lack of time, resources, prioritisation or motivation—as noted for the NGOs. In theory, stakeholders not providing comments could simply be in agreement with the comments already provided, or stakeholders could have coordinated who should comment on what, thus making it an active decision not to provide a comment. Nonetheless, it is noteworthy that more than one-fifth of the nano-specific PEG members passed up the chance to influence the guidance revisions. In the opinion of the authors, this skewed tendency severely threatens to undermine some of the purposes of PEGs, namely to take “*due account of the particularities of all concerned stakeholders...*” [8] and to provide input to ECHA. To address this, and to minimise the impact of a lack of resources by stakeholders, we suggest that invitations to future PEGs should be accompanied by an economic allowance for stakeholders with limited financial resources, thereby covering their expenses in terms

Table 2 Number of comments provided by nano-specific PEG members, number of adopted or partially adopted comments by ECHA, number of comments dismissed by ECHA, number of comments neither adopted nor dismissed (n/a), acceptance rate as a percentage of comments provided and the number of PEGs in which the stakeholder is represented

Stakeholder organisation	No. of comments	Adopted	Dismissed	n/a	Adopted (%)	No. of PEGs
MSCA	924[†]	678[†]	209[†]	37[†]	68[‡]	5
Austria	13	6	7	0	46	1
Belgium	18	12	4	2	67	3
Denmark	20	9	9	2	45	3
Finland	24	22	2	0	92	1
France	62	40	15	7	65	5
Germany	275	185	70	12	67	5
Italy	13	7	5	1	54	2
Lithuania	0	0	0	0	–	2
Netherlands	271	222	41	0	82	5
Norway	92	69	22	1	75	5
Poland	14	11	3	0	79	1
Sweden	19	13	4	2	68	4
United Kingdom	103	82	19	2	80	4
<i>EUB</i>	771[†]	547[†]	183[†]	41[†]	71[‡]	5
DG Env	102	71	23	8	70	5
DG Grow	332	199	126	7	60	5
ECHA	2	0	0	2	–	5(2*)
JRC	335	277	34	24	83	5
I&Ts	876[†]	494[†]	330[†]	52[†]	54[‡]	5
CEFIC	345	191	133	21	55	5
CheMI	0	0	0	0	–	1
ECETOC	144	67	68	9	47	4
ECPA	0	0	0	0	–	1
EFCC	0	0	0	0	–	2
EFFCI	0	0	0	0	–	1
ETRMA	6	1	5	0	17	1
ETUC	0	0	0	0	–	2
ETUI	22	10	12	0	45	3
EuPC	17	15	1	1	88	1
Eurometaux	166	100	61	5	60	5
FEPA	0	0	0	0	–	1
IMA	0	0	0	0	–	1
NIA	168	106	48	14	63	4
SME United	8	4	2	2	50	4
NGOs	126[†]	70[†]	52[†]	4[†]	50[‡]	5
ECOPA	3	1	2	9	33	1
EEB	41	20	21	0	49	5
HSI	28	16	10	2	57	2
PISC	54	33	19	2	61	5
Other	3[†]	0[†]	3[†]	0[†]	0[‡]	1
Unknown*	3	0	3	0	0	1

In total, 2700 comments were provided by PEG members. Note that Academia is not represented

[†] Total number of comments provided by the stakeholder group

[‡] Group average

*ECHA provided a comment for themselves for two PEGs

*Unknown is not considered a separate stakeholder in this analysis

of engaging and at least some of the time related to the task. Importantly, such economic support must not be tempting or lure stakeholders to sign up for PEGs with the purpose of sourcing this funding. Furthermore, economic support must not influence the independence of the parties involved, meaning that clear and transparent rules for when and how stakeholders are eligible for economic support, and the amount of money to which they are entitled, have to be established. Also, active engagement should be a requirement for all paid parties.

It is interesting to observe how actively different PEG members contribute to the revision process. However, providing a vast number of comments is not the same as having a direct impact on the final revised guidance documents, albeit it might influence the length of the subsequent process time spent by ECHA. A more direct measure of PEG members' influence on the revision process is the number of comments provided and subsequently adopted by ECHA in the final revised guidance documents. The numbers in this regard are available in Table 2. As observed for the total number of comments provided, there is a good balance in the number of comments adopted by ECHA amongst the most engaging stakeholder groups. MSCAs, EUB and I&Ts account for 678, 547 and 494 adopted comments, respectively. However, again, it is evident that NGOs are poorly represented, accounting for only 70 adopted comments. PEG members providing the most adopted comments represent the JRC, the Dutch MSCA, DG Grow and CEFIC, corresponding to 277, 222, 199 and 191 adopted comments, respectively. Also ECETOC, representing industry, provides 147 comments, 67 of which were adopted into the guidance documents. A full overview of the number of comments adopted by ECHA is presented in Table 2.

