

Ex-post evaluation of ECHA's Committees (RAC, SEAC, MSC)

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1.1. Executive summary

The Committee for Risk Assessment (RAC), the Committee for Socio-economic Analysis (SEAC) and the Member State Committee (MSC) are part of the European Chemicals Agency (ECHA) organisational structure. In line with the requirements and principles of the applicable EU laws and internal policies, ECHA strives to ensure appropriate and timely coordination between the Committees, that the time-limits laid down in Union legislation for the adoption of opinions are complied with, and that the scientific decision and opinion making is transparent and independent. The evolving EU chemicals policy, especially the implementation of the Commission's Chemicals Strategy for Sustainability (CSS)¹ requires that functioning of RAC, SEAC and MSC be evaluated. This is relevant for the planned Commission proposal for a self-standing basic regulation for ECHA, which has as one of its objectives to strengthen the governance of ECHA and its bodies.

The current framework of the Committees, as defined by the REACH Regulation, is considered to have been mostly adequate for the current regulatory tasks assigned to the Committees. The Committees met their objectives and targets, including legislative deadlines, on all processes managed by them. On average RAC adopted 104 and SEAC 60 opinions annually in 2019-2022. MSC has a very strong track record of reaching unanimous agreements or concluding its assessment (DEV, SEV and SVHC) within the legal deadlines after referral to MSC. However, in the context of the increasing workload, potential new tasks and the factually decreasing capacity, in RAC and SEAC, this framework is no longer sustainable.

RAC and SEAC are working at their capacity limits, must deal with high turnover and a significant untapped potential for Member States to nominate more members to these committees. This is partly due to the high workload of the committees, but primarily a consequence of resource constraints and low prioritisation of EU-level tasks in some Member States. In combination with the absence of obligation of Member States to nominate members to these two Committees, and with a lack of promotion of RAC and SEAC's work within the MS, this has also resulted in certain competence gaps. Despite the best efforts of the ECHA secretariat to support Member States in capacity building over the years, the problems with capacity have increased, as ECHA has limited ability to influence Member States' priorities and resources. In addition, under the current remuneration schemes, established under the REACH Fee Regulation, RAC and SEAC members mostly work more days when taking on rapporteurships than they can be remunerated for. The

¹ [Circabc \(europa.eu\)](https://eur-lex.europa.eu/eli/reg/2020/138/oj)

combination of the above factors risks hampering the efficient and effective performance of RAC and SEAC and negatively impacting the subsequent institutional decision-making process.

The situation is distinct for MSC, which differs in terms of the nature of tasks and membership from RAC/SEAC. Contrary to the latter, which are independent scientific committees, MSC is composed of Member State representatives. There is a legal obligation for Member States to appoint a members without the involvement of the Agency's Management Board. Given the different function of the MSC, Member States are furthermore entitled to instruct their MSC members, something they cannot do for the expert(s) they nominated for appointment to RAC/SEAC. Member States have complied with their obligations and MSC operates at the foreseen capacity. No competence gaps were identified with a view to the specific scientific-technical tasks performed by MSC. Again, this is likely to be related to its function and the use of specific expert working groups.

MSC has managed to achieve certain efficiency gains throughout the years, thanks to the decreased proposals for amendments (PfAs) by Member State Competent Authorities (MSCA), mainly as a result of agreements reached on certain scientific approaches. In combination with the increased use of written procedures and certain process improvements this led to a lower workload and increased capacity of the MSC.

Incidentally, MSC has also had the most positive feedback from the stakeholders for each of the evaluation criteria. Without affecting the overall positive conclusion, it is noted that a number of stakeholders have expressed concern over the transparency of the closed sessions. For RAC and SEAC, there was overall positive feedback of the Committee members, ECHA staff and the Commission. Stakeholders have also an overall good level of trust in the outputs of RAC and SEAC, although there has been certain criticism on behalf of the regular stakeholder observers for example, with regard to the perceived reliance on industry data, limited transparency and competence for analysis of alternatives.

Regular stakeholder observers are invited on the initiative of the Agency to attend Committee meetings and to provide, on request, technical and scientific input based on the specific expertise of the interest group in question and to contribute to the information flow from ECHA and its bodies to stakeholders².

² ECHA's Executive Director decision ED-0031 (18.12.2020) "Code of conduct for observers at ECHA meetings"

Main findings and conclusions

Committee for Risk Assessment (RAC)

Conclusion 1:

- Continue to work closely with Member States in the process of nominating members to find a more balanced selection of specialisations to fulfill the developing needs of the Committee.
- Raise awareness of and promote together with the Member States the professional development aspects of being a (co-opted) member.
- Further improve the coordination between RAC and SEAC to minimise the rework in SEAC processes should the RAC opinion change at a later stage.
- Liaise further with the Commission to clarify the information needed for the institutional decision making and to make the scientific-technical Committee opinions more concise and conclusive without compromising the independence of the Agency's opinions.

Conclusion 2:

- Consider if the available expertise of ECHA expert groups³ currently supporting Member states (for example on endocrine disruptors) could be used for the opinion-making process in RAC.

Conclusion 3:

- Consider increasing the ceiling of the transfer of funds to Member States and remuneration of co-opted members for rapporteurships, under the conditions and within the limits stipulated by the REACH Fee Regulation.
- Continue raising awareness at MSCA senior management level on the need to appoint committee members of those Member States not having appointed members.

Conclusion 4:

- Consider options to increase the capacity of the Committee. This could include:
- Alternative legislative structures for ECHA to get the needed expertise as per the competence gaps identified.

³ See description of expert groups in Section 1.7.3.1. of MSC

- Assigning a more active regulatory role to the ECHA secretariat for certain tasks and processes, with relevant human and financial resources allocation, thus compensating for the identified resource and competence issues.
- Increasing the number of the co-opted members above the current legislative maximum of five.
- Making the appointment of one or more members compulsory for Member States or proposing a minimum number of members.
- Establishing an appropriate reimbursement mechanism, if (co-opted) members will in the future have to act as rapporteurs in areas where currently no remuneration scheme exists, e.g. in the area of harmonised classification and labelling or under the Drinking Water legislation
- Establishing an improved and unified remuneration scheme, which would potentially apply to all regulatory processes, and would require less administrative burden both for the ECHA secretariat and the Member States / rapporteurs.

Conclusion 5:

- Continue to engage relevant public health and environment NGOs to ensure that there are no misconceptions about their role as regular stakeholder observers or about the use of industry data under the legislative frameworks (for example in the context of the established regular ECHA-NGO platform).
- Consider proposing legislative changes to clarify the role of stakeholder observers in the Committees.

Committee for Socio-Economic Analysis (SEAC)**Conclusion 1:**

- see above conclusion 1 related to RAC

Conclusion 2:

- see above conclusion 3 related to RAC

Conclusion 3:

- see above conclusion 4 related to RAC

Conclusion 4:

- see above conclusion 5 related to RAC

Member State Committee (MSC)

Conclusion 1:

- Consider improving the substance evaluation (SEV) process, to ensure the legal robustness of the decisions, re-consider the current role of the ECHA secretariat and Member States in the process, as well as the potential for further standardisation of the current criteria specified in REACH.

Conclusion 2:

- Consider training, awareness raising or other ways for capacity building to further strengthen the capacity of the members in view of encouraging all members' participation and covering a potentially higher workload in the future.

Conclusion 3:

- Consider the competences and capacity of the MSC in view of its available expertise and the new tasks to be allocated to ECHA.

1.2. Background

The European Chemicals Agency (ECHA) manages and in some cases undertakes the technical-scientific aspects of key parts of the EU's chemical legislation (REACH, CLP and Biocides Regulations). As such, ECHA relies on several Committees to provide scientific technical opinions and make decisions within areas of the Agency's legislative mandate. These Committees work to provide unbiased, scientific and technical opinions and decisions to advise the European Commission by reviewing scientific and technical evidence and stakeholder inputs.

RAC⁴ currently has risk assessment tasks from REACH (restrictions and authorisation), hazard assessment tasks (CLH) and hazard-based limit value tasks (OEL). Of these tasks, the latter work is not based on legislation but is done in line with an SLA with the relevant Commission service. Furthermore, the Drinking Water Directive (DWD) has assigned a task to RAC to provide opinions on inclusion or removal of substances from the positive list(s) and the revised Batteries Regulation foresees a task for RAC to provide opinions on restrictions.

SEAC⁵ deals with tasks where opinions on socio-economic aspects of substances and alternatives are needed and is generally invoked in cases where otherwise the Commission would be bound to do an impact assessment. This is currently the case for restrictions and authorisations under REACH and a new restrictions task under the new Batteries regulation has been defined.

MSC⁶ delivers decision on evaluations based on diverging opinions between evaluating authorities (decisions on testing proposals, compliance checks and requests for information following substance evaluation), prioritisation tasks (CoRAP for substance evaluation and recommendations for inclusion of substance in authorisation list) and hazard identification tasks (identification of SVHCs).

According to REACH Art.85 each member state shall appoint one member to the MSC. In the case of RAC and SEAC, REACH states that each member state may nominate candidates to membership and ECHA's MB shall appoint the members, including at least one member, but not more than two, from the nominees of each member state that has nominated candidates.

⁴ [Committee for Risk Assessment - ECHA \(europa.eu\)](https://echa.europa.eu)

⁵ [Committee for Socio-Economic Analysis - ECHA \(europa.eu\)](https://echa.europa.eu)

⁶ [Member State Committee - ECHA \(europa.eu\)](https://echa.europa.eu)

1.3. Objective

Upon request of the services of the European Commission, this ex-post evaluation analyses the degree of effectiveness, relevance, efficiency, proportionality, coherence, added value and sustainability of the Committees established by the REACH Regulation as bodies of the European Chemicals Agency (ECHA), namely the Committee for Risk Assessment (RAC), the Committee for Socio-economic analysis (SEAC), and the Member State Committee (MSC). The results will be used to support the Commission's work on improving the governance of ECHA, for which the Chemicals Strategy for Sustainability (CSS) foresees the establishment of a self-standing basic regulation for the ECHA. Some process results may be used by the Commission in the foreseen REACH revision.

1.4. Scope

The scope covers both the functioning of RAC, SEAC and MSC Committees and the functioning of the respective processes that they manage and that are contributing to the opinion or decision-making of the Committees.

1.5. Methodology

ECHA follows the methodology and tools as specified in the Commission's Better Regulation guidelines⁷ and toolbox⁸ covering ex-post evaluations, according to which an evaluation is an evidence-based assessment of the extent to which an intervention:

- a. is effective in fulfilling expectations and meeting its objectives;
- b. is efficient in terms of cost-effectiveness and proportionality of actual costs to benefits;
- c. is relevant to current and emerging needs;
- d. is coherent (internally and externally with other EU interventions or international agreements); and
- e. has EU added value — i.e. produces results beyond the legal reasons and objectives of the intervention, analyses the added value for the stakeholders/parties involved.

⁷https://commission.europa.eu/law/law-making-process/planning-and-proposing-law/better-regulation/better-regulation-guidelines-and-toolbox_en

⁸https://commission.europa.eu/law/law-making-process/planning-and-proposing-law/better-regulation/better-regulation-guidelines-and-toolbox_en

1.6. Assessment approach

The assessment approach covers the analysis of multiple sources, to triangulate the evidence and draw conclusions. ECHA and the European Commission agreed on specific evaluation criteria and questions before the onset of the work⁹. The evaluation criteria and questions have been used as a basis for this assessment. Survey and interview questions have been designed in line with the evaluation criteria and questions¹⁰.

ECHA contracted an external consultant – WSP - to analyse the results of the conducted surveys, to create competence maps from the competence grids of RAC and SEAC members and to perform a number of interviews with targeted stakeholders¹¹. In parallel, ECHA has analysed the internal data and statistics on the Committee's make-up and output and has performed a number of interviews with ECHA and Commission colleagues¹². In this evaluation report, relevant findings from the consultant's report are cross-referenced and triangulated with other sources to derive conclusions.

All internal statistics are cross-referenced in this report in sections 2 to 4 (Detailed analysis). The detailed analysis contains links and references to all data that has been used to derive a particular finding and conclusion. In the executive summary and in the key conclusions per Committee (Section 1), no links and references are repeated.

The detailed findings from the analysis of the surveys and interviews, as well as the details of the competence maps are available in the report of the consultant (Annex 1b to this report). More than half of the survey respondents are members of the respective committees or working for ECHA's secretariat, thus certain bias in their replies cannot be excluded. The evaluators have tried to mitigate this by comparing the information received with other relevant sources.

It needs to be noted also that the competence maps are based on self-assessment competence grids which are not always corresponding to the interview and survey results. It is also not investigated to what degree the interviewees have been in all aspects familiar with the details of RAC's and SEAC's current tasks, compared to possible future tasks that are not within the scope of this evaluation.

⁹ List of the evaluation criteria and questions is available as Annex 1a to the current report

¹⁰ List of the survey and interview questions is available in WSP report, attached as Annex 1b

¹¹ 30 interviews in total with members and stakeholders (10 per Committee), breakdown is available in WSP report, attached as Annex 1b

¹² 7 interviews for RAC, 6 for SEAC and 6 for MSC

1.7. Summary per evaluation criterion

1.7.1. RAC

1.7.1.1. Effectiveness, relevance, competences, quality of opinions

RAC is considered effective in performing its tasks and has achieved its objectives in terms of producing scientific opinions within the legislative processes as stipulated in REACH and CLP. RAC has the necessary competences to perform its tasks and human health competences are well covered. Human health matters are in general better covered than environmentally focused dossiers where, as already recognised by ECHA, there is a need for more specialists.

As per the interviews and competence maps, there would be a need to reinforce RAC's expertise if its range of tasks increases, such as in areas of endocrine disruptors, measurement of exposure, epidemiology, occupational hygiene, physical hazards. Interviews indicated that there has been little awareness raising on potential professional development opportunities of being a Committee member at least among those who have been appointed as co-opted members. From the survey results, RAC seems to need to reinforce the understanding of its members on the tasks that fall under SEAC.

The quality of the RAC opinions is generally considered high in the Commission decision making process. Nevertheless, interviews with the Commission representatives indicate that RAC opinions on REACH Applications for Authorisation (AfA) and restrictions are sometimes very long and a large part of the opinion is not used in the final decision making in the REACH Committee. The need to make justifications and conclusions more explicit in the opinions was also indicated by several stakeholders in the survey.

1.7.1.2 Efficiency, proportionality, capacity and remuneration

Even if some stakeholders consider RAC has gained efficiency with the recent move to working groups, statistics and interviews indicate that the benefit from the working groups could mainly be seen in the plenaries, allowing members to focus on new tasks. The overall number of meeting days has increased with the introduction of working groups. It has also increased the overall workload for the staff of the ECHA secretariat. There is good satisfaction with the focus and work of the working groups. Nevertheless, interviews highlighted that more participation of the members is needed in the restrictions working group.

Currently, RAC could have 17 more members if Member States would make use of their rights to nominate the maximum number of members foreseen in the legislation. This is mainly due to resource and prioritisation issues in the Member States, particularly in the smaller Member States (the number of RAC members has decreased from 52 in 2018 to 43 in April 2023). Despite annual alerts from RAC and SEAC to the Management Board on the need to fill the empty seats, the situation has not improved. From the current number of members, the proportion of inactive RAC members overall is estimated to be around 15 %. The workload with regard to undertaking rapporteurships is also unevenly spread among RAC members thus increasing the burden for some of the rapporteurs and the ECHA secretariat.

The survey indicates that in some cases, the 50 % contribution threshold for members is not sufficient to devote enough time to RAC work. Member States who nominate committee members as well as time of advisors and experts amount to more than 50 %.

Views of the RAC members were split regarding rapporteurship remuneration. Especially for regular Committee members the "remuneration" does not make a difference to their role as rapporteur since the funds are paid to the nominating authority or another general national budget under the terms for the transfer of fees to Member States, as foreseen in the REACH Fee Regulation. Others do not feel the remuneration is equivalent to the workload or express preference to working on CLH dossiers since there are no administrative formalities linked to a reimbursement or transfer of fees. From the data kept in ECHA, it is evident that rapporteurs work more days than remunerated or compensated for by fee transfers, especially in the case of restrictions. This is due to remuneration ceilings established by a Management Board¹³ based on an opinion of the European Commission: As stipulated in the REACH Fee Regulation, these arrangements also aim at safeguarding sufficient resources for the Agency.

Even if most co-opted members have indicated in the survey that remuneration is not sufficient, they have been the most active in taking up rapporteurships for the authorisation process. Over the last two years co-opted members have undertaken around 30-40 % of the overall rapporteurships' workload for Authorisations, thus creating dependency on co-opted members. Since their number is limited to five in the legislation, the capacity cannot currently be further increased.

¹³ Management Board decisions on Transfer of fees 2020; Management Board decision of December 2022 MB/46/2022

1.7.1.3. Coherence

Not all Stakeholders were aware of what ECHA's current Strategic Plan 2019-2023 is, and therefore could not judge how well RAC and the work of the Committee supports this strategy. When clarified for stakeholders during interviews, stakeholders do think that RAC currently supports ECHA's strategy, but would like to see this strategy discussed during plenary sessions.

1.7.1.4. Added value

Overall RAC's work is adding value to the applicants, ECHA, members, stakeholders and the Commission. Stakeholders have a good level of trust overall in the outputs of RAC and consider it independent of political influence or conflict. Regular stakeholder observers are most critical, some considering transparency to be lacking in the opinions. Some NGOs have also indicated that they view that RAC over uses and heavily relies on industry data and that their contributions are not assessed to the full extent. It is noted that these comments from NGOs need to be appreciated also in the light of the regulatory framework applicable to RAC.

