

Annual reports from the Committees

49th Meeting of the Management Board 22-23 March 2018

Key messages

- The Management Board is invited to consider the proposed qualifications and process improvements to be applied to the (re-)nominations of RAC and SEAC members.
- The Management Board is invited to take note of this document on the specifics and functioning of MSC and BPC. Management Board members are specifically invited to further consider MSC's workload drivers and the recommended minimum work time allocation of 30% for MSC members.

Background

RAC and SEAC

The functioning of RAC and SEAC was last reported to the Management Board in September 2013; matters for consideration were the capacity of both Committees and how the pool of active members and rapporteurs could be increased by ensuring adequate support from Member State competent authorities. At the December 2014 Management Board meeting the workload of RAC and SEAC was discussed, focussing on means to increase membership and further mobilise members and rapporteurs to address the rapidly increasing workload due to the peak of authorisation applications throughout 2015 and 2016. In December 2017 the issue of considering the activity level of the members in the context of re-appointment was raised.

Since the discussions in 2014 several measures have been taken to increase the capacity of the regular Committee members (i.e. those nominated by Member States) together with re-nominations for RAC and SEAC and co-option of members:

- Actions to increase the pool of active members;
- Nomination of members with stronger national support – commitment of 50% of each member's work time;
- Recruitment and appointment of co-opted members;
- Streamlining and sharpening the expectation for drafting Committee opinions.

This document focusses on the functioning of the members in RAC and SEAC, their rapporteurships, activity level and their expertise profile. The reason for bringing this forward is to raise awareness of changes in the specific expertise needed in the two Committees and to gain a better match between nominated expertise and the Committee's needs via specified criteria for selecting new members. In addition, a need for active dialogue between the nominating MSCAs and the ECHA Secretariat in the recruitment of new members and in the evaluation process of possible renewal of members is identified. A minimum engagement level of members is also envisaged.

MSC and BPC

Reporting on the functioning of MSC and BPC to the Management Board has mainly taken place in the context of the quarterly reports or agenda points related to the specific regulatory work. Both for MSC and BPC the focus of the document is the overall workload and the capacity to manage it.

During summer 2017 a round of telephone interviews with MSC members took place to review the MSC-related part of the evaluation and risk management processes. Subsequently, MSC discussed priority actions regarding the three most time consuming processes (i.e. dossier evaluation, substance evaluation and SVHC identification, consuming 85% of MSC's plenary meeting time in 2017). Awareness raising about MSC work in the member's home organisations was called for, among other actions.

PART 1: RAC and SEAC

Rationale

Number of members

As a response by MSCAs to support the increasing workload of the Committee Members, as requested by ECHA through the MB, the number of regular members rose steadily **in RAC from 42 in December 2013 to 50 in December 2017**. Over the same period membership has increased proportionately **in SEAC from 32 to 37**. Resignations averaged 7% and nominations 12% over the five years in RAC.

Overview of the functioning of the members of RAC and SEAC in 2013-2017

Table 1 gives the number of finalised rapporteurships per process/per RAC/SEAC member in 2013-2017. Note that the numbers are not the same as the number of opinions agreed, as many opinions require two rapporteurs with different expertise, e.g. toxicology and environment, or socio-economics and alternatives in RAC and SEAC, respectively.

Table 1. SEAC and RAC members' rapporteurships¹ during 2013-2017. Including co-opted members from December 2015.

Process	Restrictions		Applications for Authorisation		Harmonised Classification & Labelling RAC	Article 77(3)(c) COM requests	Article 95 COM requests
	RAC	SEAC	RAC	SEAC	RAC	RAC	RAC
<i>Committee</i>							
2013	4	5	2	1	35	4	
2014	3	5	41	39	66	2	
2015	9	7	38	36	59		
2016	2	3	113	107	57		
2017	8	6	105	104	52	8	8
Total	26	25	299	287	269	14	8

Based on number of RAC and SEAC rapporteurships completed, an average of 27.5% of RAC-SEAC members showed a high level of activity. A larger group of 36% cleared a moderate number of dossiers each. The number of dossiers completed by a further 20.5% was low, out of which 6 for RAC and 2 for SEAC where without any rapporteurships. A total of 16% are recent nominations (2017) in RAC and SEAC with no track record as yet.

Thus, for both Committees, excluding new members, roughly one third show a high level of activity and commitment, one third a moderate and one third a low level of activity.