Another interesting observation is members' adoption rate of comments, provided in percentage terms (Table 2). The average adoption rates for the five stakeholder groups are 68%, 54%, 50% and 71% for the MSCA, I&Ts, NGOs and EUB. Note that Academia is not represented. The adoption rates vary greatly for the different stakeholders and within different stakeholder category groups. The highest adoption rate of 88% is observed for European Plastics Converter (EUPC). In comparison to the other industry representatives, this is noteworthy, as their adoption rates range from 17 to 63%. Also, the JRC have a pronounced high adoption rate (83%). This is remarkably high, as they also provide a substantial amount of comments (335). The lowest rates are observed for the industry representative European Tyre & Rubber Manufacturers' Association (ETRMA) (17%) and the European Consensus Platform for 3R Alternatives to Animal Experimentation (ECOPA) (33%). However, these

low percentage rates might be a consequence of the relatively low number of comments provided (six and three, respectively), meaning that one comment corresponds to as much as 17% and 33%. Thus, the adoption rates of the two stakeholders might change substantially if they provided more comments. Also, three comments were provided anonymously (Table 2).

Overall, nano-specific PEG consultations seem to be influenced by a relatively small group of very active stakeholders, as only ten provided more than 100 comments. Not that a cut-off of a 100 provided comments can be used as a measure for when a stakeholder is considered active or not but it does indicate a high level of engagement. The ten stakeholders previously mentioned represent three MSCA, four I&Ts and three EUB, seven of which influence nano-specific guidance revisions with 100 adopted comments or more. This is a quite a narrow segment of stakeholders which might be a result of the inclusion scheme but may lead to biased decisions or neglecting the needs of other parties. In addition, it is evident that a core group of stakeholder organisations is represented in all or most of the five nano-specific PEGs, while others are only represented in a few. Furthermore, a few stakeholder organisations represented in all or most of the nano-specific PEGs, only make a limited number of contributions. NGOs and SMEs especially do not proffer many comments and might be at risk of not being taken into account. In this regard, Chalmers concluded that gaining a seat in an EG is a matter of superior resources, EU-level interests and existing institutionalised ties to decision-makers [14]. Our study supports the findings offered by Chalmers, indicating that stakeholders with limited resources are not well represented in nano-specific PEGs, and those who are represented do not have the resources, motivation or capabilities to engage substantially.

An obvious limitation of our study is that our observations only apply to the nano-specific PEGs analysed herein. Analysis of PEGs within other fields might yield much different results. Nevertheless, the study does offer an indication that some stakeholder groups might be heavily underrepresented in some PEGs. The data on which this study builds are generated and made available by ECHA itself, and hence it has a high degree of credibility. Also, as the availability of studies of ECHA's PEGs is limited, our study relies on and compares data generated for the Commission's EGs. In this regard, it is important to note that EGs and PEGs might not be fully comparable, as they diverge in terms of scope, purpose, when they are counselled, to whom they answer and how they are established. Despite of these disparities, we believe the many similarities identified in our study justifies comparison.

In our study, we address the number of comments provided by individual stakeholders and then take the number of comments adopted by ECHA as a measure of the stakeholder's influence. This approach, though, has an inherent limitation, as comments are not just “comments”—some might address fundamental issues, such as a proposal for a new definition, and some might be of a more superficial nature, such as editorial comments. Our analysis assigns equal weight to all comments provided, and we used this as an approximation of the involved stakeholders' respective influence over the revision process. As the PEG comment are of a quite technical character and only contain a limited number of editorial comments, these were deemed negligible for the overall analysis. At this point in time, we do not believe that an in-depth analysis and evaluation of the merits of each individual comment is profitable, as no universal truth exist to hold these comments up against. Furthermore, providing firm arguments for assigning different weight of the comments risks clouding the analysis. Many stakeholders did not provide any comments, hence foregoing the opportunity to influence the guidance revisions directly. However, they might still have engaged actively in PEG discussions. For very engaging stakeholders, even vast numbers of trivial comments do not change the fact that they have been actively engaging and influential, and so the overall picture still holds true.