1.7.1.5. Sustainability

Stakeholders responded that they find RAC to be a critical part of ECHA and are of the view that the expertise within the Committee will remain relevant regardless of evolving policy. From all data gathered, it is clear that the Committee does not currently have the capacity to take on further tasks, and that the current mandated tasks the Committee has should be reviewed.

1.7.2. SEAC

1.7.2.1. Effectiveness, relevance, competences, quality of opinions

SEAC is considered effective by stakeholders in performing its tasks and has achieved its objectives in terms of producing scientific opinions within the legislative processes as stipulated in REACH.

SEAC has a good competence in socio-economic analysis, although it was noted that there was a clear gap in the competences of SEAC with regard to the analysis of alternatives.

The quality of the SEAC opinions is generally considered high in the Commission decision-making process. Nevertheless, interviews with the Commission representatives indicated that SEAC AfA opinions are not conclusive enough on aspects related to the analysis of alternatives, and this often hampers the decision-making process in the REACH Committee. In this regard it is noted that the issue of the opinion format for opinions on authorisation applications was discussed between the Agency and the Commission previously, with regular reports provided to the Management Board¹⁴. Besides the competence gap in the analysis of alternatives, another reason for that perception is the lack of good quality data, submitted by the applicant, and the fact that REACH Committee has no remit to contact the applicant at the stage of the Commission's decision-making.

Stakeholders also noted that the restriction opinions of SEAC can be long and complex at times, which can make it difficult for the stakeholders to provide relevant data and justifications.

1.7.2.2. Efficiency, proportionality, capacity and remuneration

While SEAC is found to be mostly efficient for both restrictions and authorisations in the survey, it is difficult to quantify the efficiency gains made. There is a need for more capacity within the Committee as the workload is increasing for both processes. However, it has been noted by the MSCAs that it can be challenging to find qualified members to nominate to the Committee. Currently, there is a potential for 27 more members in SEAC. Member States do not nominate more members mainly due to resource and prioritisation issues, particularly in the smaller Member States. The proportion of inactive SEAC members (excluding SEAC members having

¹⁴ Reference to MB docs

restriction rapporteurships) is estimated to be around 15 % of the total number of appointed members.

The workload with regard to undertaking rapporteurships is unevenly spread among SEAC members, thus increasing the burden for some of the rapporteurs and ECHA secretariat.

The survey indicates that in some cases, the 50 % contribution threshold for members is not sufficient to devote enough time to SEAC's work. Based on interviews, some members perceive not all SEAC members to be equally involved in the work of SEAC, and that this may sometimes be due to the lack of emphasis their Member States place on the work of SEAC by asking the member to spend more time on other work.

Regarding the remuneration / transfer of fees, the finding below is based only on the views of regular members who work for the Member States and the co-opted members. The regular members were not able to address the adequacy as the remuneration is organised under the framework for the transfer of fees to Member States. Some co-opted members find that the remuneration is adequate for authorisations. Some members who said 'not attractive' all voiced that the work is often higher than the number of working days the remuneration provides for, which is also evidenced by the internal statistics kept by ECHA.

Some stakeholders would like to see the introduction of a working group model similar to that which RAC has adopted to focus discussions and allow for further data evaluation to be undertaken by the Committee.

1.7.2.3. Coherence

Similarly to RAC, not all stakeholders were aware of what ECHA's Strategic Plan 2019-2023 is, and therefore could not judge how well SEAC and the work of the Committee supports this strategy. When clarified for stakeholders during interviews, stakeholders do think that SEAC currently supports ECHA's strategic plan and would like to see it discussed during plenary sessions.

1.7.2.4. Added value

Overall SEAC's work is adding value to the applicants, ECHA, members, stakeholders and the Commission. Stakeholders have overall a good level of trust in the outputs of SEAC. From the respondents to the specific survey undertaken for this evaluation, most consider its opinions

independent of political influence or conflict. Some NGOs note that at times, SEACs opinions are based on information with a high uncertainty and would like opinions to be justified to the fullest extent. NGO stakeholders also perceive SEAC to rely too much on industry data, often as the only data available, and consider both ECHA and the Commission to interfere in the opinions in favour of their arguments.

1.7.2.5. Sustainability

SEAC is found to be a critical part of ECHA, and many stakeholders view that the Committee will remain relevant in the evolving policy context. Many stakeholders of all types recommend that the tasks undertaken by SEAC are reviewed as policy evolves, as the expertise within the Committee, similarly to RAC, is invaluable and should be continued to be utilised. Some stakeholders have stated that the current working methods are not sustainable in the long run. Some recommend that SEAC adopts a working group method similar to RAC, while others would like to see all possible nomination options by Member States used in the Committee filled to manage the increasing workload. From all the data gathered, it is clear that SEAC does not currently have the capacity to undertake further tasks.

1.7.3. MSC

1.7.3.1. Effectiveness, relevance, competence, quality of decisions

Stakeholders found MSC to be 'effective' to 'very effective' for all of the processes the Committee undertakes, and consider that the plenary sessions are being used for high level, open and insightful discussions.

From the interviews with ECHA and the Commission's observers it emerges that MSC is strong on hazard assessment, toxicology, ecotoxicology and CLP. There are experts' groups in ECHA currently supporting the Member States in a number of areas, in particular for topics such as persistent, bioaccumulative and toxic (PBT), nanomaterials and endocrine disruptors (ED). No gaps in the expertise were found. Stakeholders also consider MSC to have the necessary competences to complete its tasks and note that decisions by the Agency's Board of Appeal have been taken into account by the Committee.

ECHA's decisions are referred to the REACH Committee only in case a unanimous agreement is not reached in MSC. In the latest years, there has been a decreasing trend getting to an average of one decision annually referred to the REACH Committee, which is a good indicator that MSC is achieving its objectives via unanimous agreements.

To judge on the quality of the decisions, the evaluators have used data from relevant appeal and court proceedings, as well as some survey results. From those, it could be overall concluded that the quality of decisions related to dossier evaluation (DEV) and substances of very high concern (SVHC) is high, while there is still some room for improvement in the quality of the substance evaluation (SEV) decisions. It should be noted that those improvements refer to the legislative requirements for the SEV process and not to the functioning of MSC (since an error of assessment of MSC is only found in one SEV decision appealed). MSC is tasked with finding agreement on the draft SEV decisions, evaluation of SEV dossiers is not part of the tasks of MSC, but part of the Member States' tasks. Since the SEV evaluation process is considered to impact the quality of the SEV decisions, it has been analysed in that context. The main reason for the appeals has been that REACH Regulation leaves room for interpretation on the proportionality and the scope of assessment. Over the years, however, there have been improvements in clarifying the scope and proportionality of SEV decisions mainly as a result of decisions by the Board of Appeal.

1.7.3.2. Efficiency, proportionality, capacity

The overall efficiency of MSC has improved throughout the years. Besides the indication in the survey and interview results, the statistics show a decreasing trend of plenary discussions, which are replaced by written procedures. Efficiency in MSC could also be proven by the decreasing trend of proposals for amendments by Member States Competent Authorities on draft decisions prepared by the ECHA secretariat. This is most prominent in the process of dossier evaluation. Stakeholders also view MSC as 'efficient' to 'very efficient' for all the processes the Committee undertakes.

The majority of stakeholders find that MSC 'to a large extent' has sufficient capacity to perform all tasks, with most MSC members considering the workload of MSC as manageable thanks to streamlining certain processes. MSC members also consider that the current 30 % threshold for them is adequate for the current workload.

There is an indication that not all members are equally active in plenaries for the opinion-forming processes. This is not posing a risk at the moment, since MSC's workload is manageable and there is sufficient capacity to perform all MSC tasks, however, should the workload increase, this may pose more burden on the active members.

1.7.3.3. Coherence

The stakeholders for MSC have a higher understanding of ECHA's strategic plan 2019-2023 than the stakeholders of RAC and SEAC and find that the Committee is well aligned with ECHA's strategy.

1.7.3.4. Added value

Stakeholders have a very high trust in the outputs of the MSC. For the regular stakeholders, this comes from the continued learnings of the Committee from the outcomes of appeals from the BoA as well as the high level of transparency surrounding decisions that the Committee provides.

The regular stakeholders find that the communication between NGOs and trade associations and the Committee is strong, and these regular stakeholders feel that their opinions and viewpoints are heard by the Committee. Stakeholders find that the Committee is independent of political influence and based in science to a large extent.

Some stakeholders note that they would like to see a continued high level of transparency regarding all the tasks the Committee undertakes and that there should be further documentation for the learnings of the Committee. Some trade associations note that their main concern is regarding the closed sessions of the MSC, as they do not view these as transparent.

1.7.3.5. Sustainability

The current working methods of MSC are currently sustainable as the workload is manageable and the Committee has the necessary competences. However, in the evolving policy context, many stakeholders view that the tasks the Committee undertakes will need to be reviewed to ensure that the expertise within the Committee continues to be used in the most effective and efficient manner. Some members and regular stakeholders view that there may be opportunities for the Committee to undertake further work.

DETAILED ANALYSIS AS CROSSCHECKED WITH CONTRACTORS' REPORT AND INTERNAL FINDINGS

2. RAC

2.1. Effectiveness

Objectives

RAC is responsible for evaluating proposals on: Harmonised classifications and labelling, REACH restrictions and authorisations, as well as occupational exposure limits. RAC has achieved its objectives in terms of producing scientific opinions within the legislative processes as stipulated in REACH, CLP and CMRD. On average 104 opinions were adopted annually from 2019-2022¹⁵. The survey indicates that RAC is effective in performing its tasks. The highest score was received for the Harmonised classification and labelling (CLH) process¹⁶. The scores are somewhat lower for effectiveness in the Restriction (RESTR) process¹⁷ and Authorisation (AfA) process¹⁸. As stakeholders are not involved in all processes RAC undertakes, there are a significant number of 'cannot say' responses.

Competences

Of the stakeholders who were able to assess the competences of RAC members for each of the tasks RAC undertakes, most stakeholders found that RAC has the necessary competences from a moderate to a large extent. The survey indicates that the RAC has the necessary competences for the CLH process¹⁹. The score is lower for restrictions²⁰ and AfA²¹ processes. Again here, as stakeholders are not involved in all processes RAC undertakes, there are a significant number of 'cannot say' responses. Interviews indicated that there is good coverage of toxicologists, specialised in human health, reproductive toxicity, also of eco-toxicologists, mainly involved in

¹⁵ [Number of RAC outputs 2016-2022](#)

¹⁶ 62 % of survey respondents consider the tasks as very effective or effective, 28 % cannot say

¹⁷ 54 % of survey respondents consider the tasks as very effective or effective, 19 % cannot say

¹⁸ 50 % of survey respondents consider the tasks as very effective or effective, 29 % cannot say

¹⁹ 55 % of respondents consider that RAC has the necessary competences for CLH to a large extent, 28 % cannot say

²⁰ 47 % of respondents consider that RAC has the necessary competences for RESTR to a large extent, 19 % cannot say

²¹ 41 % of respondents consider that RAC has the necessary competences for AfA to a large extent, 28 % cannot say

CLH and occupational safety and health and occupational exposure limits. There are also environmental toxicologists dealing with human health, experts specialised in workers' protection and exposure of workers. Human health is better covered than environmental protection where there is need for more specialists, as already recognised by ECHA. Here it needs to be noted that ECHA depends on the Member States to nominate suitably qualified specialists for appointment by its Management Board to serve on RAC.

As per the interviews and competence maps, expertise could be reinforced in physical hazard and flammability²², measurement of exposure, epidemiology, occupational hygiene, endocrine disruptors²³.

From the survey results, RAC seems to need to reinforce the understanding of its members on the tasks that fall under SEAC.

Quality of RAC opinions

The quality of the RAC opinions is generally considered high in the Commission decision making process. Nevertheless, interviews with the Commission representatives indicated that RAC opinions on AfA and restrictions are sometimes very long and a large part of the opinion is not used in the final decision making in the REACH Committee. Despite the details however, the REACH Committee sometimes considers the opinion not to be conclusive enough and re-opens the discussion that has already taken place in RAC. Sometimes the REACH Committee may block the RAC opinion due to high reported risk values. It needs to be noted that there is a big variation of reported risk values between the Member States and each Member State has their own acceptable and tolerable risk values in particular with regards to the environment. In terms of risk values with regards to the workers protection under the OSH legislation, there is a range which gives tolerable and acceptable risk values. Besides the impact on the work of the REACH Committee, the change of the environmental risk values at a stage when the RAC opinion is ready impacts the work of SEAC thus causing re-work of the SEAC opinion.

A majority of survey respondents considered only 'to a moderate extent' that RAC opinions as clear²⁴, complete and conclusive²⁵. Stakeholders of all types noted that the high workload of RAC at times impedes these aspects, as they do not feel the justifications for opinions are always well

²² Only 5 RAC members said that they are in-depth experts regarding physico-chemical properties, and only 3 are in-depth experts regarding classification and labelling of dangerous substances

²³ While RAC members have good in-depth expertise of ED properties as related to human health, there is little in-depth expertise regarding the assessment of ED properties as it pertains to the environment

²⁴ 29 % to a large extent, 57 % to a moderate extent, 10 % to a small extent; 2 % not at all; 2 % cannot say

²⁵ 34 % to a large extent; 57 % to a moderate extent; 3 % to a small extent; 2 % not at all; 3 % cannot say

explained in documents. Stakeholders want the conclusions of RAC to be explicit, so that further legislation can use the opinions and data that comes out the Committee is the way RAC has intended.

One SEAC member also noted in their interview that for restrictions, when RACs opinion changes due to new data, SEAC at times does not have sufficient time to assess the new conclusions and the effects. The SEAC member noted that sometimes this can cause delays for SEAC as the members have to assess the further information to take into account in their opinions, and the SEAC member did not feel that RAC has a good understanding of the work SEAC does. This SEAC member suggested that it would be preferable if RAC was a step ahead of SEAC, i.e., RAC completed their opinions fully before SEAC began working on the same substance. Some regular observer stakeholders who are involved in both RAC and SEAC have also noted that there is a perceived lack of coherence and understanding of what the other Committee does, and at times it can hamper the decision-making process.

2.2. Efficiency, proportionality, capacity and remuneration

Some stakeholders mentioned that the adaptation of working groups has improved the Committee's overall ability to produce high quality scientific dossiers, and the regular stakeholders are pleased with the level of engagement they are offered. The introduction of working groups²⁶ and the optimisations of the AfA process is considered to have contributed to certain extent to the ability of the RAC plenary to produce a higher number of opinions than their [calculated max. capacity of 105 per year](#), reaching a peak of 153 in 2020. Besides the fact that the capacity of the Committee and ECHA was significantly exceeded, mainly by working extra hours to manage the workload, handling the peak was to a certain extent also facilitated by moving most of the detailed discussions to the working groups, while only presenting a summary to the plenary, and thanks to the increased use of advisors²⁷. It needs to be noted though that the working groups have overall increased the number of meeting days²⁸, the meeting cost and the workload for ECHA's secretariat, thus their benefits of shorter and more focused discussions are experienced only in the plenary which has freed capacity to focus on new tasks such as DWD for example. Interviews with ECHA staff however indicate that restrictions working group is not

²⁶ Survey respondents who consider that RAC has streamlined its working methods to a large extent: 33 % in CLH, 17 % in restrictions and 24 % in authorisations; Survey respondents who consider that RAC has streamlined its working methods to a moderate extent: 26 % in CLH, 40 % in restrictions and 26 % in authorisations

²⁷ 20 advisors on the average p.a. for 2020-2022 vs 12-13 advisors in 2018/2019 and none before that

²⁸ The [total meeting days increased from 26 in 2018 when the working groups were introduced to 40 in 2022](#)

working at its full capacity, with only few active members contribute to the restriction opinions²⁹. In addition, the survey responses indicate that RAC has not fully streamlined its working methods and adopted its working procedures to optimally use its cumulative expertise for restriction³⁰.

Participation/Capacity

All RAC members are expected to take on rapporteurships, comment in writing on other dossiers in RAC consultations, participate in plenary and working group debates.

The number of RAC members has decreased from 52 in 2018 to 43 regular members as of March 2023. Thus, there are 17 vacancies currently in RAC, many of which are from smaller member states³¹. The five year average of [104 adopted opinions per year](#) was generated by a [decreasing number of members](#) over that period. Without a return to at least 50 regular members (excl. co-opted), maintaining this output will not be possible. Conversely, with more than 50 members contributing, further output should be possible.

Competent rapporteurs and members reviewing draft opinions are essential to RAC's output and the decreasing number of RAC members urgently needs the attention of the Member States. With Member States support in nominating sufficient number of regular members lagging behind, there is an insufficient number of members to take on all rapporteurships. In the latest years there has been a dependence on co-opted members to achieve a significant part of the Committee's goals in some processes such as authorisations³². Currently, the mechanism for co-opting members is limited to five members and this is seen as inadequate³³. Interviews indicated that there is little awareness raising on the benefits of being a Committee member at least among those who have been nominated as co-opted members.

After 2018, RAC has started using advisors as well in an attempt to manage the increasing workload.

The survey indicates that in some cases, the 50 % contribution threshold for members is not sufficient to devote enough time to RAC's work. The members also voiced in interviews that not all Member States place equal support to their members to be able to dedicate time to RAC, so there are a few member states that are dedicating far above 50 % and a few below 50 %. Those interviewed were all members spending far above 50 %, and these members represented a mix

²⁹ Survey results with regards to restriction also indicate that only 7 % of stakeholders find that RAC has sufficient capacity 'to a large extent'.