These numbers do not provide a full picture, as dossier size and effort varies greatly from a few weeks to very exceptionally, more than a year. Generally, the support needed and the input from the Secretariat is already high, especially with complex cases or less experienced rapporteurs, and can currently not be increased.

¹ Figures in Table 1 refer to number of rapporteurships and co-rapporteurships of current membership of RAC and SEAC. An additional 16 members in RAC and 15 members in SEAC members that left the Committees during 2013-2017 had rapporteurships or co-rapporteurships.

It is important to note that some members are supported by advisors who contribute greatly to their work, thus in particular the mid and high activity group contains members who in practice provide much more than 50% of their time to ECHA.

Steps have been taken to encourage new members to engage with the work of the Committees more quickly, e.g. pairing with experienced rapporteurs.

Expected workload in 2018-2020

Assessing the workload on the basis of numbers of opinions has limitations, as dossiers can vary considerably in scale. One dossier such as the harmonised classification and labelling of Glyphosate in 2017 would exceed 10 or more normal harmonised classification and labelling dossiers. Also, a restriction dossier takes normally three times more work than an authorisation application.

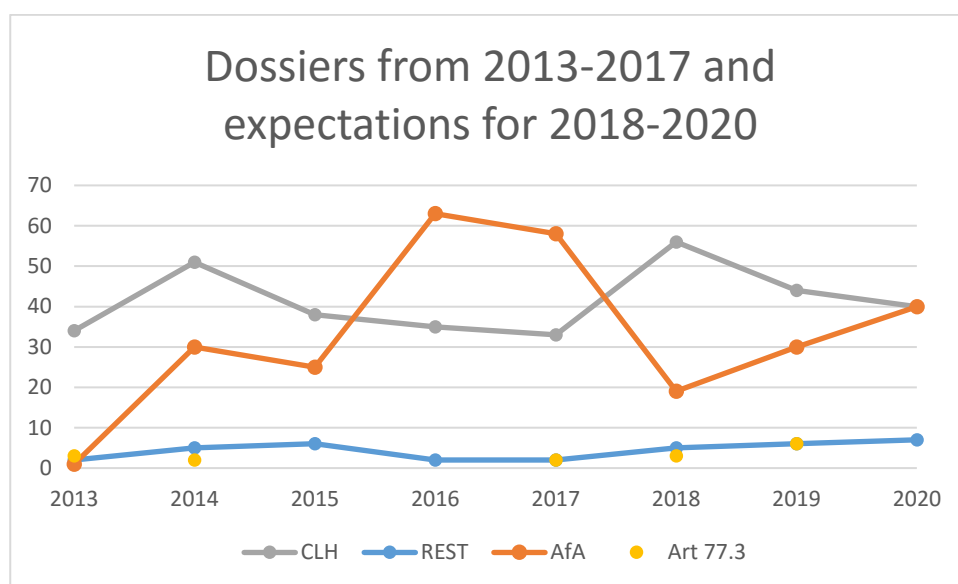


Figure 1. Trends in numbers of finalised dossiers from 2013-2017 and the tentative numbers for 2018-2020².

In short, RAC will be expected to adopt at least 75 to 85 opinions per year for the foreseeable future; SEAC's workload will be similarly determined by the upward trend in authorisations for 2018 to 2020. If RAC is more systematically assigned the task on opinion-forming on related to occupational exposure limits (OEL), this will increase the workload respectively (best current estimate around 10 opinions annually).

While this document focuses on the expertise and capacity of the membership, the Committees together with the Secretariat continue also to improve the effectiveness and efficiency of the processes, including optimising the time spent for discussions in the plenaries vs. outside of them. A successful example is the fast track process of CLH dossiers.

² Number of CLH dossiers may not decrease, and may even increase if all PPP's go through the CLH and MS's take up all relevant dossiers following new information generated via evaluation.

Required expertise

For RAC there is a need to partly strengthen the current expertise, and partly, to extend to new areas:

- There is a continued need for toxicologists to service the human health risk assessment needs of all processes - this is wider than just a background in classification and labelling.
- A small group of environmental specialists are needed for classification and labelling, Restrictions and Authorisations (indirect exposure - man via the environment).
- Expertise in occupational hygiene, workplace exposure and chemical risk management measures is needed for evaluating Authorisation dossiers.
- For any future OEL work, experts in cancer risk assessment, occupational medicine, and epidemiology are needed.

