

Annual report and exchange of views with Committee Chairs

58th Meeting of the Management Board 17-18 June 2020

Key messages

RAC and SEAC

The available members achieved the required level of contribution to the work of both Committees during 2019. In RAC there were no shortages of rapporteurs and it was possible to allocate all dossiers in the pipeline throughout the year. This was not possible in SEAC, where a shortage of rapporteurs continues (lower number of members, see further below).

RAC noted again a larger number of CLP dossiers (51 adopted in 2019 and 62 in 2018 against a previous 5 year average of 35); this is set to increase further.

The Management Board is requested to:

- note the quite large turnover in RAC members and the continuing fall in the number of SEAC members (also reported in March 2019)
- provide further resources to help make up the shortfall in rapporteurs, especially in the case of SEAC, and to **appoint advisors to current members** who can accompany them in plenary and support their work¹ as rapporteurs for restrictions and AfA.
- recommended to their MS that a dialogue with ECHA and the Chairmen as to the suitability of new and existing members is essential prior to their (re-)appointment.
- note the plans under development for the further restructuring of RAC

MSC

- The Management Board is invited to note MSC's preference to allow alternate members take on the task of Rapporteur in the MSC Opinion forming on the draft annual update of the CoRAP and the draft ECHA recommendation for inclusion of priority substances in Annex XIV. Implementation of this preference requires an update of the MSC Rules of Procedure (see AP B.5.B).

BPC

The Management Board is invited to take note of the specifics and functioning of BPC.

Background

This is the third report from the Committees to the MB since annual reporting began in 2017.

PART I RAC and SEAC

Member's performance

Annex III of the nomination papers to RAC and SEAC contains a requirement that the nominee for appointment by the MB will be available for at least 50% of their time for the work of the Committees. The Chairmen of RAC and SEAC have not interviewed the full membership during

¹ The required experience is: **socio-economic analysis, analysis of alternatives and substitution of SVHCs.**

this reporting period but consider that this target was met on aggregate across the membership. Members are required to:

- take on a number of rapporteurships per year,
- comment on opinions during written RAC and SEAC consultation rounds and
- play an active role in working groups and plenary discussions in order to achieve consensus on the opinions of RAC and SEAC.

Further steps have been taken in consultation with MS to replace less active/non-contributing members.

Rapporteurships in RAC and SEAC in 2019

The number of rapporteurships for dossiers adopted in the years 2015 to 2019 can be seen in Table 1 below.

Table 1. SEAC and RAC members' rapporteurships² during 2013-2018. Including co-opted members from December 2015.

Process	Restr.		AfA		CLP	Article 77(3)(c) COM requests		Article 95 COM requests	Total	
	RAC	SEAC	RAC	SEAC	RAC	RAC	SEAC	RAC	RAC	SEAC
2015	9	7	38	36	59				106	43
2016	2	3	113	107	57				172	110
2017	8	6	105	104	52	8		8	181	110
2018	6	6	42	44	107	9	1		164	50
2019	6	6	105	119	90	2			203	125

For RAC, the number of rapporteurships needed annually is relatively steady for the moment (many recent extra rapporteurs appointments for AfA). For SEAC, the picture is less stable, as the AfA peaks have a greater impact.

Numbers, turnover of members, renewals and new nominations

In 2018, MB members were requested to inform their MSCAs that a dialogue with ECHA and the Chairmen as to the suitability of new and existing members is needed prior to their (re)appointment. First signs of MS responding to this request were observed in 2019 and the Chairmen were actively involved in several selection procedures (Ireland, Romania, Portugal, Spain, Norway); this was greatly appreciated but would need to be expanded, as some MS continue to (re-) nominate members of RAC and SEAC largely without reference to ECHA and sometimes without adequate arrangements with the nominee's employer to secure their time.

The activities of the RAC and SEAC UK members were wound down in 2018 pending Brexit and they did not attend the September or December 2019 meetings.

RAC

RAC had a total of 49 EU/EEA members in December 2019 (compared to 47, 49, 50, and 52 in 2015, 2016, 2017, 2018 respectively). Almost from the start of the Committee, growth has been linear but has now reached a peak and dropped slightly (not only due to Brexit).

SEAC

SEAC had a total of 35 EU/EEA members in December 2019 (compared to 40, 39, 35 and 34 in 2015, 2016, 2017 and 2018 respectively). Here the trend has been declining for some time.

² 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.