Trends within individual PEGs

The trends described so far cover those based on an analysis of all closed nano-specific PEGs, represented stakeholders and their comments. Overall, many of the same trends are similar when considering individual nano-specific PEGs; however, some of them are slightly more extreme. One example in this regard is the percentage of

stakeholders that do not engage in the process or offer comments. In the case of the PEG on revision of the “Guidance on registration and guidance on substance identification”, non-engaging stakeholders constitute as much as ~31% of the PEG contra the overall 22%. Another example is the engagement or lack of visibility of the different stakeholder groups, as measured by the number of comments provided against the total amount of comments, as a percentage (Table 3). For the PEG on “Guidance relating to information requirements and chemical safety assessments (IR&CSA) for environmental endpoints”, MSCAs provide as much as ~44% of the total amount of comments. This is very much in line with the observations made by Gornitzka and Sverdrup, in that officials from national administrations can be quite dominant in EGs [17].

In general, and as also seen from the overall analysis of the nano-specific PEGs, MSCA, EUB and I&Ts are very engaging. Conversely, NGOs and Academia are not well represented (both with respect to the numbers of organisations represented and comments provided), if represented at all; for example, NGOs provide as few as ~2% of the overall comments for the PEG on the revision of “Guidance on registration and guidance on substance identification”. This is in contrast to the findings of Chalmers, who revealed that NGOs are well represented in EGs overall, even though he only assessed EG composition and not their individual member contributions [14]. Also, Table 3 reveals that the stakeholder group I&T varies the most with regard to their activity. For the PEG on “Guidance on IR&CSA regarding quantitative structure–activity relationship models (QSARs) and the grouping of chemicals”, I&Ts provide approximately 17% of the total comments. However, for the PEG on the revision of the “Guidance on registration and guidance on substance

Table 3 The stakeholder group's comment contribution per nano-specific PEG, given as a percentage (%) of the total amount of comments provided by the PEG

Stakeholder group	Overall	Reg. and Sub. ID ¹	Reg. ²	IR&CSA env ³	IR&CSA QSARs ⁴	IR&CSA Human ⁵
MSCA	~34	~32	~35	~44	~34	~29
EUB	~29	~24	~29	~19	~37	~36
I&Ts	~27	~37	~30	~25	~17	~19
NGOs	~5	~2	~3	~5	~5	~10
Other	~5	~5	~4	~8	~5	~6

The numbers are rounded values

¹ PEG for consultation on the update of the Guidance on Registration and Guidance on Substance ID

² PEG for the update of the Guidance on registration regarding “recommendations for nanomaterials”

³ PEG on the update of Chapters R.7a, R.7b and R.7c of the Guidance on IR&CSA on “recommendations for nanomaterials” covering environmental endpoints

⁴ PEG on the update of Chapter R.6 of the Guidance on IR&CSA on “recommendations for nanomaterials” regarding QSARs and grouping of chemicals

⁵ PEG on the update of Chapters R.7a and R.7c of the Guidance on IR&CSA on “recommendations for nanomaterials” regarding human health endpoints

identification”, I&Ts represent 37% of the total amount of comments. With this in mind, for some individual PEGs, some stakeholder groups are almost not visible, while others seem to be very active.

Ongoing nano-specific PEG on IR&CSA for endpoint-specific guidance

In addition to the already closed nano-specific PEGs analysed herein, ECHA has established another PEG on “IR&CSA for endpoint-specific guidance”. This PEG consultation is currently ongoing, and so no comments are currently available for analysis. However, as the PEG has been established, member composition is available from the ECHA webpage [63]. A description of the members represented in the ongoing PEG consultation on “IR&CSA for endpoint-specific guidance” is available in Additional file 1: Table S6. Interestingly, the PEG introduces nine new stakeholders. Of these, three represent MSCAs, one a European agency, four I&Ts and one falls within Other. A list of the newly identified stakeholders is provided in Table 4, together with a short description of each of them. The addition of these nine new stakeholders does not change the overall PEG composition much,

and it will be interesting to see how much they engaged in the consultation process when it has come to an end.

Conclusions and recommendations

Overall, we find that many of the observations that have been reported on EGs also hold true for ECHA’s PEGs. From our analysis of the comments provided by the PEG members of the five closed nano-specific PEGs and their corresponding PEG composition lists, a total of 36 stakeholders were identified. In addition to these, nine stakeholder organisations were identified as members of an ongoing nano-specific PEG on “IR&CSA for endpoint-specific guidance”. From the stakeholder identification, it is evident that two stakeholder groups, MSCAs and I&Ts, were substantially more represented in the PEGs, together constituting 78% of PEG member institutions. In contrast, NGOs constituted less than 5%. In theory, issues are solved by a majority vote if consensus cannot be reached during PEG consultations [8]. This stakeholder distribution may pose threat to minority groups in nano-specific PEGs and may result in biased outcomes. For future PEG consultations, we recommend that ECHA strives to have a stronger representation of NGOs