In the case of SEAC, general regulatory experience is well represented but the Secretariat proposes to boost the expertise of the Committee in the field of:

- Economics, in particular welfare, public sector, environmental or health economics.
- Methodologies analysing costs and benefits of regulation, including the analysis of technical feasibility of alternatives and their costs.
- Knowledge about substitution of substances of concern, such as SVHCs.

As previously reported to the Management Board, the specific expertise provided by the co-opted members is needed going forward for new Annex XIV substances, restriction dossiers, and (for RAC) the OEL work.

Matters for consideration

For both Committees:

- The activity level of some members is still too low and although there are more members, there is a mismatch with the required expertise which needs to be addressed.
- The core group of about one third of the regular members has the best expertise, absorbs most of the work, and are the most active in consultations and plenary discussions.
- Only a few MSCA's has actively contacted the Chairmen for consultation before nominating or re-nominating members.

The Secretariat therefore proposes the following as measures to increase the efficiency of recruiting members to RAC and SEAC:

- It would be highly desirable to improve the recruitment process for members so that all appointed members will actively contribute to the Committee processes via rapporteurships, commenting on draft opinions, and via contributions in the meetings.
- It could be considered that there should be prior consultation between nominating MSCA and ECHA (Committee Chairmen) before a nomination or re-nomination is submitted. This would require the process to start earlier.
- Furthermore, more MSCA's should broaden the recruitment outside their own organisation(s) to make use of the best available expertise.
- Finally, the Secretariat will launch a selection of co-opted members via a call for expression of interest and in parallel to renew productive co-opted members.

Proposed qualifications:

Apart from the formal eligibility criteria the nominees need to

- Be qualified in a branch of regulatory science of value to the current and future work of the Committees.
- Have very good command of written and oral English.
- Be available for at least 50% of their work time for Committee work.

Nomination process

- Discuss mutual needs and candidates with the Committee Chairman before nomination.
- Discuss performance of existing members with the Committee Chairman before re-nomination.

Duties attached to membership

- Take on an appropriate number of rapporteurships every year.
- Routinely comment on draft opinions during written consultations.
- Participate actively during meetings.
- Inactive second members should not be re-appointed³

PART 2: MSC and BPC

Rationale

MSC

MSC is involved in five REACH processes i.e. agreement seeking on dossier evaluation (DEv) and substance evaluation (SEv) draft decisions, SVHC identification, and giving opinions on the annual draft CoRAP and on the draft recommendation of ECHA on inclusion of substances into authorisation list (RECOM). The two opinions require the appointment of a rapporteur, generally supported by a working group.

Each Member State is required to appoint a MSC member, and alternate members may be appointed. The (alternate) member can be accompanied by an expert or advisor(s) during the plenary, or provide inputs by following the MSC deliberations through WebEx. So far, the Secretariat has not observed a lack of the required expertise to enable an adequate discussion on the topics addressed by MSC.

The number of meetings in 2017 was six plenaries with a total of 21 meeting days in 2017. MSC spend 85% of its plenary time on dossier evaluation, substance evaluation and SVHC identification.

MSC PLENARY MEETINGS IN 2017

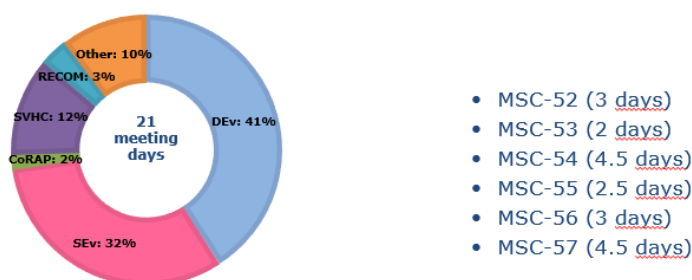


Figure 2. Number of MSC plenary meeting days in 2017, number of days per meeting and the fraction of time spend for each of the different processes⁴.

³ According to Article 85 of REACH the MB shall appoint at least one member but not more than two members of each Member State that has nominated candidates.