Prognosis and workload management

Looking ahead to 2020 and 2021, the workload projections for RAC and SEAC are challenging to say the least, with a high number of Restrictions still in the system (6 to 7, against a previous annual average of 2 to 3), most of which should be adopted by mid year; a large increase in AfA in the second half of 2019 (106 opinions on octyl and nonylphenol ethoxylates alone) was spread out as far as possible, by pushing the peak forward well into 2020; the numbers of opinions adopted in 2020 will reach a record high.

RAC experienced a continued high number of CLP dossiers in 2019 (51), with 54 projected with certainty for 2020 (against a previous 5 year average of 35). The publication of implementing legislation – (EU) 2020/103 - to the plant protection products (PPP) regulation this January is expected to further increase this number from 2021 onwards (for renewals after mid 2023), as harmonised classification and labelling becomes a fixed part of PPP renewals.

The effect of efficiency measures

RAC met for 10 working days in September 2019, mainly to handle the volume of complex restrictions on hand; without further action, most meetings are expected to be two weeks long in 2020. SEAC commenced two week meetings at its 2019 December plenary.

A series of related efficiency measures have already been implemented:

- The AfA working group of RAC mentioned in the 2019 MB report has been successfully set up to prepare Applications for Authorisation outside of plenary. It met three times in 2019, reducing debating time in the December meeting by about 1 day of plenary time and at the March 2020 meeting by about 2.5 days. We are pleased to report that the working group was supported by not only Members but by an additional 5 member's advisors with specialist expertise. SEAC will continue to shorten the debating time for individual dossiers and as noted above, has expanded to double meetings as needed without a working group;
- 'A-listing' of simpler AfA opinions i.e. with scrutiny by the members but without plenary debate has been implemented through the Working group for small numbers of opinions as yet but this may grow;
- The lower quorum in both Committees endorsed in the rules of procedure by the MB in March 2019 has indeed made it easier for members to handle longer meetings more effectively.

Further working groups of RAC

With one standing working group successfully installed and against a background of unpredictable peaks in AfA workload combined with an increasing trend in CLP dossiers for RAC, consideration will be given by the secretariat to setting up further working groups as the need arises, in order to take pressure off plenary by pre-preparing opinions. This is intended to bring RAC plenaries back to one week by 2022.

PART II

MSC³

Numbers, turnover of members, renewals and new nominations

In 2019 MSC had 29 members and 22 alternate members. All MSCAs were represented in the MSC and additionally also NO was represented. In 2019 ES appointed an alternate member to the MSC and the NL member and alternate member crossed over their roles. In addition 6 MSC member and 4 alternate member mandates were renewed.

Main achievements and challenges

MSC reached **unanimous agreements on all of the SEV, DEV and SVHC cases⁴** in 2019, within the legal deadline (of 60 or 30 days after referral to MSC).

Process	Agreed cases	Agreed in WP	Agreed in MTG
DEv- TPE	23	16	7
DEv - CCH	42	32	10
SEV	9	4	5
SVHC	3	1	2
<i>Sum</i>	<i>77</i>	<i>44</i>	<i>45</i>

MSC also issued its opinion on two draft CoRAPs and two draft recommendations for inclusion of priority substances in Annex XIV, so actually this sums up to **81 agreements and opinions**.

To achieve this, MSC held **5 plenary meetings** (MTG) (total duration of 13 full days, spread over 15 calendar days), **9 written procedures** (WP) for agreement seeking or decision making prior to the meeting, and also 9 preparatory WebEx meetings. Also three working groups and seven rapporteurs and co-rapporteurs contributed to the work, and held smaller meetings and WebExes during the year.

The members continue to show **interest and commitment** to their tasks as shown in the very high participation to both the plenaries (av. >25 in a meeting out of 29) and to the written procedures.

One of MSC's main challenges remains the unpredictability of its workload.

Dossier evaluation

The REACH Evaluation Joint Action Plan⁵ introduced a number of actions for improving efficiency to allow an increasing number of dossiers being checked for compliance. MSC reached a general agreement on the approach for case by case mandates for finalisation of evaluation decisions after the meeting. This action is expected to reduce the workload for MSC members during a meeting, possibly leading to shorter meetings.

In 2019, the fraction of all dossier evaluation draft decisions which received PfAs was further reduced compared to years 2017 and 2018, and the fraction of cases agreed in written procedure increased.

³ Details on REACH processes requiring MSC involvement is available in the 2018 MB report, on ECHA's website and in the REACH legal text.

⁴ Abbreviations: CCH – Compliance Check; CoRAP – MSC opinion on the ECHA draft Community Rolling Action Plan; DEv – Dossier evaluation; 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; TPE – Testing Proposal Evaluation.