Table 4 A short description of the “new” institutions introduced by the ongoing nano-specific PEG on “IR&CSA for endpoint-specific guidance”

MSCA	Description
Latvia	The competent authority of Latvia
Malta	The competent authority of Malta
Portugal	The competent authority of Portugal
European bodies	
EFSA—European Food Safety Authority	A European agency, which operates independently of the Commission, the council, the parliament and European member states. Based in Parma, Italy [64]
Industry and trade ass	
CEMBUREAU—The European Cement Association	The voice of Europe’s cement industry and communicates the industry’s views on all technical, environmental, energy and downstream issues and policy developments to both policymakers and their relevant stakeholders. Based in Brussels, Belgium [65]
CONCAWE—The oil companies’ European organisation for the environment, health and safety in refining and distribution	A confederation of the European oil industry aiming at conducting research on environmental issues related to their business. Based in Brussels, Belgium [66]
FECC—European Association of Chemical Distributors	Represents approximately 1600 companies. Many of these are SMEs. The members distribute a wide range of chemicals and ingredients to users, ranging from automotive, electronics, paint, construction to pharmaceutical, cosmetics, food and nutrition industries. Based in Brussels, Belgium [67]
Eurocolour	An umbrella organisation for the manufacturers of pigments, dyes, fillers, frits, ceramic and glass colours and ceramic glazes in Europe. Based in Frankfurt, Germany [68]
Other	
EUROTOX—Federation of European Toxicologists & European Societies of Toxicology	A union of European toxicologists and societies of toxicology. Represents around 6000 members across Europe and over 200 individual members from around the world. Based in Brussels, Belgium [69]

Note that Academia is not represented. A full list of PEG compositions can be obtained from the ECHA webpage [63]

and Academia and provides a short justification for the inclusion of the PEG member organisations, in order to overcome the current lack of transparency related to how they are included. In addition, we recommend broadening the list of ASOs, in order to encourage a more diverse set of ASOs from which the PEGs are formed.

The unbalanced member distribution of nano-specific PEGs is likewise evident when it comes to the number of comments provided. In general, MSCAs, I&Ts and EUBs are the most active stakeholder groups, reflected by the fact that the most comments were provided by the JRC, CEFIC, DG Grow and the German and Dutch MSCAs, accounting for 335, 345, 332, 275 and 271 comments, respectively. In fact, there are nine very engaging stakeholder institutions (ten if I&Ts: ECETOC is included—144 comments provided), seven of which have the influence to achieve 100 or more adopted comments across the five closed nano-specific PEGs. This indicates that nano-specific PEGs are influenced to a large extent by a small number of very active stakeholders that have the time, resources and motivation to engage extensively. With respect to the number of comments adopted by ECHA, European bodies have the highest average adoption rate of 71%, which is close to the adoption rate of MSCAs (68%). The other three stakeholder groups have lower—but also similar—adoption rates of 53% and 50% for I&Ts and NGOs, respectively.

Finally, eight stakeholders (~22%) did not provide any comments which might be a reflection of a lack of time, motivation, prioritisation or resources to engage more actively in the process after having being selected as a nominee. No matter the contributory causes, and without passing judgement on the current efforts to make stakeholders engage, this should be addressed further, in order to secure the more active engagement of nano-specific PEG members and to ensure that everybody is taken into account in the consultation process. We recommend that ECHA provides funding opportunities for less resourceful stakeholders, to increase their level of engagement.

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s12302-021-00541-8>.

Additional file 1. Supplementary information - Table S1-5.

Acknowledgements

The authors would like to acknowledge the partners of the MISTRA Environmental Nanosafety Phase II project for competent discussion and input.

Authors' contributions

All authors helped in conceptualisation of this study. MBN did the initial literature review. LPWC did the data curation and data analysis with SFH. LPWC and

SFH drafted the paper and all authors contributed to finalise it. SFH secured the funding. All authors read and approved the final manuscript.

Funding

The authors gratefully acknowledge MISTRA Environmental Nanosafety Phase II for providing funding for the research.

Availability of data and materials

All data generated or analysed during this study are included in this published article and its Additional files.

Declarations

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Competing interests

LPWC and MBN declare no conflicts of interest. SFH would like to declare that he has represented the NGO, the European Environmental Bureau (EEB), as a scientific and technical consultant in all the closed Partner Expert Groups (PEGs) and still represents the EEB in the on-going PEG.

Received: 29 April 2021 Accepted: 7 August 2021

Published online: 23 August 2021

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