³⁰ 17 % of survey respondents consider that RAC has streamlined to a large extent its working methods and adopted its working procedures to optimally use its cumulative expertise for restriction

³¹ [Number of vacant RAC seats per member state](#)

³² 33 % in 2021 and 41 % in 2022 of the rapporteurships' workload of RAC is covered by co-opted members. [The proportion of rapporteurships undertaken by co-opted members of RAC & SEAC for AfAs](#)

³³ WIN-0253.01: Selection procedure for RAC/SEAC co-opted members

of MS who have many resources for members such as advisors and experts, and MS where the RAC member is the only expert in many of the areas and is being asked to offer support elsewhere as an expert as well. Interviews indicated that for some, 70 % is more realistic.

The workload with regard to undertaking rapporteurships is unevenly spread among RAC members thus creating a burden for some of the rapporteurs³⁴. In addition, interviews indicate that this workload, in particular for restrictions is also absorbed by ECHA's secretariat which increases the scientific and administrative overload for ECHA as well.

Evaluators aimed to identify the proportion of inactive RAC members overall. The proportion of current RAC members³⁵ who did not provide written comments to AfA draft opinions³⁶ in 2022, have less than the average annual 3.3 RAC rapporteurships and who have not focused the work on CLH or RESTR, is approximately 15 % of all RAC members.

From the sampling in the meetings management audit, the active RAC capacity overall used for discussions in plenaries is around 35 %. From interviews with ECHA staff, participation is considered higher in the CLH working group but lower in the AfA and RESTR working groups. Interviews and surveys have also indicated uneven participation of the members in the plenaries.

Remuneration

ECHA is applying different remuneration schemes for the different processes, thus adding on the complexity and administrative burden when implementing those in practice.

From the statistics on the time it takes for the rapporteurs to complete the dossiers, supported with the findings from the interviews and surveys below, it can be concluded that remuneration is not proportionate to the efforts the rapporteurs invest. In addition, there is an indication from the interviews with ECHA staff that both ECHA secretariat and the rapporteurs face administrative burden from preparing individual contractual arrangements and filling in time sheets for each dossier.

³⁴ 18 members have had above the average number of rapporteurships per year (3.3 rapporteurships per year per member), including 3 co-opted members, while 31 members are below the average. [Average annual rapporteurships/ RAC member](#)

Average [annual rapporteurships / RAC member, excluding CLH](#)

Average [annual RAC rapporteurships / nominating Member state/co-opted member](#)

³⁵ excluded those RAC members who started in 2022 in RAC

³⁶ Statistics on written comments for RESTR and CLH draft opinions was not available and was therefore not used.

As per the MB decision on transfer of fees³⁷, ordinary member rapporteurs are remunerated up to 25 days per RESTR dossier per RAC rapporteurship and up to 30 days per Restriction dossier per SEAC rapporteurship. For AfA dossiers, the remuneration is maximum 12.5 % of the AfA fees received for both RAC and SEAC rapporteurs. Linking the AfA remuneration to the AfA fees should reflect the difficulty level and time spent by the rapporteur on an AfA application.

Where RAC and SEAC co-opted members are appointed as rapporteurs, they are paid per actual day of work (300 euros/day of work) to a maximum ceiling of 6 000 euros until December 2022. In December 2022 ECHA's Management Board increased the remuneration to co-opted members to 450 euros/day of work for (co-) rapporteurship, with a ceiling of this remuneration to 9 000 euros (20 person-days)³⁸.

The remuneration for 20 person-days for RAC RESTR co-opted members has been significantly lower in 2020 and 2021 than the workload in the rapporteurs' timesheets (for all members) where the average amount of days spent per restriction dossier is 65 days (for regular and co-opted members) in 2021. In the case of SEAC, the remuneration for 30 person-days for SEAC RESTR co-opted members has been significantly lower in 2020 and 2021 than the workload in the rapporteurs' timesheets where the average amount of days spent per restriction dossier is 74 days (for regular and co-opted members) in 2021³⁹. It needs to be noted that there are big variations in the volume and complexity of a restriction dossier, where the volume could even reach 1600 pages as indicated during the interviews⁴⁰.

The remuneration of 20 person-days for RAC and SEAC AfA co-opted members has been significantly lower in 2020 and 2021 than the workload in the rapporteurs' timesheets (both regular and co-opted members) where the average amount of days spent per AfA dossier is 35 days in RAC and 33 days in SEAC in 2021⁴¹. Workload of an AfA dossier varies depending on the number of uses and applicants⁴².

RAC members' replies to the survey question: "*In your role as a rapporteur, how attractive is the remuneration to you?*" were split⁴³. A few RAC members noted that the remuneration is not enough for authorisation and restriction. Most of the 'cannot say' replies came from rapporteurs for CLH dossiers, where there is no remuneration. One member voiced that it seems unfair that there is no remuneration for CLH related work. Many RAC members take CLH dossier

³⁷ MB decision on Transfer of fees 2020

³⁸ Management Board decision of December 2022 MB/46/2022

³⁹ [Average RAC/SEAC RAP person-days per RESTR 2018-2021](#)

⁴⁰ [RAC/SEAC RAP person-days per RESTR opinions](#)

⁴¹ [Average RAP person-days per AfA application 2019-2021](#)

⁴² [Average RAP person-days per various types of AfA applications](#)

⁴³ Replies are as follows: 'cannot say' (24 %), 'not attractive at all' (29 %), 'somewhat attractive' (28 %), 14 % 'quite attractive', 5 % 'very attractive'.

rapporteurships even though these are not remunerated⁴⁴. Some RAC members noted that the remuneration does not make a difference for them since it goes back into their government or institute, so it is somewhat attractive to them as it can fund institutional research or the betterment of the Member State⁴⁵. Others however do not feel the remuneration is equivalent to the workload. Most co-opted members noted that the remuneration is not sufficient in their eyes, and one co-opted member said in an interview that the disproportionality of remuneration to workload is the reason they are opting to leave RAC at this time. The regular members did also voice that the remuneration does not seem sufficient for the current workload, but that in the long run it does not matter to them since being a rapporteur is often required in their job description within their Member State.

SEAC members overall found it difficult to respond regarding the attractiveness of remuneration as all of the regular members who responded to the survey said remuneration goes back to their MSCA or institution.⁴⁶ Members indicating 'not attractive' all voiced that the workload is often higher than the number of working days the remuneration provides for. Interviews with SEAC members indicated that the remuneration often is distributed to the budget of their MSCA and they do not directly benefit from it.⁴⁷

RAC members' views were again split regarding if remuneration attracts the right expertise for RAC.⁴⁸ One RAC member noted that for co-opted members, remuneration does seem to attract the right expertise, however it does not make a difference for regular members as remuneration goes back to the MSCA or institute.

⁴⁴ [CLH dossier rapporteurships have the highest cumulative number of all: approximately 400](#). One explanation gathered in the interviews was that no time sheets or remuneration formalities are required from the members which makes this task attractive to them when they work in a MSCA and would not receive the remuneration themselves anyways.

⁴⁵ There were also views from members that they did not join RAC for remuneration and that it was never a factor, but because they considered the work in restrictions to be useful. Due to this, some of RAC's tasks are not attractive to experts, as it is a high time commitment for no pay. While expertise within RAC is critical to the effectiveness and efficiency of the committee, the lack of remuneration could be hampering this.

⁴⁶ The replies were as following: 'cannot say' (48 %), 'not attractive at all' (14 %), 'somewhat attractive' (10 %), 19 % 'quite attractive', 9 % 'very attractive'.

⁴⁷ When asked what makes rapporteurship attractive to SEAC members in interviews, the members noted that they will take on rapporteurships for restrictions or authorisations they find particularly interesting or feel they have specific expertise that will improve the quality of the opinion. The one co-opted member who was interviewed said that for them, rapporteurship is a way for them to express their continued interest in their field and being a rapporteur increases their excitement and interest in the work of the Committee as a whole.

⁴⁸ 'cannot say' 28 %, 'not at all' 36 %, 'to a small extent' 16 %, 'to a moderate extent' 20 %.

Several SEAC members found it difficult to judge when asked if remuneration is attracting the right expertise to SEAC⁴⁹ as for regular members, remuneration most often goes back to the MSCA or institute. Several members said in interviews that the remuneration has nothing to do with attracting experts to SEAC in their opinion.

2.3. Coherence

RAC carries out the work that MS (CLP), MS and ECHA/COM (Restr.), Applicants (AfA) and ECHA/COM (OELs) tasks it with. It has no mandate for self-tasking. So, the coherence of its output with ECHA's and the European Commission's strategy on chemicals is determined by all of the above parties.

A total of 60 % of respondents considered that RAC's output was coherent with ECHA's strategy on chemicals to a moderate or large extent, while a surprising 34 % did not know. Of those who responded 'cannot say' six stakeholders (including regular stakeholders and RAC members) indicated that they do not know what ECHA's strategy is.

2.4. Added value

From the data we have, we could conclude that overall RAC's work is adding value to the applicants, ECHA, members, stakeholders and the Commission.

Most survey respondents say that the work of RAC positively influences their trust in ECHA⁵⁰.

A majority of the survey respondents have a high level of trust in the outputs of RAC⁵¹. The stakeholders made further comments that they find the outputs of RAC to be in line with scientific evidence on the whole. Some noted that should the workload of RAC continue to increase without additional resources, the quality of outputs may decrease and therefore decrease their trust.

A majority of survey respondents considered that RAC is independent of political influence or conflicts⁵² and that RAC opinions are based on science and the legal provisions of REACH/CLP⁵³. However, a majority of regular stakeholder observers who responded confirm these statements

⁴⁹ 39 % 'cannot say'; 13 % 'to a small extent'; 31 % 'to a moderate extent' 31 %; 17 % 'to a large extent'

⁵⁰ 72 % consider RAC work positively influences their trust in ECHA; 9 % are negative; for 16 % it does not have an impact and 3 % cannot say

⁵¹ 59 % have high trust in the scientific outputs of RAC; 36 % medium; 3 % low; 2 % cannot say

⁵² 60 % of respondents consider RAC opinions are independent of political influence or conflicts to a large extent; 24 % to a moderate extent; 10 % to a small extent; 2 % not at all; 1 % cannot say

⁵³ 66 % agree that RAC opinions are based on science and on legal provisions of REACH/CLP to a large extent; 22 % to a moderate extent; 9 % to a small extent and 3 % cannot say

only to a moderate or small extent.⁵⁴ Some trade associations indicated in interviews that the perceived political influence is actually based in the shift of the Committee in general to a more precautionary perspective on authorisations and restrictions due to the large number of human health experts. The six regular and occasional stakeholders who said 'not at all' and 'to a small extent' representing primarily NGOs voiced that they view that RAC over-uses and heavily relies on industry data. Some regular observer stakeholders responded that they find the transparency regarding the opinions to be lacking, and that at times the scientific quality of the opinions is not what they would like to see as there are some areas of expertise which they do not think are well covered, such as risk assessment and non-human health related assessments, as noted above.

2.5. Sustainability

74 % of survey respondents find that RAC's tasks are 'to a large extent' still relevant within the evolving policy context, in particular the Chemicals Strategy for Sustainability (CSS). Stakeholders of all types said that they see RAC as becoming more relevant in the context of the CSS, however the RAC members who left further comment did note that they are concerned that the already high workload will increase further and hinder the Committee in producing quality opinions. When speaking to stakeholders in interviews, RAC members voiced similar concerns regarding the new tasks and directions that RAC may undertake as the policy context evolves, as they have taken on a number of tasks since the start of RAC already.

From all data gathered (See Section on capacity), it is clear that the Committee does not have the capacity to take on further tasks, and that the tasks the Committee has undertaken should be reviewed as compared to their original mandate.

⁵⁴ Regular SH observers: RAC opinions are independent of political influence or conflicts: to large extent 24 %, moderate 35 %, small 29 %, not at all 6 %, cannot say 6 %.

Regular SH observers: RAC opinions are based on science and on legal provisions of REACH/CLP: to large extent 35 %, moderate 35 %, small 24 %, cannot say 6 %.

3. SEAC

3.1. Effectiveness

Objectives

SEAC has achieved its objectives in terms of producing scientific opinions on the legislative processes as stipulated in REACH.: On [average 60 opinions annually from 2019-2022](#). The survey indicates that SEAC is effective in performing its tasks in the Restriction (RESTR) process⁵⁵ and Authorisation (AfA) process⁵⁶.

Competences

The survey indicates that the SEAC has the necessary competences for RESTR process⁵⁷ and AfA⁵⁸. Even if some committee members have assessed that they have in-depth expertise in the analysis of alternatives⁵⁹, interviews with Commission representatives and some regular stakeholders indicated that SEAC has a good competence in socio-economic analysis, while there is a clear gap in the competences of SEAC with regard to analysis of alternatives. It needs to be noted that the scope of SEAC is much wider compared to RAC, since it covers the whole EU market and the analysis of alternatives is very sector specific, since it may refer to each potential use of the substance in one or more sectors. One environmental NGO stakeholder responded that they perceive the socio-economic assessment methods used by SEAC to be outdated. The lack of knowledge around alternatives within the Committee is echoed by various NGO stakeholders and ECHA management board and was also voiced by trade associations during the interviews. Another area where there are fewer in-depth experts within the SEAC members is the assessment of the effectiveness and the costs linked to risk management options.

It needs to be noted also, that during Covid-19 pandemic, possibly as a result of the high peak in the workload of 2020 (104 opinions adopted vs 17 in 2019), SEAC lost a significant expertise

⁵⁵ 78 % of survey respondents consider the tasks as very effective or effective

⁵⁶ 68 % of survey respondents consider the tasks as very effective or effective

⁵⁷ 53 % of survey respondents consider that SEAC has the necessary competences for RESTR to a large extent.

⁵⁸ 50 % of survey respondents consider that SEAC has the necessary competences for AfA to a large extent.

⁵⁹ The competence maps indicate that the in-depth expertise of the Committee members is as follows: 13 members for the availability of alternatives; 4 members for alternative risk management options; 4 members for social implications; between 4-9 members in the different streams under cost-benefit assessment.

with the high turnover of its members reaching 50 %. SEAC is still rebuilding that capacity, as it takes some time for members to gain the experience to tackle e.g. complex restriction proposals.

Quality of SEAC opinions

The quality of the SEAC opinions is generally considered high in the Commission decision-making process. Nevertheless, interviews with the Commission representatives indicated that sometimes AfA opinions are not conclusive enough and this triggers discussions in the REACH Committee that have already taken place in SEAC. The main problem in the REACH Committee, as repeated by a number of interviewees, is with the analysis of alternatives, as sometimes the AfA opinion of ECHA is not covering all necessary aspects for the REACH Committee to take a decision. As the REACH Committee can no longer contact the applicant for further information, in the cases of an opinion containing inconclusive information (in particular with regards to alternatives), this may hamper their decision-making process.

The stakeholders are split between 'to a moderate extent' and 'to a large extent' regarding the completeness, conclusiveness⁶⁰ and clarity⁶¹ of SEAC opinions. Stakeholders noted that the opinions of SEAC at times can be long and complex. One TA and one NGO stakeholder both mentioned in interviews that they find sometimes the clearness, completeness and conclusiveness of SEAC opinions is moderate as they do not fully understand the justifications of how SEAC has reached an opinion. This may be related to the length of the opinions that was mentioned by one ECHA Management Board stakeholder in their survey response, as they noted that the length and complexity of the opinions makes it difficult to distil information.

3.2. Efficiency, proportionality, capacity

A majority of the survey respondents indicated that SEAC is efficient when performing its tasks in RESTR process⁶² and AfA process⁶³. The positive comments indicated that SEAC spends time at the plenary meetings thoroughly discussing complex cases. Most stakeholders consider that

⁶⁰ 35 % consider that SEAC opinions are complete and conclusive to a large extent; 43 % to a moderate extent; 13 % to a small extent; 5 % not at all; 5 % cannot say

⁶¹ 43 % consider that SEAC opinions are clear to a large extent; 45 % to a moderate extent; 8 % to a small extent; 3 % not at all; 3 % cannot say

⁶² 15 % of survey respondents consider SEAC to be very efficient; 40 % efficient; 35 % somewhat efficient; 3 % not efficient and 8 % cannot say

⁶³ 10 % of survey respondents consider SEAC to be very efficient; 40 % efficient; 25 % somewhat efficient; 10 % not efficient and 15 % cannot say

there is still further room for streamlining SEAC working methods and procedures⁶⁴. Some stakeholders of each type have suggested that more SEAC members may increase efficiency. One regular stakeholder suggested that working groups may help members to engage further in opinions and prepare for plenary meetings when complex cases need to be discussed with the entire Committee. From the statistics in house, no significant efficiency gains are seen in the [meetings' organisation](#). The meeting days have increased significantly in 2020 to handle the opinions peak and have slightly decreased afterwards following the decrease in the workload.

Participation/Capacity

Most stakeholders find that SEAC has the necessary capacity to execute its tasks for both restriction and authorisation to a moderate extent⁶⁵. Two environmental NGO stakeholders noted that they have the impression that not all SEAC members are participating in discussions, which is further expanded on in the added value section of this report. The main comment from stakeholders of all types is that there are not enough active members nominated by Member States to SEAC.