⁴ Abbreviations: DEv – Dossier evaluation; CoRAP – MSC opinion on the ECHA draft Community Rolling

In addition to the plenary meeting time and its preparations, members cast their votes in written procedures used to reach agreement more efficiently for more 'easy' cases (e.g. where the proposals for amendment result in editorial suggestions or alignments of the draft decision with previous agreements by MSC). In 2017, 70% of DEv cases and almost 50% of SEv cases were concluded by MSC using written procedures. This is done in order to use the plenary time for the more complex cases. Written procedures may still take up a significant portion of a member's time due to the increasing number of cases handled this way, while they still need to review draft decisions and agreements, their support documents as well as the response to comments documents and solicited their organisations views on them. Although no formal quantitative assessment, limited inputs indicate that MSC membership could require at least 30% working time to perform the MSC tasks, possibly supplemented by significant additional time for experts and advisor(s).

While the MSC is conducting its business based on scientific and technical arguments MSC members operate within a mandate provided by their organisations, in contrast to the RAC and SEAC members. Some Member States have significant scientific resources dedicated to support their MSC members, whereas others only have limited scientific support from their Member States and mainly focus on an assessment and implementation of the regulatory process. In dossier and substance evaluation most proposals for amendment are submitted by a small group of active Member States, which is also reflected in the discussion time by the members or their expert(s)/advisor(s) from these Member States, both in the plenary meeting as well as the introduction/preparation meetings (e.g. through WebEx) and discussion groups.

Currently, the MSC has two main challenges: the constantly high workload and the unpredictability of the workload. The unpredictability stems from the substance evaluation and SVHC identification cases attributing to 46% of the MSC's work where Member States submit when they are ready with the dossier. This may lead to extending the June and December meetings into a second week⁵.

The MSC involvement is triggered when proposals for amendment (for substance evaluation) or comments on the hazard profile of a substance (for SVHC identification) are received. For both, a close coordination and collaboration is needed between staff preparing evaluation decisions and SVHC dossiers and/or MSC members submitting proposals for amendments or comments.

In 2017 44% of all DEv draft decisions and 97% of SEv draft decisions received proposals for amendments. For 2018 it is still early but the respective figures are around 37% and 82%, respectively. In average, a proposal for amendment on a draft evaluation decision leads to doubling the workload of the Secretariat compared to the case where no proposal for amendment is received. Where continuous differences of view across several dossiers are seen, there is a need to discuss and come to a common approach in order to both increase efficiencies, but also to ensure consistency. While Member States retain the right to submit proposal for amendments other, less costly, means need to be explored. Recurring proposals for amendments are discussed few times in plenary, but when a clear MSC (majority) position has been developed agreement seeking through written procedure increases efficiency. In addition, MSCAs and MSC members are invited to communicate actively so that the learnings and agreements of the MSC are known by MSCAs when considering proposals for amendments.

In contrast to RAC and SEAC, MSC appoints a rapporteur in few cases only, e.g. for drafting an opinion on the yearly draft update of the ECHA CoRAP, and the draft ECHA recommendation on the inclusion of priority substances for inclusion in Annex XIV of REACH; until now 8 MSC opinions for each. Every year it has proven challenging to find a volunteer from the MSC membership. The Chairman noted that one of the main arguments for not volunteering has been a lack of allocation of time and appreciation by the member's organisation when the MSC task is to be allocated (often during the second part of the year). For this reason, the Chairman has advised each member to discuss the opportunity for an MSC rapporteurship with their own organisation at the time of their personal objectives setting. The Secretariat is currently reviewing the Annex XIV recommendation process to i.a. make the MSC role in it more efficient and less time

Action Plan; SEv – Substance evaluation; SVHC – identification of Substances of Very High Concern; RECOM – MSC opinion on the ECHA draft Recommendation for inclusion of substances in Annex XIV.

⁵ This has been the case for MSC-48 (June 2016) and may be required for MSC-60 (June 2018).

consuming. In addition, the Secretariat considers that communicating to MSCAs the estimated minimum of 30% of every members' worktime allocated to MSC work could help in the nomination of rapporteurs. The Secretariat will continue with the annual interviews of members and will keep the Management Board informed of any major observations or measures for improvement.

BPC

The BPC is a relatively 'young' ECHA Committee being operational since 2014. Members and their alternates are appointed by the Member States. Currently BU and LT have not appointed a member. The members have the possibility to nominate an adviser for individual meetings.

The majority of opinions adopted by the BPC are related to the active substance approval process. At the December 2017 BPC meeting the first two opinions were adopted related to the Union authorisation process. In addition, the first opinion was adopted at that meeting related to dispute settlement under the mutual recognition process (Article 38). Last, the BPC has delivered several opinions related to an Article 75(1)(g) requests from the Commission. These opinions were on a wide range of topics: comparative assessment for rodenticides, eligibility for Annex I inclusion for food and feed active substances, etc.