⁵ See

https://echa.europa.eu/documents/10162/21877836/final_echa_com_reach_evaluation_action_plan_en

Agreement process	Percentage of cases					
	2017		2018		2019	
	Referred to MSC	Agreed in written procedure	Referred to MSC	Agreed in written procedure	Referred to MSC	Agreed in written procedure
Compliance check (CCH)	51	67	35	66	24	76
Testing proposals (TPE)	52	59	16	63	20	70

MSC-65 (June 2019) was the first meeting ever where no dossier evaluation cases had to be discussed as all of them were agreed in written procedure before the meeting. In line with the REACH Evaluation Action Plan, MSC has been spending more time discussing general approaches such as the available options for requesting *in vivo* mutagenicity testing on germ cells under CCH of Annex IX or X dossiers, or the conditions for a request of the fish early-life stage test (OECD TG 234) when there is a data gap for fish long-term toxicity information.

Substance evaluation and SVHC identification

In 2019, out of 10 SEv draft decisions notified to MSCAs nine had to be referred to MSC. Of these, 44% were agreed in written procedure (slightly more than in 2018). All three SVHC cases referred to MSC were identified under Art 57(f). One was agreed in written procedure as an endocrine disruptor for the environment (TNPP), and two perfluorinated substances and their salts (HFPO-DA and PFBS) were agreed after a generic discussion (MSC-64) on possible concern elements which could lead to an overall equivalent level of concern.

Other aspects

The Rapporteur and Working Group for the development of the MSC opinion on the 9th draft ECHA recommendation for inclusion of priority substances in Annex XIV applied the new opinion format and suggested further improvements to MSC's opinion forming process. For the first time MSC also issued an opinion on a draft recommendation to amend existing entries (of four phthalates) in Annex XIV. Furthermore, MSC issued an opinion on the draft CoRAP update (2019-2021) and the draft CoRAP update (2020-2022) making use of a new opinion format. The latter opinion was issued ahead of schedule, and we will perform a process review to assess whether this efficiency can be consolidated.

To address potential challenges to find a volunteer from the MSC membership for Rapporteurs, MSC discussed and supported a fall-back approach which uses for each opinion forming process a randomised ordered list of Member States from which the rapporteur may be picked. MSC also expressed preference to allow that alternate members can take on the task of Rapporteur. Implementation of this preference requires an update of the MSC Rules of Procedure. A text proposal is submitted to the MB for this purpose (AP B.5.B).

MSC Secretariat organised capacity building sessions for MSC on new approach methodologies (NAMs) in chemical risk assessment, and mutagenicity. It changed its approach to drafting minutes and has stopped recording the MSC meetings. The risk mitigation measures put in place by MSC Secretariat made that the 64th MSC meeting did not experience any noticeable disruption despite Internet access and IT-issues on ECHA premises.

MSC agreed to a schedule with four meetings in 2021. There will be additional MSCA notifications for dossier evaluation cases, not synchronised with an MSC meeting, to cope with the increasing number of draft decisions. In case of proposals for amendment the agreement seeking may have to take place in a written procedure.

BPC

Numbers, turnover of members, renewals and new nominations

The number of BPC members is 28 where 26 members have appointed an alternate member. Currently all MSCAs except PL and BG are represented in the BPC. In addition, CH and NO are represented in the BPC. BE, LT and IT have appointed both a new member and an alternate member to the BPC. CH, CZ and IE has appointed a new member. AT, DE, FR, HR HU, PT, SI and SK have renewed their memberships. FI, LV, RO, SE and UK have renewed the membership of the BPC member and have appointed a new alternate members.

For the Working Groups the number of core and flexible members has increased compared to 2018 with the total of 38 core and 299 flexible members⁶. In 2019, there were no WG-members from BG, LT, LU and MT. Due to the large number of experts, the turnover of flexible members is relatively high. The WG-members are nominated until further notice.

Performance 2019

The total opinions adopted by the BPC in 2019 decreased from 31 for 2018 to 20 in 2019. In 2019 two BPC meetings had to be cancelled as no evaluations were submitted by the MSCAs. Main cause for this decrease were the delays in the active substances Review Programme.

The BPC adopted:

- 3 opinions on an application for approval of an active substance; all for the Review Programme. In addition, 6 opinions⁷ were adopted at the BPC where the evaluating Competent Authority (eCA) performed an assessment of the endocrine disrupting (ED) properties. Also these opinions were all for the Review Programme.
- 10 opinions on an application for Union authorisation where for all opinions the BPC proposed to grant the authorisation.
- 1 opinion on a disagreement in a mutual recognition process (Article 38).