The workload on rapporteurships is unevenly spread among SEAC members, where only eight members have had above the average rapporteurships per year (average 3.5 rapporteurships per year per rapporteur)⁶⁶, while the rest 26 members (including a few whose membership just ceased) have been less active in undertaking rapporteurships. Two of the most active rapporteurs are co-opted members. It needs to be noted though that this is indicative since the nature of rapporteurships vary for time spent and expertise needed depending on the process (restriction or application for authorisation). Additional check indicates that in SEAC those with a lower number than average of rapporteurships do have restriction dossier rapporteurships which are the most-time consuming (50 % from all above the average and 50 % from all below the average have undertaken restriction dossier rapporteurships). On the other hand, SEAC has four members who have above the average number of rapporteurships and do have more time-consuming restriction dossier rapporteurships.

⁶⁴ 38 % of survey respondents consider SEAC has streamlined its working methods and adapted its working procedures to optimally use its cumulative expertise for restriction to a large extent; 40 % to a moderate extent; 10 % to a small extent; 13 % cannot say; 38 % of survey respondents consider SEAC streamlined its working methods and adapted its working procedures to optimally use its cumulative expertise for AfA to a large extent; 28 % to a moderate extent; 18 % to a small extent; 18 % cannot say

⁶⁵ 15 % of survey respondents consider that SEAC has the necessary capacity for RESTR to a large extent; 65 % to a moderate extent; 8 % to a small extent; 3 % not at all; 10 % cannot say; 8 % of survey respondents consider that SEAC has the necessary capacity for AfA to a large extent; 60 % to a moderate extent; 13 % to a small extent; 3 % not at all; 18 % cannot say;

⁶⁶ [Average annual number of rapporteurships per SEAC member](#) ;
[Average annual SEAC rapporteurships / nominating Member state or co-opted member](#)

Evaluators aimed to identify the proportion of inactive SEAC members overall. The proportion of current SEAC members⁶⁷ who did not provide written comments to AfA draft opinions⁶⁸ in 2022, have less than the average annual 3.5 SEAC rapporteurships and who have not focused the work to RESTR is approximately 15 % of all SEAC members. From the meetings management audit sampling, the active SEAC capacity overall used for discussions in plenaries is around 30 %.

Many of the [27 vacancies in SEAC](#)⁶⁹ are from the smaller Member states. It is possible that these Member states will not be able to nominate committee members in the future either. When discussing in interviews with some SEAC members and MSCA, they noted that they can see a difference in the way the MS value the work of SEAC from their interactions with current SEAC members, and that there are some members who have low involvement and others who are extremely involved. The members noted that this level of involvement is based on a number of factors, including the value the MS places on the work of SEAC, the external work of some of the members, and the support of experts or advisors from the MS. Not all MS are able to offer SEAC members an advisor to help manage the workload as there are just not available experts in the MS.

With MS support in nominating sufficient regular members lagging behind, there is a dependence on co-opted members to achieve a substantial part of the Committee's goals⁷⁰. Currently, the mechanism for co-opting members⁷¹ is limited in numbers allowable, is fairly time consuming, and presents difficulties in adapting capacity at short (or even medium-term) notice.

Remuneration

See findings above in the section for RAC remuneration.

3.3. Coherence

SEAC carries out the work that MS and ECHA/COM (Restr.), and Applicants (AfA) task it with. It has no mandate for self-tasking. So, the coherence of its output with ECHA's and the European Commission's strategy on chemicals is determined by all of the above parties.

73 % of survey respondents say that the work of SEAC positively influences their trust in ECHA.

⁶⁷ excluded those SEAC members who started in 2022 in SEAC

⁶⁸ Statistics on written comments for RESTR draft opinions was not available and was therefore not used.

⁶⁹ For comparison RAC has 17 vacancies

⁷⁰ 35 % in 2021 and 42 % in 2022 of all rapporteurships' workload is covered by co-opted members

⁷¹ WIN-0253.01: Selection procedure for RAC/SEAC co-opted members

The views of the survey respondents were split when it came to SEAC's coherence with ECHA's strategy⁷². Comments of respondents indicated that not all are fully aware of ECHA's long term strategy.⁷³

3.4. Added value

From the data we have, we could conclude that overall SEAC's work is adding value to the applicants, ECHA, members, stakeholders and the Commission.

Majority of the survey respondents have a high level of trust in the outputs of SEAC⁷⁴, and consider that the work of SEAC positively influences the level of trust in ECHA⁷⁵ and that SEAC opinions are based on science and legal provisions of REACH⁷⁶. The stakeholders left further comments that they find the outputs of SEAC to be in line with scientific evidence on the whole, and some noted that should the workload of SEAC continue to increase without review, the quality of outputs may decrease and therefore decrease their trust. The regular stakeholder observers were most critical in their perception⁷⁷. Of the 3 regular observer stakeholders who responded 'low' all are NGOs who do not perceive the opinions to be fully scientific, but rather best judgements. These NGO stakeholders responded that the level of uncertainty from the data should be taken into account by the Committee when providing final opinions, and that any opinions that come from data with a high uncertainty need to have a higher level of justification provided.

Most of the stakeholders consider SEAC is independent of political influence or conflicts⁷⁸. Perception is more negative among the NGOs, where the main reasons specified come from high reliance on industry data as the only data available, which in turn leads to uncertainties in the analysis, and perceived steering/interference in favour of ECHA and the Commission's arguments.

⁷² 30 % responding 'cannot say', 30 % responding 'to a moderate extent' or 'to a small extent', and 38 % responding 'to a large extent'

⁷³ Two NGOs indicated that SEAC's current way of working does not provide a high level of protection to people and the environment, and is not in line with ECHA's management board mid-term strategy.

⁷⁴ 57.5 % have a high level of trust; 32.5 % medium and 10 % low

⁷⁵ 73 % consider SEAC work positively influences their level of trust in ECHA; 13 % are negative; 13 % consider it does not have an impact; 3 % cannot say

⁷⁶ 63 % consider that SEAC opinions are based on science and legal provisions of REACH to a large extent; 23 % to a moderate extent; 10 % to a small extent; 3 % not at all; 3 % cannot say

⁷⁷ 2 regular stakeholder observers had only a medium and 3 - low trust in the outputs of SEAC

⁷⁸ 38 % consider SEAC opinions are independent of political influence or conflicts to a large extent; 43 % to a moderate extent; 5 % to a small extent; 5 % not at all; 10 % cannot say.

3.5. Sustainability

73 % of survey respondents find that SEAC's tasks are 'to a large extent' still relevant within the evolving policy context. Stakeholders of all types note that the work of SEAC is indispensable, and that the role of independent experts to assess socio-economic impacts is crucial in the decision-making process for authorisation and restriction. The stakeholders view the transparency that SEAC offers as necessary to continue to uphold the accountability of final decisions of parties to the general public.

Some stakeholders have stated that current working methods are not sustainable in the long run, some recommend that SEAC adopts a working group method similar to RAC, while others would like to see all possible nomination options by Member States used in the Committee filled to manage the increasing workload.

Environmental NGOs consider that the envisioned focus on essential use may make the work of SEAC less relevant in the future and that growing the expertise in the area of alternatives and understanding of industrial processes will be necessary for SEAC to support the CSS objectives. Similarly to RAC, stakeholders express worries about the increasing workload of SEAC, which they fear it may impact the quality of the opinions.

From all data gathered (see Section on capacity), it is clear that SEAC does not have capacity to undertake further tasks.

4. MSC

4.1. Effectiveness

Objectives

MSC has a different function than the previous scientific committees. The function of MSC is reaching collective agreement⁷⁹ among member states competent authorities. MSC has achieved the objectives in terms of producing scientific decisions on the legislative processes as stipulated in REACH and CLP. The survey indicates that MSC is very effective in performing its tasks. In comparison with RAC and SEAC, where most of the survey scores on effectiveness are in the range of 40-60 %, MSC is above 80 % in four of its processes (dossier evaluation⁸⁰, SVHC identification⁸¹, Annex XIV recommendations⁸² and CORAP⁸³) and a bit below in substance evaluation⁸⁴.

MSC has a very strong track record of reaching unanimous agreements or concluding its assessment on all of the DEV, SEV and SVHC cases within the legal deadlines of 60 days and 30 days after referral to MSC. This has enabled decision-making to continue without any delays. The vast majority of cases referred to MSC (draft decisions and SVHC proposals) have been unanimously agreed in MSC. From 2015 onwards the number of cases where unanimous agreement could not be reached by MSC has been low⁸⁵.

Competences

From the interviews with ECHA and the Commission's observers, MSC is strong on hazard assessment, toxicology, ecotoxicology and CLP. No gaps in the expertise are found. From the interviews, MSC members have the necessary competences to achieve the objectives of the different processes they deal with and to produce sound decisions. Here it needs to be noted that RAC for example is missing expertise in endocrine disruptors.

⁷⁹ Preambles 67 and 103 of Regulation (EC) No 1907/2006

⁸⁰ 86 % of survey respondents consider the tasks as very effective or effective

⁸¹ 82 % of survey respondents consider the tasks as very effective or effective

⁸² 80 % of survey respondents consider the tasks as very effective or effective

⁸³ 81 % of survey respondents consider the tasks as very effective or effective

⁸⁴ 74 % of survey respondents consider the tasks as very effective or effective

⁸⁵ SEV 0.7 %, DEV 1.3 %, SVHC 11.8 % on the average from 2015 onwards

Often Member States use expert groups, in particular for topics such as persistent, bioaccumulative and toxic (PBT)⁸⁶, nanomaterials⁸⁷ and endocrine disruptors (ED)⁸⁸, where experts may be provided by the competent authorities. Some members have experts' support in their home countries too⁸⁹.

Quality of the decisions

ECHA's decisions are referred to the REACH Committee in case unanimous agreement is not reached in MSC and this has been [extremely rare](#) in the latest years⁹⁰. This is a good indicator that MSC is achieving its objectives via collective agreement.

To judge on the quality of the decisions, the evaluators have used the appeal and court proceedings as well as some survey results. From those, it could be overall concluded that the quality of the DEV and SVHC decisions is high, while there is room for improvement in the SEV decisions. It needs to be noted that the SEV evaluation is not part of the tasks of MSC, but part of the Member States' tasks. Since the SEV evaluation process is considered to impact the quality of the SEV decisions, it has been analysed in that context.

[The statistics of SEV appeals](#) from 2014 to 2021 show that out of the 26 appeals lodged against ECHA decisions, 13 (50 %) have resulted in the decision being annulled or partially annulled. It has to be noted though that an error of assessment by MSC has been found only in 1 SEV decision. The rest of the reasons for annulment point to omissions during the SEV process, mainly failures or weak grounds to establish a concern or risk and some procedural errors, or other items which are not part of MSC assessment. For substance evaluation quite a few decisions of the BoA from 2014 clarified the scope of substance evaluation (i.e., what ECHA could ask under substance evaluation and when is it proportionate). This was of course an issue which was relevant for ECHA-S, MSC and Member States. It needs to be noted though that the appeals trend has slowed down after 2019 and the learnings from the appeals have helped in clarifying the scope of the assessment.

Here, it needs to be noted also that ECHA has been the main initiator of PfAs on the SEV dossiers, as evaluated by the Member States over the years 2013-2022. ECHA's PfAs account for 33 % on the average of all cases⁹¹, which combined with the opinion of some ECHA interviewees,

⁸⁶ PBT Expert group

⁸⁷ Nanomaterials Expert group

⁸⁸ Endocrine Disruptor (ED) Expert group

⁸⁹ Those are informal expert groups, for which there is no official appointment

⁹⁰ 1 case on the average for DEV, SEV and SVHC processes for the period of 2018 to 2022

⁹¹ In addition to ECHA, there have been five main countries providing PfAs on substance evaluation.

indicates that ECHA has been re-working most of the SEV evaluations, before submitting the SEV dossiers to the MSC meeting. It needs to be noted, however, that the majority of SEV cases are very complex due to the need for non-standard information⁹², and some Member States do not have the capacity or competence to effectively conclude a SEV evaluation. On the positive side, however there has been a [decreasing trend of ECHA's PfAs](#) in the last years⁹³ as well as of the total number of PfAs in SEV, as a result of the support ECHA is providing to the evaluating MSs, the early interaction well in advance of the formal PfAs consultation period and the multiple appeals that have helped to clarify aspects such as proportionality of the requested information.

[The statistics of DEV appeals](#) from 2011 to 2021 show that out of the 29 appeals lodged against ECHA decisions only four in total (14 %) have resulted in the decision or action being annulled or partially annulled. For dossier evaluation the reasons for annulment were mainly procedural and therefore not due to an error of assessment made by MSC or ECHA. Only the first ever compliance check case was annulled due to an error of assessment and was about the scope of a very specific provision in the REACH annexes⁹⁴.

The General Court has upheld all the SVHC decisions that have been brought to it. From these 20 cases MSC was involved in the SVHC identification process in all except one case. One of the cases was a challenge of a Commission SVHC decision based on a majority opinion of the MSC (the matter was referred to COM as the MSC could not reach unanimous agreement). The Court also dismissed that case.

Most of the stakeholders consider that the MSC outputs are clear, complete and conclusive⁹⁵. Some improvements with the templates for decisions were appreciated, while one trade association considers the clarity could be further improved regarding the justifications of decisions that are made after closed sessions. Another one noted that sometimes the decisions are heavy in terms of the legal text and can be difficult to narrow down to the actionable aspects.

⁹² Many SEV cases can be unique in terms of the information requested, testing strategy, and/or justifications for the approach taken

⁹³ 10 in 2021 and 15 in 2022 vs 24 in 2020 and 44 in 2019

⁹⁴ Section 8.6.4. of Annex X of REACH.

⁹⁵ 67 % of stakeholders agree that MSC outputs are clear, complete and conclusive to a large extent; 23% to a moderate extent; 5 % to a small extent and 5 % cannot say

4.2. Efficiency, proportionality, capacity

The overall efficiency of MSC has improved throughout the years. Besides the indication in the survey and interview results, the statistics show a decreasing trend of plenary discussions, which are replaced by written procedures⁹⁶.

Efficiency in MSC could also be illustrated by the [number of decreasing PfAs](#) over the years in particular in the process of dossier evaluation, where the percentage of draft decisions with PfAs has decreased from an average 37-40 % in the period of 2016-2018 to an average of 10 % in the period of 2019-2022. As per the opinion of some ECHA staff, the reasons for that decrease could be contributed to the increased trust from the MSCA in the scientific output of ECHA, the aligned views between ECHA and MSCAs through the generic approaches agreed at MSC for dossier evaluation and gaining routine in the process. Most of the PfAs received throughout the years have been on the substance and on topics such as extended one-generation reproductive toxicity study (EOGRTS) and requests for mutagenicity tests. In 2021, MSC discussed and agreed on the approach to the Extended One-Reproductive Toxicity study (EOGRTS) for ECHA to follow for future DEV cases thus further decreasing the PfAs.

Since only the cases that have received PfAs are presented in MSC, the [decreased number of cases brought to MSC in the last three years](#)⁹⁷ has led to a decrease in the overall workload of the Committee.

The decreased number of cases referred to MSC (due to the lower number of PfAs) has also enabled ECHA to increase its output in evaluation, while [maintaining the same level of resources over the years](#)⁹⁸.

Participation/Capacity

The majority of stakeholders find that MSC 'to a large extent' has sufficient capacity to perform all tasks. From the interviews, two MSC members as well as the advisor/expert to a member voiced that the workload for MSC is currently manageable, even a little less than they believe they can manage.

⁹⁶ Written procedures (WP) in 2022 reach over [90 % of all CCH dossiers](#), over [70 % of TPE](#), over [80 % of SVHC](#) and [60 % in SEV dossiers](#)

⁹⁷ The average annual number of SEV cases brought to MSC has decreased from 22 in 2014-2019 to 10 in 2020-2022; The average annual number of DEV cases brought to MSC has decreased from 84 in 2014-2019 to 24 in 2020-2022; The average annual number of SVHC cases brought to MSC has decreased from 7 in 2014-2019 to 6 in 2020-2022.

⁹⁸ Around 100 staff members have processed 122 final decisions in 2019 vs 421 final decisions in 2022

During the stakeholder interviews, MSC members shared that the current 30 % threshold for them is adequate for the workload and allows them time to still speak with experts when needed. The members do suggest that this may change in the evolving policy context if the MSC undertakes more aspects of tasks, such as endocrine disruptors (ED). The regular stakeholders (TAs and NGOs) mentioned in interviews that from their perspective MSC has sufficient capacity and that the members appear to be dedicating adequate time to all processes the Committee undertakes.

The participation rate in plenary meetings is on the average 97 % of members or alternates (data from 2021-2022). Based on the below data, evaluators estimate that the active participation in the plenaries discussions is indicatively around 30 %. This is not posing a risk at the moment since the workload of the Committee is manageable, but may increase the workload for the more active members should the overall MSC workload increase.

One sampling under the Meetings management audit where auditors observed the oral interventions per member at the MSC meeting concluded that 30 % of all members were active in the discussions. Interventions submitted via the chat during plenary were not included. From the stakeholder interviews, one MSC member noted that roughly 30 % of members are regularly active, and about 15 % trigger discussions within the Committee⁹⁹.

Some ECHA staff consider the cumulative yearly statistics on the proposals for amendments (PfAs) an indirect indication of the level of participation of the members during plenaries. That is why the below data were used to indirectly judge on the members' activity, contributing to the above conclusion that not all members are equally active. In dossier evaluation, 4 main countries account for [90 % of all PfAs](#) for the period of 2009-2022. However, it should be noted that in the latest years Member States have been requested not to submit PfAs where already addressed by PfAs from other Member States. It should also be considered that PfAs have overall decreased throughout the years, leading to some efficiency gains (see above under the same Section).