For the active substance approval and Union authorisation the evaluating MSCA acts as the rapporteur, while for the Article 38 request this is ECHA. For the Article 75(1)(g) requests normally one of the members is asked to act as the rapporteur.

The BPC is supported by four permanent Working Groups (Human Health, Environment, Efficacy and on Analytical methods and Physico-Chemical Properties) in which the scientific and technical aspects are agreed before the discussion at the BPC. In addition, the BPC is supported by four ad-hoc Working Groups: Human Exposure, Assessment of Residue Transfer to Food, Environment Exposure, Microorganisms. The permanent Working Groups consist of core and flexible members. Core members are appointed for a 3 year renewable term and each Member State may nominate two core members for each Working Group. Flexible members contribute to a particular meeting of a given Working Group. Each Member State is entitled to nominate an unlimited number of flexible members. For the Ad hoc Working Groups there is no distinction between core and flexible members.

With respect to the functioning of the BPC, the Secretariat would like to present the following observations:

- The BPC opinions encompass a variety of fields of expertise. In principle, the BPC focusses on risk management measures (for example related to the conditions for approval) based on the outcome of the risk assessment which has been reviewed and normally agreed by the permanent working groups. However, sometimes unresolved issues of the risk assessment still need to be discussed at BPC level. The BPC has up to now managed to discuss and resolve such issues as the members do cover a wide range of fields of expertise reflecting to a certain extent the four permanent Working Groups and can also be supported during the meeting by experts in an advisory role.
- With respect to the activity level of the members in terms of commenting on the draft opinions and active participation in the meeting it can be stated that a minority of the members is active: on average something like 5 to a maximum of around 10 members contribute.
- In the near future Union authorisation will become a process as important as the active substance approval process. Here the Secretariat would like to mention two aspects:
 - o It is expected that this will lead to a higher input of the BPC members as these authorisations affect potentially the markets in all EU Member States. This was indicated by most members in interviews carried out by the Secretariat in the beginning of 2016.
 - o Expertise on risk management and also on how the biocidal product(s) applied for

is used, is even more important here compared to active substance approval. Here there is probably room for improvement.

With respect to the functioning of the permanent Working Groups the Secretariat would like to present the following observations:

- The core members nominated represent 7 to 11 of the Member States. Some Member States nominate two core members for the Environment and Human Health Working Group⁶.
- Overall, the activity level⁷ of the core members is in line with what is expected from a core member. However, it can be noted that some core members do either not contribute to commenting on the draft evaluations and/or do not participate actively (or sometimes do not attend) in Working Group meetings. Up to now this has not been taken into consideration by the Secretariat in the renewal exercise nor has it investigated in detail the reasons for these phenomena.
- Some flexible members contribute actively in the Working Groups, similar to a core member. In total there are 261 flexible members, most of which do not participate directly to the meetings but potentially providing support to their colleagues.
- With respect to the activity of the core and flexible members it can be noted that some members often comment on the same issue while it is expected that they comment on all aspects of the concerned evaluation.

For this Management Board meeting the Secretariat has not looked into the functioning of the ad-hoc Working Groups. If required this can be reported at a future MB meeting⁸.

It is the intention of the Secretariat to interview all the BPC members in 2018, where the issues mentioned above will be discussed with the aim to see what potentially can be done by the Secretariat to support the members in their work. Similarly, the chairs of the permanent and ad-hoc Working Groups will consider how to best initiate a discussion with their members (with a focus on the core members) on the same topic. The Secretariat will keep the Management Board informed of any major observations or measures for improvement.

Drawbacks

N/A

For questions: jukka.malm@echa.europa.eu with copy to mb-secretariat@echa.europa.eu

⁶ One expert on effect and one on exposure assessment (in total there are 35 core members and 18 alternates).

⁷ Core members are required to spend a substantial amount of their working time to the activities related to the permanent Working Group. Primarily this means commenting on draft evaluations and active participation in Working Group meetings and so-called ad-hoc follow-ups. In addition, this means volunteering to prepare meeting documents for general discussions on methodology.

⁸ The number of members are in total 84 with Human Exposure: 21; Assessment of Residue Transfer to Food: 20; Environment Exposure: 30; Microorganisms: 13.