The workload of the Working Groups remained high in the past year although the peer review activities were reduced for active substances. The Union authorisation peer review discussions have continued to increase. The Working Groups were also increasingly involved in harmonisation discussions and support to the evaluating Competent Authorities through early WG discussions (e.g. harmonisation of the assessment of related UA applications, assessment of endocrine disrupting properties). The Working Groups addressed also many guidance related issues.

Prognosis and workload management

Looking ahead to 2020 and 2021 the relevant processes show the following developments:

- For active substance approval the submission of draft evaluations by the MSCAs to ECHA for peer review almost came to a standstill in 2019. For 2020 it is foreseen that the number of submissions is increasing again: a total of 31 opinions is expected for active substance approval⁸. No concrete forecast is available for 2021 but is expected that the number of adopted opinions will at least be on the same level as for 2020.
- For Union authorisation the workload is – as expected – increasing. For 2020 it is foreseen

⁶ There are 9 core members in the Efficacy Working Group (WG) representing AT, HR, FR, DE, EL, NL, RO, SI and UK; 5 alternate members representing FR, DE, EL, NL and UK and 71 flexible members. The Analytical methods and Physico-chemical Properties WG is composed of 8 core members representing FR, DE, EL, NL, PO, SI and UK; 3 alternate members representing FR, DE and NL and 43 flexible members. In the Human Health WG, there are 13 core members representing CZ, FR, DE, EL, ES, IE, NL, SI and UK; 6 alternate members representing DE, EL, IE, NL and UK and 95 flexible members. The Environment WG includes 8 core members representing FR, DE, EL, IE, NL, SI and UK; 6 alternate members representing DE, EL, IE, NL and UK as well as 90 flexible members.

⁷ The BPC adopted already an opinion for these active substance PT combinations. However, after the ED criteria became applicable the opinions were returned by DG SANTE via an Article 75(1)(g) request.

⁸ This contains 10 BPC opinions adopted for active substance PT combinations returned by DG SANTE via an Article 75(1)(g) request to assess ED properties.

that 17 opinions will be adopted, which is an increase of 7 compared to 2019. No concrete forecast is available for 2021 but is expected that the number of adopted opinions will at least be on the same level as for 2020.

- At least one opinion on an Article 75(1)(g) request will be adopted in 2020. In addition, several opinions on an Article 38 request are expected.
- In conclusion, the overall workload for the BPC and the Working Groups is manageable for 2020 considering the total number of expected opinions of 50. It is foreseen that the situation will be similar for 2021. Maybe there will be an increase in the number of Article 38 opinions due to the increasing number of referrals occurring in the Coordination Group.

Reflections for the MB

Considering the previous annual report and the current and future developments the following points are brought to the attention of the MB:

- It remains difficult to schedule the meeting agendas for the BPC due to the unpredictability of incoming draft evaluations by MSCAs. MB members are asked to increase their planning capacities to allow for a realistic and timely planning. This applies to the active substance approval process as well as Union authorisation process.
- Still only a limited number of members comment for the Union authorisation process on draft BPC opinions, SPCs and PARs. In this respect the secretariat is especially concerned about the quality of the SPC as a high quality English version of the draft SPC adopted at the BPC prevents further issues being raised during the decision-making process and/or during the quality check of the translations. Together with DG SANTE the SECR has streamlined the process as much as possible. However, MB members are asked to investigate if more capacity can be freed to comment on Union authorisation applications and in particular on draft SPCs.
- The BPC capacity and expertise can still be improved related to risk management, which is even more relevant with the increase in Union authorisation applications. The BPC explored in 2019 the possible involvement of the Forum sub-group on the BPR (BPRS) with respect to advice on the enforceability of risk management measures. The BPRS agreed on the possibility of ad-hoc advice related to either active substance approval or Union authorisation.
- The progress of the Review Programme was discussed in a dedicated workshop organised by ECHA in February 2019. This resulted in the Action Plan on Active Substances which was agreed by the CA meeting in their meeting in February 2020. Several possibilities for improvement of the peer review process in the Working Groups were agreed. MB members are asked to contribute to the implementation of these improvements.

For questions: peter.vanderzandt@echa.europa.eu (RAC, SEAC, BPC)
christel.musset@echa.europa.eu (MSC) with copy to mb-secretariat@echa.europa.eu