In the opinion-forming processes, [19 MSs have acted as MSC rapporteurs or co-rapporteurs](#) over the years 2009-2022 with the minimum of one and max. of four rapporteurships per country for the three processes of CoRAP, Art 77(3) requests and recommendation for inclusion of

⁹⁹ Evaluators did not have access to further data, such as written comments to be able to judge on the overall activity of the members, thus the above data should be considered only as indicative

substances in Annex XIV list. There is no remuneration to the MSC rapporteurs in any of the opinion forming processes of MSC.

4.3. Coherence

The stakeholders for MSC have a higher understanding of ECHA's strategy than other stakeholders did and find that the Committee is well aligned with ECHA's strategy¹⁰⁰. One NGO stakeholder would like to see the time gap between the decisions of MSC and the actions on RAC and SEAC to provide opinions decrease, and they believe that this will lead to better coherence within ECHA as a whole.

4.4. Added value

The added value of MSC is considered high based on the transparency of the process (participation of regular stakeholder observers, registrants, publication of minutes) and the 'buy-in' (among all MSs) to the decisions that MSC issues. MSC offers a forum to discuss among Member States and to strengthen the expertise needed to draft good quality decisions which also stand in front of the BoA or Court¹⁰¹.

The majority of stakeholders have a high level of trust in the scientific outputs of MSC¹⁰², find that the Committee is full of scientific experts who produce good quality scientific outputs, and that MSC's work positively influences their trust in ECHA¹⁰³ and most of them consider MSC to be independent of political influence or conflicts¹⁰⁴.

Two trade associations note that their main concern is regarding the closed sessions of the MSC, as they do not view these as transparent and do not always understand the justifications for the decisions made in closed sessions.

¹⁰⁰ 67 % consider MSC's current way of working coherent with ECHA's long term strategy to a large extent; 12 % to a moderate extent; 5 % to a small extent; 2 % not at all and 19 % cannot say

¹⁰¹ For the statistics on the appealed and challenged in Court decisions, please, see the quality of the decisions as described in Section 4.1.

¹⁰² 72 % of survey respondents have a high level of trust in the scientific outputs of MSC; 26 % medium and 2 % cannot say

¹⁰³ 84 % of survey respondents consider that MSC's work positively influences their trust in ECHA; 5 % are negative; for 7 % it does not have an impact and 5 % cannot say.

¹⁰⁴ 60 % of the survey respondents consider MSC to be independent of political influence or conflicts to a large extent; 26 % to a moderate extent; 5 % to a small extent; 9 % cannot say

4.5. Sustainability

The work of MSC is considered to be relevant in the evolving policy context¹⁰⁵.

The workload of the MSC has decreased in the past years, as confirmed by the statistics on the decreasing number of cases brought to MSC. MSC could continue working and delivering with its current resources and capacity. Stakeholders note that overall, MSC is well equipped to take on new parts of their existing processes, such as classification of PBTs and endocrine-disrupting chemicals (EDCs). These stakeholders state that the continued operation of the MSC is critical regardless of policy context. One alternate member noted that they see the potential for MSC to play a role in the transition to the one substance, one assessment approach.

¹⁰⁵ 63 % of stakeholders find the work of the MSC to be relevant in the evolving policy context, in particular CSS to a large extent; 26 % to a moderate extent; and 12 % cannot say

Annexes

Annex 1a Evaluation questions

Table 1 Evaluation criterion and questions for RAC and SEAC.

Evaluation Criterion	Evaluation Questions and Sources
EFFECTIVENESS AND RELEVANCE	<ul style="list-style-type: none"> • To what extent have the objectives of RAC/SEAC been achieved? • Are the objectives of RAC/SEAC still relevant in line with the evolving policy context, in particular the CSS? • Do the Committees have the necessary competences to achieve their objectives? • To what extent have RAC&SEAC adapted their working procedures to optimally use their cumulative experience (for example in the development of opinions on applications for authorisation that are highly similar to previous applications)? • What (if any) obstacles do RAC/SEAC and their members encounter, which hampers the achievement of their objectives? • To what extent are the RAC&SEAC opinions questioned in the REACH Committee? To what extent do the final Commission Decisions deviate from the RAC&SEAC opinions? <p><i>(Sources: annual reports; overall competence map/competence grid per member, no. of opinions over the years, number of opinions returned from Commission, relevant audit findings, stakeholders' survey, targeted surveys, interviews)</i></p>
EFFICIENCY, PROPORTIONALITY	<ul style="list-style-type: none"> • To what extent is the remuneration of rapporteurs in RAC/SEAC proportionate to the efforts they are investing? • Have the rapporteurs' different scales of remuneration affected the ability of RAC/SEAC to deliver efficiently? To what extent is the remuneration adequate to attract the necessary expertise to the committees? • What is the existing capacity of RAC/SEAC for opinion /decision making? How has the membership developed? • Is there any spare capacity (are all seats occupied)? • To what extent have RAC/SEAC managed to achieve their specific objectives in an efficient way? How is their current work organisation helping them for delivering output efficiently?

- What (if any) obstacles do RAC/SEAC and their members encounter, which undermines the efficiency of their work?
(Sources: rapporteurs' timesheets, targeted surveys, interviews, historic remuneration analysis, MS resources, legislative hurdles- deadlines, MB latest paper on the functioning of the Committees; analysis of the different scales of remuneration in Europe, numbers of opinions adopted vs number of members p.a; trends over the years on the number of opinions produced; relevant audit findings; targeted survey, examples from the Secretariat – highlighting the changes between 2017 and 2018 and after the reorganisation; time spent per individual processes and trends over time; samples from the time in plenary meetings dedicated to authorisations/restriction/horizontal issues).

ADDED VALUE

- To what extent have ECHA and RAC/SEAC been effective in establishing a strong and trustful relationship with their stakeholders?
- To what extent are member states able to find the necessary expertise to staff the committees?
- What are the main impediments in the nomination of MSs?
(Sources: stakeholders' surveys, relevant audit findings, media report, 117.2 report, court cases, targeted surveys, interviews)

COHERENCE

- How coherent is the current way of working of RAC/SEAC with ECHA's long term strategy?
(Sources: audits on ECHA's strategy, 117.2 report, interviews)

SUSTAINABILITY

- How sustainable is the current way of working of RAC/SEAC?
(Sources: historic trends; paper on the future of the Committees as submitted to the Commission; targeted surveys, interviews, judgement based on the data under the rest of the criteria)

Table 2 Evaluation criterion and questions for MSC.

Evaluation Criterion	Evaluation Questions and Sources
EFFECTIVENESS AND RELEVANCE	<ul style="list-style-type: none"> • To what extent have the objectives of MSC been achieved? • Are the objectives of MSC still relevant in line with the evolving policy context, in particular the CSS?

- Do the Committees have the necessary competences to achieve their objectives?
- To what extent have MSC adapted their working procedures to optimally use their cumulative experience?
- What obstacles MSC and their members encounter, which hampers the achievement of their objectives?
- To what extent are the MSC opinions questioned in the REACH Committee?

(Sources: Management board reports; reduction in CCH and TPE going to MSC over the years due to agreed general approaches, IRS report, IAC data, stakeholders' audit, surveys, targeted surveys, interviews)

EFFICIENCY AND PROPORTIONALITY

- How efficiently the MSs support the work of MSC? Do they contribute 30% of their time as foreseen?
- What is the existing capacity of MSC for opinion /decision making? How has the membership developed?
- To what extent have MSC managed to achieve their specific objectives in an efficient way? /
- How is the MSC current work organisation helping them for delivering output efficiently?
- What (if any) obstacles do MSC and their members encounter, which undermines the efficiency of their work?

(Sources: MSs surveys, MB papers, legislative hurdles, MSs commitment, downwards trends over the years on the number of opinions produced, save the required ones by legislation, examples from the Secretariat, time spent per individual processes and trends over time, targeted surveys, interviews)

ADDED VALUE

- To what extent has ECHA and MSC been effective in establishing a strong and trustful relationship with their stakeholders?

(Sources: stakeholders' surveys, IAC reports, media report, 117.2, targeted surveys, interviews)

COHERENCE

- How coherent is the current way of working of MSC with ECHA's long term strategy?

(Sources: audits on ECHA's strategy, 117.2 report, interviews)

SUSTAINABILITY

- How sustainable is the current way of working of MSC?

(Sources: historic trends; paper on the future of the Committees as submitted to the Commission, judgement based

*on the data under the rest of the criteria, targeted surveys,
interviews)*

Annex 1 WSP report

WSP survey and interviews report which was used as input to the evaluation.

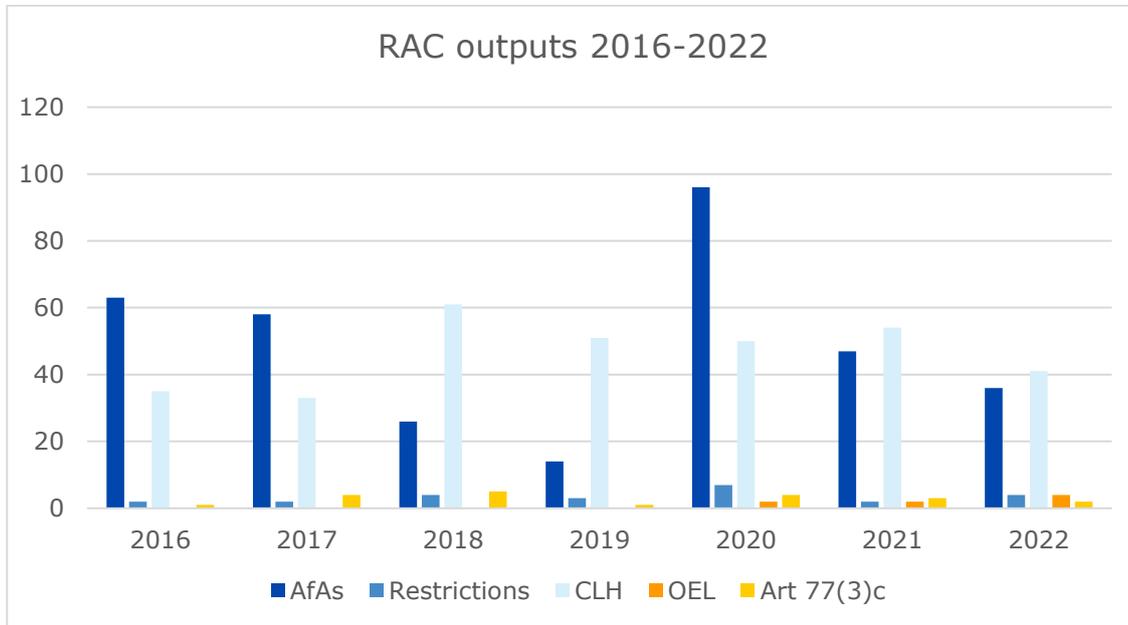
Annex 1c Acronyms list

AfA	Application for Authorisation
CLH	harmonised classification and labelling
CLP	Classification, Labelling and Packaging Regulation
CMRD	Carcinogens, Mutagens or Reprotoxic substances Directive
CSS	chemicals strategy for sustainability
DEV	dossier evaluation
DWD	Drinking Water Directive
ECHA	European Chemicals Agency
ED	endocrine disruptor
EDC	endocrine disrupting chemical
EU	European Union
MS	Member State
MSC	Member State Committee
MSCA	Member State competent authority
NGO	non-governmental organisation
OEL	occupational exposure limit
PBT	persistent, bioaccumulative and toxic
PfAs	proposals for amendments
RAC	Committee for Risk Assessment
REACH	(Regulation on) Registration, Evaluation, Authorisation and Restriction of Chemicals
RESTR	Restriction
SEAC	Committee for Socio-economic Analysis
SEV	substance evaluation
SVHC	substance of very high concern
TA	trade association

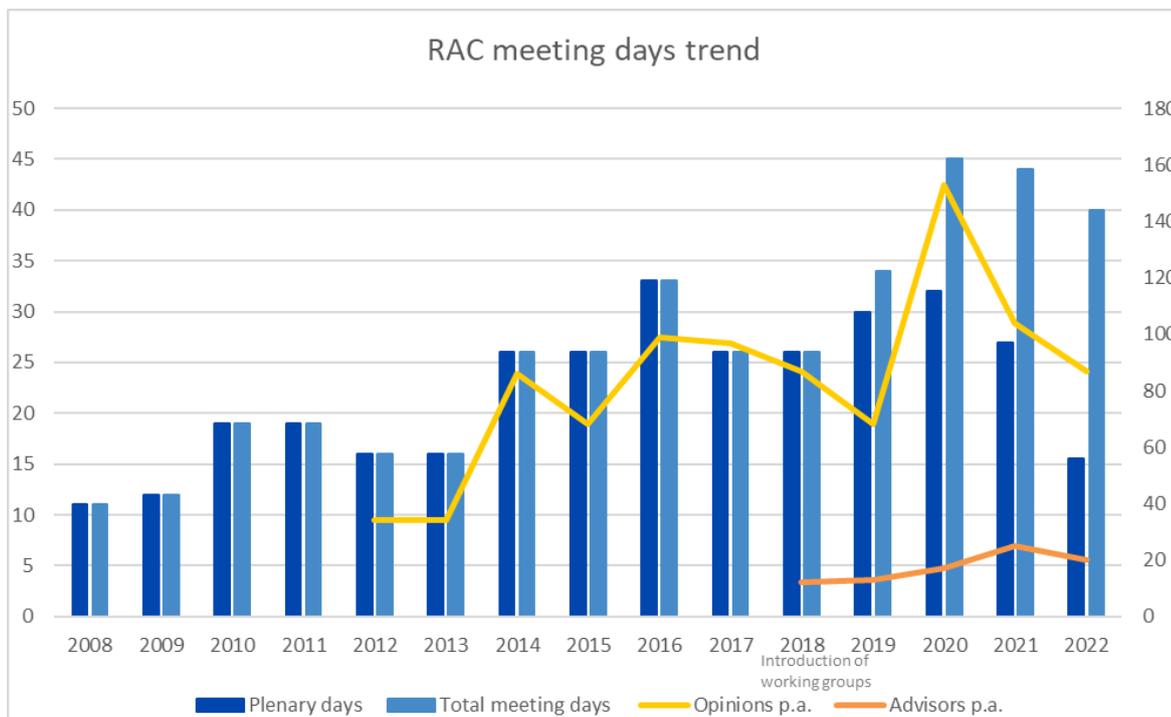
Annex 2 RAC

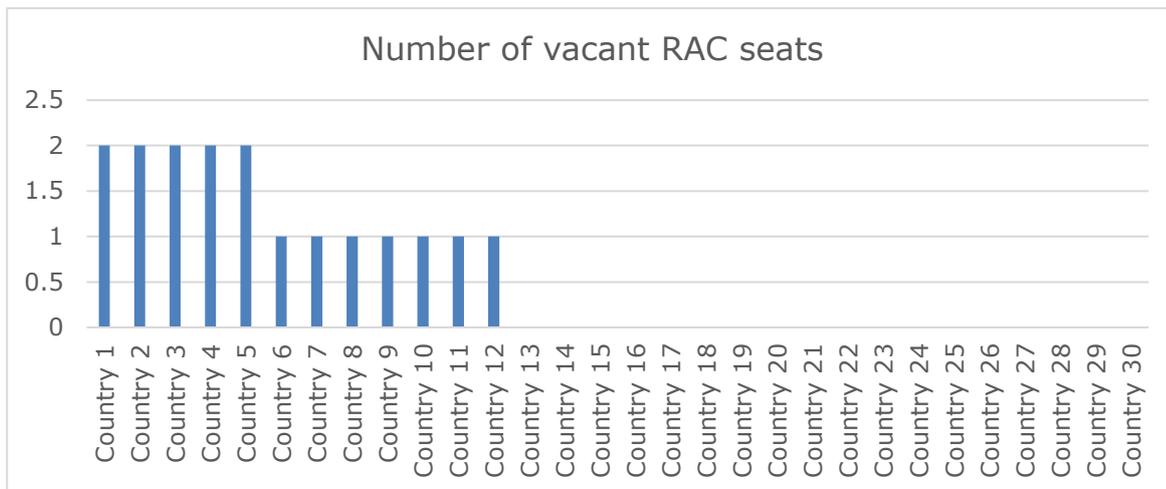
2.1. Statistics on Effectiveness

Number of RAC outputs 2016-2022

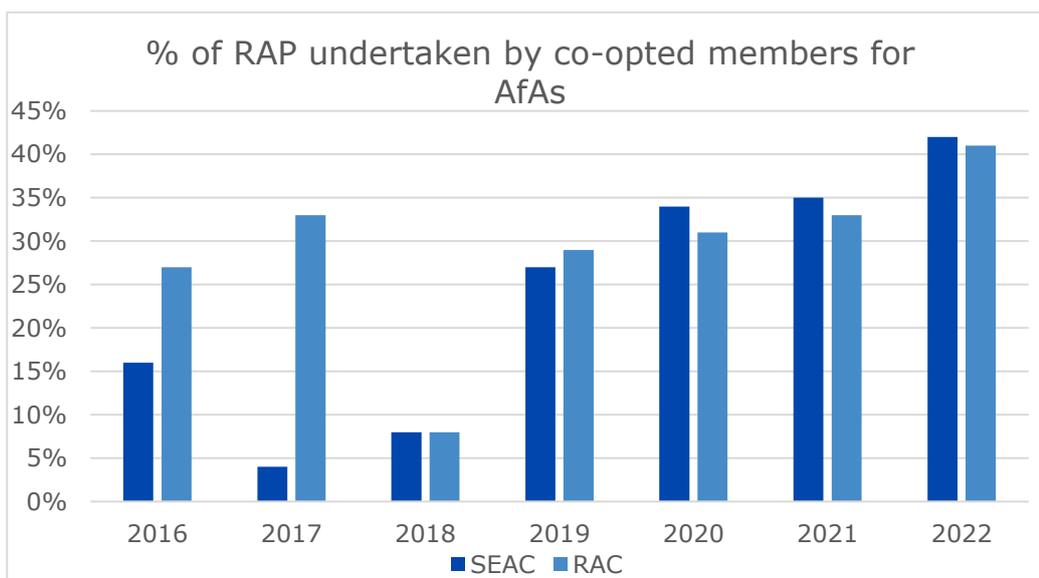


2.2. Statistics on Efficiency, economy, proportionality



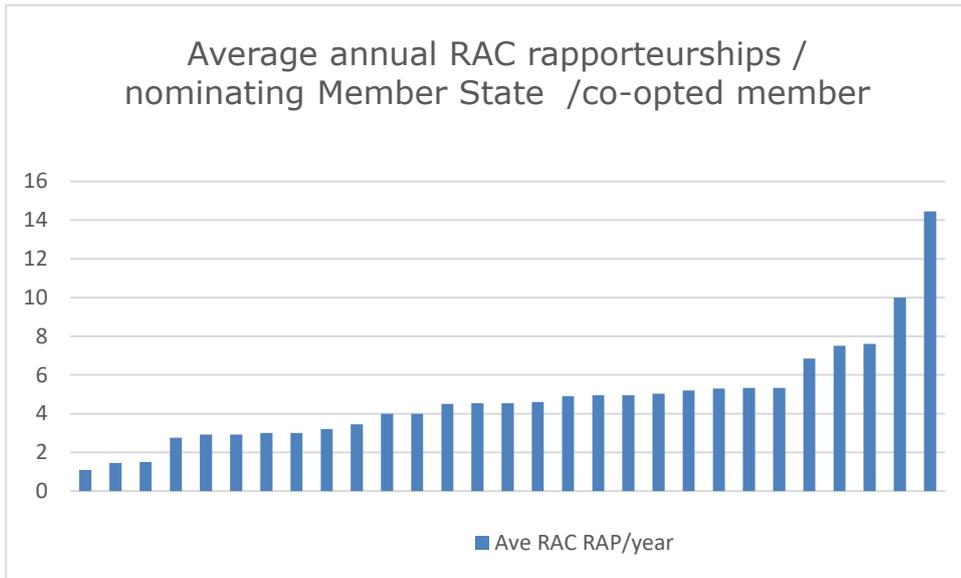


The proportion of rapporteurships undertaken by co-opted members of RAC & SEAC for AfAs:

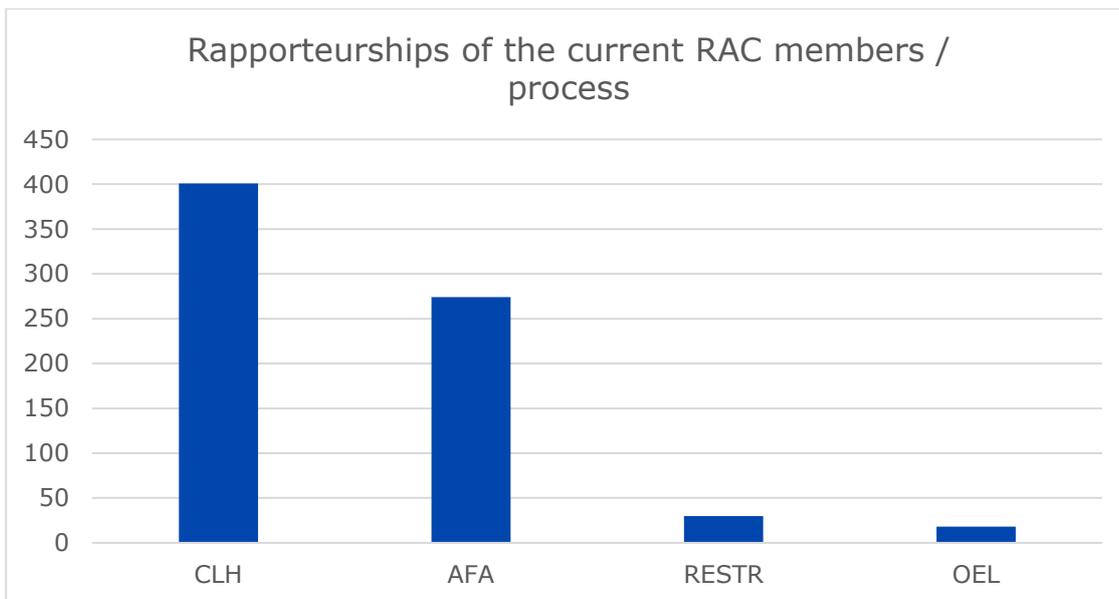


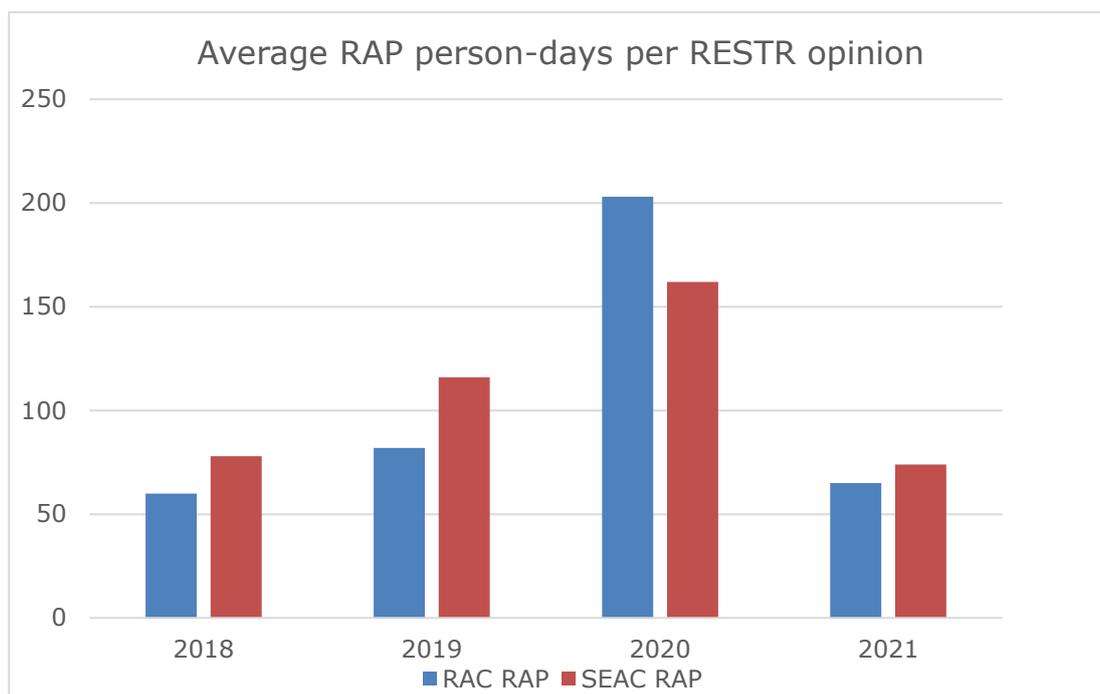
Average annual number of rapporteurships per member in RAC

The following chart show on how many rapporteurships each current RAC member (including a few whose membership just ceased) has had from the beginning of the appointment. Calculation for years started from 2011 to remove the early preparative years from the statistics. Evaluators acknowledge that the work needed for different process types (Restriction, Afa, CLH and OEL) is not the same. In addition, each member has different scientific competencies, and their expertise may be used in other tasks than rapporteurships. Still this analysis provides indicative information on the workload for each member.



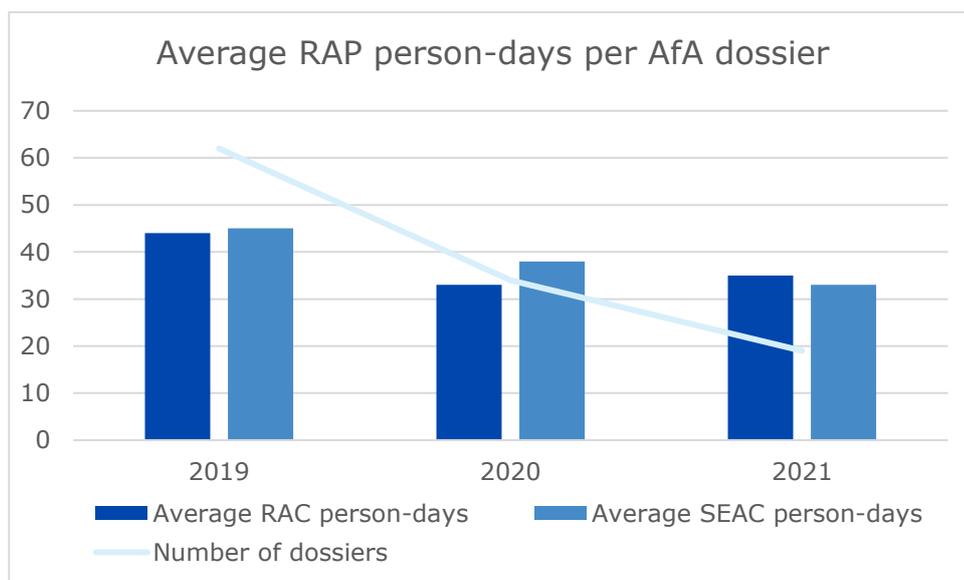
2.3. Statistics on Remuneration





RAC and SEAC rapporteur person-days for restrictions (source RAC and SEAC secretariats):

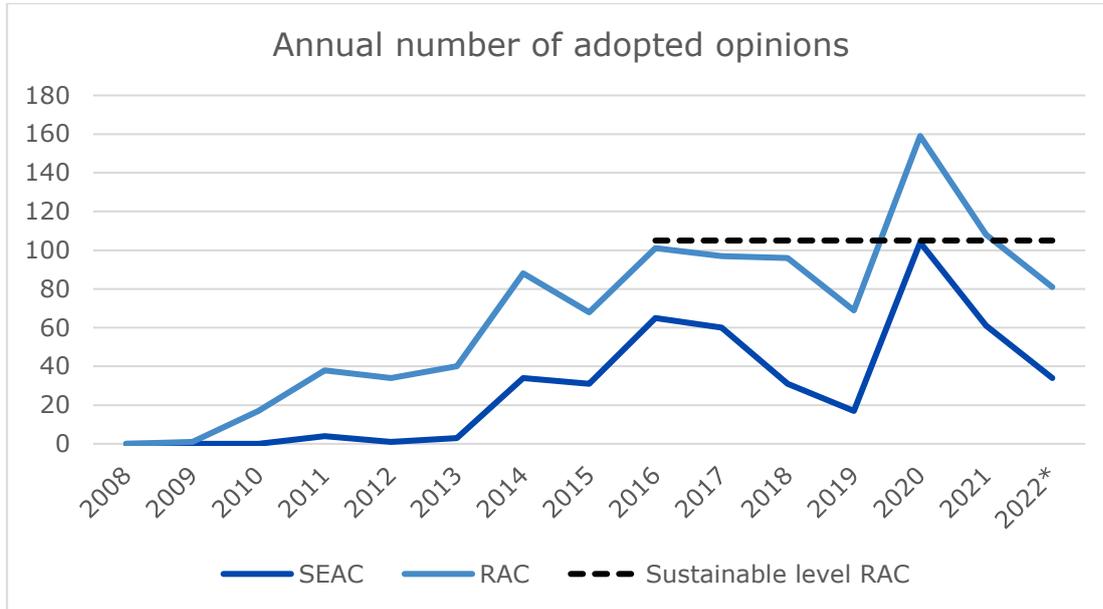
	RAC Rapporteurs (days)	SEAC Rapporteurs (days)
Rubber granulates	47	62
Cobalt salts	68	122
DMF	64	49
D4, D5, D6	60	91
Microplastics	58	148
Skin sensitisers	50	85
Formaldehyde	170	77
PFHxS	102	107
Calcium cyanamide	50	185
Single-use diapers	129	83
PFHxA	277	241
AVERAGE	98	114



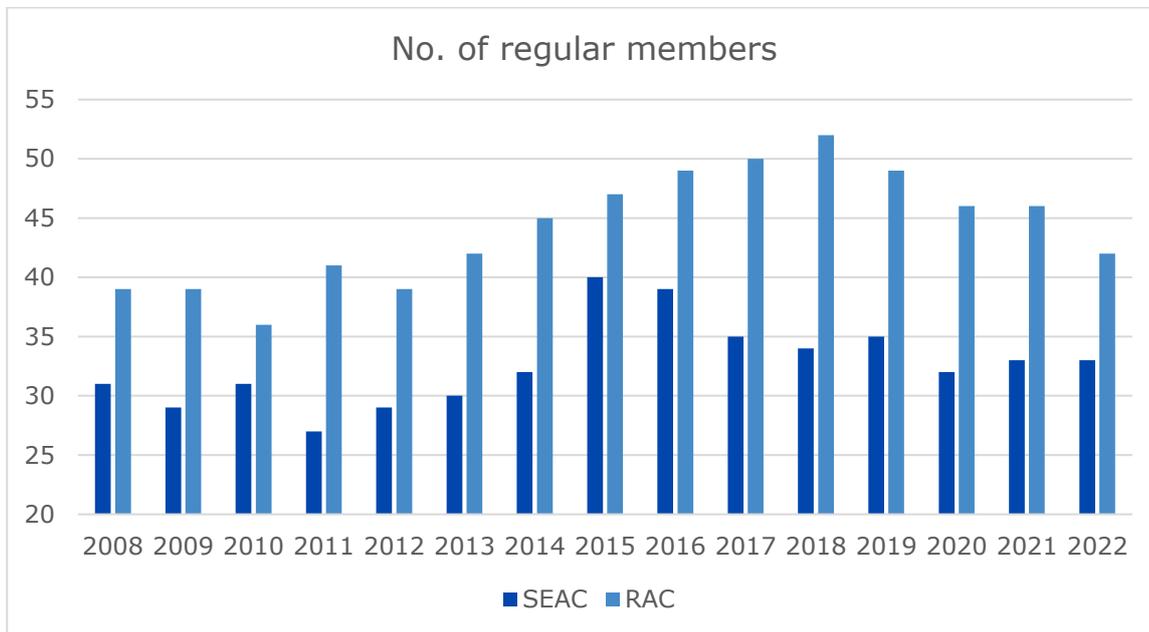
For AfAs (note that this is per AfA case, rather than per AfA opinion – a case may include several uses, and an opinion is produced per use). The data is available to do an aggregation per substance, if required (this analysis has, however, not been done yet). (Source RAC and SEAC secretariats)

Application type	RAC rapporteurs (days)	SEAC rapporteurs (days)
Simple (1 use, 1 applicant)	14	14
Normal (1 ½ uses, some applicants)	26	26
Complicated (2 uses, many applicants)	39	37
Average	26	26

2.4. Statistics on capacity

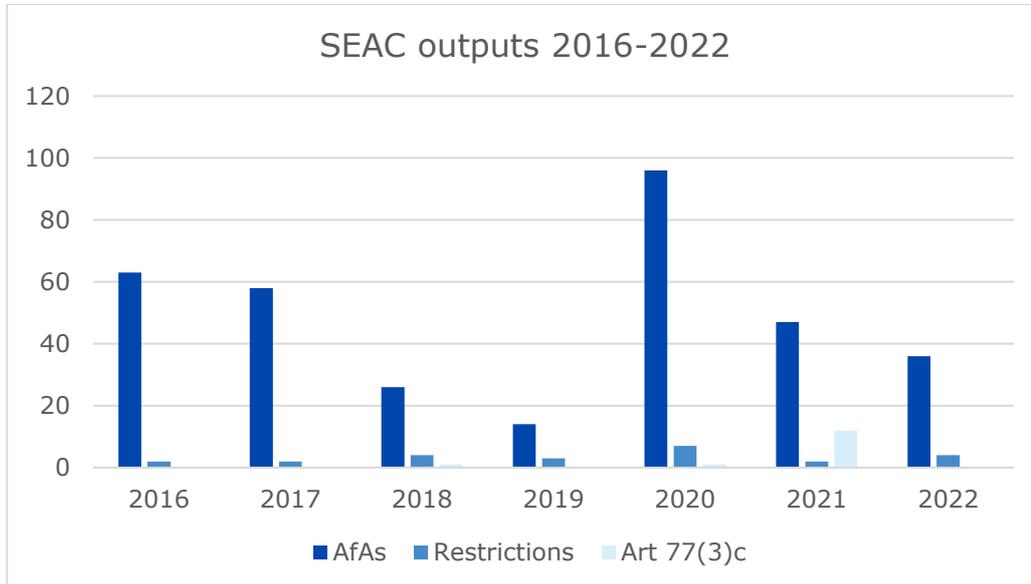


Evolution of number of RAC and SEAC regular members 2008-2022:

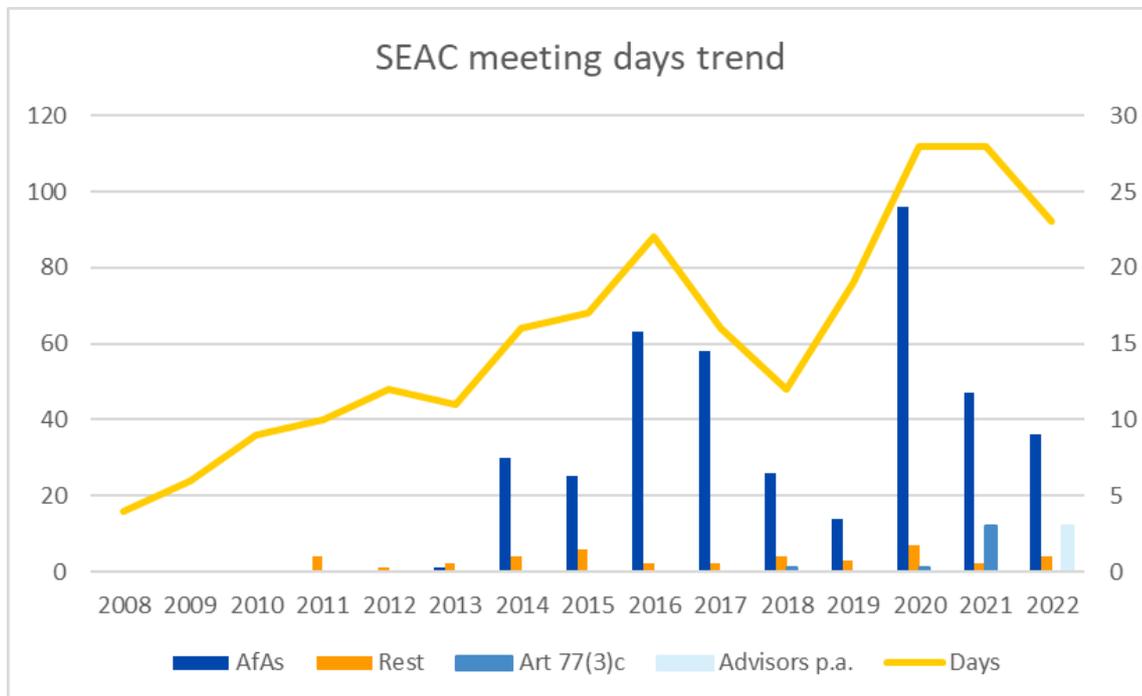


Annex 3 SEAC

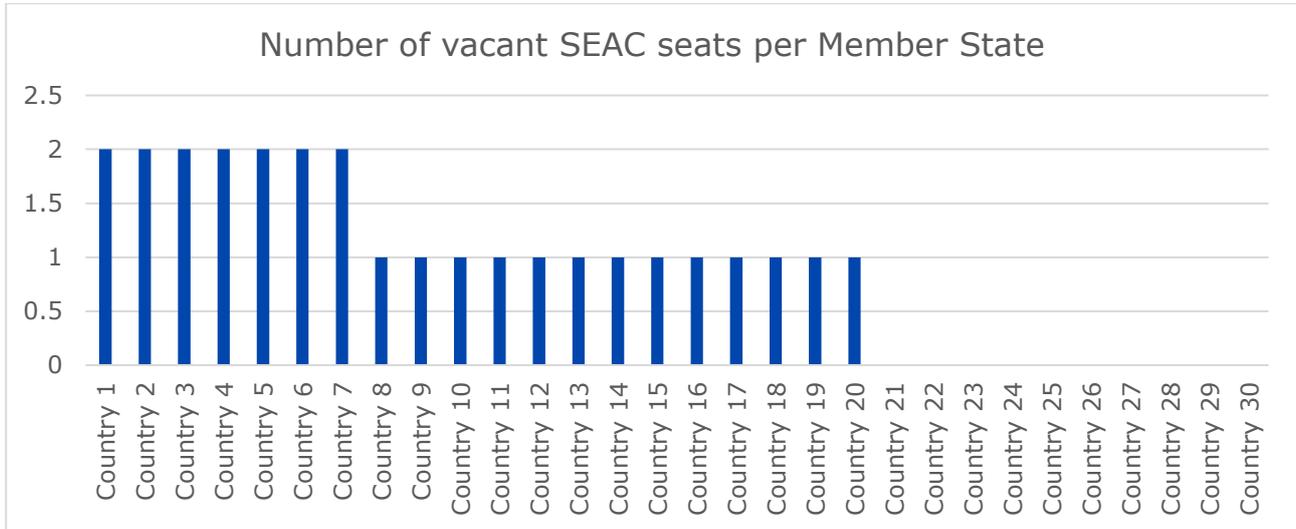
3.1. Statistics on Effectiveness



3.2. Statistics on Efficiency, economy, proportionality

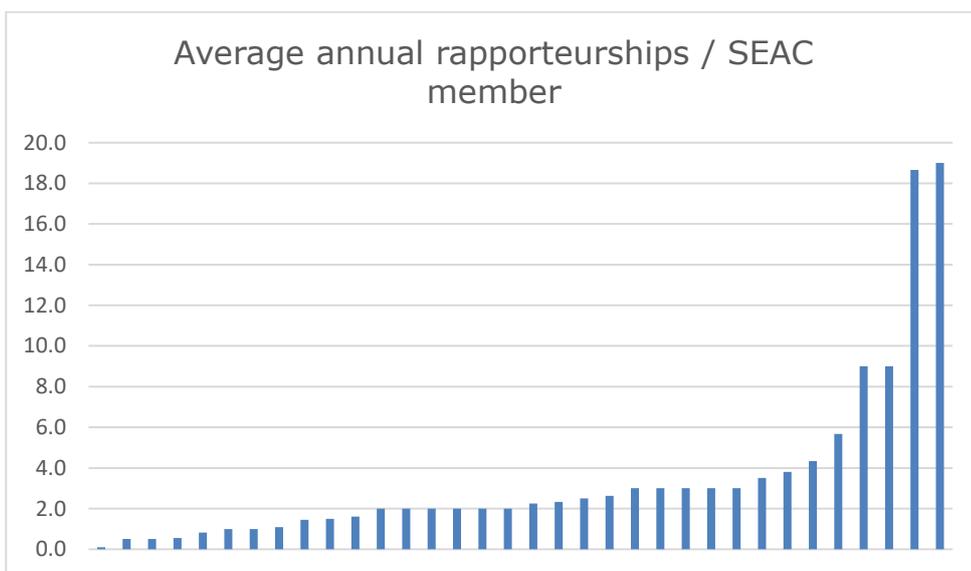


3.3. Statistics on Capacity

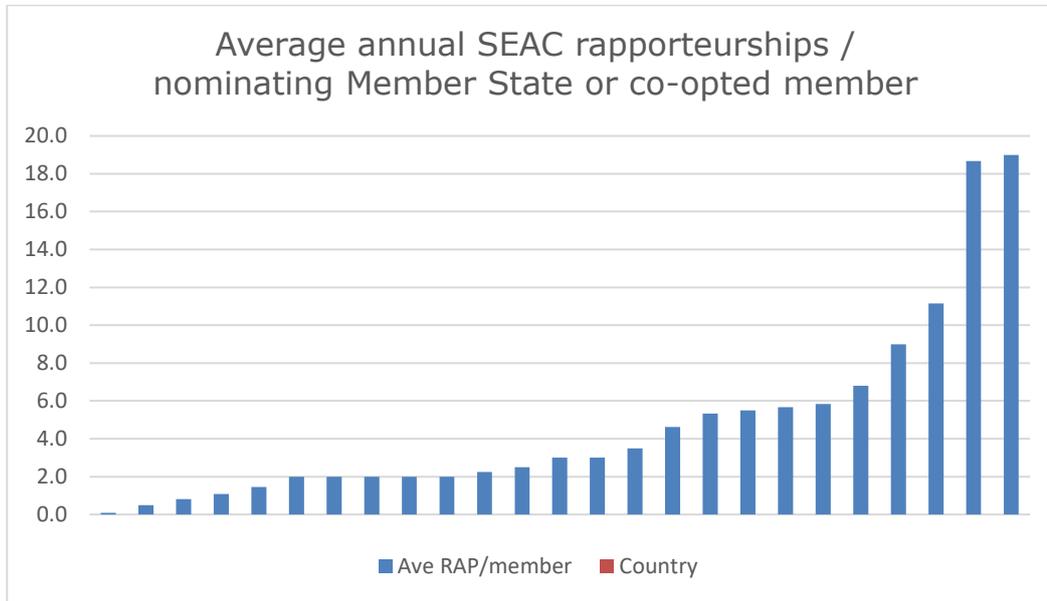


Average annual number of rapporteurships per member in SEAC:

Following chart shows on how many rapporteurships each current SEAC member (including a few whose membership just ceased) has had from the beginning of the appointment. Calculation for years started from 2011 to remove the early preparative years from the statistics. Evaluators acknowledge that the work needed for different process types (Restriction, AfA) is not the same. In addition, each member has different scientific competencies, and their expertise may be used in other tasks than rapporteurships. Still this analysis provides indicative information on the workload for each member.

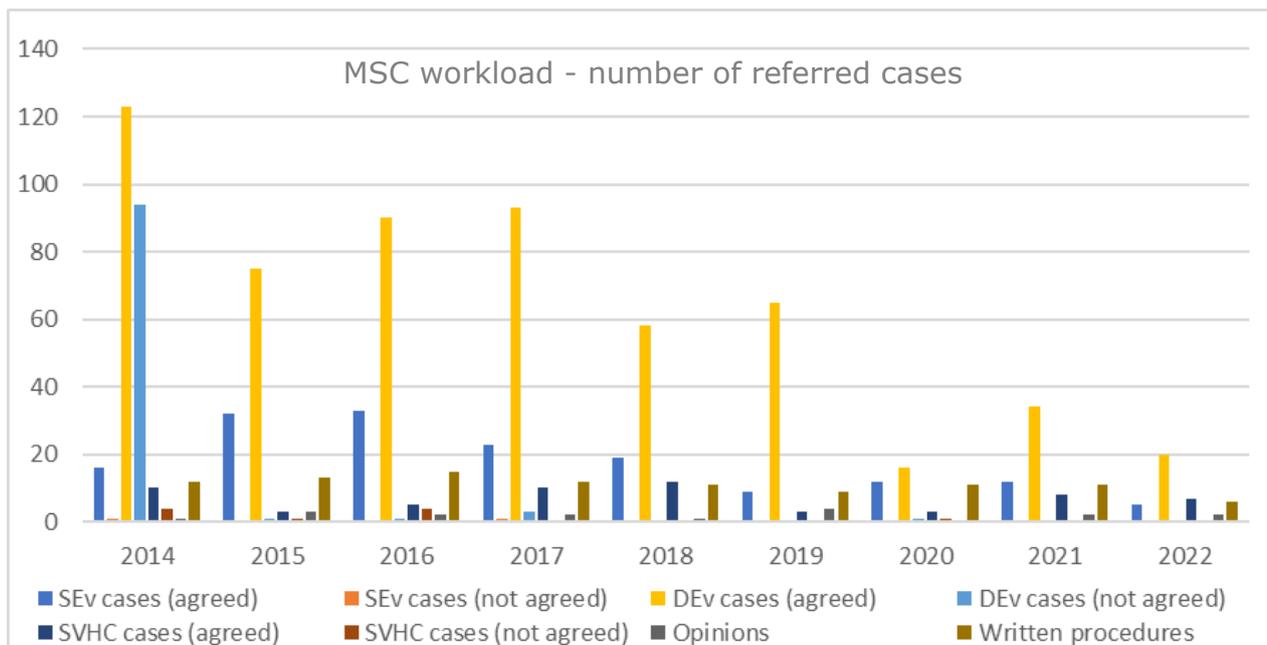


Average 4.8 rapporteurships per year per nominating Member State or co-opted member. Nine Member states or co-opted members above the average, 16 below the average. Two highest are co-opted members.

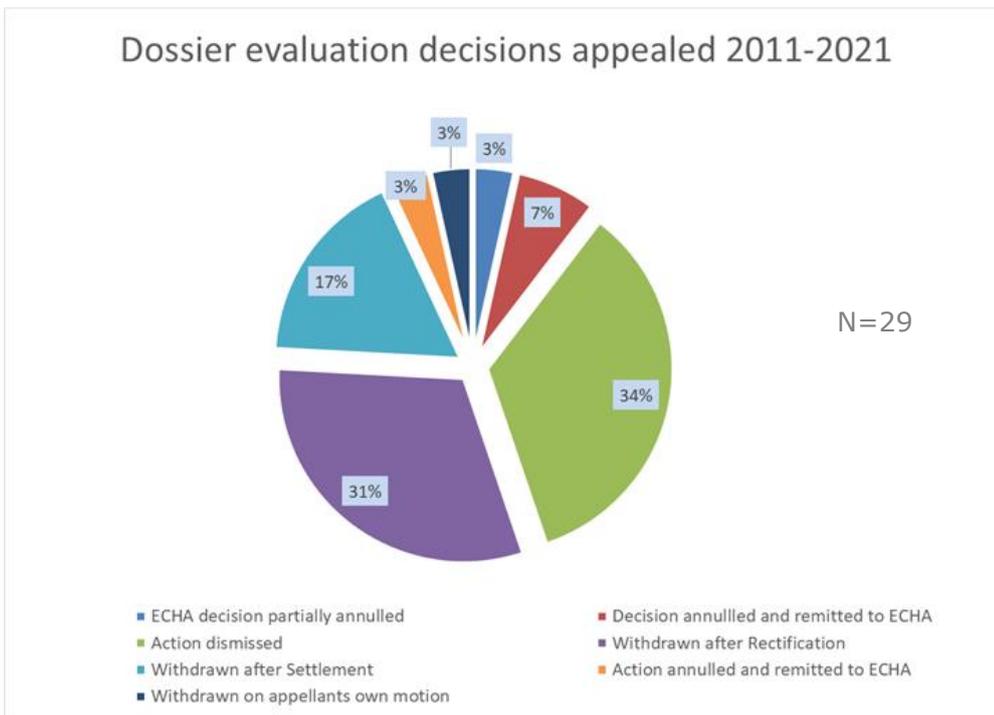
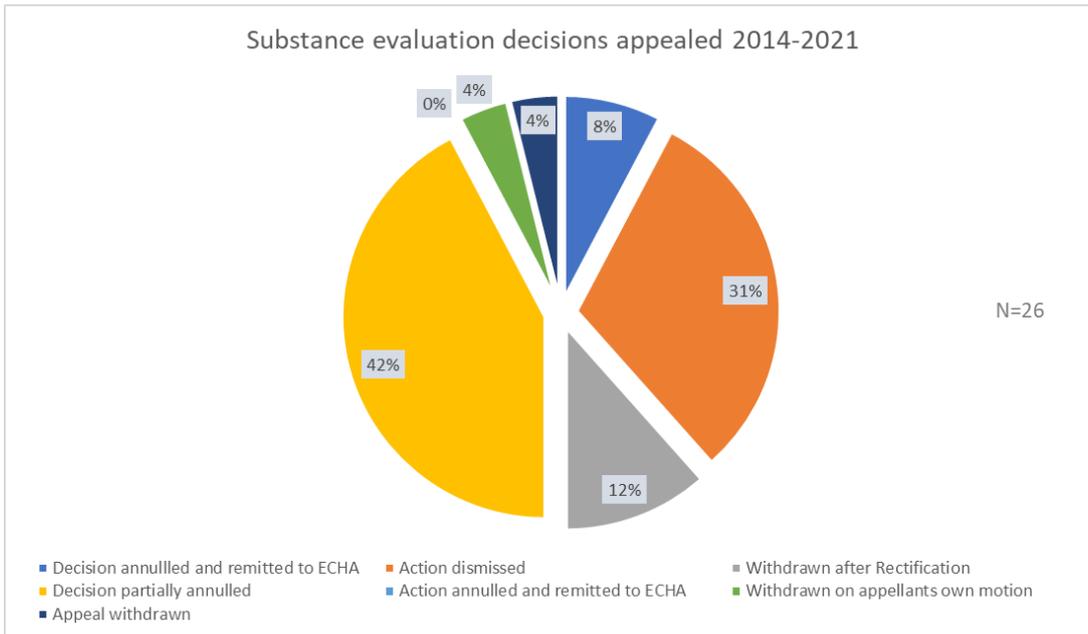


Annex 4 MSC

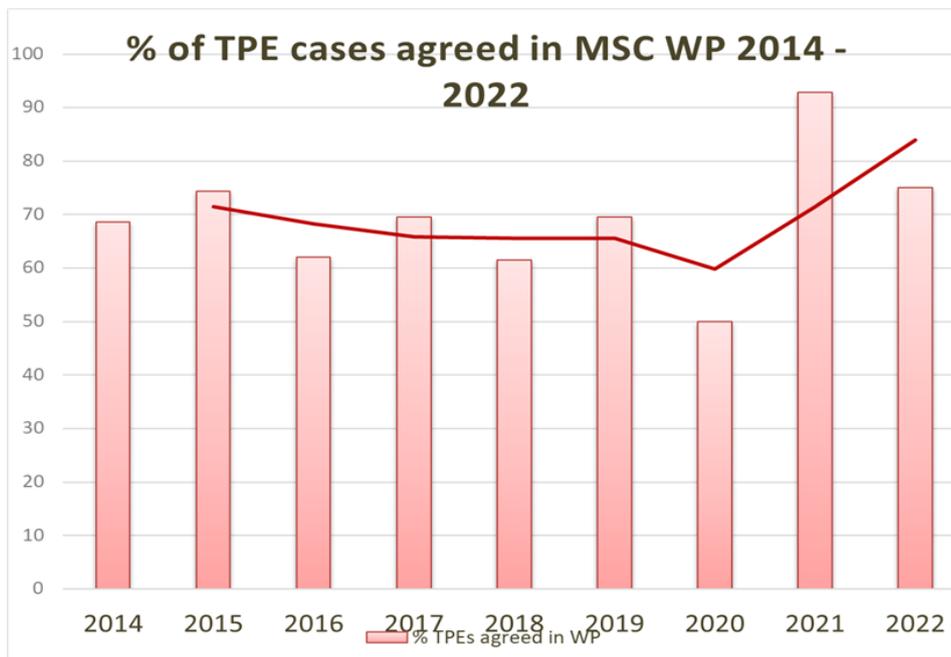
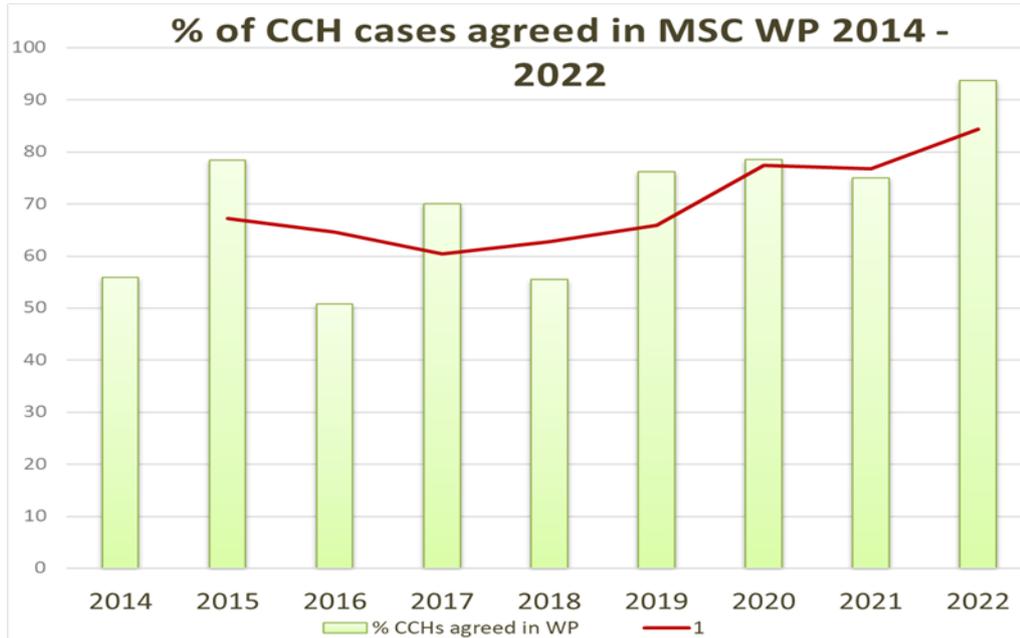
4.1. Statistics on Effectiveness

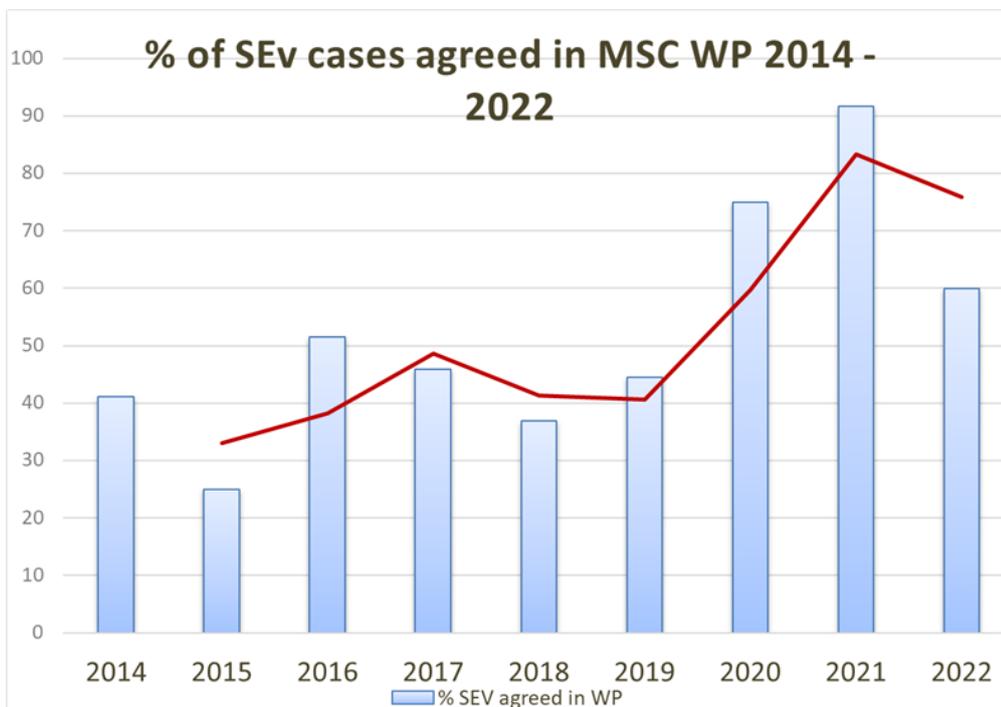
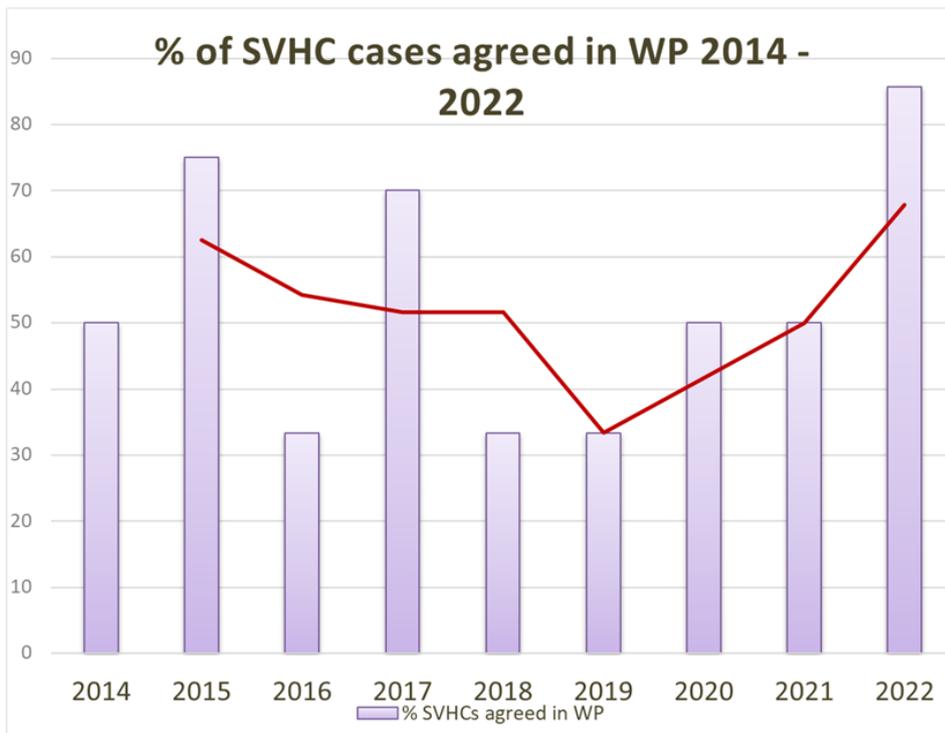


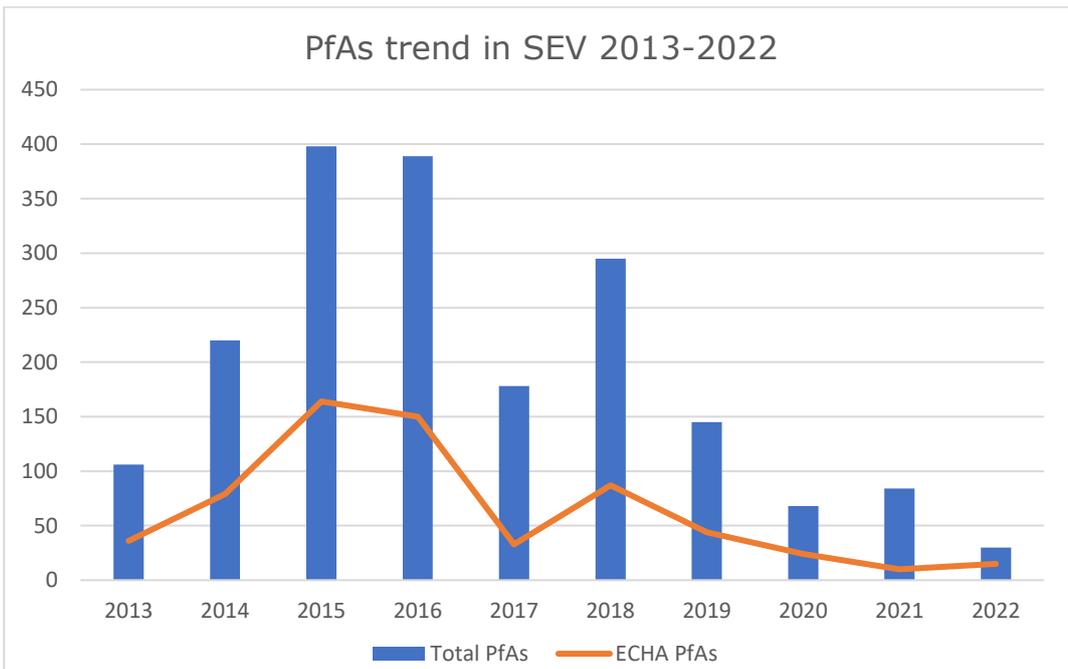
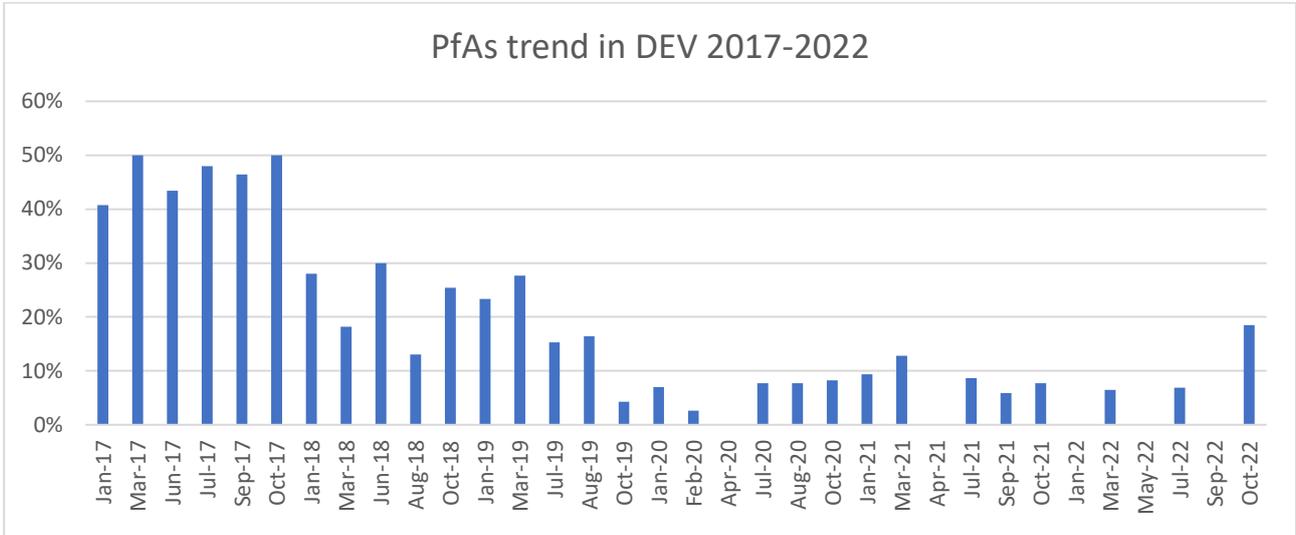
Note: The cases not agreed have been referred to the Commission.

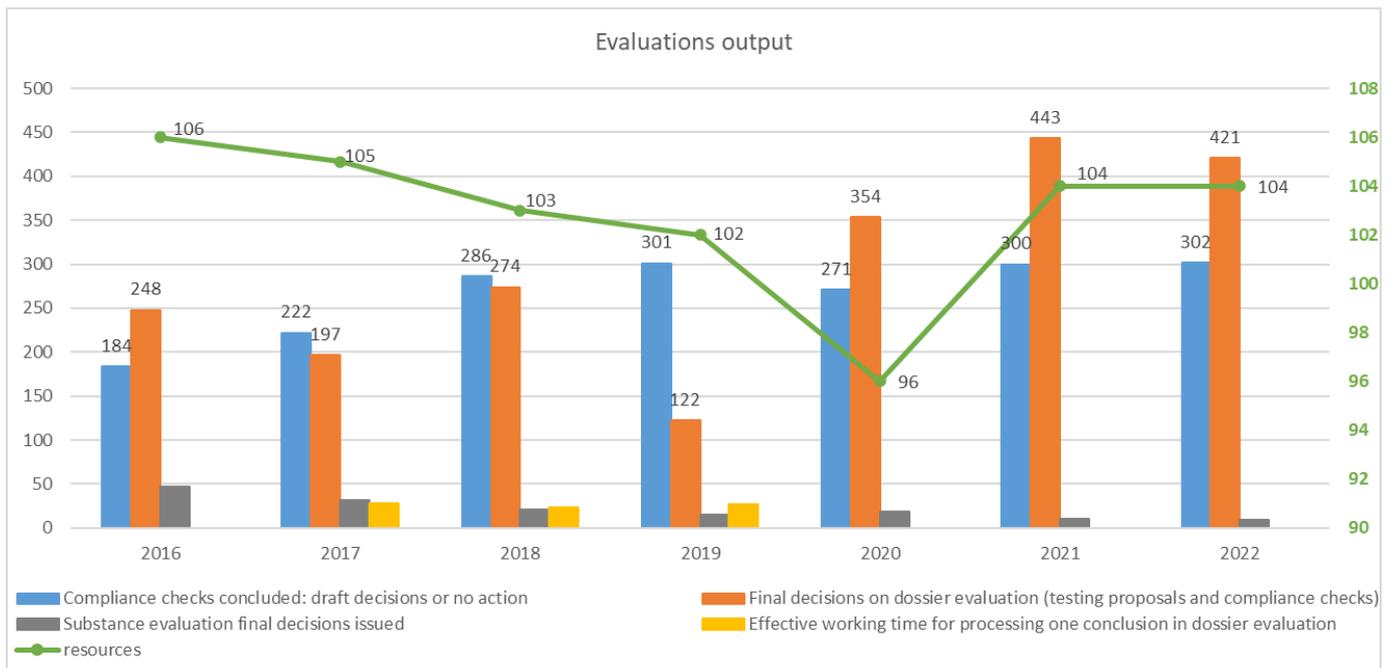
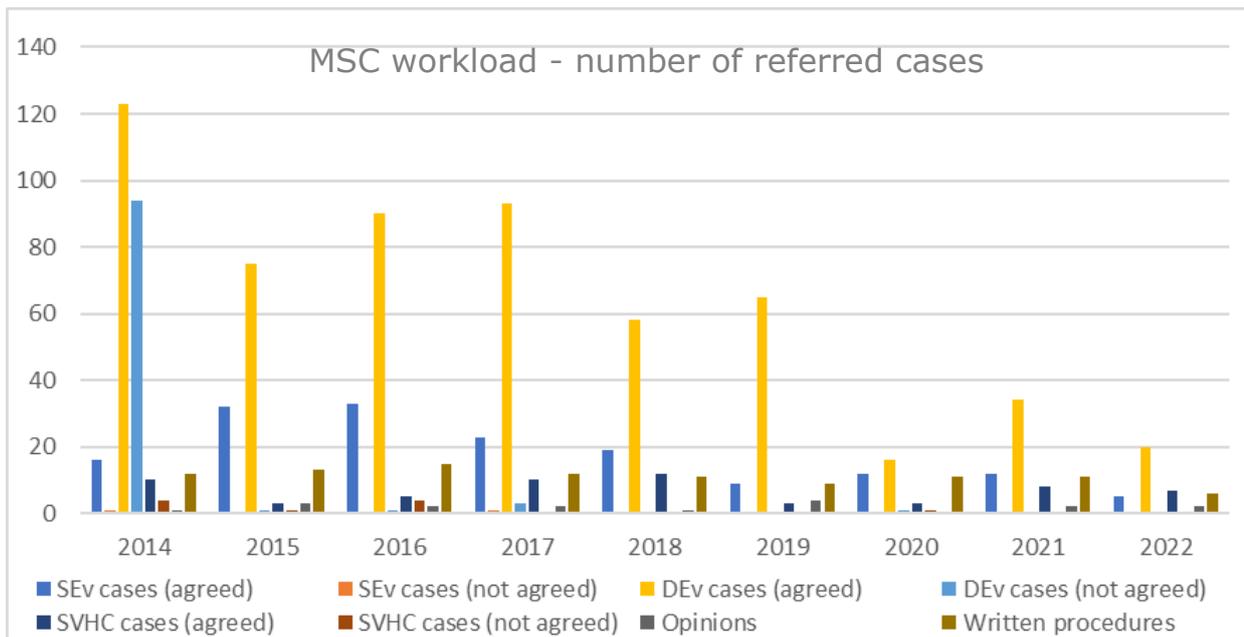


4.2. Statistics on Efficiency, economy, proportionality









4.3. Statistics on Capacity

